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Radiation Safety and Requirements Regulations, 2026

PART I: GENERAL PROVISIONS

Pursuant to section 64 of the Radiation Protection Agency Act of 2018[1], I,

THABO MOFOSI,

Minister responsible for environment and forestry, make the following regulations:

Citation and commencent

1. These regulations may be cited as the Radiation Safety and Requirements Regulations, 2026 and shall come into operation on the date of publication in the Gazette.

Interpretation

In these Regulations,

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

"activity" means the quantity A for an amount of radionuclide in a given energy state at a given time, defined as -

$$A(t) = \frac{dN}{dt}$$

where dN is the expectation value of the number of spontaneous nuclear transformations from the given energy state in the time interval dt. The SI unit for activity is reciprocal second (s^{-1}), termed the Becquerel (Bq).

"Agency" means the Radiation Protection Agency established under the Radiation Protection Agency Act, 2018.

"authorization" means the granting by the Agency or other governmental body

of written permission for an operator to conduct specified activities;

“authorized discharge” means discharge in accordance with an authorization;

“authorized party” means an operator responsible for an authorized facility or an authorized activity that gives rise to radiation risks who has been granted authorization by the Agency or other governmental body to conduct specified activities;

“carers and comforters” means persons who willingly and voluntarily help in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment;

“clearance” means removal of regulatory control by the Agency from radioactive material or radioactive objects within notified or authorized facilities and activities. Removal of regulatory control in this context refers to regulatory control applied for radiation protection purposes;

“clearance level” means a value established by the Agency and expressed in terms of activity concentration at or below which regulatory control may be removed from a source of radiation within a notified or authorized practice;

“consumer product” means a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale;

“contamination” means radioactive substances on surfaces or within solids, liquids or gases, including the human body, where their presence is unintended or undesirable, or the process giving rise to their presence in such places;

“controlled area” means a defined area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing the spread of contamination in normal working conditions and preventing or limiting the extent of potential exposures;

“CT” means computed tomography;

“decommissioning” means an administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility;

"Decommissioning Plan" means a document containing detailed information on the proposed decommissioning of a facility;

"defense in depth" means a hierarchical deployment of different levels of diverse equipment and procedures to prevent the escalation of anticipated operational occurrences and to maintain the effectiveness of physical barriers placed between a radiation source or radioactive material and workers, members of the public or the environment, in operational states and, for some barriers, in accident conditions.

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

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

"disposal" means emplacement of waste in an appropriate facility without the intention of retrieval;

"disused source" means a radioactive source that is no longer used, and is not intended to be used, for the practice for which an authorization has been granted.

"dose" means -

(a) a measure of the energy deposited by radiation in a target; or

(b) absorbed dose, committed equivalent dose, committed effective dose, effective dose, equivalent dose or organ dose, as indicated by the context;

"dose constraint" means a prospective and source related value of individual dose that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization;

"dose limit" means the value of the effective dose or the equivalent dose to individuals in planned exposure situations that is not to be exceeded;

"emergency" means -

(a) a non-routine situation or event that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human life, health, property and the environment;

(b) nuclear and radiological emergencies and conventional emergencies such as fires, releases of hazardous chemicals, storms or earthquakes; or

(c) situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

"emergency exposure situation" means a situation of exposure that arises as a result of an accident, a malicious act, or any other unexpected event, and requires prompt action to avoid or reduce adverse consequences.

"emergency plan" means a description of the objectives, policy and concept of operations for the response to an emergency and of the structure, authorities and responsibilities for a systematic, coordinated and effective response. The emergency plan serves as the basis for the development of other plans, procedures and checklists.

"emergency worker" means a person having specified duties as a worker in response to an emergency;

"environment" means the conditions under which people, animals and plants live or develop, and which sustain all life and development; especially such conditions as affected by human activities;

"exemption" means the determination by the Agency that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure and the potential exposure due to the source or practice are too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of the doses or risks;

"exemption level" means a value, established by the Agency and expressed in terms of activity concentration, total activity, dose rate or radiation energy, at or below which a source of radiation need not be subject to some or all aspects of regulatory control;

"existing exposure situation" means a situation of exposure that already exists when a decision on the need for control needs to be taken;

"external exposure" means exposure to radiation from a source outside the body;

"facilities and activities" includes nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be subject to exposure to radiation from naturally occurring or artificial sources;

"graded approach" means a process or method, in respect of a regulatory system or a safety system, in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control;

"health professional" means an individual who has been formally recognized through appropriate national procedures to practise a profession related to health;

"health screening programme" means a programme in which health tests or medical examinations are performed for the purpose of the early detection of disease;

"health surveillance" means a medical supervision intended to ensure the initial and continuing fitness of workers for their intended tasks;

"individual monitoring" means monitoring using measurements by equipment worn by individuals, or measurements of quantities of radioactive substances in or on, or taken into, the bodies of individuals, or measurements of quantities of radioactive substances excreted from the body by individuals;

"inspection imaging device" means an imaging device designed specifically for imaging persons or cargo conveyances for the purpose of detecting concealed objects on or within the human body or within cargo or a vehicle;

"interested party" means a includes a person who is concerned with or interest in the activities and performance of an organization, business or system;

"internal exposure" means exposure to radiation from a source within the body;

"investigation level" means the value of a quantity such as effective dose, intake or contamination per unit area or volume at or above which an investigation would be conducted;

"Justification" means a process of determination for -

(a) a planned exposure situation whether a practice is, overall, beneficial; that is, whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm, including radiation detriment, resulting from the practice; or

(b) an emergency exposure situation or an existing exposure situation whether a proposed protective action or remedial action is likely, overall, to be beneficial; that is, whether the expected benefits to individuals and to society (including the reduction in radiation detriment) from introducing or continuing the protective action or remedial action outweigh the cost of such action and any harm or damage caused by the action;

"License" means a valid license issued by the Agency granting authorization to perform specified activities relating to a facility or activity;

"Licensee" means a holder of a license issued by the Agency;

"management system" means a set of interrelated or interacting elements for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner;

"medical exposure" means diagnostic exposure, therapeutic exposure, incurred by patients for the purposes of their own medical diagnosis or medical treatment; carers and comforters; and volunteers subject to exposure as part of a programme of biomedical research;

"medical physicist" a health professional, with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practice independently in one or more of the sub-fields of specialty of medical physics.

"medical radiation facility" means a medical facility in which radiological pro-

cedures are performed;

"medical radiation technologist" means a health professional, with specialist education and training in medical radiation technology, competent to perform radiological procedures, on delegation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology;

"medical radiological equipment" means a radiological equipment used in medical radiation facilities to perform radiological procedures that either delivers an exposure to a person or directly controls or influences the extent of such exposure;

"notification" means a document submitted to the Agency by a operator to notify it of an intention to carry out a practice or other use of a source;

"operator" means a person responsible for an authorized facility or an authorized activity that gives rise to radiation risks who has been granted authorization by the Agency or other governmental body to conduct specified activities;

"optimization of protection and safety" means a process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals subject to exposure and the likelihood of exposure being as low as reasonably achievable, economic and social factors being taken into account;

"person" includes natural and juristic person;

"planned exposure situation" means a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source;

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

"profession related to health" include medicine, dentistry, chiropractic, podiatry, nursing, medical physics, medical radiation technology, radiopharmacy, occupational health;

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

"qualified expert" means an individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, for example medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety specialty;

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

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

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

"radiation protection officer" means a person technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of regulatory requirements;

"radiation protection programme" means systematic arrangements that are aimed at providing adequate consideration of radiation protection measures;

"radioactive material" means material designated in national law or by the Agency as being subject to regulatory control because of its radioactivity;

"radioactive source" means -

(a) source containing radioactive material that is used as a source of radiation; or

(b) radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. This also includes any radioactive material

released if the radioactive source is leaking or broken but does not include material encapsulated for disposal, or nuclear material within the nuclear fuel cycles of research and power reactor;

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

"radiological medical practitioner" means a health professional with specialist education and training in the medical uses of radiation, who is competent to perform independently or to oversee radiological procedures in a given specialty;

"radiological procedure" means a medical imaging procedure or a therapeutic procedure that involves ionizing radiation, including a procedure in diagnostic radiology, nuclear medicine or radiation therapy, or a planning procedure, image guided interventional procedure or other interventional procedure involving radiation, delivered by a radiation generator, a device containing a sealed source or an unsealed source, or by means of a radiopharmaceutical administered to a patient;

"radiopharmacist" means a health professional, with specialist education and training in radiopharmacy, who is competent to prepare and dispense radiopharmaceuticals used for the purposes of medical diagnosis and therapy;

"radon" means any combination of isotopes of the element radon;

"radon progeny" means a short-lived radioactive decay products of ^{220}Rn and of ^{222}Rn;

"reference level" for an emergency exposure situation or an existing exposure situation, means the level of dose, risk or activity concentration above which it is not appropriate to plan to allow exposures to occur and below which optimization of protection and safety would continue to be implemented;

"referring medical practitioner" means a health professional who, in accordance with national requirements, may refer individuals to a radiological medical practitioner for medical exposure;

"registrant" means a holder of a valid registration;

"registration" means a form of authorization for facilities and activities of low or moderate risks whereby the person or organization responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the Agency;

"regulatory control" means any form of control or regulation applied to facilities or activities by the Agency for reasons relating to nuclear and radiation safety, radiation protection or to nuclear security;

"remedial action" means the removal of a source or the reduction of its magnitude, in terms of activity or amount, for the purposes of preventing or reducing exposures that might otherwise occur in an emergency or in an existing exposure situation;

"representative person" means an individual receiving a dose that is representative of the doses to the more highly exposed individuals in the population;

"RPO" means radiation protection officer;

"safety case" A collection of arguments and evidence in support of the safety of a facility or activity. This will normally include the findings of a safety assessment and a statement of confidence in these findings;

"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 radioactive source in which the radioactive material is; permanently sealed in a capsule or closely bonded; and in a solid form;

"source" means anything that may cause radiation exposure, including by emitting ionizing radiation or by releasing radioactive substances or radioactive material, and can be treated as a single entity for purposes of protection and safety;

"storage" means the holding of radioactive sources, radioactive material, spent fuel or radioactive waste in a facility that provides for their/its containment with the intention of retrieval;

"structures, systems and components" means all elements of a facility or activity that contribute to protection and safety, except human factors;

"supervised area" means a defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though specific protection measures or safety provisions are not normally needed; and

"supplier of a source" means any person or entity to whom a registrant or licensee assigns duties, totally or partially, in relation to the design, manufacture, production or construction of a source.

Objective

3. (1) The objective of these Regulations is to specify the basic requirements -

(a) for protection of people against exposure to ionizing radiation, for the safety of radiation sources;

(b) for the safety of radioactive waste management;

(c) for protection of the environment, hereinafter termed 'protection and safety'; and

(d) to implement Lesotho's international commitments relevant to radiation protection and safety.

(2) The application of these Regulations shall be in accordance with a graded approach and shall conform to any requirements specified by the Agency.

Application

4. (1) These Regulations shall apply to all -

(a) situations involving exposure to ionizing radiation that is amenable to control;

(b) activities giving rise to radiation risks;

(c) emergency exposure situations in respect of public exposure and protection of emergency workers for activities undertaken in preparedness for, and in response to a nuclear or radiological emergency; and

(d) the following exposure situations and their categories of exposure:

(i) the production, supply and transport of radioactive material including sealed sources and unsealed sources, of devices that contain radioactive material and of consumer products;

(ii) the production and supply of devices that generate ionizing radiation;

(iii) the use of radiation or radioactive material for medical, industrial, veterinary, agricultural, legal or security purposes and the use of associated equipment, software or devices which may contribute to the likelihood and magnitude of exposure to radiation;

(iv) the use of radioactive material or radiation generators for education, training or research and the conduct of activities for such purposes that potentially or certainly involve exposure to radiation;

(v) mining and processing of raw materials that involve exposure to radioactive material including naturally occurring radioactive material;

(vi) any other practice, as specified by the Act, that introduces additional risk of exposure or additional exposure pathways or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure or the number of people exposed.

(2) The requirements for planned exposure situations shall apply to -

(a) facilities that contain radioactive material and facilities that operate radiation generators, including nuclear installations, medical radiation facilities, veterinary radiation facilities, facilities for the management of radioactive waste, installations for the processing of radioactive material, irradiation facilities, and mineral extraction and mineral processing facilities that involve or could involve exposure to radiation;

(b) individual sources of radiation, including sources within the types of facility listed in paragraph 4(a) in accordance with the requirements of the Radiation Protection Agency;

(c) exposure due to -

(i) material in any practice specified in these regulations where the activity concentration in the material of any radionuclide in the uranium decay chain or the thorium decay chain is greater than 1 Bq/g or the activity concentration of ^{40}K is greater than 10 Bq/g;

(ii) discharges or due to the management of radioactive waste arising from a practice involving material as specified in paragraph 3;

(iii) ^{222}Rn and to ^{222}Rn progeny and due to ^{220}Rn and to ^{220}Rn progeny in workplaces in which occupational exposure due to other radionuclides in the uranium decay chain or the thorium decay chain is controlled as a planned exposure situation;

(iv) ^{222}Rn and to ^{222}Rn progeny where the annual average activity concentration of ^{222}Rn in air in workplaces re mains above the reference level established in regulation 53;

(v) contamination of areas by residual radioactive material deriving from;

(vi) past activities never subject to regulatory control or previously subject to regulatory control but not in accordance with these Regulations;

(vii) a nuclear or radiological emergency, after an emergency has been declared to be ended;

(viii) commodities, including food, feed, drinking water and construction materials, that incorporate radionuclides deriving from residual radioactive material;

(ix) natural sources, including -

(aa) ^{222}Rn and its progeny and ^{220}Rn and its progeny, in workplaces other than those workplaces for which exposure due to other radionuclides in the uranium decay chain or the thorium decay chain is controlled as a planned exposure situation, in dwellings and in other buildings with high occupancy factors for members of the public;

(ab) radionuclides of natural origin, regardless of activity concentration, in commodities, including food, feed, drinking water, agricultural fertilizer and soil amendments and construction materials, and residual radioactive material in the environment;

(ac) materials, other than those stated in paragraph 6(c)(ii), in which the activity concentration of no radionuclide in either the uranium decay chain or the thorium decay chain exceeds 1 Bq/g and the activity concentration of ^{40}K does not exceed 10 Bq/g;

(ad) exposure of aircrew and space crew to cosmic radiation; and

(ae) any other source of exposure as specified by the Agency;

(3) The following exposures are not included in the scope of these Regulations:

(a) exposures from natural radioactivity in the human body;

(b) exposure of members of the public or workers, other than air or space crew, to cosmic radiation in flight or in space, or to cosmic radiation prevailing at ground level; and

(c) any other radiation source that is essentially unamenable to control as may be determined by the Agency.

(4) Exposures deemed not amenable to control are out of scope of these Regulations.

Principal parties

5. (1) A person who is defined in the authorization as responsible for any facility or activity that gives rise to radiation risks shall have the prime responsibility for protection and safety, which cannot be delegated.

(2) The principal parties responsible for the application of these Regulations shall include;

(a) registrants and licensees responsible for regulated facilities and activities;

(b) the person or organization responsible for facilities and activities for which notification only is required;

(c) employers, in relation to occupational exposure;

(d) medical radiological practitioners, in relation to medical exposure; and

(e) those persons or organizations designated to deal with

emergency exposure situations or existing exposure situations.

(3) Parties not mentioned in subregulation (2) shall have specified responsibilities for the application of these Regulations. These parties may include -

(a) suppliers of radiation sources, providers of equipment and software, and providers of consumer products;

(b) radiation protection officers;

(c) referring medical practitioners;

(d) qualified experts, or any other party to whom a principal party has assigned specific responsibilities;

(e) workers involved in activities utilising radiation sources, other than those workers listed in paragraphs (a)–(d); and

(f) ethics committees.

(4) The principal parties shall establish and implement a protection and safety programme appropriate for the exposure situation. The protection and safety programme shall -

(a) adopt objectives for protection and safety in accordance with the requirements of these Regulations; and

(b) apply measures for protection and safety commensurate with the radiation risks associated with the exposure situation and sufficient to ensure compliance with the requirements of these Regulations.

(5) The principal parties shall ensure that, in the implementation of the protection and safety programme -

(a) measures and resources have been determined and duly provided to achieve the objectives for protection and safety;

(b) the programme is periodically reviewed to assess its effectiveness and continued fitness for purpose;

(c) any failures or shortcomings in protection and safety are identified and corrected, with steps being taken to prevent their recurrence;

(d) arrangements are made to consult with interested parties on matters of protection and safety; and

(e) appropriate records are maintained.

(6) The principal parties shall grant facility access to authorized representatives of the Agency to carry out inspections of the facilities and activities, and to review protection and safety records. The principal parties shall cooperate in their conduct.

(7) The principal parties shall ensure that qualified experts are identified and consulted as necessary on the proper observance of these Regulations.

(8) The principal parties and other parties having specified responsibilities in relation to protection and safety, shall ensure that personnel engaged in activities relevant to protection and safety have and maintain appropriate education, training, and qualifications sufficient to understand their responsibilities and perform their duties competently, with appropriate judgement and in accordance with procedures.

Unauthorized interpretation

6. Except as specifically authorized, no official interpretation of these Regulations binding on the Agency shall be made by any officer, employee or other representative of the Agency, except in the case of a written interpretation by Chief Executive Officer or the Board of Directors of the Agency.

Applicability of other Regulations and Requirements and Resolution of Conflicts

Nothing contained in these Regulations shall be construed as -

(a) relieving principal parties and employers from a duty to

ensure compliance with applicable national and local laws and regulations governing safety; and

(b) restricting any actions that may be necessary for the continued assurance or restoration of protection and safety.

PART 2: REGULATORY CONTROL

General Obligations

8. A person shall not adopt, introduce, conduct, discontinue or cease a practice or, as applicable, mine, extract, process, design, manufacture, construct, assemble, install, acquire, import, export, supply, provide, distribute, loan, hire, receive, site, locate, commission, possess, use, operate, maintain, repair, transfer, decommission, disassemble, transport, store or dispose of a source, as defined in regulation 4, within a practice other than in accordance with the requirements of these Regulations.

Exemption

9. (1) Practices and sources within practices may be exempted from some or all the safety requirements of these Regulations provided they comply with criteria for exemption, or any exemption levels defined by the Agency in paragraphs 3 and 4 of Schedule I of these Regulations.

(2) Exemptions shall not be granted for practices deemed not justified, as specified in regulation 24.

(3) A practice or a source within a practice may be exempted by the Agency from some or all requirements of these Regulations where risks arising from the practice or source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption.

(4) A practice or source within a practice may be exempted without further consideration from some or all requirements of these Regulations provided that under reasonably foreseeable circumstances, the effective dose expected to be incurred by any individual owing to the exempt practice or exempt source within the practice, is of the order of 10 μSv or less in a year. Where there is a low probability of exposure, the effective dose expected to be incurred by

any individual shall not exceed 1 mSv in a year.

(5) The following practices and sources within a practice are generically exempted from the requirements of these Regulations, including requirements for notification, registration or licensing -

(a) material in a moderate amount for which either the total activity of an individual radionuclide on the premises, or the activity concentration used in the practice, does not exceed the applicable exemption level given in Schedule I;

(b) radioactive material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Annex I of these Regulations;

(c) radiation generators of a type approved by the RPA, or in the form of an electronic tube, such as a cathode ray tube for display of visual images, provided that;

(i) under normal operating conditions they do not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the equipment; and

(ii) the maximum energy of radiation generated is no greater than 5 keV.

(6) In the case of practices involving radionuclides of natural origin, exemption of bulk amounts of material shall be considered on a case-by-case basis using a dose criterion to be established by the Agency commensurate with typical doses due to natural background levels of radiation.

(7) Where a practice or source within a practice does not comply with generic exemptions, or the exemptions cannot be applied, the applicant may make an application for specific exemption on a case-by-case basis, providing the appropriate justification of the exemption.

(8) Radioactive material arising from authorized discharges is exempted from any requirements for notification, registration or licensing unless otherwise specified by the Agency.

(9) The values provided in Schedule I of these Regulations are not intended to be applied to the control of discharges or to the control of residual radioactive material in the environment.

Requirements for Notification

10. (1) A person intending to carry out any of the activities specified in regulation 8 shall submit a notification to the Agency of such intention.

(2) Notification alone is sufficient for facilities or activities that are to be specified by the Agency.

(3) For consumer products, notification is sufficient for manufacture, maintenance, import, export, provision, distribution and (except in specified cases) disposal.

Requirements for Authorization

11. (1) Except as provided in regulations 9 and 10 of these Regulations, any person intending to operate a facility or conduct an activity involving a radiation source shall apply to the Agency for an authorization which shall take the form of either a registration or a licence.

(2) An authorization for a facility shall include authorization of the activities taking place at the facility.

(3) Authorization by registration is required for practices that pose a low to moderate radiation risk.

(4) Schedule II sets out the risk criteria determined by the Agency and provides an illustrative list of practices subject to registration.

(5) Authorization by licensing is required for facilities and activities that pose or potentially pose a high radiation risk.

(6) Schedule II "Categories for sealed sources used in common prac-

tices" includes risk criteria determined by the Agency and provides an illustrative list of practices subject to authorization by licensing.

(7) An applicant is not allowed to engage in practice or carry out activities specified in regulation 8 until an authorization is issued in the form of a registration or licence, as applicable.

(8) An applicant seeking authorization shall -

(a) assess the nature, likelihood and magnitude of expected exposures to people due to the facility or activity and take all necessary measures for protection and safety;

(b) perform a safety assessment in accordance with regulation 34 and submit the assessment to the Agency as part of the application;

(c) perform an assessment of radiological environmental impact associated with the facility or activity, following guidance issued by the Agency; and

(d) demonstrate compliance with all applicable requirements for safety following relevant guidance issued by the Agency, including application of a graded approach to risk, based on the probability and potential magnitude of harm to people and the environment.

(9) An applicant seeking authorization shall submit to the Agency relevant information necessary to support the application, including -

(a) legal and administrative information about the applicant;

(b) responsibilities and organizational arrangements for protection and safety;

(c) characteristics of the facility;

(d) information on radiation sources;

(e) staff qualifications and training;

(f) description of the management system;

(g) safety assessments in accordance with paragraph 6(b);

(h) arrangements for protection of workers, under the radiation protection programme;

(i) arrangements for protection of the public and environment;

(j) arrangements for radiation protection of patients under going medical exposure;

(k) radioactive waste management plan describing arrangements for the management of radioactive waste generated throughout the lifetime of the facility or activity, including decommissioning and management of disused sealed radioactive sources;

(l) preliminary decommissioning plan;

(m) clearance and conditional clearance;

(n) financial arrangements for activities related to decommissioning and management of disused sources, as applicable;

(o) emergency preparedness and response plan describing arrangements for preparedness and response to emergencies, as applicable;

(p) information on other programmes established in support of its safety activities, such as maintenance and testing of equipment and sources; and

(q) a description of arrangements for safe management of the source, including financial provisions where appropriate once they become disused.

(10) Different authorizations shall be obtained for the different stages in the lifetime of a facility or the duration of an activity.

(11) In the granting of an authorization for a facility or an activity, the Agency may impose limits, conditions and controls on the authorized party's subsequent activities.

(12) The registrants and licensees may appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization.

(13) An authorization may have to be reconsidered or renewed in the different stages in the lifetime of the facility or the duration of the activity concerned. In this case the authorized party shall apply for a new regulatory decision which may require the amendment, renewal, suspension, or revocation of the authorization.

(14) The fees to be charged for the issuance of license under section 54 of this Act, permits or certificates, authorization fees and charges for the services rendered by the Agency shall be as set out in Schedule V to the Regulations. Provided that administrative matters and administrative fees including dosimemetry laboratory fees, application fees, radiation hazard assessment fees and any other administrative fee that may be charged for the service offered by the RPA shall be determined by the Chief Executive Officer of the Agency from time to time as he may deem necessary.

Clearance from Regulatory Control

12. (1) Radiation sources, including radioactive substances, radioactive material, radioactive waste and objects within notified or authorized practices may be cleared from regulatory control provided they comply with the general criteria for clearance specified by the Agency.

(2) The general criteria for clearance are -

(a) radiation risks arising from the cleared material are sufficiently low as to not warrant regulatory control and there is no likelihood of a future circumstance leading to failure to meet the general criterion for clearance; or

(b) continued regulatory control of the material would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction

of individual doses or reduction of health risks.

(3) Material may be cleared without further consideration in terms of subregulation 2(a) provided that, in reasonably foreseeable circumstances, the effective dose expected to be incurred by any individual owing to the cleared material is of the order of 10 μSv or less in a year.

(4) For low probability scenarios whereby the effective dose expected to be incurred by any individual does not exceed 1 mSv in a year, material may be cleared without further consideration.

(5) Radioactive material within a notified or authorized practice may be cleared without further consideration provided that -

(a) The activity concentration of an individual radionuclide of artificial origin in solid form does not exceed the relevant level given in Annex I of these Regulations;

(b) the activity concentrations of radionuclides of natural origin does not exceed the relevant level given in Annex I of these Regulations; or

(c) for radionuclides of natural origin in residues that might be recycled into construction materials, or for the disposal of radionuclides of natural origin which may contaminate drinking water supplies the activity concentration in the residues does not exceed specific values derived to meet a dose criterion of 1 mSv in a year, this being commensurate with typical doses due to natural background levels of radiation.

(6) A Clearance may be granted by the Agency for specific situations, on the basis of the criteria in Schedule I, with account taken of the physical or chemical form of the radioactive material, and its use or the means of its disposal. Such clearance levels may be specified in terms of activity concentration per unit mass or activity concentration per unit surface area.

(7) For clearance of bulk quantities of material containing a mixture of radionuclides of natural origin and radionuclides of artificial origin, the relevant levels given in Schedule I of these Regulations shall not be exceeded for

individual radionuclides and for their mixture.

(8) The registrant or licensee shall adopt provisions for clearance and its control to ensure that -

(a) a formal mechanism is in place, including control measures, to demonstrate compliance with regulatory requireents in respect of clearance;

(b) deliberate dilution of material to meet clearance criteria is prohibited, unless dilution takes place in normal operations performed in compliance with regulatory requirements; and

(c) radiation marking is removed from any material no longer subject to these Regulations.

(9) Information on material removed from regulatory control shall be recorded, retained within the management system of the registrant or licensee for 20 years.

(10) Notification of the clearance of material in accordance with these Regulations shall be made to the Agency.

Review and Assessment

13. On receipt of an application, and during the process of its review and assessment, the Agency may request the applicant, to submit further information or modify the application as appropriate, respecting the time limit set by the Agency.

Regulatory Inspections

14. (1) The registrant, licensee or employer shall permit access to authorized representatives of the RPA to carry out inspections of facilities and activities and of protection and safety records.

(2) The registrant, licensee or employer shall cooperate in the conduct of inspections.

Enforcement

15. (1) A person responsible for a facility or activity is subject to administrative or legal enforcement actions in accordance with Act of and other applicable laws of Lesotho as appropriate.

(2) Willful violations or attempted violations of the regulations or requirements may be referred to the courts of law for prosecution under the laws of Lesotho.

(3) A person responsible for a facility or activity who fails to notify the Agency, in accordance with regulation 10, is subject to administrative or legal enforcement action in accordance with the law of Lesotho.

Consultation and Communication

16. Interested parties shall be actively involved in communication and consultation, on a regular basis, to allow individuals and societal groups to participate in the regulatory decision making process and to influence or even challenge the Agency and the information it uses to perform its regulatory functions.

Interfaces Between Safety and Security.

17. (1) The registrant or licensee shall implement measures in accordance with the requirements of the related regulatory framework to ensure the security of authorized facilities to prevent unauthorized access by individuals and the unauthorized removal of radioactive material.

(2) Safety measures and security measures shall be designed and implemented in an integrated manner, so that security measures do not compromise safety and safety measures do not compromise security.

Nuclear Safeguards

18. The registrant or licensee shall consider nuclear safeguards requirements in the design, operation and decommissioning of facilities to which nuclear safeguards apply. These requirements shall be implemented in such a way that the safety of the facility is not compromised. Relevant records will be maintained by the registrant or licensee.

Technical Service Providers

19. (1) Any person or organization proposing to provide services relating to radiation protection and safety shall apply to the Agency for an authorization as appropriate.

(2) Applicants shall submit relevant documentation with regard to the legal status of the person, administrative data, organizational structure and working environment, control of products, monitoring and review of the management system and independent assessment.

(3) The application shall demonstrate -

(a) suitable qualification of the experts, and experience in relevant areas including, accreditation, certification and a list of references;

(b) adequate knowledge of specific methodologies, applicable criteria and requirements, codes, tools or approaches for the work it proposes to undertake;

(c) effective access directly or through subcontractors, to necessary tools, codes and data, for which permissions and competences for use can be demonstrated, standards and expertise to accomplish the scope of work.

Requirements for Existing Exposure Situations

20. (1) Identified existing exposure situations shall be evaluated to determine the magnitude of risk of public and occupational exposures taking into account the existing exposure situations described in the scope of these Regulations under regulation 3.

(2) Those persons or organizations designated by the Agency or any other governmental authority to deal with existing exposure situations have the prime responsibility for safety.

(3) For existing exposure situations, registrants and licensees with responsibilities for protection and safety shall ensure that remedial actions and protective actions are justified, and that protection and safety are optimized.

(4) Licensees in planning for the preparedness and response for a radiological emergency shall ensure that arrangements are planned and implemented as appropriate for the transition from an emergency exposure situation to an existing exposure situation.

PART 3: REQUIREMENTS FOR RADIATION PROTECTION AND SAFETY

General Principles of Radiation Protection

21. (1) Each party with responsibilities for radiation protection and safety shall ensure -

(a) for all exposure situations, that protection and safety is optimized;

(b) for planned exposure situations, that no practice is undertaken unless it is justified;

(c) for planned exposure situations other than for medical exposure, specified dose limits are not exceeded;

(d) for emergency exposure situations and existing exposure situations, that protective actions or remedial actions are justified and undertaken in such a way as to achieve the objectives set out in a protection strategy.

(2) The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation in accordance with a graded approach.

Responsibilities of Registrants and Licensees in Planned Exposure Situations

22. The registrant or licensee -

(a) shall bear responsibility for establishing and implementing technical and organizational measures necessary for protection and safety for their authorized facilities and activities;

(b) may designate suitably qualified persons to carry out tasks relating to these responsibilities but shall retain prime responsibility for protection and safety;

(c) shall document the names and responsibilities of persons designated to ensure compliance with the requirements of these Regulations;

(d) shall notify the Agency of any intention to introduce modifications to an authorized facility or activity that could have significant implications for protection and safety and any such modification shall not be carried out until it is specifically authorized by the Agency;

(e) establish clear lines of responsibility and accountability for protection and safety for the facilities and activities for which they are authorized and shall establish organizational arrangements for protection and safety;

(f) ensure that any delegation of responsibilities by a principal party is documented;

(g) conduct a safety assessment for the facilities and activities for which they are authorized and for which a safety assessment is required and keep it up to date;

(h) conduct and maintain a prospective assessment for the facilities and activities for which they are authorized and for which the Agency requires such an assessment to be made for radiological environmental impacts under regulation 11;

(i) assess the likelihood and magnitude of potential exposures, their likely consequences and the number of individuals who may be affected by them;

(j) have operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system;

(k) establish procedures for reporting on and learning from accidents and other incidents;

(l) establish arrangements for the periodic review of the overall effectiveness of measures for protection and safety;

(m) ensure that maintenance, testing and servicing are carried out as necessary in accordance with supplier specifications and authorisation conditions or annually but not to exceed every 12 months, so that sources remain capable of fulfilling their design requirements for protection and safety throughout their lifetime; and

(n) ensure safe management and control of all radioactive waste generated and dispose of such waste in accordance with the national strategy and regulatory requirements.

Justification

23. (1) Practices resulting in exposure to ionizing radiation shall be justified before being adopted, taking into account occupational and public exposure.

(2) For planned exposure situations only justified practices may be authorized.

(3) The following practices shall not be justified:

(a) practices that result in an increase in activity by the deliberate addition of radioactive substances or by activation, in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person, unless they are justified practices involving medical exposure;

(b) practices involving the frivolous use of radiation or radioactive substances in commodities or in consumer products such as toys and personal jewellery or adorn-

ments, which result in an increase in activity by the deliberate addition of radioactive substances or by activation;

(c) human imaging using radiation that is performed as a form of art or for publicity purposes; and

(d) human imaging using radiation for theft detection purposes.

(4) Human imaging, using radiation, performed for occupational, legal or health insurance purposes and undertaken without reference to clinical indication, shall not be justified.

(5) If, in exceptional circumstances, the justification of human imaging is to be considered for specific practices, such as those in subregulation 4, regulation 25 and 40 shall apply.

(6) Human imaging using radiation for anti-smuggling purposes or to detect concealed objects that can be used for criminal acts or that pose a national security threat shall be justified only by the government. If, in exceptional circumstances, the government or the Agency decides that the justification of such human imaging is to be considered, the requirements of regulation 40 shall apply.

Optimization of Protection and Safety

24. (1) The applicant for an authorization shall present to the RPA documentation addressing the optimization of protection and safety in the associated facilities and activities. The registrant or licensee shall ensure that protection and safety is optimized.

(2) With regard to occupational exposure and public exposure, the registrant or licensee shall ensure the optimization of protection and safety to contribute to achieving the following objectives:

(a) to determine and implement measures for protection and safety, optimized for the prevailing circumstances, with account taken of the nature, likelihood and magnitude of exposures, appropriate for each use and location;

(b) to establish criteria for restricting the likelihood and magnitudes of exposures by means of measures for incident/accident prevention and for mitigating the consequences of such events if they do occur.

(3) In respect of remedial or protective actions, the registrant or licensee shall -

(a) ensure that the form, scale and duration of such actions are optimized to provide protection for all individuals subject to exposure;

(b) give priority to those individuals for whom dose exceeds the reference level; and

(c) prevent doses from remaining above reference levels set in accordance with regulation 26.

Dose constraints

25. (1) Dose constraints proposed by the registrant or licensee and approved by the Regulatory Bodies or established by the Agency shall be used for optimization of protection and safety, such that all exposures are controlled to levels that are as low as reasonably achievable.

(2) In respect of -

(a) occupational exposure, the registrant or licensee shall, where appropriate, optimize protection and safety by setting and applying dose constraints within the radiation protection programme for each source under control;

(b) public exposure in planned exposure situations, the dose constraints will be established by the Agency; and

(c) medical exposure, dose constraints shall apply for the optimization of protection of carers and comforters and volunteers participating in a justified programme of medical or biomedical research in terms of regulation 65.

(3) Dose constraints, established by the Agency, for human imaging shall apply to the use where justified, of radiation without clinical indications for employment, legal or health insurance purposes.

(4) All procedures referred to in subregulation (3) shall be performed by medical personnel in terms of regulation 40.

Reference Levels

26. (1) Reference levels established by Agency shall be used for optimization of protection and safety in existing exposure situations and emergency exposure situations.

(2) Strategies established in the radiation protection programme shall be applied to keep doses below the reference level. In an emergency exposure situation or where an existing exposure situation has been identified, the reference level shall be used to determine whether further protective actions are necessary and, if so, to prioritize their application.

(3) In respect of emergency exposure situations and existing exposure situations, the person or response organization designated to deal with an emergency exposure situation or existing exposure situation shall ensure as appropriate, that relevant reference levels are used in the optimization of protection and safety.

(4) Reference levels proposed by the licensee in the remediation plan and approved by the Agency shall typically be expressed as an annual effective dose to the representative person in the range of 1–20 mSv or other corresponding quantity, the actual value depending on the feasibility of controlling the situation and on experience in managing similar situations in the past.

(5) Reference levels shall be periodically reviewed and updated by the licensee and presented to the Agency for approval to ensure that they remain appropriate in the light of the prevailing circumstances.

Dose Limits

27. (1) The registrant or licensee shall ensure that exposures of individuals due to authorized facilities and activities are restricted so that neither the effective dose nor the equivalent dose to tissues or organs exceeds the applicable

dose limit specified in these Regulations.

(2) occupational exposure of workers over the age of 18 years, the dose limits shall be -

(a) an effective dose of 20 mSv per year averaged over five consecutive years and of 50 mSv in any single year;

(b) an equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years and of 50 mSv in any single year;

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

(3) In respect of occupational exposure of apprentices of 16 to 18 years of age being trained for employment involving radiation and for exposure of students of age 16 to 18 years who use sources in the course of their studies, the dose limits shall be -

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

(b) an equivalent dose to the lens of the eye of 20 mSv in a year; and

(c) an equivalent dose to the extremities such as hands and feet or to skin of 150 mSv in a year.

(4) In respect of public exposure, the dose limits shall be -

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

(b) in special circumstances, a higher value of effective dose in a single year, provided the average effective dose over five consecutive years does not exceed 1 mSv per year; and

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

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

Management System Elements

28. (1) Registrants and licensees shall ensure that protection and safety is effectively integrated into the overall management system of the organizations for which they are responsible, in line with a graded approach.

(2) Registrants and licensees shall demonstrate commitment to protection and safety at the highest levels within the organizations for which they are responsible.

(3) Registrants and licensees shall explicitly include policies, rules and procedures for the assurance of radiation protection and safety.

(4) The registrants and licensees shall ensure that their management system is designed and applied to enhance protection and safety by -

(a) applying requirements for protection and safety coherently with other requirements, including requirements for operational performance and guidelines for security;

(b) describing the planned and systematic actions necessary to ensure protection and safety requirements are fulfilled;

(c) ensuring that protection and safety is not compromised by other requirements;

(d) providing for regular assessment of the effectiveness of protection and safety policies, rules and procedures and for applying lessons learned from experience;

(e) promoting safety culture.

Safety culture

29. The principal parties shall promote and maintain a safety culture by -

(a) demonstrating commitment to protection and safety at

all levels of the organization ensuring a common understanding through training and safe performance of the key aspects of safety culture and prioritizing good safety practice during operation of regulated facilities and activities;

(b) providing resources to individuals and teams that ensure safe completion of tasks, with account taken of the interactions between individuals, technology and the organization;

(c) formally, through the management system, involving workers, their and other relevant persons in the development and implementation of protection and safety policies, rules and procedures;

(d) ensuring through the management system and job descriptions, the protection and safety accountability of in dividuals at all levels of the organization;

(e) establishing through the management system, mechanisms for open communication about protection and safety within the organization and externally with relevant parties, as appropriate;

(f) establishing formal mechanisms to support a questioning and learning attitude and discourage complacency with regard to protection and safety; and

(g) establishing mechanisms through the management system for continuous improvement of the safety culture.

Human Factors

30. The registrant and licensee shall take into account human factors and support good performance and practices to prevent human and organizational failures, by ensuring that -

(a) equipment design and operating procedures facilitate safe operation, minimize operator errors and reduce the

potential for misinterpretation of indicators of normal and abnormal conditions;

(b) appropriate equipment, safety systems and procedural requirements are provided, and other necessary provision is made to -

(i) reduce, as far as practicable, the possibility that human errors or inadvertent actions give rise to accidents or to other incidents leading to the exposure of any person;

(ii) provide means for detecting human errors and for correcting or compensating for them;

(iii) facilitate protective actions and corrective actions in the event of failures of safety systems or failures of measures for protection and safety.

Responsibilities for Education, Training and Provision of Information

31. (1) The registrant or licensee shall ensure that personnel engaged in activities relevant to protection and safety have, and can show evidence of continuing education, training and qualifications sufficient to understand their responsibilities and perform their duties competently and safely, with appropriate judgement and in accordance with procedures.

(2) The employer, in cooperation with the registrant or licensee shall -

(a) Provide all workers with adequate information on health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions, adequate instruction and training and periodic retraining in protection and safety, and adequate information on the significance of their actions for protection and safety;

(b) provide all workers who could be involved in, or affected by the response to an emergency, with appropriate

information and adequate instruction, training and periodic retraining on protection and safety; and

(c) maintain records of the education, training and qualifications of all personnel, including periodic re-training or new learning.

Radiation Protection Officers

32. (1) The registrant or licensee, in cooperation with employers where appropriate, shall establish, maintain and keep under review a programme for workplace monitoring under the supervision of a radiation protection officer or qualified expert.

(2) The registrant or licensee shall designate one or more RPOs for each facility and activity as specified by the Agency and provide them with the means necessary to perform their tasks.

(3) An RPO shall be technically competent in radiation protection matters relevant to a given practice.

(4) The RPO shall oversee application of the requirements of these Regulations relevant to each facility and/or activity to which they have been assigned.

(5) The RPO shall report directly to the person responsible for the facility or activity to which the RPO has been assigned.

(6) The organization's management system, policy and procedures shall explicitly state the responsibilities and duties of the RPO in relation to protection and safety, including at least the following:

(a) supervising the work to ensure compliance with local rules, national regulations and authorization limits and conditions;

(b) carrying out, or supervising workplace monitoring;

(c) supervising arrangements for individual monitoring and health surveillance;

(d) making and keeping radiation sources, including the dis used sealed radioactive sources and radioactive waste records updated;

(e) ensuring the safe and secure management, including storage, of disused sealed radioactive sources and radioactive waste;

(f) ensuring safety and warning systems are maintained and checked;

(g) ensuring that equipment is appropriately validated and tested before first use and maintained thereafter;

(h) reviewing emergency plans and supervising emergency drills;

(i) ensuring the provision of information and training for exposed workers;

(j) liaising with qualified experts, facility management and with the Agency, as may be necessary;

(k) drafting and presenting to the registrant or licensee reports or other documents required by the Agency;

(l) implementing the radiation protection programme and t the radioactive waste management plan.

8. If other responsibilities are assigned, on case by case basis, caution shall be exercised to avoid conflict with the criteria established by the Agency for any specific RPO's designation.

Qualified Experts

33. (1) Qualified experts shall be identified and consulted on the proper observance of the requirements of these Regulations for protection and safety for all the categories of exposure, and for ensuring the safety of sources.

(2) The following two main categories of qualified expert can be

identified:

(a) in medical physics, to ensure protection of patients during medical exposures; and

(b) in radiation protection, to ensure protection of the workers and the public, and the safety of sources.

(3) The registrant or licensee shall identify and engage qualified experts formally recognised by Agency to advise on the fulfilment of the regulatory requirements in specific technical matters, when so required by the Agency.

(4) Where the practice involves medical exposure and the conditions of the licence so require, the registrant or licensee shall employ a qualified expert. Some of the duties of this qualified expert are the oversight of the technical parameters of radiological equipment, the performance of physical measurements, calculations, calibrations of radiation sources and evaluation in accordance with both the equipment specification and the practice, ensuring that technical parameters including radiation doses to patients and others remain within specified tolerances.

Safety Assessment

34. (1) The persons or organizations responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of that facility or activity, as required under regulation 11.

(2) This safety assessment shall be either generic or specific to the practice or source for which they are responsible, according to guidance issued by the Agency.

(3) Safety assessments shall be conducted at a periodicity established by the Agency and at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance, and decommissioning of facilities or parts thereof, as may be appropriate to -

(a) identify ways in which exposures might be incurred, account being taken of the effects of external events as well as of events directly involving the sources and associated equipment;

(b) determine the expected magnitudes and likelihood of exposures in normal operation and, to the extent practicable, make an assessment of potential exposures; and

(c) assess the adequacy of existing provisions for protection and safety.

(3) A safety assessment shall include as appropriate, a systematic critical review of the -

(a) operational limits and conditions for the operation of a facility;

(b) ways in which structures, systems and components, including software and procedures relating to protection and safety might fail, singly or in combination, or might otherwise give rise to exposures and the consequences of such events;

(c) ways in which external factors could affect protection and safety;

(d) ways in which operating procedures relating to protection and safety might be erroneous and the consequences of such errors;

(e) implications for protection and safety of any modifications;

(f) implications for protection and safety of security measures, or of any modifications to security measures; and

(g) uncertainties or assumptions and their implications for protection and safety.

(4) The registrant or licensee shall take into account in the safety assessment -

(a) factors that could give rise to -

(i) a substantial release of radioactive material, the measures available to prevent or to control such a release and the maximum activity of radioactive material that, in the event of a major failure of the containment, could be released to the environment;

(ii) a smaller but continuing release of radioactive material and the measures available to detect and to prevent or to control such a release;

(iii) unintended operation of any radiation generator or a loss of shielding and the measures available to detect and prevent or control such occurrences; and

(b) the extent to which the use of redundant and diverse safety features, that are independent of each other so that failure of one does not result in failure of any other, is appropriate to restrict the likelihood and magnitude of potential exposure.

(5) The registrant or licensee shall ensure the safety assessment is documented and where appropriate, independently reviewed under the relevant management system.

(6) The registrant or licensee shall perform additional safety assessment reviews as necessary to ensure technical specifications or conditions of use continue to be met when -

(a) significant modifications to the facility or to its operating procedures or maintenance procedures are envisaged;

(b) significant changes occur on the site that could affect the safety of the facility or of activities on the site;

(c) information on operating experience, or information about accidents and other incidents that could result in

exposures, indicates that the current assessment might be invalid;

(d) any significant changes in activities are envisaged;

(e) any relevant changes in guidelines or standards have been made or are envisaged.

(7) If, as a result of a safety assessment or for any other reason, any changes to the radiation protection programme or modifications to the facility or activities are deemed necessary or desirable, the changes shall be approved by the Agency prior to implementation.

Monitoring, Testing and Verification of Compliance

35. (1) Registrants, licensees and employers shall ensure the conduct of monitoring to verify compliance with the requirements for protection and safety and the conditions and controls established in the authorization.

(2) The registrant, licensee and employers shall ensure that -

(a) monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of regulations and authorization conditions and in accordance with equipment specifications;

(b) suitable measurement and testing equipment is provided and procedures for verification are implemented;

(c) the equipment is properly maintained, tested and calirated at appropriate intervals with reference to standards traceable to national or international standards;

(d) the records are maintained of the results of monitoring and verification of compliance, including records of tests and calibrations carried out in accordance with these Regulations and authorization conditions; and

(e) the results of monitoring and verification of compliance

are shared with the Agency as required by these Regulations or in the authorization conditions.

Inventory and Records

36. (1) The registrant or licensee shall establish, maintain and be able to retrieve records relating to -

(a) the inventory of sealed sources and radiation generators, including disused sealed radioactive sources;

(b) records of doses from occupational exposures;

(c) records relating to facilities and activities;

(d) the inventory of radioactive waste;

(e) records of events, including non-routine release of radioactive material to the environment;

(f) records necessary for decommissioning or closure of facilities;

(g) the transfer of radioactive sources;

(h) records of discharged materials;

(i) records of cleared radioactive material;

(j) records of workplace monitoring;

(k) records of training of the occupationally exposed workers;

(l) the testing of instruments and safety systems and calibrations carried in accordance with the requirements of these Regulations;

(m) records related to medical exposure;

(n) changes to procedures;

(o) changes to the radiation protection programme;

(p) lists of personnel having access to certain sources or devices.

Individual sealed source records shall include the following information:

(a) location of the source;

(b) radionuclide;

(c) activity on a specified date;

(d) serial number or unique identifier;

(e) chemical and physical form;

(f) source use history, including recording of all movements into and out of the storage location;

(g) receipt, transfer or disposal of the source;

(h) leak test certificates;

(i) other information, as appropriate, to enable the source to be identifiable and traceable.

(3) The records will be kept for Minimum of 100 years.

(4) The registrant or licensee shall provide the Agency as required, with appropriate information from their inventory records.

(5) The registrant or licensee shall check the inventory periodically to confirm that radiation sources and radioactive waste are in their assigned locations and remain under control.

Prevention and Mitigation of Accidents

37. (1) The registrant or licensee shall apply good engineering practice and shall take all practicable measures to prevent accidents and to mitigate the consequences of those accidents that do occur.

Good engineering practice

(2) The registrant or licensee, in cooperation with other responsible parties, shall -

(a) ensure the relevant protection and safety requirements of these Regulations and all other applicable legislation and requirements are applied to the siting, location, design, construction, assembly, commissioning, operation, maintenance and decommissioning of facilities or parts, taking due account of international and national standards;

(b) through the management system, establish the managerial and organizational infrastructure to ensure protection and safety throughout the lifetime of the facility;

(c) demonstrate that safety margins in the design and construction of the facility and in activities involving the facility, ensure reliable performance in normal operation, and take account of the necessary quality, redundancy and capability for inspection, with emphasis on preventing accidents, mitigating their consequences that do occur and restricting any possible future exposures;

(d) in the continuous improvement of policy, rules and procedures, take account of relevant developments concerning technical criteria, including relevant research on protection and safety and feedback of information on lessons learned from experience.

Defence in depth

(3) The registrant or licensee shall ensure that a multilevel system

of sequential, independent provisions for protection and safety commensurate with the likelihood and magnitude of potential exposures is applied to sources for which the registrant or licensee are authorized, ensuring that if one level of protection fails, the subsequent independent level of protection is available. Such defence in depth shall be applied for the purposes of -

(a) preventing accidents;

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

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

Accident prevention

(4) The registrant or licensee shall, through the management system, implement policy, rules and procedures to ensure that structures, systems and components, including software, related to protection and safety of facilities and activities are designed, constructed, commissioned, operated and maintained so as to prevent accidents as far as reasonably practicable.

(5) The registrant or licensee shall maintain resources, competencies and other capacity as may be necessary to -

(a) to prevent reasonably foreseeable accidents in the facility or during the conduct of the activity;

(b) mitigate the consequences of accidents and incidents;

(c) provide workers with information, instruction, training and equipment necessary to restrict potential exposures;

(d) ensure continued control and management of the facility in the event of reasonably foreseeable accidents and incidents;

(e) ensure that structures, systems and components important to safety, including software and other equipment, is inspected and tested regularly for any degradation that

could lead to abnormal conditions or inadequate performance;

(f) ensure that maintenance, inspection and testing appropriate to protection and safety provisions can be carried out without undue occupational exposure;

(g) provide, wherever appropriate, automatic systems for safely shutting off or reducing radioactive releases from facilities in the event that operating conditions are outside stipulated ranges;

(h) ensure that abnormal operating conditions that could significantly affect protection and safety are detected by systems that respond sufficiently quickly to allow for corrective actions to be taken in a timely manner;

(i) ensure that all relevant safety documentation is available in the appropriate languages understandable to users.

Emergency preparedness and response

(6) Where the safety assessment indicates that there is a reasonable likelihood of an emergency, the registrant or licensee shall -

(a) prepare an emergency plan for the protection of people and the environment; and

(b) make arrangements for -

(i) the prompt identification of an emergency; and

(ii) determination of the appropriate level of the emergency response.

(7) The emergency plan referred to in subregulation (6) shall include:

(a) provision for individual monitoring and area monitoring, and arrangements for medical treatment; and

(b) arrangements for assessing and mitigating any consequences of an emergency.

(8) Registrants and licensees shall be responsible for the implementation of their emergency plans and shall take any necessary action for effective response.

(9) In order to prevent the occurrence of conditions that could lead to a loss of control over a source or to the escalation of such conditions, registrants and licensees shall -

(a) develop, maintain and implement procedures to provide the means for preventing loss of control over the source and for regaining control over the source as necessary;

(b) make available equipment, instrumentation and diagnostic aids that may be needed;

(c) train and periodically retrain personnel in the procedures to be followed in the exercise of the procedures.

Investigations and feedback of operating experience

38. (1) The registrant or licensee shall conduct formal investigations of abnormal conditions arising in the operation of facilities or the conduct of activities.

(2) Registrant or licensee shall ensure that information and lessons learned on both normal operation and abnormal conditions that are significant for protection and safety are disseminated or made available, as appropriate, to the Agency and relevant parties, as specified by the Agency.

(3) Where applicable, the registrant or licensee shall make arrangements with suppliers of sources to establish and maintain mechanisms for the transfer of information on use, maintenance, disposal and malfunctioning that may be relevant for future improvements in the design and manufacture of sources supplied.

(4) The registrant or licensee shall communicate to the Agency and to any other relevant parties, as appropriate, a written report of any formal in-

vestigation relating to events as prescribed by the Agency, including exposures giving rise to doses exceeding a dose limit.

(5) The registrant or licensee shall immediately report to the Agency any event in which a dose limit is exceeded.

(6) The registrant or licensee shall conduct an investigation as specified by the Agency in the event that -

(a) a quantity or operating parameter relating to protection and safety exceeds an investigation level;

(b) a quantity or operating parameter relating to protection and safety is outside the stipulated range of operating conditions; and

(c) any equipment failure, accident, error, mishap or other unusual event or condition occurs having the potential for causing a quantity to exceed any relevant limit or operating restriction.

(7) As soon as possible after an event the registrant or licensee shall conduct an investigation and prepare a written record of its causes, or suspected causes, including verification or determination of doses received or committed and recommendations for preventing recurrence of the event and occurrence of similar events.

Radiation generators and radioactive Sources

39. (1) A manufacturer and a supplier of a radiological device associated with the production or release of ionizing radiation, shall ensure, where applicable, that -

(a) the processes of design, manufacture and construction of such devices -

(i) provides for protection and safety in accordance with the requirements of these Regulations;

(ii) meets engineering, performance and functional

specifications established in these Regulations or other such national legislation, requirements or standards, including international standards as listed in Annex III of these Regulations;

(iii) meets quality standards defined in national legislation for protection and for the safety of systems and components, including software;

(iv) provide clear displays, gauges and instructions on operating consoles in a language understandable to the users;

(b) the device is tested prior to delivery and on commissioning at the regulated facility, to demonstrate compliance with relevant specifications;

(c) the information shall be available, in an appropriate language understandable to users, on proper installation and safe use of such radiological devices including performance specifications, instructions for operating and maintenance and instructions for protection and safety in compliance with relevant national and international standards regarding documentation; and

(d) the protection provided by shielding and by other protective devices is optimized and in accordance with the requirements of these Regulations and other applicable national and international requirements.

(2) Where applicable, the registrant or licensee shall make suitable arrangements with suppliers of radiation generators and radioactive sources, the Agency and relevant parties for the purposes of -

(a) obtaining information on conditions of use and operating experience that may be important for protection and safety;

(b) providing feedback and information that may have implications for protection and safety for other users, or

that may have implications for the possibility for improvements in protection and safety for radiation generators and radioactive sources.

(3) When choosing a location to use or to store a radiation generator or radioactive source, the registrant or licensee shall take due account of factors relating to -

(a) safe and secure management and control of the radiation generator or radioactive source;

(b) occupational exposure and public exposure due to the radiation generator or radioactive source, in use and in storage; and

(c) engineering design with respect to paragraphs (a) and (b) above.

(4) In selecting a site for a facility that will use radioactive material and have the potential for release of radioactive material, the registrant or licensee shall consider protection and safety with emphasis on the integrity and functioning of the facility and feasibility of performing off-site protective actions if they become necessary.

(5) The registrant or licensee shall maintain an inventory that includes records of the -

(a) location and description of each radiation generator for which they are responsible; and

(b) activity and form of each radioactive source for which they are responsible.

(6) The registrant or licensee shall make available to the Agency all such information from their inventory records of radiation generators and radioactive sources as may be required.

(7) The registrant or licensee shall take measures to prevent loss or damage to radiation generators and radioactive sources and prevent unauthorized persons from taking actions specified in regulation 7, by ensuring that -

(a) control over a radiation generator or radioactive source is relinquished only in compliance with all relevant requirements specified in the registration or licence;

(b) the Agency is notified immediately if a radiation generator or radioactive source is lost, missing or no longer under control;

(c) a radiation generator or radioactive source is transferred only if the recipient possesses the necessary authorization; and

(d) an inventory of radiation generators or radioactive sources is checked periodically to confirm that all regulated sources are in their assigned locations and remain under control.

(8) The registrant or licensee shall categorize all sealed radioactive sources in accordance with the requirements of the Agency.

(9) The manufacturer of a radioactive source or a device containing a radioactive source shall ensure that both source and its container are marked with the symbols recommended by the International Organization for Standardization.

(10) The registrant or licensee, in cooperation with the manufacturer, shall ensure that sealed sources are identifiable and traceable in accordance with international standards and requirements.

(11) The registrant or licensee shall ensure that radioactive sources not in use are stored in accordance with the requirements of these Regulations, and in the case when disused sealed radioactive sources are declared as radioactive waste in accordance with the regulations for the safe management of radioactive waste, to ensure their security and radiation protection and safety.

(12) The registrant or licensee shall promptly arrange for the safe management and continued control of radiation generators and disused radioactive sources, including appropriate financial provision in accordance with regulation 11 or other national legislation.

Radiation imaging of humans for non-medical purposes

40. (1) Any practice involving human imaging in which radiation is used for purposes other than for medical diagnosis or treatment shall not be undertaken until authorized by the Agency; and where appropriate, by other competent bodies.

(2) The justification principle in regulation 23 shall be applied to any practice involving human imaging in which radiation is used for purposes other than for medical diagnosis or medical treatment or other than as part of an authorized programme of biomedical research.

(3) Subject to subregulation (2), the justification process for the practice shall include consideration of -

(a) the benefits and detriments of implementing the type of human imaging;

(b) the benefits and detriments of not implementing the type of human imaging;

(c) legal or ethical issues associated with the introduction of the type of human imaging;

(d) the effectiveness and suitability of the type of human im aging, including the appropriateness of the radiation equipment for the intended use;

(e) the availability of sufficient resources to safely conduct the human imaging procedure throughout the intended period of the practice.

(4) If determined by means of the process specified in subregulation (2), that a human imaging practice using radiation for non-clinical reasons is justified, then such a practice shall be subject to regulatory control.

(5) The registrant or licensee shall ensure that appropriate optimization requirements are applied, including dose constraints in terms of regulation 25, where humans are exposed to radiation for employment related, legal or health insurance purposes. Furthermore, all such exposures shall be performed

using medical radiological equipment operated by medical personnel.

(6) A practice by which an inspection imaging device is used to expose humans to radiation for the purpose of detection of concealed weapons, contraband or other objects on or within the body, shall be considered to give rise to public exposure. In such cases the registrant or licensee shall apply the requirements of the Regulations relating to public exposure in planned exposure situations.

(7) The registrant or licensee shall ensure that for practices described in subregulation (5), optimization of protection and safety is subject to dose constraints for public exposure.

(8) The registrant or licensee shall ensure that any inspection imaging device used for the detection of concealed objects on or within the human body, irrespective of the country of manufacture or supply, conforms to the applicable standards of the International Electrotechnical Commission or the International Organization for Standardization or to equivalent national standards.

(9) Registrant or licensee shall ensure that all persons who are to undergo procedures with inspection imaging devices in which ionizing radiation is used are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionizing radiation, where available.

PART 4: OCCUPATIONAL EXPOSURE

General Responsibilities Specific to Occupational Exposure

41. (1) The registrant or licensee shall be responsible for -

(a) the radiation protection of workers engaged in activities in which they are, or could be subject to occupational exposure;

(b) ensuring that protection and safety is optimized, and that the dose limits for occupational exposure are complied with; and

(c) compliance with the relevant requirements of these Regulations and authorization conditions.

(2) For the protection and safety of workers in existing exposure situations, other than in the specific situations identified in regulations 53 to 55, requirements in respect of public exposure described in Part 6 of these Regulations shall be applied.

(3) An employer who is also a registrant or licensee shall have the responsibilities of both employer and registrant or licensee.

(4) Nothing in these Regulations shall be construed as relieving an employer from the requirement to comply with applicable national and local legislation and regulations, or authorization conditions governing hazards in the workplace.

(5) As part of the authorization process of a new or modified practice, the applicant shall, as appropriate, present for review by the Agency, among others, supporting documents that state design criteria and design features -

(a) relating to the exposure and potential exposure of workers in normal operation, anticipated operational occurrences and accident conditions; and

(b) design criteria and design features of the appropriate systems and programmes for monitoring of workers for occupational exposure in normal operation, anticipated operational occurrences and accident conditions.

(6) For workers who are, or could be subject to occupational exposure, the employer, the registrant or licensee shall ensure that -

(a) occupational exposure is controlled so that the relevant dose limits for occupational exposure specified in regulation 27 are not exceeded;

(b) protection and safety are optimized in accordance with the requirements of these Regulations;

(c) decisions regarding measures for protection and safety are recorded and made available as appropriate and as specified by the Agency to relevant parties through their representatives;

(d) documented policies, procedures and organizational arrangements for occupational protection and safety are established to implement the relevant requirements of these Regulations, with priority given to design measures and technical measures for controlling occupational exposure;

(e) facilities, equipment and services for protection and safety are provided, the type and extent of which are commensurate with the expected likelihood and magnitude of the occupational exposure;

(f) workers' health surveillance and health services are provided;

(g) monitoring equipment and personal protective equipment are provided in accordance with the requirements of these Regulations and arrangements are made for its proper use, calibration, testing and maintenance;

(h) suitable and adequate human resources and training in protection and safety is provided, including periodic retraining to maintain the necessary levels of competence;

(i) records pertaining to occupational radiation protection are maintained in accordance with the requirements of these Regulations and authorization conditions;

(j) arrangements are made to facilitate consultation and cooperation with workers, through their representatives where appropriate, with regard to protection and safety and on all measures to achieve effective application of these Regulations; and

(k) necessary conditions for promoting safety culture are provided.

(7) The employer and registrant or licensee shall -

(a) involve workers, through their representatives where ap-

propriate, in optimization of protection and safety; and

(b) establish and use dose constraints where applicable, as part of optimization of protection and safety.

(8) Employers, registrants or licensees shall take measure to ensure that workers exposed to radiation from sources within a practice that are not required by or directly related to their work have the same level of protection against such exposure as members of the public.

(9) The employer and registrant or licensee shall take such administrative actions as are necessary to ensure that workers are informed that protection and safety is an integral part of a general occupational health and safety programme in which they have specific obligations and responsibilities for their own protection and the protection of others against radiation exposure and for the safety of sources.

(10) The employer and registrant or licensee shall record any report received from a worker that identifies circumstances that could affect safety conditions or compliance with the requirements of these Regulations and shall take appropriate action.

(11) The employer and registrant or licensee shall facilitate compliance by workers with the requirements of these Regulations.

Compliance by workers

42. (1) Workers engaged in activities in which they are, or could be subject to occupational exposure, shall -

(a) fulfil their obligations and carry out their duties for protection and safety;

(b) follow applicable rules and procedures for protection and safety as specified by the employer, registrant or licensee;

(c) properly use the monitoring equipment and personal protective equipment provided;

(d) cooperate with the employer and the registrant or licensee with regard to protection and safety and programmes for workers' health surveillance and dose assessment;

(e) provide the employer and registrant or licensee with sufficient information about their past and present work to ensure effective and comprehensive protection and safety for themselves and others;

(f) abstain from any wilful action that could put themselves or others in situations not in accordance with the requirements of these Regulations;

(g) accept such information, instruction and training in protection and safety to enable them to conduct their work in accordance with the requirements of these Regulations.

(2) Workers engaged in activities in which they may be subject to occupational exposure shall at the earliest opportunity, report to the employer, registrant or licensee any circumstances that may adversely affect protection and safety.

Cooperation between employers, registrant and Licensee

43. (1) The employer and registrant or licensee shall cooperate to the extent necessary for ensuring compliance with the requirements of these Regulations by all responsible parties.

(2) Where workers are engaged in work that could involve a source not under the control of their employer, the registrant or licensee responsible for the source shall cooperate with the employer to the extent necessary for compliance by both parties with the requirements of these Regulations.

(3) cooperation between the employer and registrant or licensee shall include, where appropriate -

(a) restrictions on exposure and other means of ensuring protection and safety of workers engaged in work that

involves or could involve a source not under the control of their employer, such measures being the same or more stringent than for employees of the registrant or licensee;

(b) specific assessments of doses received by workers as specified in paragraph (a);

(c) clear allocation and documentation of the respective protection and safety responsibilities of the employer and registrant or licensee.

(4) To facilitate cooperation between parties, the registrant or licensee responsible for the source or for the exposure shall, where appropriate -

(a) obtain from the employer, including self-employed persons, the occupational exposure history of workers as specified in regulation 48 and any other necessary information;

(b) provide all such information to the employer as may be necessary to ensure compliance with the requirements of these Regulations;

(c) provide both workers and employer with the relevant exposure records.

Radiation protection programme

44. (1) The employer and registrant or licensee shall establish and maintain organizational, procedural and technical arrangements in a radiation protection programme for occupational exposure, including arrangements for the designation of controlled areas and supervised areas, for local rules and for the monitoring of the workplace.

(2) The content of the radiation protection programme shall include the following, in accordance with the specific requirements of these Regulations -

(a) assignment of responsibilities for workers' protection and safety to the various specified management levels;

(b) designation and functions of qualified experts and of RPOs;

(c) integration of occupational radiation protection with other areas of health and safety, such as industrial hygiene, industrial safety and fire safety;

(d) the system of accountability for control of radiation generators and radioactive sources;

(e) designation of controlled areas and supervised areas;

(f) local rules for workers and the supervision of work;

(g) provision of personal protective equipment where required;

(h) arrangements for monitoring workers and the workplace, including the acquisition and maintenance of suitable instruments specified in regulation 47;

(i) the system for recording and reporting information relating to control of exposures and decisions regarding measures for occupational radiation protection and safety and the monitoring of individuals; the education and training programme on the nature of radiation hazards and measures to ensure radiation protection and safety;

(j) a methodology for periodic review and audit of the performance of the radiation protection programme;

(k) the emergency plan, where the need for such a plan is indicated by the safety assessment;

(l) workers' health surveillance programme;

(m) requirements for assurance of quality and process improvement; and

(n) procedures needed for the implementation and control of the radiation protection programme.

(3) The registrant or licensee shall clearly designate controlled areas and supervised areas based on operational experience and in accordance with the guidance of the Agency. The registrant or licensee shall:

(a) designate as a controlled area any area in which specific measures for protection and safety are, or could be required for:

(b) controlling exposures or preventing the spread of contamination in normal operations;

(c) preventing or limiting the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions;

(d) in defining the boundaries of any controlled area, consider the magnitude of exposures expected in normal operation, the likelihood and magnitude of exposures in anticipated operational occurrences and in accident conditions and the type and extent of procedures required for protection and safety;

(e) delineate a controlled area by physical means or, where this is not reasonably practicable, by some other suitable means;

(f) delineate a controlled area by appropriate means where a source is intermittently brought into operation, energized or moved from place to place and specify exposure times;

(g) display the warning symbol recommended by the International Organization for Standardization and display instructions at access points to and at appropriate locations within controlled areas;

(h) establish measures for occupational protection and

safety, including, as appropriate, physical measures to control the spread of contamination and local rules and procedures for controlled areas;

(i) restrict access to controlled areas by means of administrative procedures, such as the use of work permits and by physical barriers which could include locks or interlocks; the degree of restriction being commensurate with the likelihood and magnitude of exposures;

(j) provide, at entrances to controlled areas,

(i) personal protective equipment;

(ii) equipment for individual monitoring and workplace monitoring;

(iii) suitable storage for personal clothing;

(k) provide, at exits from controlled areas,

(i) equipment for monitoring for contamination of skin and clothing;

(ii) equipment for monitoring for contamination of any objects or material being removed from the area;

(iii) ashing or showering facilities and other personal decontamination facilities; and

(iv) suitable storage for contaminated personal protective equipment;

(l) periodically assess the need for modifying protection and safety measures or to the boundaries of controlled areas; and

(m) provide information, instruction and training for persons working in controlled areas.

(4) The registrant or licensee shall designate as a supervised area any area not already designated as a controlled area, but where occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed.

(5) The registrant or licensee, taking into account of the nature, likelihood and magnitude of exposures or contamination in the supervised areas, shall -

(a) delineate the supervised areas by appropriate means;

(b) display approved signs, as appropriate, at access points to supervised areas; and

(c) periodically review conditions to assess the need for further measures for protection and safety or for changes to the boundaries of supervised areas.

Use of Portable and Mobile X-ray Machines

45. Restriction on Use

(a) Portable X-ray equipment shall only be operated under conditions that ensure adequate radiation protection for patients, workers, and members of the public.

(b) The use of portable X-ray equipment shall be permitted only when installed and operated within specially designed shielded mobile units (trucks or vans) that provide sufficient structural shielding in accordance with national radiation protection standards.

46. Design Requirements

(a) Be constructed with appropriate shielding materials to limit radiation exposure to permissible dose limits;

(b) Be designed to ensure protection of the operator and any assisting personnel during operation

(c) Include designated controlled areas and operator positions

(d) Be subject to approval by the Agency prior to use

Use of Mobile X-ray Equipment in Wards

47. Radiation Protection Requirements

(a) Mobile X-ray equipment shall only be operated if adequate radiation shielding measures are in place to protect patients, workers, and members of the public

48. Mandatory Shielding During Operation

(a) Protective shielding devices (such as mobile lead screens or barriers) are used to protect nearby individuals

(b) The operator maintains a safe distance or remains behind appropriate shielding

(c) Other patients in the ward are protected using shielding or by maintaining adequate distance, consistent with dose limitation requirements.

Local rules and personal protective Equipment

49. (1) The employer and registrant or licensee shall not rely solely on administrative controls and personal protective equipment, but shall also provide well engineered controls and safe working conditions in accordance with the following hierarchy of preventive measures:

(a) engineered controls;

(b) administrative controls; and

(c) personal protective equipment.

(2) The employer and registrant or licensee, in consultation with workers through their representatives where appropriate, shall -

(a) establish the written local rules and procedures necessary for protection and safety of workers and other persons;

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

(c) ensure the local rules, procedures and measures for protection and safety are known to those workers to whom they apply and to other persons who may be affected by them;

(d) ensure that any work in which workers are, or could be subject to occupational exposure, is adequately supervised and take all reasonable steps to ensure that the rules, procedures and measures for protection and safety provisions are observed;

(e) designate as appropriate, an RPO in accordance with criteria established by the Agency.

(3) The employer and registrant or licensee shall ensure that -

(a) workers are provided with suitable and adequate personal protective equipment that meets relevant standards or specifications, including where appropriate -

(i) protective clothing;

(ii) respiratory protective equipment, the characteristics of which are known to the users;

(iii) protective aprons, protective gloves and organ shields;

(b) where appropriate, workers receive adequate instruction in the proper use of respiratory protective equipment, including testing for good fit;

(c) tasks requiring the use of certain personal protective

equipment are assigned only to workers who, on medical advice, are capable of safely sustaining the extra effort necessary;

(d) all personal protective equipment including equipment for use in an emergency, is maintained in proper condition and if appropriate, tested at regular intervals recommended by the manufacturer or supplier and in accordance with the frequency of use of the equipment;

(e) account is taken of any additional exposure owing to time taken or inconvenience arising from the use of personal protective equipment and the non-radiological risks associated with performing a task using the personal protective equipment.

Workplace monitoring

50. (1) The registrant or licensee, in cooperation with the employer where appropriate, shall establish, maintain and periodically review a programme of workplace monitoring commensurate with a graded approach under the supervision of a RPO or qualified expert.

(2) The type and frequency of monitoring of workplaces shall be sufficient to enable -

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

(b) assessment of exposures in controlled areas and supervised areas; and

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

(3) The type and frequency of monitoring of workplaces shall be based on dose rate, activity concentration in air and surface contamination and their expected fluctuations and on the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions.

(4) The registrant or licensee, in cooperation with the employer where appropriate, shall maintain records of the workplace monitoring programme. The findings of the workplace monitoring programme shall be made available to workers, where appropriate through their representatives.

(5) The programme for workplace monitoring shall specify -

(a) the quantities to be measured;

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

(c) the measurement methods and procedures;

(d) investigation levels and actions to be taken if the levels are exceeded.

Assessment of occupational exposure

51. (1) The employer and registrant or licensee shall be responsible for making arrangements for the assessment and record of the occupational exposure of workers, with individual monitoring where appropriate.

(2) The registrant or licensee shall ensure that arrangements are made with authorized or approved dosimetry service providers that operate under a system of quality management in accordance with the requirements of these Regulations and with applicable national legislation.

(3) Where feasible, individual monitoring shall be undertaken of any worker who routinely or occasionally works in a controlled area and may receive a significant occupational exposure dose.

(4) In cases where individual monitoring of the worker is inappropriate, inadequate or not feasible, the occupational exposure shall be assessed on the basis of workplace monitoring results together with information on the locations and durations of exposure of the worker.

(5) The occupational exposure of any worker who regularly works in a supervised area or who enters a controlled area only occasionally, shall be assessed on the basis of workplace monitoring or individual monitoring results,

as appropriate.

(6) The employer and registrant or licensee shall clearly identify workers who could be subject to exposure due to contamination, including workers who use respiratory protective equipment.

(7) The employer shall arrange for appropriate monitoring of such workers to the extent necessary to demonstrate the effectiveness of the measures for protection and safety and to assess intakes of radionuclides and the committed effective doses.

(8) Where accidental occupational exposure occurs, the registrant or licensee shall assess the doses and their distribution in the human body and record the results of the assessment.

(9) The registrant or licensee shall ensure that arrangements are in place to the extent possible for implementing an analysis system as appropriate and shall take remedial actions.

(10) The registrant or licensee shall, without delay, communicate the results of the dose assessment to both the workers affected and to the Agency.

Records of workers exposure

52. (1) The employer and registrant or licensee shall maintain records of occupational exposure for each worker for whom assessment of occupational exposure is required under regulation 47.

(2) The employer and registrant or licensee shall maintain records of occupational exposure for each worker during and after the worker's working life, at least until the worker attains or would have attained the age of 75 years and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure.

(3) Records of occupational exposure shall include:

(a) information on the general nature of the work in which the worker was subject to occupational exposure;

(b) information on dose assessments, exposures and intakes

at or above the relevant recording levels and the data upon which the dose assessments were based;

(c) information on dates of employment with each employer of the worker's relevant career and on the doses, exposures and intakes in each such employment;

(d) records of any assessment of doses, exposures and intakes due to actions taken in an emergency or due to accidents or other incidents, which shall be distinguished from doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations.

(4) The employer and registrant or licensee shall -

(a) provide workers with access to records of their own occupational exposure;

(b) provide the supervisor of the programme for workers' health surveillance, the Agency and the relevant employer, with access to workers' records of occupational exposure;

(c) facilitate the provision of copies of workers' exposure records to new employers when workers change employment;

(d) make arrangements for the retention of exposure records for former workers by the employer or licensee, as appropriate.

(5) In complying with subregulation 4, due care and attention shall be given to unauthorized modification or processing of data related to occupational exposure, or provision of these data to unauthorized persons.

(6) The registrant or licensee shall make arrangements for restricted access to records of occupational exposure with respect to confidentiality, availability and integrity of these records.

(7) If the employer or registrant or licensee ceases to conduct activities in which workers are subject to occupational exposure, that party shall make arrangements for workers' records of occupational exposure to be retained by the Agency, other state registry or by the subsequent employer, registrant or licensee.

Workers' health surveillance

53. (1) The employer and registrant or licensee, in accordance with the rules established by the Agency, shall make arrangements for appropriate health surveillance based on the general principles of occupational health and designed to assess the initial fitness and continuing fitness of workers for their intended tasks.

(2) If one or more workers are to be engaged in work in which they are or could be exposed to radiation from a source not under the control of their employer, the registrant or licensee responsible for the source shall, as a precondition of engagement of such workers, agree with the employer any special arrangements for workers' health surveillance necessary to comply with the requirements of these Regulations or the requirements of any other relevant competent authority.

Information, instructions and training

54. The employer, in cooperation with the registrant or licensee, shall -

(a) provide all workers with comprehensive information on health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions;

(b) provide all workers with appropriate instruction and training and periodic retraining in protection and safety in accordance with a graded approach based on the probability and potential magnitude of harm together with detailed information on the significance of their actions for protection and safety;

(c) provide workers who could be involved in or affected by the response to an emergency, with appropriate infor-

mation and specific instruction and training and periodic retraining, for protection and safety in emergency situations; and

(d) maintain records of all safety and radiation protection training provided to individual workers.

Workers' conditions of service

55. (1) The conditions of service of workers shall be independent of whether they are or could be, subject to occupational exposure.

(2) Special compensatory arrangements or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor used as substitutes for measures for protection and safety in accordance with the requirements of these Regulations.

(3) The employer shall make all reasonable efforts to provide workers with suitable alternative employment in circumstances for which it has been determined, either by the Agency or in the framework of the programme for workers' health surveillance in accordance with the requirements of these Regulations, that workers, for health reasons, may no longer continue in employment in which they are or could be, subject to occupational exposure.

Specific requirements for female workers and trainees under 18 Years of Age

56. (1) With the purpose of providing protection of the embryo or fetus and breastfed infants, the employer, in cooperation with the registrant or licensee, shall provide female workers, liable to enter controlled or supervised areas, or who may undertake emergency duties, with appropriate information on -

(a) the risk to an embryo or fetus due to exposure of a pregnant woman;

(b) the importance of notifying her employer as soon as possible if a female worker suspects she is pregnant or if she is breast-feeding; and

(c) the risk of health effects for a breastfed infant due to ingestion of radioactive substances.

(2) Notification of the employer by a female worker who suspects she is pregnant or confirms she is breast-feeding shall not be a reason to exclude the female worker from work.

(3) The employer of a female worker, once notified of her suspected pregnancy or that she is breast-feeding, shall adapt the working conditions in respect of occupational exposure to ensure the embryo, fetus or infant is afforded the same level of protection as for members of the public.

(4) The employer and registrant or licensee shall ensure no person under the age of 16 years is or could be, subject to occupational exposure.

(5) The employer and registrant or licensee shall ensure that persons under the age of 18 years are allowed access to a controlled area only under supervision and only for the purpose of training for employment in which they are, or could be subject to occupational exposure, or for the purpose of academic studies in which sources are used.

Exposure due to radon in workplaces

57. (1) The reference level for ^{222}Rn in a workplace is set at a value that does not exceed an annual average activity concentration of ^{222}Rn of 1000 Bq/m^3, with account taken of the prevailing social and economic circumstances.

(2) The reference level for annual average activity concentration of ^{222}Rn shall be set at 300 Bq/m^3 with account taken of the prevailing social and economic circumstances.

(3) The employer and registrant or licensee shall ensure that activity concentrations of ^{222}Rn in the workplace are as low as reasonably achievable below the reference level established in accordance with subregulation (1) and shall ensure that protection is optimized.

(4) If, despite all reasonable efforts by the employer to reduce it, the activity concentration of ^{222}Rn in the workplace remains above the reference level established in accordance with subregulation (1) the requirements for occupational exposure in planned exposure situations as stated in Part 4 of these

Regulations shall apply.

Remediation of areas with residual radioactive Material

58. (1) The employer, registrant or licensee shall ensure that the exposure of workers undertaking remedial actions is controlled in accordance with the relevant requirements on occupational exposure in planned exposure situations as established in Part 4 of these Regulations.

(2) The authorized party shall establish an appropriate system for maintaining, retrieving and amending records that cover the nature and the extent of contamination; the decisions made before, during and after remediation; and information on verification of the results of remedial actions, including the results of all monitoring programmes after completion of the remedial actions.

(3) The authorized party shall ensure that the remediation plan is consistent with the national policy and strategy for radioactive waste management.

Protection of workers in emergency exposure situations

59. (1) In an emergency exposure situation, the relevant requirements for occupational exposure in planned exposure situations shall be applied for emergency workers, in accordance with a graded approach, except as described in subregulation (2).

(2) Response organizations and employers shall ensure that no emergency worker is subject to exposure in an emergency in excess of 50 mSv other than -

(a) for the purposes of saving life or preventing serious injury;

(b) undertaking actions to prevent severe deterministic effects and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment; or

(c) undertaking actions to avert a large collective dose.

(3) In these exceptional circumstances, response organizations and employers shall make all reasonable efforts to keep doses to emergency workers below the values in Schedule IV.

(4) In addition, emergency workers undertaking actions as a result of which their doses could approach or exceed the values set out in Schedule IV shall do so only when the expected benefits to others would clearly outweigh the risks to the emergency workers.

(5) Response organizations and employers shall ensure that -

(a) emergency workers who undertake actions in which the doses received might exceed 50 mSv do so voluntarily;

(b) they have been clearly and comprehensively informed in advance of the associated health risks, and of available measures for protection and safety;

(c) they are, to the extent possible, trained in the actions that they may be required to take.

(6) Workers who receive doses in an emergency exposure situation shall not be precluded from incurring further occupational exposure. Provided that, qualified medical advice shall be obtained before any further occupational exposure if such a worker has received a dose exceeding 200 mSv or at the request of the worker.

(7) Response organizations and employers shall keep records of emergency occupational exposure that include the records of any assessments made of doses, exposures and intakes due to actions taken in the emergency or due to accidents or other incidents, which shall be distinguished from assessments of doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations.

(8) Information on the doses received and information concerning the associated health risks shall be communicated to the workers involved.

Radiation exposure of aircrew and space Crew

60. (1) When the Agency or other relevant authority determines that an assessment of the exposure of aircrew or space crew due to cosmic radiation is deemed to be warranted, a framework shall be established which shall include a reference level of dose and a methodology for the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation.

(2) Where the exposure of aircrew or space crew is deemed justified and are likely to exceed the reference level, employers shall assess and keep records of doses and make the records of doses available to the aircrew or space crew.

(3) The employer and registrant or licensee shall inform female aircrew or space crew of the risk to the embryo or fetus due to exposure to cosmic radiation and of the need for early notification of pregnancy.

(4) Notification of the employer by a female aircrew or space crew who suspects she is pregnant shall not be considered a reason to exclude her from work.

(5) The employer of a female aircrew or space crew member, once notified of her suspected pregnancy, shall adapt the working conditions in respect of occupational exposure to ensure the embryo or fetus is afforded the same level of protection as for members of the public.

(6) All reasonable efforts shall be made to optimize protection for individuals in air and space-based activities by restricting the doses received by such individuals while not unduly constraining such activities.

PART 5: MEDICAL EXPOSURE

General responsibilities specific to medical Exposure

61. (1) The registrant or licensee shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical radiation exposure, unless -

(a) it is a radiological procedure requested by a referring medical practitioner and information on the clinical con-

text has been provided, or it is part of an approved health screening programme;

(b) the medical exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, or it is part of an approved health screening programme;

(c) a radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in subregulation 5(a);

(d) the patient or patient's legal authorized representative has been informed of the expected diagnostic or therapeutic benefits of the procedure as well as the radiation risks.

(2) The registrant or licensee shall ensure that no human incurs a medical exposure as part of a programme of biomedical research unless -

(a) the exposure has been approved by an ethics committee or other institution assigned similar functions by the relevant authority;

(b) a radiological medical practitioner has assumed responsibility as specified in subregulation 5(a); and

(c) the requirements specified in subregulation 65(2) are met for optimization of protection and safety for persons subject to exposure as part of the programme of biomedical research.

(3) The registrant or licensee shall ensure all necessary devices to limit patient movement are available during a radiological imaging procedure, with the objective of optimising image quality and avoiding, to the extent possible, the need for a carer or comforter to be present in the radiation area during exposure.

(4) The registrant or licensee shall ensure that no carer or comforter

incurs a medical exposure unless prior to providing essential care and comfort to an individual undergoing a radiological procedure, the carer or comforter has received and indicated understanding of information on radiation protection and the radiation risks.

(5) The registrant or licensee shall ensure that requirements specified in subregulation 65(1) are fulfilled for optimization of protection and safety of any radiological procedure in which an individual acts as a carer or comforter.

(6) The registrant or licensee shall ensure that -

(a) the radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for the radiation protection and safety of patients in the planning and delivery of the medical exposure, including justification of the radiological procedure and optimization of protection and safety in cooperation with other clinical radiological professionals, such as the medical physicist and medical radiation technologists, as applicable;

(b) radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with specific duties in relation to protection and safety for patients undergoing a given radiological procedure are specialized in the appropriate area;

(c) the requirements of these Regulations for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiation equipment are conducted by or under the supervision or with the documented advice of a medical physicist whose degree of involvement is determined by the complexity of the radiological or oncological procedures and the associated radiation risks;

(d) any delegation of responsibilities by a principal party is documented; and

(e) sufficient medical personnel and paramedical personnel

are available as specified by the health authorities.

Education, training and competence

62. The registrant or licensee shall ensure that radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals having duties in relation to the radiation protection of patients or medical exposure control -

(a) are specialized in the appropriate area as prescribed by the relevant professional body, health authority or other appropriate organization;

(b) meet the requirements of these Regulations for education, training and competence in radiation protection and, as applicable, the respective requirements of the professional body for each clinical discipline;

(c) are named in a record of the qualifications, experience, continuous professional development, unique skills and competences of qualified clinical practitioners maintained by the registrant or licensee and/or the relevant Lesotho's registration body as applicable.

Justification of medical exposures

63. (1) The justification principle under regulation 23 shall be applied to any practice involving ionizing radiation for medical diagnosis or treatment. The justification process for all such practices shall include consideration of -

(a) the benefits and detriments of the imaging or treatment procedure;

(b) legal or ethical issues associated with the procedure;

(c) the effectiveness and suitability of the procedure, including appropriateness of the radiation equipment for the intended use or the availability of alternative techniques that do not involve medical exposure; and

(d) the availability of the necessary competences and experience to safely conduct the procedure throughout the intended period of the practice.

(2) The registrant or licensee shall include with an application for authorization of a medical radiation practice or procedure, the basis of the conclusion that the medical benefits justify the radiation detriment the practice or procedure might cause, with account taken of the benefits and risks of available alternative techniques that do not involve medical exposure.

(3) The registrant or licensee shall require in formal documentation that the justification of each medical exposure of a patient shall be a process of consultation between the radiological medical practitioner and referring medical practitioner, with account taken, in particular, for patients who are pregnant or breast-feeding or are pediatric, of -

(a) the appropriateness of the request;

(b) the urgency and necessity of the radiological procedure;

(c) the characteristics of the medical exposure;

(d) the characteristics of the individual patient;

(e) relevant information relating to the patient's previous radiological procedures.

(4) The registrant or licensee shall ensure that national and international referral guidelines are taken into account for the justification of the medical exposure of individual patients.

(5) The registrant or licensee shall ensure that before the performance of radiological procedures as part of a health screening programme for asymptomatic populations, justification is obtained from the health authority in conjunction with appropriate professional bodies.

(6) The registrant or licensee shall require that any radiological procedure on an asymptomatic individual performed for the early detection of disease, but not as part of an approved health screening programme, is justified for that individual by the radiological medical practitioner and referring medical

practitioner together and is in accordance with the guidelines of relevant professional bodies and the health authority.

(7) Subject to subregulation (7), the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

(8) Medical exposure of volunteers as part of a programme of biomedical research shall be subject to approval by an ethics committee, other competent body assigned similar functions and subject to any dose constraints that may be specified by these Regulations and other relevant provisions of national legislation.

Optimization of protection and safety in medical Exposures

64. (1) The registrant or licensee shall ensure, through policy and implementation of procedures, that radiological medical practitioners in cooperation with medical physicists and medical radiation technologists optimize protection and safety for each medical exposure in regulation 24.

(2) The registrant or licensee shall, in cooperation with suppliers, ensure that medical radiological equipment and software that may influence medical exposure conforms to the applicable standards of the International Electrotechnical Commission, the International Organization for Standardization, applicable national standards and to the requirements of these Regulations.

(3) The registrant or licensee shall ensure through written protocols that for diagnostic radiology and image guided interventional procedures, the radiological medical practitioner, in cooperation with the medical physicists and medical radiation technologists, medical physicist and radiopharmacist or radiochemist (as appropriate) use only the following:

(a) medical radiological equipment and software identified in the protocol, as appropriate for the procedure;

(b) nuclear medicine radiopharmaceuticals listed in the protocol, as appropriate for the procedure;

(c) appropriate techniques and parameters to deliver a patient exposure that is the minimum necessary for the

clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable image quality or diagnostic value established by relevant professional bodies and of relevant diagnostic reference levels established in accordance with regulation 63.

(4) For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient the exposure of volumes other than the planning target volume are kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within required tolerances.

(5) With regard to therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner in cooperation with the medical physicist and the medical radiation technologist, and if appropriate with the radio pharmacist or radiochemist shall ensure through written protocols, that the appropriate radiopharmaceutical with the appropriate activity is selected and administered to each patient such that radioactivity is primarily localized in the organ of interest, while radioactivity in the rest of the body is kept as low as reasonably achievable.

(6) The registrant or licensee shall ensure through written protocols that particular aspects of medical exposures are considered in the optimization process for -

(a) pediatric patients subject to medical exposure;

(b) individuals subject to medical exposure as part of a health screening programme;

(c) volunteers subject to medical exposure as part of a programme of biomedical research;

(d) exposure of the embryo or fetus, in particular for radiological procedures in which the abdomen or pelvis of the pregnant female patient is exposed to the primary radiation beam or could otherwise receive a significant dose;

(e) relatively high doses to the patient;

(f) exposure of a breastfed infant as a result of a female patient having undergone a radiological procedure with radiopharmaceuticals.

Calibration of equipment used in medical Exposures

65. In accordance with regulation 57, the medical physicist shall ensure that -

(a) all sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;

(b) calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the Agency;

(c) calibrations of radiotherapy units are subject to independent verification prior to clinical use; and

(d) calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.

Patient dosimetry

66. The registrant or licensee shall ensure that patient dosimetry is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:

(a) for diagnostic radiological procedures, typical doses to patients for common procedures;

(b) for image guided interventional procedures, typical doses to patients;

(c) for therapeutic radiological procedures, absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and

(d) for therapeutic radiological procedures with unsealed sources, typical absorbed doses to patients.

Diagnostic reference levels

67. The registrant or licensee shall ensure that -

(a) local assessments, on the basis of measurements required by regulation 62, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established; and

(b) a review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure -

(i) typical doses or activities exceed the relevant diagnostic reference level; or

(ii) typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

Quality assurance for medical exposures

68. (1) The registrant or licensee shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and for nuclear medicine facilities, radio pharmacists and radiochemists together with other health professionals, as appropriate.

(2) The registrant or licensee shall ensure that a programme of quality assurance for medical exposures appropriate to the medical radiation facility, activity or practice includes:

(a) measurements of the physical parameters of medical radiological equipment made by or under the supervision of, a medical physicist -

(i) at the time of acceptance and commissioning of the equipment prior to its clinical use on patients, and periodically thereafter;

(ii) after any major maintenance procedure that could affect protection and safety of patients;

(iii) after installation of new software or modification of existing software that could affect protection and safety of patients;

(b) prompt implementation of corrective actions if measured values of the physical parameters mentioned in subparagraph (a) are outside established tolerance limits;

(c) verification of appropriate physical and clinical factors used in radiological procedures;

(d) maintenance of records of relevant procedures and results;

(e) periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.

(3) The registrant or licensee shall commission regular independent audits of the quality assurance programme for medical exposures at a frequency that reflects the complexity of radiological procedures performed and the associated risks.

Dose constraints for carers and comforters and volunteers participating in biomedical research programmes

69. (1) The registrant or licensee shall ensure that dose constraints referred to in 25 are used in the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

(2) The registrant or licensee shall ensure that dose constraints specified or approved by the ethics committee, or by another institutional body assigned similar functions, are used in the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research referred to in regulation 59.

Protection of pregnant or breast-feeding patients in medical Exposures

70. (1) The registrant or licensee shall have specific arrangements in place for radiation protection in cases where a female patient is or might be pregnant or is breast-feeding.

(2) The registrant or licensee shall use all appropriate means of communication to alert female patients to the risks of radiation to the unborn baby or breastfed child.

(3) The registrant or licensee shall ensure that signs in appropriate languages are prominently visible in public places, patient waiting rooms, cubicles and other appropriate places to urge female patients to notify the radiological medical practitioner, medical radiation technologists or other clinical professional in the event that she is or might be pregnant, or that she is breast-feeding if the procedure includes administration of a radiopharmaceutical.

(4) The registrant or licensee shall have arrangements in place for establishing that a female patient is not breast-feeding before commencing any radiological procedure involving administration of a radiopharmaceutical that could result in a significant dose to a breastfed infant and shall ensure this information is considered in the process of justification of the procedure and optimization of protection and safety.

Release of patients after radionuclide therapy

71. (1) The registrant or licensee shall have arrangements in place to

ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.

(2) The registrant or licensee shall require through written protocols, that the radiological medical practitioner does not discharge a patient having undergone a therapeutic radiological procedure with sealed or unsealed sources until it has been established by a medical physicist or the facility's radiation protection officer that -

(a) the activity of radionuclides in the patient is such that doses to the public and family members would be in compliance with the requirements of these Regulations;

(b) the patient or legal guardian of the patient has been provided with -

(i) written instructions for keeping doses to persons in the vicinity of the patient as low as reasonably achievable;

(ii) advice on avoiding the spread of contamination; and

(iii) information on the radiation risks.

Unintended and accidental medical exposures

72. (1) Subject to regulations 37 and 38, the registrant or licensee shall take all practicable measures to reduce the likelihood of unintended or accidental medical exposures arising from design flaws and operational failures of medical radiological equipment; from failures of and errors in software; or from human error.

(2) The registrant or licensee shall promptly investigate any unintended or accidental medical exposure, including:

(a) medical treatment delivered to the wrong individual or the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, dose or dose fractionation differing substantially from values

prescribed by the radiological medical practitioner, or that could lead to significant secondary effects;

(b) any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or wrong tissue or organ of the patient is subject to exposure;

(c) any exposure for diagnostic purposes that is substantially greater than intended;

(d) any exposure arising from an image guided interventional procedure that is substantially greater than intended;

(e) inadvertent exposure of the embryo or fetus during a radiological procedure;

(f) failure of medical radiological equipment, failure of software or system failure, accident, error, mishap, or other unusual occurrence with the potential for subjecting the patient to a medical exposure substantially different from that intended.

(3) The registrant or licensee shall, as part of the investigation of any unintended or accidental medical exposure -

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

(b) indicate the corrective actions required to prevent recurrence of the unintended or accidental exposure;

(c) describe the strategy for implementation and implement of all corrective actions under their own responsibility;

(d) ensure that the radiological medical practitioner promptly informs the referring medical practitioner and the patient or patient's legal authorized representative of the unintended or accidental medical exposure;

(e) prepare a written report, as soon as possible after the investigation or as otherwise required by the Agency, of the apparent and root causes of the unintended or accidental medical exposure, incorporating the information and evidence of actions specified in paragraphs (a) to (c), together with any other information as required by the Agency;

(f) for significant unintended or accidental medical exposures, submit the written report, as soon as possible to the Agency and to the relevant health authority.

Radiological review of medical exposures

73. (1) The registrant or licensee shall establish a process for periodic radiological review of the medical radiation facility. This review shall be conducted by a radiological medical practitioner in cooperation with the medical radiation technologists and the medical physicists.

(2) The radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility.

Records related to medical Exposure

74. The registrant or licensee shall maintain the following records relating to medical exposure and shall make them available to the Agency on demand:

(a) personnel, which shall consist of records of -

(i) delegation by principal parties of the responsibilities for medical exposure, which shall be kept for a period of time determined by Agency;

(ii) personnel radiation protection training, which shall be kept for at least 100 years.

(b) calibration, dosimetry and quality assurance, which shall consist of -

(i) results of calibrations and periodic checks of relevant physical and clinical parameters selected during radiological examination or treatment of patients, which shall be kept for at least 100 years;

(ii) records of patient dosimetry, as required by regulation 62, which shall be kept for at least 100 years;

(iii) records of local assessments and reviews made with regard to diagnostic reference levels as required by regulation 63, which shall be kept for at least 100 years;

(iv) records associated with the quality assurance programme, as required by regulation 64, which shall be kept for at least 100 years.

(c) diagnostic radiology, shall consist of information necessary for retrospective assessment of doses, including exposure parameters, number of exposures and duration of fluoroscopic exposure, which shall be kept for 100 years;

(d) image guided interventional procedures, which shall consist of information for retrospective assessment of doses, including exposure parameters, duration of fluoroscopic exposure and number of images acquired, which shall be kept for at least 100 years;

(e) nuclear medicine, which shall consist of details of radiopharmaceuticals administered and their activity, which shall be kept for at least 100 years;

(f) external beam radiation therapy or brachytherapy -

(i) a description of the planning target volume;

(ii) absorbed dose at the center of the planning target volume and maximum and minimum absorbed

doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume;

(iii) absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner;

(iv) for external beam radiation therapy, dose fractionation and overall treatment time, which together with the records listed in subparagraphs f(i), (ii) and (iii), shall be kept for at least 100 years;

(g) exposure records of volunteers subject to medical exposure as part of a programme of biomedical research, which shall be kept for at least 100 years;

(h) reports on investigations of unintended and accidental medical exposures as required in regulation 68, which shall be kept for at least 50 years.

Medical Physicist

75. (1) At a level commensurate with the complexity, dose and radiological risks of medical radiological procedures, the registrant or licensee shall involve a medical physicist having qualifications and competences in accordance with subregulation 5(3) and subregulation 33(1).

(2) The registrant or licensee shall assign responsibility to a medical physicist for optimization of radiation protection and safety in medical exposures, including source calibration, clinical dosimetry, image quality and patient dose assessment, and physical aspects of the programme of quality assurance, including medical radiological equipment acceptance and commissioning.

(3) The registrant or licensee shall require through documented procedures, that the medical physicist actively participates in the investigation following any unintended or accidental medical exposure as described in regulation 68.

(4) The registrant or licensee shall require through procedures, that the medical physicist communicates and cooperates with other qualified experts and health professionals in working towards establishing an integrated programme for radiation protection and safety at the medical radiation facility.

Specific requirements for radiation protection and safety in diagnostic radiology and image guided interventional procedures

76. (1) The registrant or licensee shall ensure for every diagnostic radiology examination or treatment room, that the shielding requirements of the Agency are met. The adequacy of shielding shall be verified during construction and before first clinical use of a room and similarly after any structural modifications.

(2) The registrant or licensee shall ensure that equipment for diagnostic radiology and image guided interventional procedures which can affect radiation exposure includes design features for -

(a) immediate detection of any malfunction of a component of the system leading to unplanned exposure of the patient or staff;

(b) minimizing the potential for human error;

(c) displaying the radiation generator operating parameters;

(d) controlling the radiation beam;

(e) ensuring adequate filtration, inherent and added, to remove low energy components of the X ray beam;

(f) collimation to define the primary radiation beam;

(g) ensuring that X ray tube assembly radiation leakage is as low as reasonably achievable and less than 1 mGy in an hour measured at 1 metre from the focal spot;

(h) automatic termination of exposure after a pre-set time or when the ‘dead man’ exposure button is released;

(i) tube current/time product (mAs) or automatic exposure control detection; and

(j) indication of air kerma/area product and/or incident air kerma.

(3) The registrant or licensee shall ensure dental imaging equipment includes the following operating and radiation safety design features:

(a) a minimum tube potential of 50 kVp;

(b) for intraoral dental systems, an open-ended collimator providing a tube focus to skin distance of at least 20cm and a field size at the collimator not exceeding 4cm x 5cm if rectangular, or 6cm diameter if cylindrical and limitation of field size to the dimensions of the image receptor;

(c) for panoramic dental systems, limitation of field size to the area required for diagnosis by means of programmed field size trimming, including specific exposure and beam collimation settings for pediatric patients;

(d) for dental cone beam computed tomography adjustable X ray tube potential (kVp) and current/time product (mAs) with a choice of volume sizes and voxel sizes.

(4) The registrant or licensee shall ensure computed tomography devices include the following operating and radiation safety design features:

(a) console display of all CT parameters that directly influence image acquisition;

(b) console display of estimated volume CT air kerma index and CT air kerma/length product for the procedure or image acquisition;

(c) operator alert if exposure factors are set too high;

(d) a means of dose modulation, rotational and z-axis, and

means for selection of noise index or equivalent;

(e) a comprehensive range of beam widths and pitches and other ancillary devices such as dynamic collimation to ensure 'over ranging' in CT is kept as low as reasonably achievable by facilitating the appropriate choice of beam width and pitch to limit patient dose while maintaining diagnostic image quality; and

(f) reconstruction algorithms that result in dose reduction without compromising image quality.

(5) The registrant or licensee shall ensure mammography equipment includes the following operating and radiation safety design features:

(a) various anode and filter combinations;

(b) compression and immobilization capabilities;

(c) magnification views;

(d) console display of dose index; and

(e) image receptors to accommodate all breast sizes.

(6) The registrant or licensee shall ensure medical fluoroscopy devices include the following operating and radiation safety design features:

(a) device that energizes the X ray tube only when continuously depressed;

(b) indications both at the control console and on monitors, of elapsed time, air kerma/area product and cumulative reference air kerma;

(c) automatic brightness control or automatic dose rate control;

(d) pulsed fluoroscopy and pulsed image acquisition modes;

(e) the capture and display of the last acquired frame;

(f) interlocks to prevent inadvertent energizing of the X ray beam when the image detector is removed from the imaging chain;

(g) capability to deactivate the exposure footswitch between cases;

(h) a timer with alarm sound after a pre-set period of continuous fluoroscopy.

(7) The registrant or licensee shall ensure that equipment for paediatric diagnostic and interventional radiology procedures include design features specific to children, such as restraints and exposure controls, imaging field and other elements specific to facilitate the imaging of very small patients.

Specific requirements for radiation protection and safety in nuclear medicine

77. (1) The registrant or licensee shall ensure nuclear medicine facilities using unsealed sources have areas for the following:

(a) source storage and preparation;

(b) radiopharmaceutical administration to patients;

(c) uptake rooms;

(d) imaging in vivo and sample measurement in vitro;

(e) separate waiting areas for patients before and after radiopharmaceutical administration;

(f) changing areas and toilets; and

(g) radioactive waste storage and predisposal processing.

(2) For nuclear medicine facilities at which therapy with radiopharmaceuticals is performed, the registrant or licensee shall ensure there are dedi-

cated wards for patients undergoing such treatments.

(3) The registrant or licensee shall ensure that adequate shielding is provided for workers, patients and other persons in the facility.

(4) Shielding calculations shall take into consideration the classification of areas within the facility, type of work to be performed, the radionuclides and their activity intended to be used, as well as the structural and ancillary protective barriers.

(5) The adequacy of the shielding shall be verified during construction and before the facility enters clinical use, and similarly after any structural modifications.

(6) The registrant or licensee shall provide equipment for manipulation of unsealed radioactive material in radiopharmaceuticals, laboratories and other work areas.

(7) During construction or prior to commissioning and operation of a medical radiation facility or rooms within a facility in which unsealed radioactive material is prepared, handled or administered to patients, the registrant or licensee shall ensure that the drainage system from such areas to the main building sewer is structured to prevent radionuclide contamination of non-controlled areas.

(8) The registrant or licensee shall ensure floors and other surfaces of nuclear medicine facilities where manipulations of unsealed sources take place are covered with smooth, continuous, and non-absorbent materials that can be easily cleaned and decontaminated.

(9) The registrant or licensee shall ensure radiopharmaceuticals are manufactured according to good manufacturing practice following relevant international standards for radionuclide purity, specific activity, radiochemical purity, chemical purity and pharmaceutical aspects, such as toxicity, sterility and pyrogenicity.

(10) The registrant or licensee shall ensure that probes used for uptake measurements include design features for energy response, energy resolution, sensitivity, counting precision, linearity of count rate response and geometrical dependence.

(11) The registrant or licensee shall ensure that probes used intra-operatively include design features for energy resolution, background count rate, sensitivity in scatter, sensitivity to scatter radiation, shielding side and back, counting precision, 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.

(12) The registrant or licensee shall ensure that gamma cameras incorporate the following design features:

(a) detector: pulse height analysis; uniformity; spatial resolution and linearity; energy resolution; sensitivity; count rate performance; 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, general acquisition features, static acquisition, dynamic acquisition, list mode acquisition, gated cardiac acquisition, whole body imaging, tomography;

(h) data processing system, data display, image manipulation, region of interest generation and display, curve generation, display, arithmetic, quality control software and test data;

(i) accessories, such as features for physiological triggering, anatomical landmarking and phantoms.

(13) The registrant or licensee shall ensure that PET scanners incorporate the following design features:

(a) detector: spatial resolution; sensitivity; scatter fraction, count losses and random measurements; energy resolution; image quality and accuracy of attenuation and scatter correction and quantitation; coincidence timing resolution for time-of-flight PET accuracy;

(b) time-of-flight capability;

(c) data acquisition: 2-D and 3-D whole body imaging and cardiac and respiratory gating;

(d) data processing system: image reconstruction algorithms, image manipulation and image correction; and emergency stop.

(14) The registrant or licensee shall develop procedures for safe receipt and movement of radioactive sources within the nuclear medicine facility and establish controls to prevent theft, loss and unauthorized withdrawal of radioactive material, or entrance of unauthorized personnel to controlled areas.

(15) The registrant or licensee shall maintain an inventory of sources and have procedures to confirm that sources are in their assigned locations and are secure.

Specific requirements for radiation protection and safety in radiation therapy

78. (1) The registrant or licensee shall ensure that regulatory siting and shielding requirements for a radiation therapy facility are met;

(2) Siting and shielding calculations shall take into consideration inpatient and outpatient access, operational efficiencies, potential for future expansion, adjacent areas or rooms, occupancy factors and the physical weight of shielding;

(3) Shielding adequacy shall be verified during construction and before the facility is placed in clinical use and similarly, after future structural modifications;

(4) Radiation treatment room shielding shall be constructed such

that its integrity as a radiation barrier is not compromised by joints, duct openings, pipes or other objects passing through the shielding, or by conduits, service boxes or other embedded structural elements.

(5) The registrant or licensee shall ensure that within a single facility, external beam radiation therapy and High Dose Rate (HDR) brachytherapy are performed in treatment rooms designed for those radiotherapeutic procedures.

(6) The registrant or licensee shall ensure the radiotherapy Record and Verify System interfaces with image and administrative data storage systems throughout the facility, including operational information systems such Picture Archiving and Communications and the Radiology Information System or their equivalents.

(7) The registrant or licensee shall ensure the Record and Verify System is subject to a comprehensive quality assurance programme.

(8) In addition to power-off switches on the control panel outside a treatment room, there shall be additional power-off switches located within easy reach inside the treatment room, so that personnel can instantly shut down radiation generating equipment in an emergency.

(9) The registrant or licensee shall provide communication systems and audio-visual devices or other means for clinical staff to be in continuous contact with and maintain a clear view of the patient.

(10) The registrant or licensee shall ensure medical radiological equipment includes:

(a) provisions for selection, reliable indication and confirmation of operating parameters such as type of radiation, indication of energy, beam modifiers, treatment distance, field size, beam orientation and either treatment time or pre-set dose;

(b) interruption mechanisms that stop irradiation when tolerance levels are exceeded;

(c) a fail-safe mechanism in the event of a power interrup-

tion, that automatically retracts the source to its shielded position until the beam control mechanism is reactivated from the control panel;

(d) safety systems to prevent equipment operation by unauthorized personnel; and

(e) a device to manually return a source to the shielded position in the case of its failing to retract automatically.

(11) The registrant or licensee shall ensure integrity and confidentiality of data, including patient information, is maintained throughout the facility's information networks.

(12) The registrant or licensee shall ensure external beam radiotherapy equipment incorporates:

(a) safety interlocks or other means to prevent clinical use of the machine in conditions other than those selected at the control panel;

(b) means to permit interruption of treatment from the control panel;

(c) radiation beam control mechanisms, including devices that indicate in a clear and fail-safe manner, whether the radiation beam is on or off;

(d) means to keep the radiation field uniform within the treatment area in the absence of radiation beam modifiers, such as wedges or multileaf collimators;

(e) means to keep radiation leakage or scattering dose rates outside the treatment area as low as reasonably achievable;

(f) electrical or mechanical interlocks to prevent primary radiation being directed towards secondary barriers if primary shielding is not intercepting the beam.

(13) The registrant or licensee shall ensure the following regarding brachytherapy equipment and sources:

(a) low dose rate, high dose rate and pulsed dose rate brachytherapy sources are accompanied by a source certificate specifying the source strength in terms of reference air kerma rate in air or equivalent quantity at a specified distance, for a specified date;

(b) the quality control tests are applied to the source include leakage and contamination tests;

(c) applicators are manufactured specifically for the source and are compatible with it.

(14) The registrant or licensee shall develop procedures for safe receipt and movement of radioactive sources within the radiotherapy and oncology facility and establish controls to prevent theft, loss and unauthorized withdrawal of radioactive material, or entrance of unauthorized personnel to controlled areas.

(15) The registrant or licensee shall maintain an inventory of sources and have procedures to confirm that sources are in their assigned locations and are secure.

PART 6: PUBLIC EXPOSURE

General responsibilities for public exposure in planned exposure situations

79. (1) The registrant or licensee, in cooperation with suppliers and with providers of consumer products, shall apply the requirements of these Regulations and shall verify and demonstrate compliance with them, as specified by the Agency, in relation to any public exposure delivered by a source for which they have responsibility.

(2) The registrant or licensee, in cooperation with suppliers, in applying the principle of optimization of protection and safety in the design, planning, operation and decommissioning of a source, shall take into account:

(a) possible changes in conditions that could affect exposure of the public, such as changes in the characteristics and

use of the source, changes in environmental dispersion conditions, changes in exposure pathways or changes in values of parameters used for the determination of the representative person;

(b) good practice in the operation of similar sources or the conduct of similar practices;

(c) possible accumulation in the environment of radioactive substances from discharges during the lifetime of the source; and

(d) uncertainties in the assessment of doses, especially un certainties in contributions to doses if the source and the representative person are separated in space or in time.

(3) The registrant or licensee shall for all sources under their responsibility, establish, implement and maintain -

(a) policies, procedures and organizational arrangements for protection and safety in relation to public exposure, in accordance with the requirements of these Regulations, which are commensurate with the likelihood and magnitude of the exposures;

(b) measures for ensuring -

(i) optimization of protection and safety; and

(ii) limitation of exposure of members of the public from such sources, in accordance with the authorization or such that the total exposure is not higher than the dose limits for members of the public;

(c) measures for ensuring the safety of such sources;

(d) provisions for suitable and adequate resources (including facilities, equipment and services) for the protection and safety of members of the public, commensurate with the likelihood and magnitude of the exposures;

(e) programmes for appropriate training of personnel having functions relevant to the protection and safety of the public, as well as periodic retraining as required, to ensure the necessary level of competence;

(f) provision for appropriate monitoring equipment, monitoring programmes and methods for assessing public exposure;

(g) adequate records of monitoring programmes; and

(h) emergency plans, emergency procedures and emergency response arrangements, in accordance with the nature and magnitude of the radiation risks associated with the sources.

Measures for protection of members of the public and visitors

80. (1) The employer and registrant or licensee shall, where appropriate -

(a) apply the relevant requirements of these Regulations in respect of public exposure for visitors to a controlled area or a supervised area;

(b) ensure visitors are accompanied in any controlled area by a person who knows the measures for protection and safety for the controlled area;

(c) provide adequate information and instructions to visitors before they enter a controlled area or supervised area, so as to provide for protection and safety of visitors and other individuals who could be affected by their actions;

(d) ensure adequate control is maintained over the entry of visitors to a controlled area or a supervised area, including the use of signs for such areas.

(2) Where a source may give rise to external exposure of members of the public the registrant or licensee shall ensure that -

(a) floor plans and arrangements of equipment for all installations utilizing such sources, as well as all significant modifications to existing installations, are subject, as appropriate to review and approval by the Agency prior to commissioning;

(b) shielding and other measures for protection and safety, including access control, are provided, as appropriate for restricting public exposure, in particular at open sites such as for some applications of industrial radiography.

(3) The registrant or licensee shall ensure that -

(a) specific provisions for confinement are established for the design and operation of a source that could cause the spread of contamination in areas accessible to the public; and

(b) measures for protection and safety are implemented for restricting public exposure due to contamination in areas within a facility that are publicly accessible.

Radioactive waste and discharges

81. (1) The registrant or licensee shall in cooperation with suppliers, as appropriate -

(a) develop and implement a strategy for radioactive waste management and shall include appropriate evidence that protection and safety is optimized;

(b) ensure that any radioactive waste generated is kept to the minimum practicable in terms of both activity and volume;

(c) maintain an inventory of all radioactive waste that is generated, stored, transferred or disposed of;

(d) manage radioactive waste in accordance with the requirements of these Regulations and with the relevant

limits, conditions and controls established in the authorization;

(e) ensure that there is separate processing of radioactive waste of different types, where warranted by differences in factors such as radionuclide content, half-life, activity concentration, volume, and physical and chemical properties, taking into account the available options for storage and disposal of radioactive waste, without precluding the mixing of radioactive waste for purposes of protection and safety; and

(f) ensure activities for predisposal management and disposal of radioactive waste are conducted in accordance with the requirements of applicable regulations, and in accordance with the authorization.

(2) On making an application for the authorization of discharges, the registrant or licensee shall, in cooperation with suppliers and -

(a) determine the characteristics and activity of material to be discharged, and possible points and methods of discharge;

(b) perform a pre-operational study to determine all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;

(c) assess the doses to the representative person due to the planned discharges;

(d) consider the radiological environmental impact in an integrated manner with the system for protection and safety, as required by these Regulations and the limits, conditions and control established in the authorization;

(e) submit to the Agency the findings in respect of paragraphs (a) to (d) to facilitate establishment by the Agency of authorized limits on discharges and condi-

tions for their implementation.

(3) The registrant or licensee shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the limits, conditions and controls established in the authorization.

(4) The registrant or licensee shall, at a frequency determined by the Agency, review and as necessary modify discharge control measures with the agreement of the Agency, taking into account -

(a) operating experience; and

(b) any changes in exposure pathways or in the characteristics of the representative person affecting assessment of doses due to discharges.

Monitoring and reporting

82. (1) The registrant or licensee, when required by the Agency, shall establish and implement a monitoring programme to ensure public exposure due to sources under their responsibility is assessed in a manner sufficient to verify and demonstrate compliance with the authorization. Monitoring shall include the following, as appropriate:

(a) external exposure due to such sources;

(b) discharges;

(c) radioactivity in the environment; and

(d) other parameters important for the assessment of public exposure.

(2) The registrant or licensee shall maintain monitoring programme records, which shall be forwarded to the Agency at intervals defined in the authorization and include at least the following:

(a) estimated doses to members of the public;

(b) levels and composition of discharges;

(c) dose rates at site boundaries and in premises open to the public;

(d) results of environmental monitoring;

(e) retrospective assessments of doses to the representative person.

(3) The registrant or licensee shall report promptly to the Agency -

(a) any levels exceeding operational limits and conditions relating to public exposure, including authorized limits on discharges;

(b) any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the registrant or licensee.

(4) The registrant or licensee shall establish and maintain a capability to conduct monitoring in an emergency in the event of unexpected increases in radiation levels or in concentrations of radionuclides in the environment due to an accident or other unusual event attributed to the authorized source or facility.

(5) The registrant or licensee shall verify the adequacy of assumptions made for assessment of public exposure and assessment of radiological environmental impacts.

(6) The registrant or licensee shall publish or make available on request, as appropriate, the results of source monitoring and environmental monitoring programmes and assessments of doses from public exposure on a communications platform accessible by the public.

Consumer products

83. (1) Consumer products shall not be provided to the public unless such provision is justified in accordance with the requirements of these Regulations and either their use has been exempted on the basis of the criteria specified in Schedule I of these Regulations or their provision to the public has been otherwise authorized.

(2) Suppliers proposing to provide consumer products to the public shall apply to the Agency for an authorization in accordance with subregulation 11(1).

(3) Aspects of consumer product design and manufacture that could affect exposure during normal handling, transport and use, as well as in the event of mishandling, misuse, accident or disposal, shall be in compliance with the optimization of protection and safety requirements of these Regulations.

(4) Applicants seeking authorization to manufacture, import, supply or otherwise handle such consumer products shall duly account for the following:

(a) the radionuclides used in the consumer products and their radiation types, energies, activities and half-lives;

(b) the chemical and physical forms of the radionuclides used in the consumer products and their significance for protection and safety in normal and abnormal conditions;

(c) the containment and shielding of radioactive substances in the consumer products and the physical constraints on access to these radioactive substances in normal conditions and abnormal conditions;

(d) specifications for the scope and frequency of servicing or repair of the consumer products and the manner in which this would be done, taking account of the protection and safety requirements of these Regulations;

(e) relevant experience with similar consumer products.

(5) The registrant or licensee authorized to provide consumer products to the public shall -

(a) comply with the conditions of the authorization to provide consumer products to the public;

(b) ensure the consumer products comply with the require-

ments of these Regulations;

(c) have appropriate arrangements for the servicing, maintenance, recycling or disposal of such consumer products, in accordance with the requirements of these Regulations;

(d) by means of legible labels attached where feasible to a visible surface of each consumer product and to the retail packaging, indicate the following:

(i) that the consumer product contains radioactive substances;

(ii) information that clearly identifies the radionuclides in the manner required by these Regulations;

(iii) that the provision of the consumer product to the public has been authorized by the Agency;

(iv) information on required or recommended opttions for recycling or disposal.

(6) The registrant or licensee authorized to provide consumer products to the public shall provide with the consumer product, clear and appropriate information and instructions on the following:

(a) correct installation, use and maintenance of the consumer product;

(b) servicing and repair;

(c) the radionuclides and their activities at a specified date;

(d) dose rates in normal operation and during servicing and repair;

(e) required or recommended options for recycling or disposal.

(7) The registrant or licensee authorized to provide consumer products shall provide consumer product retailers with appropriate information on safety and instructions on the transport and storage of the consumer products.

Responsibilities for remediation of areas with residual radioactive material

84. (1) Persons or organizations responsible for planning, implementation and verification of the remediation of areas with residual radioactive material shall prepare and submit for Agency approval, a remedial action plan supported by a safety assessment.

(2) The objective of the remedial action plan shall be to reduce the existing radiation risk in a timely and progressive manner until restrictions on the use of, or access to the area can be eased or lifted, to the extent possible.

(3) The remedial action plan submitted for Agency approval shall identify the legal person having prime responsibility for implementing the actions set out in the plan.

(4) The remedial action plan submitted for Agency approval shall consider -

(a) that proposed remedial actions potentially causing additional doses to members of the public shall be justified in accordance with the requirements of these Regulations on the basis of the resulting net benefit, including consideration of the consequent reduction of the annual dose;

(b) that both the radiological and non-radiological impacts on people and the environment are considered together, taking into account technical, societal and economic factors;

(c) that the costs of the transport and management of radioactive waste, the radiation exposure and other health risks of workers managing the radioactive waste and any subsequent public exposure associated with its disposal are taken into account.

(5) The remedial action plan submitted for Agency approval shall include:

(a) a mechanism for public information;

(b) mechanisms to involve interested parties in the planning, implementation and verification of the remedial actions, including any monitoring following remediation;

(c) monitoring programmes for the impact of the remediation actions serving also as a tool for imposing or lifting site restrictions;

(d) a system for maintaining adequate records relating to the existing exposure situation and to actions taken for protection and safety and their outcomes;

(e) procedures for reporting to the RPA or other relevant authority on any abnormal conditions relevant to protection and safety.

(6) The person or organization having prime responsibility for the remedial action plan shall establish and implement the following:

(a) post-remediation control measures, for as long as required by the Agency or other relevant authority; and

(b) a programme, including provision for monitoring, to verify the long-term effectiveness of the completed remedial actions for areas in which controls are required after remediation.

(7) The person or organization having prime responsibility for carrying out the remedial actions shall -

(a) ensure that the work, including management of the radioactive waste arising, is conducted in accordance with the remedial action plan;

(b) take responsibility for all aspects of protection and

safety, including the conduct of a safety assessment;

(c) ensure that the area is monitored regularly during the remediation so as to verify levels of contamination, to verify compliance with the requirements for radioactive waste management, and to enable any unexpected levels of radiation to be detected and the remedial action plan to be modified accordingly, subject to approval by the Agency or other relevant authority;

(d) ensure the performance of a radiological survey after completion of remedial actions to demonstrate that the end point conditions, as established in the remedial action plan, have been met;

(e) provide for the final remediation report and submits a copy to the Agency or other relevant authority.

(8) The person or organization responsible for post-remediation control measures shall establish and maintain, for as long as required by the Agency or other relevant authority, an appropriate programme, including any necessary provision for monitoring, to verify the long-term effectiveness of the completed remedial actions for areas in which controls are required after remediation.

Public exposure due to radon indoors

85. (1) Having taken account of prevailing social and economic circumstances, the reference level for ^{222}Rn for public dwellings and other buildings with high human occupancy factors, shall be an annual average activity concentration of 300 Bq/m^3.

(2) In areas where activity concentrations of radon give concern for public health the requirements of the national radon action plan shall apply.

(3) A person or organization providing technical services for the measurement of radon shall meet the requirements stipulated in regulation 19.

Exposure due to radionuclides in commodities

86. The specific reference level for exposure due to radionuclides in com-

modities such as construction materials, food and feed and in drinking water shall be an annual effective dose of 1 mSv to the representative person.

PART 7: MANAGEMENT OF RADIOACTIVE WASTE

Radioactive waste management

87. (1) A facility or activity involving generation or management of radioactive waste shall be authorized by licensing in accordance with the requirements of these Regulations.

(2) Licensees shall ensure an adequate level of protection and safety by various means, including:

(a) demonstration of safety by means of the safety case and for an existing facility or activity, by means of periodic safety reviews;

(b) preparation and implementation of appropriate operating procedures, including monitoring;

(c) application of good engineering practice;

(d) establishment and implementation of a management system;

(e) ensuring that staff are trained, qualified and competent;

(f) establishing and implementing the overall strategy for managing radioactive waste that is generated, including waste that has arisen from past practices, and for providing financial securities, taking into account interdependencies among all steps in waste management, the available options and the national radioactive waste management policy;

(g) ensuring that generation of the activity and volume of radioactive waste are kept to the minimum practicable;

(h) ensuring that radioactive waste is managed by appropri-

ate classification, segregation, treatment, conditioning, storage and disposal, and maintaining records of such activities;

(i) ensuring that disposal of radioactive waste is not unnecessarily delayed;

(j) using relevant international experience to ensure operations are as safe as practicable;

(k) reporting to the Agency of required information at intervals as may be specified in the licence, including any changes, including those related to the ownership of waste.

(3) The licensee of a facility or activity involving generation or management of radioactive waste shall be responsible for the safety of predisposal radioactive waste management facilities or activities.

(4) The licensee shall review safety at existing facilities to verify compliance with requirements. Safety related upgrades shall be made by the licensee in accordance with the national policy and strategy for management of radioactive waste and with the requirements of these Regulations.

Safety case and safety assessment for radioactive waste

88. (1) An application for a license shall include a safety case, supporting safety assessment and, as appropriate, an environmental impact assessment.

(2) In the case of a step-by-step development, or in the event of modification of the facility or activity, the safety case and its supporting safety assessment shall be reviewed and updated as necessary.

(3) Subject to subregulation (2), the safety case shall include considerations for reducing hazards posed to workers, members of the public and the environment during normal operation, anticipated operational occurrences and accident conditions.

(4) Subject to subregulations (2) and (3), the safety case shall address operational safety and all safety aspects of the facility or activity.

(5) Subject to subregulations (2), (3, and (4), the information that is supplied shall reflect the requirements of the Agency and be commensurate with the complexity of the facility and its potential impacts.

(6) The safety case and its supporting safety assessment shall be documented at a level of detail and to a quality sufficient to demonstrate safety, to support the decision at each stage and to allow for independent review and approval of the safety case and safety assessment.

(7) Subject to subregulation (6), the documentation shall be clearly written and shall include arguments justifying the approaches taken in the safety case on the basis of traceable information.

(8) The safety case for a predisposal radioactive waste management facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility and managerial controls satisfy the regulatory requirements.

(9) Subject to Subregulation (1), the safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the A that safety requirements will be met.

Emergency preparedness and response for radioactive waste management

89. The licensee shall establish and maintain emergency plans commensurate with the hazards associated with the radioactive waste facilities and activities, and report incidents significant to safety in a timely manner to the Agency and other interested parties.

Control of the generation of radioactive waste

90. Licensees generating radioactive waste shall ensure that appropriate measures are taken to keep generation of radioactive waste to the minimum practicable. This can be accomplished by -

(a) minimizing the activity and volume of waste by using the minimum quantity of radioactive material needed;

(b) applying careful planning to the design, construction, administration, operation and decommissioning planning

of facilities so that the generation of radioactive waste is kept to the minimum practicable in terms of activity and volume;

(c) applying, to the extent possible, the reuse and recycling of materials;

(d) the authorized discharge of effluent and clearance of materials from regulatory control, after some appropriate processing and/or a sufficiently long period of storage, to reduce the amount of radioactive waste that needs further processing or storage;

(e) wherever possible, when purchasing sealed sources, establishing contractual arrangements for the return of sources to the manufacturer or predetermined waste manager following use;

(f) implementing a comprehensive management system for all activities potentially generating radioactive waste; and

(g) maintaining consistency with the radioactive management policy and strategy.

Classification, management and storage of radioactive waste

91. (1) The licensee shall ensure an integrated approach to safety and security, commensurate with the level of radiological hazard and the nature of the waste, in the predisposal management of radioactive waste.

(2) The licensee shall ensure that waste is stored such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management, taking into account the expected period of storage and to the extent possible, applying passive safety features.

(3) For long term storage, measures shall be taken to prevent degradation of the waste containment and a provision shall be made for the regular monitoring, inspection and maintenance of the waste and of the storage facility to ensure their continued integrity.

(4) The licensee shall ensure that waste packages and unpackaged waste accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case by which the authorization was granted.

(5) The licensee shall carry out periodic safety reviews and implement any safety upgrades required by the Agency further to the review.

(6) Subject to subregulation (5), the results of the periodic safety review shall be reflected in the updated version of the safety case for the facility.

Decommissioning of radioactive waste management facilities

92. (1) The licensee shall develop, in the design stage, an initial plan for the shutdown and decommissioning of the predisposal radioactive waste management facility and shall periodically update it throughout the operational period.

(2) Decommissioning of the facility shall be carried out on the basis of the final decommissioning plan, as approved by the Agency.

(3) Subject to subregulation (2), assurance shall be provided that sufficient funds will be available to carry out shutdown and decommissioning.

Management system, records and reporting for radioactive waste management

93. (1) The licensee shall establish and implement a management system, commensurate with the hazard of the waste management activities.

(2) The licensee shall promote and maintain a strong safety culture.

(3) The licensee shall develop a suitable and comprehensive recording system for radioactive waste management activities under its responsibility.

(4) Subject to subregulation (3), that recording system shall include discharges and clearance of radioactive material and shall allow for traceability of radioactive waste from the point of its collection through to its long-term storage and its disposal.

(5) All records related to the radioactive waste inventory (including

disused sealed radioactive sources) and radioactive waste management activities shall be:

(a) maintained up to date; and

(b) retained in such a way as to ensure that relevant information isaccessible in the future, as necessary.

(5) When waste is being transferred, associated records shall be provided to the licensee of the subsequent step.

(6) The licensee shall provide reports on its radioactive waste management activities to the Agency, upon demand.

Disposal of radioactive waste from radioactive sources

94. (1) The licensee of a disposal facility for radioactive waste shall be responsible for its safety.

(2) The licensee shall carry out safety assessment and develop and maintain a safety case and shall carry out all the necessary activities for site selection and evaluation, design, construction, operation, closure and, if necessary, surveillance after closure, in accordance with national strategy, in compliance with the regulatory requirements and within the legal and regulatory infrastructure.

(3) The licensee shall evaluate the site and shall design, construct, operate and close the disposal facility in such a way that safety is ensured by passive means to the fullest extent possible and the need for actions to be taken after closure of the facility is minimized.

(4) The licensee of a disposal facility shall develop an adequate understanding of the features of the facility and its host environment and of the factors that influence its safety after closure over suitably long time periods, so that a sufficient level of confidence in safety can be achieved.

Management of waste generated during remediation of areas with residual radioactive material

95. (1) The management of radioactive waste from remediation activi-

ties shall, as a planned exposure situation, comply with the requirements of these Regulations and international standards for protection and safety from ionizing radiation.

(2) Subject to subregulation (1), the waste shall be managed in accordance with the national arrangements for predisposal management and disposal of radioactive waste.

PART 8: IMPORT AND EXPORT OF CATEGORY 1 AND 2 RADIOACTIVE SOURCES

Export of Category 1 or Category 2 Radioactive Sources

96. (1) Licensees intending to export Category 1 or Category 2 radioactive sources shall apply to the Agency for an export authorization.

(2) The application for authorization to export a source or sources shall include a copy of the recipient authorization to receive and possess the source or sources to be exported that includes at least the following information:

(a) name of the recipient;

(b) recipient location and legal address or principal place of business;

(c) relevant radionuclide and activity;

(d) uses of the source, if appropriate; and

(e) recipient authorization expiration date.

(3) Other information to be submitted as part of the application for authorization to export may include:

(a) copies of relevant parts of any contractual agreements to re-import the source; and

(b) justification or explanation of any need to use the 'exceptional circumstances' provisions in the International

Atomic Energy Agency's Guidance on the Import and Export of Radioactive Sources.

(4) After receiving authorization to export the source, licensees shall ensure that:

(a) the export of the source is conducted in compliance with all applicable requirements of International Atomic Energy Agency safety standard SSR-6 (Rev. 1) on transport of radioactive material;

(b) the importer is notified, at least 7 days in advance, of each shipment with the following information in writing -

(i) the estimated date of export;

(ii) exporting facility;

(iii) recipient;

(iv) radionuclide and activity;

(v) aggregate activity level;

(vi) the number of radioactive sources and, if available, their unique identifiers;

(5) For Category 1 sources, the notification described in sub-regulation (4)(b) shall be accompanied by a copy of the importer's consent to import the sources, if applicable.

Import of Category 1 or Category 2 Radioactive Sources

97. (1) Licensees intending to import Category 1 or Category 2 radioactive sources shall apply to the Agency for an import authorization.

(2) The application for authorization to import a source or sources shall include the following information:

(a) name of the exporter;

(b) exporter location and legal address or principal place of business;

(c) name of the recipient;

(d) recipient location and legal address or principal place of business;

(e) relevant radionuclide and activity;

(f) uses of the source, if appropriate;

(g) details of the arrangements for the safe management of the source, including financial provisions where appropriate, once they have become disused, and copies of any contractual agreements;

(h) justification or explanation of any need to use the 'exceptional circumstances' provisions, if applicable.

(3) After receiving authorization to import the source(s), licensees shall, to the extent possible, ensure that the import of the source(s) is in compliance with all the requirements of International Atomic Energy Agency safety standard SSR-6 (Rev. 1).

PART 9: TRANSPORT OF RADIOACTIVE MATERIAL

Transport Requirements

98. Transport of radioactive material, by all modes on land or water, or in the air, including transport that is incidental to the use of the radioactive material, either national or international, shall be done in compliance with the requirements of International Atomic Energy Agency safety standard SSR-6 (Rev. 1).

PART 10: SPECIFIC CASES, ADDITIONAL PROVISIONS

Nuclear security

99. The licensee shall ensure an integrated approach to safety and security, commensurate with the level of radiological hazard.

Nuclear safeguards

100. The licensee shall consider nuclear safeguards requirements in the design and the operation of facilities or conduct of activities to which nuclear safeguards apply. These requirements shall be implemented in such a way as not to compromise the safety of the facility.

Trustworthiness verification

101. (1) In order to ensure the trustworthiness of persons for the purpose of granting authorized access to sensitive information, or to unescorted access to nuclear or radioactive material, the operator shall establish and implement a programme implementing measures to determine and periodically review the trustworthiness of authorized individuals with access to sensitive information and unescorted access to nuclear or radioactive material following a graded approach when implementing measures to determine and review trustworthiness.

(2) With regard to any person whose trustworthiness has not been determined such as temporary repair, service or construction worker for a limited period and a visitor the licensee shall provide escort by persons authorized unescorted access.

Nuclear security culture

102. The licensee shall -

(a) develop appropriate management structures, allocate sufficient resources and put in place appropriate management systems for motivating personnel to adopt strict and prudent approach to, and seeking continuous improvement in nuclear security;

(b) provide -

(i) commitment to quality of performance in all nu clear security activities;

(ii) high priority to nuclear security, even overriding operational demands; and

(iii) clear process to resolve any conflict regarding the relative priorities of safety, security and operations;

(c) communicate and make understood to everyone affected to give due priority to nuclear security culture; and

(5) develop a self-assessment programme to assess the nuclear security culture in its organization as a basis for identifying ways to strengthen that culture.

Transitional provisions

103. (1) On entry into force of these Regulations, its provisions shall be applied to all new and pending applications for authorization.

(2) The Agency may, on written notice, revoke any authorization condition granted, to the extent that it is inconsistent with the terms of these Regulations.

Educational Qualifications for Occupationally exposed Workers

104. The following are the educational requirements for the following workers:

(a) Minimum RPO or Radiographer Requirements -

Diploma in Radiography or Degree in Science related courses with at least 6-month certificate in Radiography

Diploma in Science related courses, not allowed to work without supervision of the senior;

(b) Technicians operating Nuclear Gauges -

Diploma in Civil Engineering or related Engineering courses plus 6 months certificate in Radiation Safety and Security; and

(c) Technicians - Industrial Radiography -

Diploma in Non-Destructive Testing plus Certificate in Radiation Safety and Security.

DATED:

THABO MOFOSI
MINISTER OF ENVIRONMENT AND FORESTRY

NOTE

1. Act No. 7 of 2018

SCHEDULE I

Exemption and Clearance

CRITERIA FOR EXEMPTION

1. The Radiation Protection Agency Act, 2018 section 3 gives provisions for exemption and exclusion below is the criteria for exemption of a practice or a source within a practice from some or all of the requirements of these Standards are that -

(a) radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption; or

(b) regulatory control of the practice or the source would yield no net benefit, in that no reasonable measures for regulatory control would achieve a worthwhile return in terms of reduction of individual doses or of health risks.

2. A practice or a source within a practice may be exempted without further consideration from some or all of the requirements of these Standards under the terms of para. I(a) provided that under all reasonably foreseeable circumstances the effective dose expected to be incurred by any individual (normally evaluated on the basis of a safety assessment) owing to the exempt practice or the exempt source within the practice is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion could be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

3. Under the criteria set out in paras I and 2, the following sources within justified practices are automatically exempted without further consideration from the requirements of these Standards, including requirements for notification, registration or licensing -

(a) material in a moderate amount for which either the total activity of an individual radionuclide present on the premises at any one time or the activity concentration as used in the practice does

not exceed the applicable exemption level.

(b) material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value.

(c) radiation generators of a type approved by the Agency, or in the form of an electronic tube, such as a cathode ray tube for the display of visual images, provided that -

(i) they do not in normal operating conditions cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the equipment; or

(ii) the maximum energy of the radiation generated is no greater than 5 keV.

4. For radionuclides of natural origin, exemption of bulk amounts of material is necessarily considered on a case by case basis by using a dose criterion of the order of 1 mSv in a year, commensurate with typical doses due to natural background levels of radiation.

CRITERIA FOR CLEARANCE

1. The general criteria for clearance are that -

(a) radiation risks arising from the cleared material are sufficiently low as not to warrant regulatory control, and there is no appreciable likelihood of occurrence for scenarios that could lead to a failure to meet the general criterion for clearance; or

(b) continued regulatory control of the material would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or reduction of health risks.

2. Material may be cleared without further consideration under the terms of para. I(a) provided that in reasonably foreseeable circumstances the effective dose expected to be incurred by any individual owing to the cleared material is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion can be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

3. Radioactive material within a notified practice or an authorized practice may be cleared without further consideration provided that -

(a) the activity concentration of an individual radionuclide of artificial origin in solid form does not exceed the relevant level provided by Agenct; or

(b) the activity concentrations of radionuclides of natural origin do not exceed the relevant level given by Agency;

(c) for radionuclides of natural origin in residues that might be recycled into construction materials, or the disposal of which is liable to cause the contamination of drinking water supplies, the activity concentration in the residues does not exceed specific values derived so as to meet a dose criterion of the order of 1 mSv in a year, which is commensurate with typical doses due to natural background levels of radiation.

4. Clearance may be granted by the Agency for specific situations, on the basis of the criteria of paras 1 and 2, with account taken of the physical or chemical form of the radioactive material, and its use or the means of its disposal. Such clearance levels may be specified in terms of activity concentration per unit mass or activity concentration per unit surface area.

5. For clearance of radioactive material containing more than one radionuclide of artificial origin, the condition for clearance is that the sum of the activity concentrations for individual radionuclides is less than the derived clearance level for the mixture (Xm), determined by the RPA.

SCHEDULE II

Categories for sealed sources Used in common practices

Table 1: categories for sealed sources used in common practices

Category	Ration of Activity in the source to Activity that is considered dangerous (A/D)	Example of sources and practices
1	A/D ≥ 1000	Teletherapy Sources: Fixed, multibeam teletherapy (gamma knife) sources
2	1000 > A/D ≥ 10	Industrial gamma radiography sources, High/medium dose rate brachytherapy sources
3	10 > A/D ≥ 1	Fixed Industrial gauges, low dose rate brachytherapy sources
4	1 > A/D ≥ 0.01	Industrial gauges with lower activity sources,
5	0.01 > A/D and A > level of exemption	Low dose brachy eye plaques and permanent implant sources, X-ray fluorescence, etc

Notes: A is the Activity in a source and D is the activity of the radionuclide in question that is regarded as dangerous and is provided in IAEA document GSR part 3. A dangerous Source is defined as one that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects.

SCHEDULE III

criteria for use in emergency preparedness And response Occupational exposure

1. For occupational exposure of workers over the age of 18 years, the dose limits are:

(a) an effective dose of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;

(b) an equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;

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

Additional restrictions apply to occupational exposure for a female worker who has notified pregnancy or is breast.

2. For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are -

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

(b) an equivalent dose to the lens of the eye of 20 mSv in a year; an equivalent dose to the extremities (hands and feet) or to the skin of 150 mSv in a year.

Public exposure

3. For public exposure, the dose limits are -

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

(b) in special circumstances, a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year; an equivalent dose to the lens of the eye of 15 mSv in a year; and

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

SCHEDULE IV

Dose limits for planned exposure situations

Table 2 generic criteria for doses received within a short period of time for which protective actions and other response actions are expected to taken.

Acute external exposure (<10h)

ADred marrow	1Gray (Gy)	If the dose is projected:
ADfetus	0.1 Gy	— Take precautionary urgent protective actions immediately (even under difficult conditions) to keep doses below the generic criteria
ADtissue	25 Gy at 0.5 cm	
ADskin	10 Gy to 100 cm2	— Provide public information and warnings
		— Carry out urgent decontamination

Acute internal exposure due to an intake (Δ = 30 d)

AD (Δ)red marrow	0.2 Gy for radionuclides with atomic number Z ≥ 90 2 Gy for radionuclides with an atomic number Z ≤ 89	If the dose has been received:
		— Perform immediate medical examination, consultation and indicated medical treatment
AD (Δ)thyroid	2 Gy	— Carry out contamination control
AD (Δ)lung	30 Gy	— Carry out immediate decorporation (if applicable)
AD (Δ)colon	20 Gy	— Carry out registration for longer term medical follow-up
AD (Δ)fetus	0.1 Gy	— Provide comprehensive psychological counselling

Note: AD(Δ) is the RBE weighted absorbed dose delivered over a period of time Δ by the intake (Io5) that will result in a severe deterministic effect in 5% of exposed individuals. For this particular case, 'Δ' means the period of in utero development of the embryo and fetus.

Table 3 Guidance values for restricting exposure of emergency workers

Note: *Hp*(10) is the personal dose equivalent *Hp*(d) where d = 10 mm.

Table 3 Guidance values for restricting exposure of emergency workers

Tasks	**Live saving Actions**
Life saving Actions	*Hp*(10) < 500 mSv This value may be exceeded under circumstances in which the expected benefits to others clearly outweigh the emergency worker's own health risks, and the emergency worker volunteers to take the action and understands and accepts these health risks
Actions to prevent severe deterministic effects and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment	*Hp*(10) < 500 mSv
Actions to avert a large collective dose	*Hp*(10) < 100 mSv

Note: H p(10) is the personal dose equivalent Hp(d) where d = 10 mm.

SCHEDULE V

Radiation Protection Agency Proposed Authorization Fees

The Radiation Protection Agency Act, 2018 gives RPA an Authority to collect Licensing fees for the use, Mining, transport, milling, import and export of Radiation Source and Radiation generators, the fee below are based on the graded approach (the higher the risk, the higher the fee) and bench-marking with other countries as well as focusing on Practices and activities relevant to Lesotho currently and in foreseeable future.

Authorization fees for Medical Practices

1.	RADIOTHERAPY		
(a)	Linear Accelerators (LINAC)		
	i.	Registration of Premises Certificate	M12,000.00 once unless the facility is Modified
	ii.	License to Import LINAC	M30,000.00 per unit
	iii.	Commissioning Licence	M12,000.00
	iv.	Licence to Operate	M15,000.00 per site per annum (p.a)
(b)	Cobalt 60 /Cesium 137 (Radiotherapy Fixed)		
	i.	Registration of Premises Certificate	M12,000.00 once

		unless the facility is Modified	
	ii.	Licence to import radioactive sources (for not more than 1000 Curies (Ci)	M6,000.00
	iii.	Commissioning Licence	M12,000.00
	iv.	Licence to Operate	M12,000.00 per site p.a
(c)	Brachytherapy		
	i.	Registration of Premises Certificate	M6,000.00 once unless the facility is Modified
	ii.	Licence to Import Radioactive Sources (for not more than 1000 Ci)	M6,000.00
	iii.	Commissioning Licence	M 6,000.00
	iv.	Licence to operate Brachytherapy Facility	M6,000.00 p.a
2.	NUCLEAR MEDICINE		
	i.	Import of Radioactive Sources (I, Tc, etc for not more than 1Ci)	M6,000.00 p.a
	ii.	Registration of Premises	M6,000.00
	iii.	Licence to Operate	M6,000.00 p.a
3.	DIAGNOSTIC RADIOLOGY		
	(a)	**Convectional Mammography, Fluoroscopy and Mobile X-ray Machine**	

i.	Registration of Premises Certificate	M1,200.00 once unless the facility is modified
ii.	Licence to Operate Conventional X-ray Machine	M1,200.00 p.a.
iii.	Licence to Operate Conventional X-ray Machine	M1,200.00 p.a.
iv.	Licence to Operate Mammography Machine	M1,200.00 p.a.
v.	Licence to Operate Fluoroscopy Machine	M1,200.00 p.a.
vi.	Licence to Operate Mobile X-ray Machine	M1,200.00 p.a.
vii.	Licence to Import X-ray Machines	M1,200.00 p.a.

(b) Computed Tomography (CT) Scanner

i.	Registration of Premises Certificate	M6,000.00 once unless the facility is Modified
ii.	Commissiong Licence	M2,400.00 once
iii.	Licence to Import	M2,400.00 per unit
iv.	Licence to use	M6,000.00 p.a.

4. CYCLOTRON FOR MEDICAL ISOTOPE PRODUCTION

i.	Registration of Premises Certificate	M60,000.00 once unless the facility is Modified
ii.	Commissioning Licence	M30,000.00 per unit
iii.	Operation Licence	M60,000.00 p.a.
iv.	Licence to import	M12,000.00 per unit
v.	Sale of Medical Radioisotopes	M15,000.00 p.a.

5.	SALE AND SUPPLY OF RADIOTHERAPY/CYCLOTRON MACHINE		
	i.	Accreditation Certificate	M120,000.00 p.a.
6.	SALE AND SUPPLY OF DIAGNOSTIC RADIOLOGY MACHINES		
	i.	Accreditation Certificate	M60,000.00 p.a.
7.	ALL MEDICAL PRACTITIONERS WORKING WITH RADIATION		
	i.	Licence to Practice	M200.00 p.a

AUTHORIZATION FEES FOR INDUSTRIAL RADIOGRAPHY

1.	**Industrial Radiography (Diamond Mines and others)**		
	(a)	Industrial X-ray Machine-Based	
		i. Registration of Premises Certificate	M90,000.00 once unless the facility Modified
		ii. Licence use	M45,000.00 p.a.
		iii. Licence to Import	M25,000.00 p.a.
		iv. Licence for Transfer of Industrial X-ray Machine	M20,000.00 per transaction
	(b)	Radiotracer Techniques	

i.	Registration of Premises Certificate	M10,000.00 once unless the facility is Modified
ii.	Licence to use	M10,000.00 p.a.
iii.	Licence to import Radiotracer Sources (not more than 1Ci)	M10,000.00 p.a.
iv.	Licence to import any additional 1Ci after the first 1Ci	M5,000.00

AUTHORIZATION FEES FOR RESEARCH AND DEVELOPMENT
(UNIVERTIES AND RESEARCH INSTITUTION

1. CALIBRATION/TEST SOURCES

i.	Licence to import (for not more than 100mCi)	M1,000.00 per unit
ii.	Licence to Supply (for not more than 100mCi)	M1,000.00 per unit

2. EQUIPMENT INCORPORATING RADIOACTIVE SOURCES

I.	Registration of Premises Certificate	M3,000.00
II.	Licence to use	M3,000.00 p.a
III.	Licence to import (for not more than 1Ci)	M3,000.00 per unit
IV.	Licence to supply (for not more than 1Ci)	M12,000.00 per unit

3. HIGH ACTIVITY SOURCES (MORE THAN 1 CURIE)

I.	Registration of Premises	M8,000.00 p.a.
II.	Licence to Use	M8,000.00 p.a.

AUTHORIZATION FOR GUAGES AND X-RAY SCANNERS

1.	INDUSTRIAL GUGES		
	(a)	Nuclear/Radioactive Based Gauges	
		i. Registration of Premises Certificate	M20,000.00
		ii. Licence to Use	M25,000.00 p.a.
		iii. Licence to Import Radioactive Sources	M10,000.00 per unit (for not more than 1Ci)
		iv. Licence to Transfer of Guage's' Sources	M10,000.00 per Transaction
2.	INDUSTRIAL GAUGES (MANUFACTURING INDUSTRIES)		
		I. Registration of premises Certificate	M15,000.00
		II. Licence to Use	M15,000.00 p.a.
		III. Licence to Import (for not more than 1Ci)	M10,000.00 per unit
		IV. Licence for transfer of a unit	M10,000.00 per Transaction
3.	X-RAY SCANNERS (LINAC- FOR CONTAINER SCANNING)		
		I. Registration of Premises Certificate	M30,000.00
		II. Commission Licence	M20,000.00 per unit
		III. Operation Licence	M30,000.00 p.a.
		IV. Licence to Import M30,000.00 per unit	
		V. De-Commissioning Licence	M40,000.00 per unit once

4.	X-RAY SCANNERS (LESS THAN 1MeV - FOR CONTAINER SCANNING)		
	i.	Registration of Premises Certificate	M15,000.00
	ii.	Commissioning Licence	M15,000.00 per unit
	iii.	Operation Licence	M15,000.00 p.a
	iv.	Licence to Import	M30,000.00 per unit
5.	X-RAY SECURITY SCANNERS (LESS THAN 150kv – FOR BUGGAGE SCANNING AT AIRPORT)		
	I.	Registration of the Premises Certificate	M10,000.00
	II.	Commissioning Licence	M5,000.00 per unit
	III.	Operation Licence	M10,000.00 p.a.
	IV.	Licence to Import	M10,000.00 per unit

AUTHORIZATION FEES FOR SERVICE PROVIDERS

1.	DOSIMETRY SERVICE PROVIDER		
	i.	Accreditation Certificate	M5,000.00 p.a
	ii.	Registration of the premises Certificate	M5,000.00
	iii.	Licence to import irradiator incorporating radioactive sources	M5,000.00 per unit

2.	LAND TRANSPORTATION OF RADIOACTIVE MATERIALS		
	I.	Accreditation Certificate	M3,000.00 p.a
	II.	Registration of Vehicle to Transport Radioactive Sources	M3,000.00 vehicle p.a
3.	ENGINEERING/ MAINTENANCE SERVICE PROVIDER		
	i.	Accreditation Certificate	M10,000.00 p.a.
4.	SALE AND SUPPLY OF EQUIPMENT INCORPORATING IONIZATION RADIATION SOURCES		
	I.	Accreditation Certificate	M10,000.00 p.a.
5.	RADIATION SAFETY ADVISER/CALIBRATION/TRAINING/ CONSULTANT SERVICES		
	I.	Accreditation Certification	M2,500.00 p.a.
6.	RADIOACTIVE WASTE MANAGEMENT		
(a)	RADIOACTIVE WASTE MANAGEMENT CONSULTANT		
	I.	Accreditation Certificate	M8,000.00 p.a.
(b)	INTERIM RADIOACTIVE WASTE STORAGE FACILITY		

	i.	Registration of the premises Certificate	M8,000.00 p.a.
(c)	RADIOACTIVE WASTE MANAGEMENT FACILITY		
	I.	Sitting Licence	M25,000.00 Once
	II.	Design and Construction Licence	M15,000.00
	III.	Commissioning Licence	M8,000.00
	IV.	Operation Licence	M15,000.00 p.a.

Radiation Protection Agency Dosimetry Service Fees

1.	Renting personal Dosimeter (Optically Stimulated Luminescence	M3000.00 p.a.
2.	Dosimeter Reading	M500.00 Quarterly per OSL

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