GOVERNMENT NOTICE NO. 22

ATOMIC ENERGY ACT

(NO. 16 OF 2011)

ATOMIC ENERGY REGULATIONS, 2012

ARRANGEMENT OF REGULATIONS

REGULATION

IN EXERCISE of the powers conferred by section 82 of the Atomic Energy Act, I CATHERINE GOTANI HARA, Minister of Environment and Climate Change Management , on the recommendation of the Atomic Energy Board, make the following Regulations—

PART I—PRELIMINARY

Citation

1. These Regulations may be cited as Atomic Energy Regulations, 2012.

Interpretation

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

"category 1, 2 or 3 radioactive source" means the International Atomic Energy Agency Categorization of Radio Active Sources contained in the Fourth Schedule;

"critical group" means a group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure pathway and is typical of individuals receiving the highest effective dose or equivalent dose, as applicable from the given source;

"defence 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;

"disused radioactive source" means radioactive source which is no longer used, and is not intended to be used, for the practice for which a licence is granted;

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

"exemption level" means a value, established by the Authority and expressed in terms of activity concentration, total activity, dose rate or radiation energy, at or below which a source of radiation may be granted exemption from regulatory control without further consideration;

"legal person" means any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action having implications for protection and safety;

"management" means the administrative and operational activities that are involved in the manufacture, supply, receipt, possession, storage, use, transfer, import, export, transport, maintenance, recycling or disposal of radioactive sources;

"principal parties" mean the persons having the main responsibilities for the application of these Regulations, including registrants, licensees and employers;

"orphan radioactive source" means radioactive source which is not under regulatory control because it has never been under regulatory control, or because it has been abandoned, lost, misplaced, stolen, or transferred without a proper licence;

"registration" means a form of licence for practices of low or moderate risks whereby the legal person responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facility and equipment to the Authority. The practice or activity is licensed with conditions or limitations, as appropriate;

"regulatory control" means any form of control or regulation applied to facilities or activities by an Authority for reasons related to radiation protection or to the safety of radiation sources;

"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;

"spent radioactive source" means radioactive source that is no longer suitable for its intended purpose as a result of radioactive decay;

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

"vulnerable radioactive source" means radioactive source for which control is inadequate to provide assurance of long term safety and security, such that it could relatively be easily acquired by unlicensed persons or could, relatively easily become orphaned.

Part II—General Provisions

Purpose

3.—(1) These Regulations specify the basic requirements:

(*a*) for the protection of people against exposure to ionizing radiation, for the safety of radiation sources, for the safety of radioactive waste management, and for the protection of the environment, (hereinafter referred to as "protection and safety") and;

(*b*) to prevent unlicensed access or damage to, and loss, theft or unlicensed transfer of radioactive sources, so as to reduce the likelihood of accidental harmful exposure to such sources.

(2) These Regulations shall not relieve a licensed legal person from the duty to take any additional actions as may be appropriate and necessary to protect the environment or the health and safety of people.

Scope

4. These Regulations shall apply to the adoption, introduction, conduct, discontinuance, or cessation of a practice and to the design, manufacture, construction or assembly, acquisition, import or export, distribution, selling, loaning or hiring, locating, commissioning, processing, possession, use and operation, maintenance or repair, transfer or decommissioning, disassembly, transport, storage and recycling or disposal of a radiation source within a practice unless exposure from the source is specifically excluded under regulation 7 or is exempted under regulation 16.

Application

5.—(1) The sources within any practice to which the requirements for practices of these Regulations shall apply include—

(*a*) radioactive materials and devices that contain radioactive material, produce radiation or nuclear material, including consumer products, sealed radioactive sources, unsealed sources, and radiation generators;

(*b*) installations and facilities containing radioactive materials or devices containing radioactive material or that produce radiation which are used for industrial, medical, agricultural, research and education purposes;

(*c*) radioactive waste resulting from applications and to radioactive waste management facilities and activities including;

(i) effluent discharges;

(ii) waste that contains only naturally occurring materials, whatever the origin of that waste;

(iii) disused radioactive sources; and

(iv) any other radiation source specified by the Atomic Energy Regulatory Authority, including sources in the environment such as radon.

(2) The specific radioactive waste provisions contained in regulations 74–78 shall apply only to waste arising from medical, agricultural, industrial, research and education applications, mining and milling activities, including associated radioactive waste management activities, such as collection, segregation, characterization, classification, treatment, conditioning, and storage.

(3) These Regulations shall apply to intervention by legal persons licensed to possess radiation sources in the event of radiological emergencies involving their sources.

Exposures

6. The exposures to which the safety requirements of these Regulations apply are any occupational exposure, medical exposure or public exposure due to any relevant practice or radiation source within the practice, including both normal exposures and potential exposures.

Exclusions

7. The following exposures are excluded from the application of these Regulations—

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

(*b*) cosmic radiation;

(*c*) unmodified concentrations of natural radionuclides in raw materials; and

(*d*) any other radiation sources that is essentially unamenable to control as may be determined by the Authority.

Responsible parties

8.—(1) The principal parties which have the main responsibilities for the application of these Regulations shall be—

(*a*) legal persons responsible for notified or licensed practices or sources within practices; and

(*b*) employers of workers who do not report directly to legal persons.

(2) Other parties which shall have subsidiary responsibilities for the application of these Regulations may include, as appropriate;

(*a*) suppliers;

(*b*) workers;

(*c*) radiation protection and waste safety officers;

(*d*) medical practitioners;

(*e*) health professionals;

(*f*) qualified experts;

(*g*) ethical review committees; and

(*h*) any other party to whom the principal party has delegated specific tasks.

(3) the general responsibilities of the principal parties include—

(*a*) to establish radiation safety objectives, to protect people and the environment from the harmful effects of ionizing radiation, in conformity with the relevant requirements of these Regulations;

(*b*) to develop, implement and document a radiation safety programme commensurate with the nature and extent of the risks associated with the practices and interventions under their responsibility and sufficient to ensure compliance with the requirements of these Regulations and in particular, this programme shall include the following actions—

(i) to determine and continually review the measures needed to achieve the radiation safety objectives, to ensure that resources needed for their implementation are provided and regularly to verify that radiation safety objectives are being achieved;

(ii) to identify and prevent, or promptly correct, any failures or shortcomings in the radiation safety measures;

(iii) to facilitate consultation and co-operation among all relevant parties with respect to radiation safety; and

(iv) to keep appropriate records regarding the discharge of their responsibilities; and

(*c*) to ensure that—

(i) radioactive sources are managed in accordance with the licence;

(ii) when radioactive sources are not in use, they are safely stored;

(iii) any transfer of sources to another person is licensed and documented and that the receiving person or entity is licensed in accordance with the applicable regulatory requirements to receive the transferred source;

(iv) arrangements are made for the safe management of radioactive sources (minimum Category 1, 2 & 3 as referred to in the Fourth Schedule), including financial provisions where appropriate, once they have become disused;

(v) the import and export of Category 1 & 2 radioactive sources is done in accordance with these Regulations;

(vi) sources are shipped and received in accordance with regulatory requirements; and

(vii) assistance is provided to relevant authorities or law enforcement authorities in recovering any lost or stolen source.

Access to premises and information

9.—(1) Legal persons responsible for notified or licensed practices or sources within practices shall permit representatives of the Authority immediate access to premises and facilities in which such practices are conducted or sources located in order to obtain information about the status of radiation safety and verify compliance with regulatory requirements.

(2) Each legal person engaged in a practice to which these Regulations apply, shall make available to the Authority, information and records regarding radiation safety and security of sources as required.

Non-compliance, incidents and accidents

10.—(1) In the event of a breach of any applicable requirement of these Regulations, principal parties shall, as appropriate—

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

(*b*) take appropriate action to remedy the circumstances and to prevent a recurrence of similar situations;

(*c*) report to the Authority within twenty-four (24) hours, or as required, on the causes of the breach, its circumstances and consequences, and on the corrective or preventive actions taken or to be taken; and

(*d*) take whatever other actions are necessary as required by these Regulations.

(2) Whenever a situation involving the loss of control through loss or theft of a Category 1, 2 or 3 radioactive source has occurred or is occurring, the Authority shall be informed as soon as it is discovered that there has been a loss of control of the Category 1, 2 or 3 radioactive source.

(3) Failure to take corrective or preventive actions within a reasonable time in accordance with these Regulations shall be grounds for enforcement in accordance with regulation 11.

Enforcement

11.—(1) The Authority may revoke, suspend or modify a licence to use a radiation source where the Authority finds that there is an undue threat to health and safety or non-compliance with the Act or other applicable regulatory requirements.

(2) Where the Authority finds that legal persons responsible for notified or licensed practices or sources within practices have not complied with the Act, applicable regulations and regulatory requirements commensurate with the nature of the infraction, the Authority shall impose upon them the prescribed fines.

(3) The Authority shall refer any wilful violations or attempted violations of these Regulations or requirements to the Director of Public Prosecutions for prosecution.

(4) Any person who contravenes any provision of these Regulations commits an offence and shall, upon conviction, be liable to a fine of five million Kwacha and to five (5) years imprisonment.

Applicability of other regulations and requirements,

12.—(1) The requirements of these Regulations are in addition to, and not in place of, other applicable national and international laws and regulations.

(2) Nothing in these Regulations shall be construed as—

(*a*) relieving employers from complying with applicable national and international laws and regulations governing safety and security of sources; or

(*b*) restricting any actions that may otherwise be necessary for safety and security of sources.

(3) Where a conflict exists between requirements contained in these regulations and other laws or regulations, the Authority shall be notified of the conflict in order to initiate steps towards resolution.

Additional requirements

13.—(1) The Authority may prescribe other requirements by order, or conditions of a licence, in addition to those established under these Regulations, as considered necessary to—

(*a*) protect the public;

(*b*) protect the environment; or

(*c*) minimize risk from radiation hazards.

(2) A licensed legal person shall comply with the additional requirements referred to in subregulation (1).

(3) Except as specifically licensed, no official interpretation of these Regulations binding on the Authority can be made by any officer or employee of the Authority other than a written interpretation by the Executive Director of the Authority.

PART III—ADMINISTRATIVE REQUIREMENT

General obligations

14.—(1) A person shall not engage in activities, which involve radioactive waste, practices or radiation sources as specified in regulation 4, unless the requirements of these Regulations, including requirements of notification and licence, are fulfilled.

(2) An applicant and a licensee, as the case may be, shall pay the applicable fees contained in the fifth schedule as prescribed by the Minister from time to time.

(3) The Authority shall determine the formula to calculate the applicable fees, and the authority may, from time to time, review the formula.

Requirements for notification

15.—(1) Unless exempt from notification as provided for in regulation 16 (1) or (3), any legal person—

(*a*) who, on the day these Regulations enter into force, is responsible for a practice or in possession of a radioactive source referred to in regulation 4, shall submit a notification to the Authority within ninety (90) days from the effective date and shall provide the information in the notification, specified in the First Schedule hereto; and

(*b*) who intends to initiate a practice or to possess a radiation source referred to in regulation 4, shall submit a prior notification to the Authority of the intention.

(2) After notification, each legal person who is required to apply to the Authority for a licence and who submits such an application in accordance with regulation 17, may continue with the existing activities specified in the notification, in conformity with the applicable requirements of these Regulations, until the Authority revokes the permission or grants the licence.

Exemption of practices and sources

16.—(1) The Authority may exempt practices and sources within a practice from the specific safety requirements specified under these Regulations:

Provided that they comply with exemption levels defined by the Authority.

(2) Exemptions shall not be granted for practices considered not to be justified as specified in regulation 22 (2) and regulation 46 (4).

(3) the following practices and sources within a practice are automatically exempt from the specific safety requirements of these Regulations, including the requirements for notification, registration or licensing—

(*a*) the radioactive materials for which the total activity of a given nuclide present on the premises at any one time or its activity concentration contained in a mass of one thousand kilograms (1000 kg) or less of material does not exceed the exemption levels; or

(*b*) the apparatus containing radioactive material exceeding the quantities or concentrations specified above:

Provided that—

(i) it is of a type approved by the Authority; and

(ii) it is constructed in the form of a sealed radioactive source, and it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus nor a dose to any member of the public exceeding 10 μSv in a year; or

(*c*) the operation of any electrical apparatus to which these Regulations apply, other than that referred to in (*d*) below:

Provided that—

(i) it is of a type approved by the Authority; and

(i) it does not cause in normal operating conditions a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus; or

(*d*) the operation of any cathode ray tube intended for the display of visual images or other electrical apparatus operating at a potential difference not exceeding 30 kV:

Provided that it does not cause in normal operating conditions a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus.

Requirements for licence

17.—(1) Except as provided in regulations 15 and 16, a legal person who wishes to engage in a practice or possess a radiation source referred to in regulation 3, shall apply to the Authority for a licence and shall pay the fees prescribed in the fifth schedule.

(2) In the case of existing practices or sources for which notification is made in accordance with regulation 15 (1) *(a)*, such application shall be submitted within ninety (90) days.

(3) Where the application is in respect of—

(*a*) an industrial irradiation installation;

(*b*) an installation processing radioactive materials;

(*c*) a medical facility;

(*d*) industrial radiography facility; or

(*e*) is for any use of source that the Authority has not designated as suitable for registration from the date these Regulations enter into force, the application shall be in respect of a licence.

(4) Any legal person applying for a licence, shall—

(*a*) submit to the Authority relevant information necessary to support the application, including—

(i) an evaluation of the nature, magnitude and likelihood of the exposures attributed to the practice and sources within the practice;

(ii) a safety assessment, in cases where this is prescribed by the Authority, to be submitted as part of the application;

(iii) an emergency plan, if applicable;

(iv) a determination of the characteristics and activity of any radioactive material to be discharged to the environment with an assessment of the resulting doses to the critical group; and

(v) a final disposal solution for generated radioactive waste and disused sealed sources according to the agreed national policy and strategy;

(*b*) take all necessary steps for the protection and safety of—

(i) Workers;

(ii) Members of the public; and

(iii) Where applicable, patients; and

(*c*) ensure the availability of human and financial resources for decommissioning of the facility and the management of radioactive waste.

(3) Applications for licences involving Category 1, 2 or 3 radioactive sources shall include a description of the arrangements for the safe management of the source, including financial provisions where appropriate, once they have become disused.

(4) The applicant shall clearly identify any information in the application which needs to be kept confidential in accordance with regulation 28.

(5) Any legal person responsible for a source to be used for medical exposure shall include in the application for a licence, the qualifications in radiation protection of the medical practitioners, who shall be designated by name or by qualification credentials, in the licence as the only individuals permitted to prescribe medical exposure by means of the licensed source.

Responsibilities of licensees

18.—(1) A licensee shall bear the responsibility of establishing and implementing the administrative and technical measures that are necessary for ensuring protection and safety for both the practices and sources for which they are licensed; and for compliance with all applicable requirements of these Regulations.

(2) The licensee may appoint and shall specifically identify other persons to carry out actions and tasks related to the responsibilities, referred to in subregulation (1) but shall retain the responsibility for the actions and tasks themselves.

(3) The licensee shall notify the Authority of his intentions to introduce modifications to any practice with a radiation source for which he is licensed where the modifications may have significant implications for safety, and the licensee shall not carry out any such modification unless specifically authorized by the Authority.

(4) The licensee shall in an application to the Authority—

(*a*) designate by name or qualifications any person who has key assignments related to safety; and

(*b*) specify other workers assigned tasks in the handling and operation of radiation sources that may substantially affect protection and safety.

(5) The licensee shall ensure that only workers referred to in subregulation (4) are permitted to fulfill such required assignments and tasks referred to in subregulation (4).

(6) The licensee shall ensure that such persons meet the requirements for training specified in these Regulations.

(7) The licensee shall ensure that, as applicable and appropriate, the location, design, construction and assembly, commissioning, operation and maintenance, and decommissioning of sources as well as devices and facilities are based on sound engineering practices that—

(*a*) take into account approved codes of practice, standards, and technical and scientific developments;

(*b*) are supported by reliable managerial and organizational features; and

(*c*) include adequate margins in the design, construction and operation of sources.

(8) The licensee shall ensure that the appropriate safety and security measures are in place and taken during the entire life cycle of radiation sources, from the moment of their manufacturing up to their final disposal.

(9) For this purpose, the licensee shall ensure that a multilayer system of provisions, defence in depth, for protection and safety commensurate with the magnitude and likelihood of the potential exposures involved is applied to the sources under his responsibility such that a failure at one layer is compensated for or corrected by subsequent layers, for the purposes of—

(*a*) preventing accidents that may cause exposure;

(*b*) mitigating the consequences of any accident should it occur; and

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

(10) the licensee shall ensure that the safety of the facility or of the waste shall not be jeopardized by any provision made for the purpose of complying with national or international requirements concerning safeguards of the material.

Requirements for reporting to the Authority

19.—(1) A licensee shall—

(*a*) notify the Authority by telephone or facsimile as soon as practicable, but in any case not later than twenty-four (24) hours after discovery of any accident or incident which has the potential for, or has resulted in, serious injury or death of a patient, or which involves more than one patient in accordance with regulation 51;

(*b*) submit to the Authority, within seven (7) days after discovery of the accident or incident, a written report which states the cause of the accident or incident and includes information on the doses, corrective measures and any other relevant information;

(*c*) report a summary of the public exposure monitoring results to the Authority as prescribed and promptly inform the Authority of any abnormal results which lead or could lead to an increase of public exposure;

(*d*) report discharges of radioactive waste into the environment to the Authority at intervals as may be specified in the licence and promptly report any discharges exceeding the licensed limits; and

(*e*) report promptly, but in any case not later than twenty-four (24) hours and within seven (7) days, submit a written report to the Authority of any releases of radioactive material into the environment above the clearance criteria established by the Authority.

(2) In addition to the radiation safety related reports above, the licensee shall make the following reports to the Authority—

(*a*) radioactive source inventory data and subsequent changes to those data, except for routine movements of the source allowed in the licence—

(*b*) unusual events or incidents, such as—

(i) loss of control over a radioactive source;

(ii) unlicensed access to, or unlicensed use of, a source; or

(iii) discovery of any orphan sources;

(*c*) any intentions to introduce modifications to any practice with a radioactive source whenever the modifications could have significant implications for safety; and

(*d*) a copy of relevant parts of any contract or acceptance document relating to the return of radioactive sources intending to be imported.

(3) The licensee shall report to the Authority any breach of these Regulations within twenty four (24) hours, and shall include the information required by Regulation 10.

(4) For radioactive sources in Category 1, 2 and 3, the licensee shall inform the Director of Public Prosecution and the Authority immediately of—

(*a*) lost sources; and

(*b*) actual or attempted theft of sources.

(5) Additional reports regarding radioactive waste shall be made in accordance with regulation 82.

(6) Unless otherwise specified, all reports required under this regulation shall be made in writing within seven (7) days.

Feedback of operating experience

20.—(1) A licensee shall ensure that information on normal operation performance as well as abnormal conditions and events significant to radiation safety is disseminated or made available, as appropriate, to the Authority and other relevant parties, including other users, as specified by the Authority.

(2) In addition, and where applicable, the licensee shall make suitable arrangements with suppliers of sources to establish and maintain mechanisms for transfer from the licensee to suppliers of any information on the use, maintenance, disposal and malfunctioning that may be relevant for future improvements in the design and fabrication of the sources they have supplied.

Clearance levels

21. Radiation sources, including substances, materials, radioactive waste and objects within licensed practices may be released from further compliance with the safety requirements of these Regulations where they comply with clearance levels established by the Authority.

Part IV—Radiation Protection Performance Requirements

Justification of practices

22. —(1) The Authority shall not license any practice unless it is likely to produce sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause, taking into account social, economic and other relevant factors.

(2) At the request of the Authority, an applicant for a licence shall provide sufficient information and evidence on the benefits and the potential harm, to support the justification of the practice or source and the Authority may refuse to grant a licence on the basis that it is not justified.

(3) The following practices are deemed not justifiable where they may result in an increase, by deliberate addition of radioactive material or by activation, in the activity of the associated commodities or products—

(*a*) except for justified practices involving medical exposures, practices involving food, beverages, cosmetics or any other commodity or product containing radioactive material and intended for ingestion, inhalation or percutaneous intake by, or application to, a human being;

(*b*) practices involving use of radiation or radioactive materials in commodities or products such as toys and personal jewellery or adornments; and

(*c*) any other practices determined by the Authority as unjustified.

Dose limitation

23.—(1) The normal exposure of individuals shall be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues, caused by the possible combination of exposures from licensed

practices, exceeds any relevant dose limit specified in the Second Schedule hereto, except in the special circumstances considered in regulation 46.

(2) Dose limits specified in the Second Schedule shall not apply to medical exposures from licensed practices.

Optimization of protection and safety

24.—(1) In relation to exposures from any particular source within a practice, a licensee shall optimize radiation safety in order that the magnitude of individual doses, except for the volume of interest in cases of therapeutic medical exposures, the number of people exposed and the likelihood of incurring exposures are kept as low as reasonably achievable, economic and social factors being taken into account, within the restriction that the dose to individuals delivered by the source be subject to dose constraints, as it is specified in Regulation 25.

(2) The licensee shall, to the extent practicable, use procedures and engineering controls based upon sound radiation safety principles to achieve this objective.

Dose constraints

25.—(1) Except for medical exposure, the optimization of the radiation safety measures associated with a given practice shall satisfy the condition that the resulting doses do not exceed dose constraints which are equal to the dose limits specified in the Second Schedule or any lower values established by the Authority.

(2) In case of any source that can release radioactive material to the environment, the Authority shall establish dose constraints so that the prospective annual doses to members of the public, including people distant from the source and people of future generations, summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits specified in the Second Schedule or any lower values.

Guidance levels for diagnostic medical exposure

26.—(1) Medical practitioners, in the conduct of diagnostic procedures involving exposure to radiation as well as in the optimization of protection of patients, shall use guidance levels for medical exposure and the guidance level of activity for discharge from a hospital, respectively.

(2) The guidance levels shall be established by relevant professional bodies or well known specialists, in consultation with the Authority, to provide an indication on what doses are achievable with current good practice for average sized patients.

(3) The guidance levels shall be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgements and shall be revised as required by technological and scientific developments and international standards.

Part V—Management Requirements

Safety culture

27. A licensee shall establish a management system, commensurate with the size and nature of the licensed activity and practice, which ensures that—

(*a*) policies and procedures are established that identify protection and safety as the highest priority;

(*b*) problems affecting protection and safety are promptly identified and corrected in a manner commensurate with their importance;

(*c*) the responsibilities of each individual for protection and safety are clearly identified and each individual is suitably trained and qualified;

(*d*) clear lines of authority for decisions on protection safety are defined; and

(*e*) organizational arrangements and lines of communications are established that result in an appropriate flow of information on protection and safety at and between the various levels in the entire organization of the licensee.

Confidentiality of information

28. A licensee shall establish an information management system, commensurate with the size and nature of the licensed activity, which ensures—

(*a*) that the confidentiality of information that it receives in confidence from another party is protected; and

(*b*) that information received in confidence from another party is only provided to a third party with the consent of the person who furnished the information.

Management system

29.—(1) A licensee shall establish management system programmes based on standards acceptable to the Authority that provide, as appropriate—

(*a*) adequate assurance that the specific requirements relating to radiation safety and radioactive waste are satisfied;

(*b*) adequate assurance that the specific requirements relating to security of sources are satisfied;

(*c*) assurance that the components of the safety systems are of a quality sufficient for their tasks; and

(*d*) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of safety measures.

(2) Management system programmes shall include periodic exercises, annually for Category 1, 2 and 3 radioactive sources, and evaluation of emergency plans with subsequent revision as necessary.

(3) Management system programmes for radioactive waste management shall be submitted to the Authority for approval as part of the licence application.

Human factors

30.—(1) A licensee shall ensure that all personnel on whom protection and safety depend, are—

(*a*) appropriately trained and qualified so that they understand their responsibilities and can perform their duties with appropriate judgement and according to defined procedures; and

(*b*) periodically retrained or re-qualified as may be appropriate.

(2) All employees shall be informed, at least annually of the importance of effective safety measures and be trained in their implementation, as appropriate.

(3) The Authority shall routinely, evaluate and require the licensee to update training programmes as necessary.

(4) The licensee, in co-operation with suppliers, as appropriate, shall follow sound ergonomic principles in designing equipment and preparing operating procedures, in order to facilitate the safe use of equipment and minimize the contribution of human errors to accidents or incidents.

(5) The licensee shall provide appropriate equipment, safety systems and procedures which—

(*a*) reduce, as far as practicable, the possibility of human errors leading to unplanned exposure of any person;

(*b*) provide means to detect human errors and correct or compensate for them; and,

(*c*) facilitate intervention in the event of an accident or incident.

Radiation protection officers and qualified experts in radiation safety

31.—(1) A licensee shall have on his staff qualified experts in radiation safety who shall be available for providing advice on the observance of these Regulations, where required by the Authority.

(2) The qualifications of experts in radiation safety shall include a level of academic knowledge and of professional experience compatible with the levels of risks associated with the licensed practices or sources within a practice.

(3) A radiation protection officer shall be technically competent in radiation protection matters relevant to a given type of practice and the radiation protection officer shall oversee the application of the requirements of these Regulations to that practice.

(4) The licensee may propose to use a radiation protection officer in place of a qualified expert in radiation safety on the basis of the relatively low risk of the practice.

(5) The licensee shall keep the Authority informed of the arrangements made with respect to subregulations (1) and (2) above.

Part VI—Verification of Safety

Safety assessment

32. Where the Authority requires, or to meet management system requirements, a licensee shall prepare safety assessments for radiation sources and for sources within practices, including radioactive waste management activities, in order to—

(*a*) identify ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment;

(*b*) determine the expected magnitudes of normal exposures;

(*c*) estimate the probabilities and the magnitudes of potential exposures; and

(*d*) assess the quality and extent of the protection and safety provisions.

Monitoring, testing and verification of compliance

33.—(1) A licensee shall conduct monitoring and measurements of the parameters necessary for verification of compliance with the requirements of these Regulations and a licence.

(2) For the purposes of monitoring and verification of compliance, the licensee shall provide suitable equipment and introduce verification procedures.

(3) The licensee shall ensure that equipment is properly maintained and tested and calibrated at appropriate intervals with reference to standards traceable to national or international standards.

Inventory and records

34.—(1) A licensee shall maintain records of the results of monitoring and verification of compliance, including the inventory of radiation sources and radioactive waste, the transfer of radiation sources, radiation monitoring, testing of instruments and safety systems, calibrations and other checks carried out in accordance with requirements of these Regulations.

(2) Individual radioactive source records shall include the—

(*a*) location of the source;

(*b*) radionuclide;

(*c*) radioactivity on a specified date;

(*d*) serial number or unique identifier;

(*e*) chemical and physical form;

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

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

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

Part VII—Occupational Exposure Protection

General responsibilities Second Schedule

35.—(1) A licensee and an employer of workers who are engaged in activities that involve or could involve occupational exposure shall be responsible for the protection of the workers against any occupational exposure which is not excluded from these Regulations.

(2) The licensee and employer shall ensure, for all workers engaged in activities that involve or could involve occupational exposure, that—

(*a*) occupational exposures are limited to the doses specified in the Second Schedule hereto;

(*b*) radiation safety is optimized in accordance with regulations 23 and 24;

(*c*) policies, procedures and organizational arrangements for occupational radiation safety are established to implement the relevant requirements of these Regulations, and the resulting decisions on measures to be adopted for this purpose are recorded and made available to relevant parties, including workers, through their representatives where appropriate;

(*d*) suitable and adequate devices and equipment for radiation safety are provided, including personal protective devices and monitoring equipment, and training arrangements are made for their proper use;

(*e*) radiation safety and health surveillance services are provided, as required, through qualified experts;

(*f*) arrangements are made to facilitate consultation and cooperation with workers, through their representatives where appropriate, about measures which are needed to achieve adequate radiation safety by an effective implementation of these Regulations;

(*g*) necessary conditions are provided and arrangements are made to promote a safety culture in the work force and achieve adequate training of workers on radiation safety matters;

(*h*) occupational exposures are limited to within the doses specified in the Second Schedule hereto;

(3) If workers are to be engaged in work that involves or could involve a radiation source which is not under the control of their employer, the licensee responsible for the source shall—

(*a*) obtain from the employer, as a pre-condition for engagement of such workers, information on their previous occupational exposure history and other information as may be necessary to provide protection and safety in compliance with these Regulations;

(*b*) provide such workers with adequate protective measures and safety provisions; and

(*c*) make dosimetric and other appropriate information available to the employer for the purpose of demonstrating that the level of protection provided to such workers is compatible with the requirements of these Regulations.

(4) The licensee and employer shall ensure that workers under their responsibility who are exposed to radiation from sources other than natural sources that are not directly related to or required by their work receive the same level of protection as if they were members of the public.

(5) The licensee and employer shall ensure that workers are informed of their obligations and responsibilities for their own protection and the protection of others against radiation and for the safety of radiation sources and in particular, the licensee and employers shall ensure that workers—

(*a*) follow any applicable rules and procedures for protection and safety;

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

(*c*) abstain from any wilful action that could put themselves or others in situations that contravene the requirements of these Regulations; and

(*d*) promptly report to the licensee and employer any circumstances that could adversely affect safety conditions or the requirements of these Regulations.

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

Conditions of service

36.—(1) A licensee or an employer shall ensure that the conditions of service of workers are independent of the existence or the possibility of occupational exposure and shall not use special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits as substitutes for the provision of proper protection and safety measures to ensure compliance with the requirements of these Regulations.

(2) The licensee or employer shall advise female workers that they should notify the employer if pregnant and where a female worker has notified the employer that she is pregnant, the employer shall adapt the working conditions with respect to occupational exposure to ensure that the unborn baby is afforded the same broad level of protection which is required for members of the public:

Provided that notification of pregnancy shall not be considered a reason to exclude a female worker from work.

(3) The licensee shall not subject a person under the age of sixteen (16) years to occupational exposure and the licensee shall not allow a person under the age of eighteen (18) years to work in a controlled area unless supervised and then only for the purpose of the training.

Classification of areas

37.—(1) A licensee shall designate as a controlled area, any area in which specific protective measures or safety provisions are or could be required for—

(*a*) controlling normal exposures or preventing the spread of contamination during normal working conditions; and

(*b*) preventing or limiting the extent of potential exposures.

(2) The licensee shall—

(*a*) determine the boundaries of any controlled area on the basis of the magnitude and likelihood of expected exposures and the nature and extent of the required protection and safety provisions;

(*b*) delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;

(*c*) where a radiation source is brought into operation or energized only intermittently or is moved from place to place, delineate controlled

area by means that are appropriate under the prevailing circumstances and specific exposure times;

(*d*) display a warning symbol, recommended by the International Organization for Standardization (ISO), and appropriate instructions at access points and other appropriate locations within controlled areas;

(*e*) establish occupational protection and safety measures, including local rules and procedures that are appropriate for controlled areas;

(*f*) 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 magnitude and likelihood of the expected exposures; and

(*g*) provide at entrances and exits of controlled areas appropriate means for change of clothing, contamination monitoring and personal decontamination.

(3) The 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.

(4) The licensee shall delineate and identify the supervised areas by appropriate means, taking into account the nature and extent of radiation hazards in those areas.

(5) The licensee shall periodically review conditions to determine the possible need to revise the protection measures or safety provisions, including the boundaries of controlled or supervised areas.

Local rules and supervision

38.—(1) A licensee and an employer shall, in consultation with workers, through their representatives, where appropriate—

(*a*) establish in writing, in a language comprehensible to the workers and others, such rules and procedures, as are necessary, to ensure adequate levels of protection and safety for workers and other persons;

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

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

(*d*) and when required by the Authority, designate a qualified expert in radiation safety as radiation protection officer.

(2) The licensee and employer shall—

(*a*) provide to all workers adequate information on—

(i) the health risks due to their occupational exposure, whether normal exposure or potential exposure;

(ii) adequate instruction and training on protection and safety, including information on general and local rules and procedures and on available protection and safety provisions; and

(iii) the significance for protection and safety of their actions;

(*b*) make arrangements for an appropriate health surveillance programme in accordance with regulation 42;

(*c*) provide to female workers who are liable to enter controlled areas or supervised areas appropriate information on—

(i) the risk to the unborn baby due to exposure of a pregnant woman;

(ii) the importance for a female worker of notifying her employer as soon as she suspects that she is pregnant; and

(iii) the risk to an infant ingesting radioactive material by breast feeding;

(*d)* provide to those workers who could be affected by an emergency plan appropriate information, instruction and training; and

(*e*) keep records of the training provided to individual workers.

Personal protective equipment

39. A licensee and an employer shall—

(*a*) minimize the need for relying on administrative controls and personal protective equipment for protection and safety during normal operations by providing appropriate well engineered controls and satisfactory working conditions;

(*b*) if necessary, ensure that workers are provided with suitable and adequate personal protective equipment, including as appropriate—

(i) protective clothing;

(ii) protective respiratory equipment with information on its protection characteristics and instructions on its proper use;

(iii) protective aprons and gloves and organ shields;

(*c*) arrange for regular testing and maintenance to be carried out on all personal protective equipment, including, as required, special equipment for use in the event of accidents and interventions;

(*d*) take into account the following factors when assigning personal protective equipment for a given task—

(i) medical fitness to sustain possible extra physical effort while using the protective equipment; and

(ii) additional work time or inconvenience or additional non-radiological risks associated with the use of the protective equipment.

Exposure assessment

40.—(1) A licensee and an employer shall arrange for the assessment of the occupational exposure of workers and ensure that adequate arrangements are made with appropriate dosimetry services under an adequate management system programme.

(2) The licensee or employer shall ensure that individual monitoring is undertaken for any worker who is normally employed in a controlled area, where this is feasible and in cases where individual monitoring is not feasible, the occupational exposure of the workers shall be assessed on the basis of the results of monitoring of the workplace and of information on the locations and duration of exposure of the workers.

(3) The licensee and employer shall ensure that for any worker who is normally employed in a supervised area or who enters a controlled area only occasionally, his occupational exposure is assessed, but the assessment may be on the basis of the results of monitoring of the workplace or of individual monitoring.

(4) The nature, frequency and precision of individual monitoring shall be determined taking into consideration the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures.

(5) The licensee and employer shall ensure that workers who may be exposed to radioactive contamination, including workers who use protective respiratory equipment, are identified and shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the protection provided and to assess the intake of radioactive material or the committed doses, as appropriate.

Monitoring of workplace

41.—(1) A licensee, in cooperation with an employer, where appropriate, shall establish, maintain and keep under review a programme for the monitoring of the workplace commensurate with the nature of and the risks associated with the radiation source.

(2) The nature and frequency of monitoring of workplaces shall—

(*a*) be sufficient to enable—

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

(ii) assessment of the exposure of workers in controlled areas and supervised areas; and

(iii) review of the classification of controlled and supervised areas; and

(*b*) depend on the levels of ambient dose equivalent and airborne and surface activity concentration, including their expected fluctuations and the likelihood and magnitude of potential exposures.

(3) The programmes for monitoring of the workplace shall specify—

(*a*) the quantities to be measured;

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

(*c*) the most appropriate measurement methods and procedures; and

(*d*) reference levels and the actions to be taken if they are exceeded.

(4) The licensee shall keep appropriate records of the findings of the workplace monitoring programme, which shall be made available to workers, where appropriate through their representatives.

Health surveillance

42. A licensee and an employer, in accordance with the rules established by the Authority, shall make arrangements for appropriate health surveillance based on the general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks.

Records of worker exposure

43.—(1) A licensee and an employer shall maintain records of exposure for each worker for whom assessment of occupational exposure is required under regulation 41 and such worker exposure records shall include information on—

(*a*) the general nature of the work resulting in exposure, the doses and intakes at or above the relevant recording levels and the data upon which the dose assessments are based;

(*b*) the periods of employment with different employers, if any, and the corresponding doses and intakes in each period of employment; and

(*c*) the doses or intakes due to emergency interventions or accidents, which shall be distinguished from doses and intakes received during work in normal conditions.

(2) The licensee and employer shall—

(*a*) provide access by workers to information regarding their own exposure records and, where appropriate, to workplace monitoring records; and

(*b*) upon request of the Authority or other persons or organizations with a demonstrated need for such records, including relevant employers and supervisors of the health surveillance programme, provide access to worker exposure records with due care and attention to the maintenance of appropriate confidentiality.

(3) Exposure records for each worker shall be retained by the licensees and employers, or by the Authority in case the licensees and employers cease their activities.

(4) These records shall be preserved at least until the worker attains or would have attained the age of seventy five (75) years, and for not less than thirty (30) years after the termination of the work involving occupational exposure.

Special circumstances

44.—(1) If a practice which is justified and for which radiation safety is optimized, presents special circumstances which require a temporary change in some dose limitation requirements of these Regulations, a licensee shall not make any such temporary change without the approval of the Authority.

(2) An application submitted by the licensee to obtain the approval referred to in subregulation (1), shall include evidence to demonstrate that—

(*a*) all reasonable efforts have been made to reduce exposures and optimize radiation safety provisions in accordance with the requirements of these Regulations; and

(*b*) the relevant employers and workers, through their representatives where appropriate, have been consulted on the need for

and the conditions of the temporary change in dose limitation requirements.

(3) Any temporary change in a dose limitation requirement of these Regulations shall be limited to specified work areas and shall be in accordance with the time and dose limitations for special circumstances specified in the Second Schedule.

Part VIII—Medical Exposure Protection

General responsibilities

45.—(1) A licensee shall ensure that—

(*a*) no patient is administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner;

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

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

(*d*) for therapeutic uses of radiation, including teletherapy and brachytherapy, the calibration, dosimetry and management system requirements of these Regulations are conducted by or under the supervision of a qualified expert in radiotherapy physics;

(*e*) the exposure of individuals incurred knowingly while voluntarily helping, other than in their occupation, in the care, support or comfort of patients be constrained as specified in the Third Schedule; and

(*f*) training of personnel is carried out according to criteria approved by the Authority.

(2) The licensee shall to the extent practicable, ensure that for diagnostic uses of radiation, the imaging and management system requirements of these Regulations are fulfilled with the advice of a qualified expert in radiodiagnostic physics, nuclear medicine physics and radiopharmacy in the compounding of radiopharmaceuticals, as appropriate.

(3) A medical practitioner shall promptly inform the licensee of any deficiencies or needs regarding compliance with these Regulations with respect to protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.

Justification of medical exposure

46.—(1) Medical practitioners shall consider the justification of medical exposures that they prescribe by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

(2) Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is

deemed to be unjustifiable unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with competent professional bodies.

(3) Mass screening of population groups involving medical exposure is deemed to be unjustifiable unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.

(4) The exposure of humans for medical research is deemed to be unjustifiable, unless it is—

(*a*) in accordance with the provisions of the World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), International Ethical Guidelines for Biomedical Research Involving Human Subjects; and

(*b*) subject to the advice of the licensee's Ethical Review Committee and to any other applicable laws and regulations.

Optimization of protection for medical exposures

47. In addition to satisfying the general requirements for optimization of radiation safety specified in these Regulations, licensees, in cooperation with suppliers, where appropriate, shall satisfy the prescriptive design and operational requirements specified in Third Schedule hereto.

Calibration, clinical dosimetry and management system for medical exposures

48.—(1) A licensee shall ensure that—

(*a*) the calibration of radiation sources used for medical exposure is traceable to a standards dosimetry laboratory in the country or abroad if accepted by the Authority;

(*b*) each type of radiotherapy equipment is calibrated in terms of the relevant dosimetric quantities and irradiation conditions;

(*c*) unsealed sources for nuclear medicine procedures are calibrated in terms of activity of the radio-pharmaceuticals to be administered; and

(*d*) calibrations of equipment are carried out at the time of commissioning of a source, after any maintenance procedure that may affect the calibration, and at regular intervals established or approved by the Authority.

(2) The licensee shall ensure that important values of clinical dosimetry parameters are determined and documented.

(3) Management system programmes for medical exposures shall include—

(*a*) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;

(*b*) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;

(*c*) written records of relevant procedures and results;

(*d*) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and

(*e*) as far as possible, regular and independent quality audit reviews of the management system programme for radiotherapy procedures.

Dose constraints

49.—(1) The optimization of protection of persons exposed for medical research purposes, if such medical exposure does not produce direct benefit to the exposed individuals, shall be subjected to individual dose constraints established on a case-by-case basis by the Authority or other institutional body assigned a similar function.

(2) A licensee shall constrain any dose to individuals incurred while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical exposure, and to visitors to patients who have received therapeutic amounts of radionuclides or who are being treated with brachytherapy sources, to a level not exceeding that specified in the Third Schedule.

Guidance levels

50. A licensee shall ensure that guidance levels for medical exposure, determined as specified in regulation 26, are revised as technology improves and are used as guidance by medical practitioners, in order that—

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

(*b*) reviews are considered if doses or activities exceed the guidance levels, as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice.

Maximum activity for patients in therapy and discharge from hospital

51.—(1) In order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and of members of the public, such a patient shall not be discharged from hospital before the activity of radioactive material in the body falls below the level specified by the Authority unless otherwise justified, and the justification is documented.

(2) A licencee shall provide written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection where necessary .

Investigation of accidental medical exposure

52.—(1) A licensee shall promptly investigate any of the following situations—

(*a*) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner;

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

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

(2) The licensee shall, with respect to any investigation required above—

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

(*b*) indicate the corrective measures required to prevent recurrence of such an accident or incident;

(*c*) implement all the corrective measures that are under his own responsibility;

(*d*) notify the Authority by telephone or facsimile as soon as practicable, but in any case not later than twenty-four (24) hours after discovery, of any accident or incident which has the potential for, or has resulted in, serious injury or death of a patient, or which involves more than one patient;

(*e*) submit to the Authority, within seven (7) days after discovery of the accident or incident, a written report which contains the cause of the incident and includes information on the doses, corrective measures and any other relevant information; and

(*f*) inform the patient and his doctor about the accident or incident.

Records related to medical exposures

53. A licensee shall keep and make available, as appropriate, records of equipment calibration, clinical dosimetry and management system, as well as any other necessary information to allow retrospective assessments of the doses received by patients.

Part IX—Public Exposure Protection

General responsibilities

54.—(1) A licensee shall apply the requirements of these Regulations to any public exposure delivered by a practice or source for which they are responsible, unless the exposure is excluded from the application of these Regulations or the practice or source delivering the exposure is exempt from the requirements of these Regulations.

(2) The licensee shall be responsible, with respect to the sources under his responsibility, for the establishment, implementation and maintenance of—

(*a*) radiation safety policies, procedures and organizational arrangements for control of public exposure;

(*b*) measures for ensuring—

(i) the optimization of the protection, subject to constraints as may be appropriate, of members of the public whose exposure is attributable to such sources; and,

(ii) the limitation of the normal exposure of the relevant critical group, which is attributable to such sources, in order that the total exposure is not higher than the dose limits for members of the public as specified in the Second Schedule;

(*c*) measures for ensuring the safety of such sources, in order that the likelihood of public exposures is controlled in accordance with the requirements of these Regulations;

(*d*) suitable and adequate facilities, equipment and services for the protection of the public, the nature and extent of which are commensurate with the magnitude and likelihood of the exposure;

(*e*) appropriate radiation safety training, and periodic retraining, to the personnel having functions relevant to the protection of the public;

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

(*g*) informing the public, and particularly critical groups, about radiation safety measures to be taken in case of an accident or incident such as lost radioactive sources; and

(*h*) adequate records of the surveillance and monitoring.

Control of visitors

55. A licensee shall—

(*a*) ensure that visitors to any controlled area are accompanied by a person knowledgeable about the radiation safety measures for that area;

(*b*) provide adequate information, instruction and protective means, as necessary, to visitors before they enter a controlled area to ensure appropriate protection of the visitors and workers who may be affected by their actions; and

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

Sources of external irradiation

56. A licensee shall ensure that, if a source of external irradiation can cause exposure to the public—

(*a*) prior to commissioning, the floor plans and equipment arrangement for all new installations and all significant modifications to existing installations utilizing such sources of external irradiation are subject to review and approval by the Authority;

(*b*) specific dose constraints for the operation of such a source are established to the satisfaction of the Authority; and,

(*c*) shielding and other protective measures that are optimized, in accordance with the requirements of these Regulations, are provided as appropriate for restricting public exposure to the satisfaction of the Authority.

Radioactive contamination in enclosed spaces

57. A licensee shall ensure that—

(*a*) for sources for which they are responsible, measures that are optimized in accordance with the requirements of these Regulations are

taken as appropriate for restricting public exposure in areas accessible to the public; and

(*b*) specific containment provisions are established for the construction and operation of those sources in order to avoid or minimize spread of radioactive contamination in areas accessible to the public.

Monitoring of public exposure

58. A licensee shall, as appropriate—

(*a*) establish and carry out a monitoring programme, of magnitude and complexity commensurate with the type of and risks associated with the sources under his responsibility, which is sufficient to ensure that the requirements of these Regulations are complied with and to assess the exposure of members of the public from sources of external irradiation or discharges of radioactive materials into the environment, as appropriate;

(*b*) keep appropriate records of the results of the monitoring programmes; and

(*c*) report a summary of the monitoring results to the Authority at approved intervals and promptly inform the Authority of any abnormal results which lead or could lead to an increase of public exposure.

Consumer products

59. —(1) A person shall not supply consumer products capable of causing exposure to radiation to members of the public unless—

(*a*) such exposure is excluded from these Regulations under regulation 7;

(*b*) such products meet the exemption requirements specified in regulation 16 or have otherwise been exempted by the Authority; or

(*c*) such products are licensed by the Authority for use by members of the public.

(2) A person who imports consumer products, as exempt products, for subsequent sale and distribution shall include in the application to the Authority for a licence to distribute, a copy of the exporter's or other legal persons' licence issued by the Authority in the country of manufacture or origin which authorizes distribution to members of the public in that country.

(3) A person who imports consumer products for sale and distribution, as exempt products shall ensure that—

(*a*) legible labels are visibly and firmly affixed to each consumer product and its package, stating, in English and the local language, that—

(i) the product contains radioactive material; and

(ii) the sale of the product to the public has been licensed by the relevant Authority; and

(*b*) basic information and instructions on the precaution of use and disposal of the product, written in English and the local language, are made available with the product.

Part X—Requirements for the Design, Protection and Supply of Radiation Sources

General responsibilities

60. A licensee shall ensure that, as applicable and appropriate, the location, design, construction and assembly, commissioning, operation and maintenance and decommissioning of sources are based on sound engineering practice that—

(*a*) takes into account approved codes of practice, standards, and technical and scientific developments;

(*b*) is supported by reliable managerial and organizational features; and

(*c*) includes adequate safety margins in the design, construction and operation of sources.

Design of radiation sources

61. A licensee, in specific cooperation with a supplier where appropriate, shall—

(*a*) ensure, on procurement of new equipment containing radiation generators or sources, that such equipment and sources conform to applicable standards of the International Electrotechnical Commission (IEC) and the International Standards Organization (ISO) except for IEC and ISO standards, other standards applied in the country of origin of such equipment and sources shall have the acceptance of the competent authority in this matter;

(*b*) ensure that sources and equipment are tested to demonstrate compliance with the appropriate specifications;

(*c*) conduct a safety assessment, either generic or specific, for the sources for which they are responsible, according to the requirements of regulation 32;

(*d*) ensure that performance specifications and operating and maintenance instructions, including protection and safety instructions, are provided in English and local languages and in compliance with the relevant IEC and ISO standards with regard to accompanying documents, and that this information is translated into the local language when appropriate; and

(*e*) ensure that, where practicable, the operating terminology and operating values are displayed on operating consoles or other control systems in an appropriate language as specified in paragraph (*d*) above.

Supply and procurement of radioactive sources

62.—(1) A licensee who supplies and distributes radioactive sources shall ensure that the persons to whom the sources are being supplied are licensed to receive the sources.

(2) The licensee shall, before purchasing or otherwise acquiring a radioactive source—

(*a*) make arrangements with respect to the safe management of the source, including financial provisions, where appropriate, once the source becomes disused; and

(*b*) submit to the Authority details of the arrangements, including copies of any contractual arrangements.

(3) The licensee supplying radioactive sources or devices incorporating radioactive sources shall provide the recipient with all relevant technical information to permit their safe management.

Domestic transfer of radiation sources

63. A licencee shall not transfer radiation sources to another party unless—

(*a*) he is licensed to do so by the Authority;

(*b*) the recipient possesses a valid licence for the sources; and

(*c*) the recipient is provided with all relevant technical information to permit the safe management of the sources.

Part XI—Import and Export of Category 1 or 2 Radioactive Sources

Export category 1 or 2 radioactive sources

64.—(1) A licensee who intends to export Category 1 or 2 radioactive source shall apply to the Authority for an export licence and shall pay the fees prescribed in the fifth schedule.

(2) The application for licence to export a source shall include a copy of the recipient licence to receive and possess the source 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 radionuclides and radioactivity;

(*d*) uses of the source, if appropriate; and

(*e*) recipient licence expiration date, if any.

(3) Other information to be submitted as part of the application for licence to export, may include, as applicable—

(*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.

(4) After receiving a licence to export the source, the licensee shall ensure that—

(*a*) the export of the source is conducted in compliance with all applicable transport requirements of the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material;

(*b*) the competent authority of the importing country is notified in advance, at least seven (7) days to the extent practicable, of each shipment with the following information in writing—

(i) the estimated date of export;

(ii) exporting facility;

(iii) recipient;

(iv) radionuclide(s) and radioactivity;

(v) aggregate activity level; and

(vi) the number of radioactive sources and, if available, their unique identifiers; and

(*c*) for Category 1 sources only, the notification described above shall be accompanied by a copy of the consent from the competent authority of the importing country to import the sources.

Import of category 1 and 2 radioactive sources

65.—(1) A licensee who intends to import Category 1 or 2 radioactive sources shall apply to the Authority for an import licence.

(2) The application for the licence to import a source 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 radionuclides and radioactivity;

(*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, including copies of any contractual agreements; and

(*h*) justification or explanation of any need to use the "exceptional circumstances"provisions, if applicable.

(3) After receiving the licence to import the source, the licensee shall ensure that the import of the source is in compliance with all applicable transport requirements of the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material.

Part XII—Radioactive Waste Management Requirements

Radioactive waste classification

66. A licensee shall classify radioactive waste in accordance with specific requirements provided by the Authority in accordance with the International Atomic Energy Agency Safety Series No.111-G 1.1-Classification of Radioactive Waste Safety Guide.

General responsibilities

67. A licensee shall be responsible for the safe management of the radioactive waste generated by the practices or sources for which he is licensed and shall take all necessary measures to ensure that—

(*a*) generation of the activity and volume of radioactive waste are kept to the minimum practicable by suitable design, operation and decommissioning of its facilities;

(*b*) radioactive waste is managed by appropriate classification, segregation, treatment, conditioning, storage and disposal, and maintaining records of such activities;

(*c*) disposal of radioactive waste is not unnecessarily delayed; and,

(*d*) submission of the necessary reports to the Authority of required information at intervals, as may be specified in the licence.

Licence application

68. A person or organization shall not generate, keep or manage radioactive waste except in accordance with a licence issued by the Authority under regulation 17.

Appointment of radioactive waste management officer

69.—(1) A licensee shall appoint, if necessary and where required by the Authority, a technically competent person with the appropriate independence and authority to be a radioactive waste management officer in order to assist the licensee in the safe and efficient on-site management of radioactive waste.

(2) In discharging his duties, the radioactive waste management officer shall—

(*a*) make and maintain contact with all relevant persons involved with radioactive waste to provide an authoritative point of advice and guidance;

(*b*) liaise as needed with the radiation protection officer and with other radioactive waste management organizations;

(*c*) establish and maintain a detailed record-keeping system for all stages of radioactive waste management, including the inventory of radioactive waste;

(*d*) ensure proper radioactive waste conditioning;

(*e*) ensure that on-site transfer of radioactive waste is carried out in accordance with written safety procedures;

(*f*) ensure that waste packages for off-site transportation are prepared to be in compliance with transport regulations;

(*g*) obtain approval from the Authority for the transport of radioactive waste;

(*h*) ensure appropriate shielding, labelling, physical security and integrity of waste packages;

(*i*) ensure that any discharge of effluents is made below the limits licensed by the Authority;

(*j*) ensure that solid waste disposed off in a municipal landfill is in accordance with clearance levels established by the Authority;

(*k*) report on accidents and inappropriate waste management practices to the licensees' management; and

(*l*) maintain an up-to-date knowledge of the characteristics of discharge and disposal options.

Control of radioactive waste generation

70. A licensee shall ensure that appropriate measures are taken to keep generation of radioactive waste and its environmental impact and cost to the minimum practicable by—

(*a*) avoiding the use of unnecessarily hazardous or toxic materials;

(*b*) minimizing the activity of waste by using the minimum quantity of radioactive material needed;

(*c*) using short lived radionuclides, where practicable and an appropriate selection of materials for the construction of facilities;

(*d*) incorporating into the design of facilities features to facilitate future decommissioning;

(*e*) minimizing the amount of waste by preventing unnecessary contamination of materials;

(*f*) applying careful planning to the design, construction, administration, operation and decommissioning of facilities so that the generation of radioactive waste is kept to the minimum practicable; and

(*g*) maintaining consistency with the management strategy and systems.

Collection, segregation, and characterization of radioactive waste

71.—(1) A licensee shall ensure that waste is collected, segregated, and characterized, at the point of origin in accordance with the classification system established by the Authority and the following criteria—

(*a*) non-radioactive and radioactive;

(*b*) short-lived, for instance half-lives less than one hundred (100) days, suitable for decay storage;

(*c*) activity and radionuclide content;

(*d*) physical and chemical form—

(i) liquid—

(A) aqueous; and

(B) organic;

(ii) non-homogeneous, for instance containing sludges or suspended solids;

(iii) solid—

(A) combustible or non-combustible, if applicable; and

(B) compactable or non-compactable, if applicable;

(*e*) spent sealed sources;

(*f*) non-radiological hazardous waste, for instance toxic, pathogenic, infectious, genotoxic or biological; and

(*g*) mixed waste, that is radioactive and hazardous waste.

(2) After segregation, each waste stream shall be kept in separate containers.

(3) The licensee shall ensure that the waste containers are—

(*a*) labeled clearly and easily identified;

(*b*) bear a radiation trefoil when in use for radioactive waste;

(*c*) robust;

(*d*) compatible with the waste contents; and

(*e*) able to be filled and emptied safely.

(4) The following information shall be recorded for each waste container—

(*a*) identification number;

(*b*) radionuclides;

(*c*) activity if measured or estimated or date of measurement;

(*d*) origin, room, laboratory, individual, etc., if applicable;

(*e*) potential or actual hazards, chemical, infectious, etc.;

(*f*) surface dose rate or date of measurement;

(*g*) quantity weight or volume; and

(*h*) responsible person.

Conditioning of radioactive waste

72.—(1) A licensee shall select waste packages that are compatible with planned storage or disposal options and which meet waste acceptance criteria as approved by the Authority for storage and disposal.

(2) In selecting a conditioning process, the licensee shall consider whether safety will be improved from the use of a matrix material and shall ensure compatibility of the radioactive waste with the selected materials and processes.

(3) The licensee shall ensure that the waste packages are designed and produced in such a way so that radionuclides are confined under both normal conditions and under the accident conditions that may occur during handling, storage, and disposal.

Radioactive waste processing facilities

73.—(1) A licensee shall ensure that facilities for the processing of radioactive waste have sufficient capacity to process all such waste generated and in particular, storage capacity is sufficient enough to account for uncertainties in the availability of facilities for treatment, conditioning and disposal.

(2) The licensee shall ensure that the design of a facility takes into account the possible need to process waste arising from incidents or accidents.

Discharge or release of radioactive materials to the environment

74.—(1) A licensee shall ensure that radioactive materials from licensed practices and sources are not discharged into the environment unless—

(*a*) such discharge is within the limits specified in the licence and is carried out in a controlled manner using licensed methods; or

(*b*) the activity discharged is confirmed to be below clearance or other disposal levels established by the Authority as specified in regulation 16.

(2) The licensee shall, during the operational stages of a source under his responsibility—

(*a*) keep all radioactive discharges as far below the licensed limits as is reasonably achievable;

(*b*) monitor and record the discharges of radionuclides with sufficient detail and accuracy to demonstrate compliance with the licensed discharge limits and to permit estimation of the exposure of the critical group;

(*c*) report discharges to the Authority at intervals as may be specified in the licence; and

(*d*) report promptly to the Authority any discharges exceeding the licensed limits.

(3) Whether an activity is released within the clearance levels established by the Authority or radioactive waste is discharged under licence, the licensee shall consider the non-radiological hazards of the released waste and shall comply with the requirements of any other regulations concerning those hazards.

Waste storage

75. A licensee shall store radioactive waste in such a way as to protect human health and the environment and in particular shall not store the radioactive waste in the vicinity of corrosive, explosive or easily flammable materials.

Acceptance criteria for storage of radioactive waste

76.—(1) A licensee shall define acceptance criteria for waste packages and after consultation with the Authority, the licensee shall decide which type of pre-treatment, treatment and conditioning is required.

(2) The licensee shall, in defining criteria for acceptance of waste packages in a storage facility, take account of the known or likely requirements for subsequent disposal of the radioactive waste.

(3) The licensee shall ensure that the integrity of waste packages in storage is maintained until it is retrieved for further treatment, conditioning or disposal.

(4) Where there may be a significant time lag before an acceptable disposal route becomes available, the licensee shall ensure that the waste package container provides integrity throughout the storage period and is capable of being—

(*a*) retrieved at the end of the storage period;

(*b*) enclosed in an overpack, if necessary; and

(*c*) transported to and handled at a disposal facility.

Radioactive waste storage facilities

77.—(1) An applicant for a licence to operate a radioactive waste storage facility shall—

(*a*) meet safety requirements for the protection of human health and the environment by appropriate planning for the design, construction, operation and maintenance of the respective facility, including provisions for eventual retrieval of the waste;

(*b*) design the facility—

(i) on the basis of assumed conditions for its normal operation and assumed incidents or accidents;

(ii) for the likely period of storage, and taking into account the potential for degradation;

(iii) in such a way that the waste can be retrieved whenever required;

(iv) so that it is adequately ventilated to exhaust any gas generated in normal conditions or under anticipated accident conditions;

(v) so that measures to prevent, detect and control fires are incorporated as required; and

(vi) so that radiological monitoring and visual inspection is readily possible.

Recycle and reuse of radioactive materials

78. A licensee shall, in relation to recycling and re-use of radioactive material—

(*a*) not disassemble any disused radioactive source unless specifically allowed in the licence;

(*b*) before declaring the radioactive material as waste, consider whether the licensee or any other organization can make use of the material; and

(*c*) if appropriate, transfer radioactive material after being licensed by the Authority.

Management of disused radioactive sources

79.—(1) A licensee shall review his radioactive source inventory at least annually to identify any sources that are not in routine use and have become disused.

(2) Unless the licence allows otherwise, the licensee shall make arrangements for the prompt management of any disused radioactive source in compliance with regulation 17 (4) (v).

Radioactive waste from mining and milling operations

80.—(1) A licensee shall ensure that the same established safety requirements that apply to the disposal of radioactive waste also apply, *mutatis mutandis*, to the waste from mining and milling operations.

(2) The licensee shall propose to the Authority which option has to be followed for the siting, design, construction, operation, closure and post-closure activity for a mining and milling waste disposal facility and the Authority shall determine whether or not to approve the option.

Existing facilities and past practices

81. A legal owner of an existing facility and past practices containing radioactive waste shall be responsible for its safe management, decommissioning and disposal.

Radioactive waste records and reports

82.—(1) A licensee shall record, report to the Authority and update the inventory of radioactive waste in his possession.

(2) The licensee shall send before the 15th of January of each year to the Authority a copy of his waste inventory and a report for the previous year, giving types, quantities and destinations of—

(*a*) cleared materials released into the environment;

(*b*) waste discharged into the environment;

(*c*) disused radioactive sources returned to suppliers; and

(*d*) such other details as the Authority may require.

(3) The Authority has the right to inspect and review the kept radioactive waste records at any time.

(4) If any radioactive waste has been lost, stolen or is missing, the licensee shall immediately, but in any case not later than twenty-four (24) hours, inform the Authority and within seven (7) days submit a written report on the matter and the actions which have been taken.

Part XIII—Decommisioning Requirements

Decommissioning

83.—(1) A licensee shall establish and maintain a decommissioning plan commensurate with the type and status of the facility.

(2) The licensee shall submit an application for permission to decommission a facility to the Authority and the application shall contain the final decommissioning plan and a justification of the proposed decommissioning option.

(3) The licensee shall remain responsible for the safety of a facility during the decommissioning operations.

(4) During all phases of decommissioning, the licensee shall ensure that workers, the public and the environment are properly protected from hazards, including radiological hazards resulting from decommissioning activities.

(5) An applicant for a licence shall ensure that the initial design and any subsequent modifications of a facility include consideration of future decommissioning requirements.

Decommissioning plan

84.—(1) An applicant for a licence for a facility shall develop a decommissioning plan which demonstrates that decommissioning can be accomplished safely and the initial decommissioning plan shall be prepared and submitted by the applicant in support of the licence application for the construction of the facility.

(2) A licensee shall periodically review the initial decommissioning plan and update it as appropriate, taking into account the operating history of the facility.

(3) When applying for a licence to decommission the facility, the licensee shall submit a final decommissioning plan to the Authority.

PART XIV—TRANSPORTATION OF RADIOACTIVE SOURCES OR WASTE

Transport requirements

85. A licensee transporting radioactive sources or radioactive waste, either domestically or internationally, shall do so in compliance with all applicable transport requirements of the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material.

PART XV—REQUIREMENTS FOR EMERGENCY INTERVENTION

Responsibilities of a licensee

86.—(1) If a licensed practice or source, including radioactive waste within a practice, has a potential for accidents that may provoke unplanned exposure of any person, a licensee shall ensure that an emergency plan appropriate for the source and its associated risks is prepared and is kept operational.

(2) The effectiveness of the emergency plan referred to in subregulation (1) shall be verified to the satisfaction of the Authority by means of systematic drills.

(3) If a licensed source is involved in an accident or incident, the licensee shall be responsible for taking such protective actions as may be required for the protection of occupationally exposed workers undertaking intervention and for the protection of the public from exposure as set forth in the licence application and emergency plans approved by the Authority, or as might otherwise by required by the Authority to protect against, mitigate or remediate a hazardous situation involving the licensed sources.

Licensee emergency response planning requirements

87. A licensee responsible for a source, including radioactive waste for which prompt intervention may be required, shall ensure that the emergency plan defines on-site responsibilities and takes account of off-site responsibilities of other intervening organizations appropriate for implementation of the emergency plan and the emergency, and the plans shall, as appropriate—

(*a*) characterize the content, features and extent of a potential emergency, taking into account the results of any accident analysis and any lessons learned from operating experience and from accidents that have occurred with sources of a similar type—

(i) identify the various operating and other conditions of the source which could lead to the need for intervention;

(ii) describe the methods and instruments for assessing the accident and its consequences on and off the site;

(iii) provide for protection and mitigation actions, and assignment of responsibilities for initiating and discharging such actions;

(iv) provide for rapid and continuous assessment of the accident as it proceeds and determining the need for protective actions;

(v) allocate responsibilities for notifying the relevant authorities and for initiating intervention;

(vi) provide procedures, including communication arrangements for contacting any relevant intervening organization, for instance civil or defence and for obtaining assistance from fire-fighting, medical, police and other relevant organizations;

(vii) provide for training personnel involved in implementing emergency plans and be rehearsed at suitable intervals based on requirements defined in regulation 29 (2) in conjunction with designated authorities; and

(viii) provide for periodic review and updating of the plan.

Implementation of intervention

88.—(1) A licensee shall ensure that the protective actions or remedial actions aimed at reducing or averting accidental exposures are only undertaken when they are justified, taking into account health, social and economic factors.

(2) The form, scale and duration of any justified intervention shall be optimized so as to produce the maximum net benefit under the prevailing social and economic circumstances.

(3) The licensee shall promptly notify the Authority when an accidental situation requiring intervention has arisen or is expected to arise and shall keep the Authority informed of:

(*a*) the current situation and its expected evolution;

(*b*) the measures taken to terminate the accident and to protect workers and members of the public; and

(*c*) the exposures that have been incurred and that are expected to be incurred.

Protection of workers undertaking an intervention

89.—(1) A worker undertaking an intervention shall not be exposed in excess of the maximum single year dose limit for occupational exposure specified in the Second Schedule hereto except—

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

(*b*) if undertaking actions intended to avert a large collective dose; or

(*c*) if undertaking actions to prevent the development of catastrophic conditions.

(2) While undertaking intervention under these circumstances, the licensee shall take reasonable efforts to keep doses to workers below twice the maximum single year dose limit, except for life saving actions, in which case every effort shall be made to keep doses below ten times the maximum single year dose limit in order to avoid deterministic effects on health.

(3) In addition, the licensee shall ensure that workers undertaking actions in which their doses may approach or exceed ten times the maximum single year dose limit do so only when the benefits to others clearly outweigh their own risk.

(4) The licensee shall only use those workers who volunteer to undertake actions in which the dose may exceed the maximum single year dose limit and

the licensee shall clearly and comprehensively inform the workers in advance of the associated health risk, and to the extent feasible, the workers shall be trained in the actions that may be required.

(5) The licensee shall ensure that once the emergency phase of an intervention has ended, workers undertaking recovery operations, such as repairs to equipment and buildings, waste disposal or decontamination are subject to the full system of detailed requirements for occupational exposure specified in these Regulations.

(6) The licensee shall take all reasonable steps to provide appropriate protection during the emergency intervention and to assess and record the doses received by workers involved in emergency intervention and when the intervention has ended, the licensee shall inform workers involved about the doses received and the consequent health risk.

(7) The licensee shall ensure that workers are not normally precluded from incurring further occupational exposure because of doses received in an emergency situation, but the licensee shall seek medical advice from a qualified medical doctor before any exposure if a worker who has undergone an emergency exposure receives a dose exceeding ten times the maximum single year dose limit, or at the worker's request.

Use of international safety standards and other publications

90.—(1) An applicant for a licence may propose to apply recommendations regarding facilities and equipment, procedures, qualifications and training of personnel, maintenance and management system contained in safety and good practice publications issued by the International Atomic Energy Agency, World Health Organization, Pan American Health Organization or other international bodies as methods by which performance requirements in these Regulations shall be met and in such cases, the applicant shall—

(*a*) identify the document; and

(*b*) identify both the particular recommendation or part of the document being adopted and the performance requirement in these Regulations it is intended to implement.

(2) The Authority shall determine whether the proposal referred to in subregulation (1) is acceptable.

(3) The applicant for a licence may adopt, by reference any of the documents listed under References, to the extent that they are relevant to the particular practice and the applicant may propose to use other relevant documents that are not listed under References provided that the documents are clearly identified and copies of the relevant parts of the documents are included with the application.

(3) The Authority, on its own initiative or upon request, may revise and update the list under References from time to time.

FIRST SCHEDULE

Form for Notification of Practices and Sources (reg. 15)

Atomic Energy Regulations Authority

(Use one form for each source to be notified)

1. Name and address of the legal person: .....
   .....
   .....
2. Name and address of the organization: .....
   .....
   .....
3. Nature of the practice in which the source is used: .....
   .....
   .....
4. Identification of each source: .....
   .....
   .....

Radionuclide

Activity (Bq): .....

Chemical form: .....

Sealed source: YES/NO If Yes = Manufacturer: .....

Model: .....

Radiation Generating Equipment

Manufacturer: .....

Model: .....

Operating potential:.....

Nature of the equipment in which the source is installed: .....

.....

Model (if appropriate): .....

Date: .....

.....

Signature for Legal Person

SECOND SCHEDULE

Dose Limits for Exposures Incurred from Practices

Occupational Dose Limits (reg. 23)

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

(*a*) an effective dose of 20 mSv per year averaged over five consecutive years; [1]

[1] The start of the averaging period shall be coincident with the first day of the relevant annual period starting from the date of entry into force of the Regulations, with no retroactive averaging.

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

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

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

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

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

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

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

Special Circumstances

When, in special circumstances, a temporary change in the dose limitation requirements is approved:

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

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

Dose Limits for the Public

The estimated average doses to the relevant critical groups of members of the public that are attributable to practices shall not exceed the following limits:

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

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

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

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

Internal Exposure

Internal exposure caused by inhalation or ingestion of radioactive material shall be estimated in accordance with the methodologies, parameters and values contained in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, International Atomic Energy Agency Safety Series No. 115 [3], Schedule II.

Dose Limitations for Comforters and Visitors of Patients

The dose limits set out in this Part shall not apply to comforters or visitors of patients. However the dose of any such comforter or visitor shall be constrained so that it is unlikely that the dose will exceed 5 mSv during the period of the diagnostic examination or treatment. The dose to children visiting patients who have ingested or have been injected with radioactive material shall be similarly constrained to less than 1 mSv.

THIRD SCHEDULE

Medical Exposure Design and Operational

REQUIREMENTS (reg. 45)

Design of sources and equipment

(1) The requirements related to the design and procurement of sources and the accountability and security of sources of these Regulations shall apply to sources used in medical exposure where relevant and, in particular, equipment used in medical exposure shall be so designed that:

(a) failure of equipment or components can be promptly detected so that any unplanned exposure of patients can be avoided or minimized; and

(b) the risk of delivering unplanned exposure to patients by human error is minimized.

(2) Licensees, in co-operation with suppliers where relevant or appropriate, shall:

(a) ensure that radiation generators, sources and accessories are designed and manufactured so as to facilitate the keeping of medical exposures as low as reasonably achievable consistent with obtaining adequate diagnostic information or therapeutic results;

(b) ensure that equipment containing sources for medical exposure is conform to applicable international (*e.g. IEC, ISO*) and national standards;

(*c*) ensure that performance specifications and operating and maintenance instructions, including radiation safety aspects, are provided in a major world language understandable to the users as well as in the local language;

(*d*) identify and take all reasonable measures to prevent failures and human errors that could result in unplanned medical exposures, including the establishment of adequate procedures for calibration, management system and operation of diagnostic and therapeutic equipment as well as the selection, training and periodic retraining of suitably qualified personnel;

(*e*) ensure that any radiation emitting equipment is provided with radiation beam control mechanisms, including safety interlocks and clear and fail-safe ‘on-off’ indicators;

(*f*) ensure that devices are provided to limit the exposure to the area being examined or treated and keep exposure rates outside this area, due to radiation leakage or scattering, as low as reasonably achievable;

(*g*) ensure that, when appropriate, monitoring equipment is installed or is available to give warning of an unusual situation or trend in the use of radiation emitting equipment for diagnostic or therapeutic applications.

Operational aspects

(1) *Diagnostic exposure*

A licensee shall make sure that—

(*a*) the medical practitioners who prescribe or conduct radiological diagnostic examinations:

(i) ensure that the appropriate equipment is used;

(ii) ensure that the exposure of patients is the minimum necessary to achieve the required diagnostic objective, taking into account norms of acceptable image quality established by appropriate professional bodies and relevant guidance levels for medical exposure;

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

(iv) avoid radiological examinations causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant unless there are strong clinical reasons for such examinations;

(v) plan any diagnostic examination of the abdomen or pelvis of women of reproductive capacity, between the ages of 12–50 years, so as to deliver the minimum dose to any embryo or foetus that might be present;

(vi) ensure that portable and mobile radiological equipment is used only for examinations where it is impractical or not medically acceptable to transfer patients to a stationary radiological installation and only after proper attention has been given to the radiation protection measures required in its use; and

(vii) ensure that, whenever feasible, shielding of radiosensitive organs such as the gonads, lens of the eye, breast and thyroid is provided as appropriate;

(*b*) the medical practitioner, the technologist or other imaging staff select the following parameters, as relevant, such that their combination produce the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination, paying particular attention to this selection for paediatric radiology and interventional radiology:

(i) the area to be examined, the number and size of views per examination (*e.g. number of films or computed tomography slices*) or the time per examination (*e.g. fluoroscopic time*);

(ii) the type of image receptor (*e.g. high versus low speed screens*);

(iii) the use of antiscatter grids;

(iv) proper collimation of the primary X ray beam to minimize the volume of patient tissue being irradiated and to improve image quality;

(v) appropriate values of operational parameters (*e.g. tube generating potential, current and time or their product*);

(vi) appropriate image storage techniques in dynamic imaging (*e.g. number of images per second*); and

(*vii*) adequate image processing factors (*e.g. developer temperature and image reconstruction algorithms*).

(2) *Nuclear Medicine*

A licensee shall make sure that:

(*a*) medical practitioners who prescribe or conduct diagnostic applications of radionuclides:

(i) ensure that the exposure of patients is the minimum required to achieve the intended diagnostic objective taking into account relevant guidance levels for medical exposure;

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

(iii) avoid administration of radionuclides for diagnostic procedures to women pregnant or likely to be pregnant unless there are strong clinical indications;

(iv) for mothers in lactation, recommend discontinuation of nursing until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the nursling; and

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

(*b*) the medical practitioner, the technologist or other imaging staff, as appropriate, endeavour to achieve the minimum patient exposure consistent with acceptable image quality by:

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

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

(iii) appropriate image acquisition and processing.

(3) *Therapeutic exposure*

A licencee shall make sure that the medical practitioners who prescribe or conduct radiotherapy procedures with radiation sources or with radionuclides:

(*a*) ensure that the prescribed absorbed dose is delivered to the planning target volume or organ;

(*b*) ensure that exposure of normal tissue during radiotherapy is kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding is used when feasible and appropriate;

(*c*) avoid radiotherapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant unless there are strong clinical indications;

(*d*) avoid administration of radionuclides for therapeutic procedures to women who are pregnant or likely to be pregnant or who are nursing, unless there are strong clinical indications;

(*e*) plan any therapeutic procedure for pregnant women so as to deliver the minimum dose to any embryo or foetus; and,

(*f*) inform the patient of possible risks.

FOURTH SCHEDULE

CATEGORIZATION OF RADIOACTIVE SOURCES (reg. 2)

The International Atomic Energy Agency Categorization of Radioactive Sources provides an internationally harmonized basis for risk informed decision making, and can be used by national authorities in establishing the appropriate degree of regulatory control for many activities relating to the safety and security of radioactive sources. The categorization system is based on the concept of 'dangerous sources' - which are quantified in terms of 'D-values'. The D-value is the radionuclide-specific activity of a source which, if not under control, could cause severe deterministic effects for a range of scenarios that include both external exposure from an unshielded source and inadvertent internal exposure following dispersal (e.g.: by fire or explosion) of the source material. A full list of radionuclide-specific D-values is given in IAEA-EPR-D-Values 2006 [30] and the D-values for the radionuclides from Annex I of the Code of Conduct are given in Table IV-1 below—

Table IV-1. Activities corresponding to thresholds of categories (From Annex I of Code)

Radionuclide	Category 1 1000 x D		Category 2 10 x D		Category 3 D	
	(TBq)	(Ci)[a]	(TBq)	(Ci)[a]	(TBq)	(Ci)[a]
Am-241	6.E+01	2.E+03	6.E-01	2.E+01	6.E-02	2.E+00
Am-241/Be	6.E+01	2.E+03	6.E-01	2.E+01	6.E-02	2.E+00
Cf-252	2.E+01	5.E+02	2.E-01	5.E-00	2.E-02	5.E-01
Cm-244	5.E+01	1.E+03	5.E-01	1.E+01	5.E-02	1.E+00
Co-60	3.E+01	8.E+02	3.E-01	8.E+00	3.E-02	8.E-01
Cs-137	1.E+02	3.E+03	1.E+00	3.E+01	1.E-01	3.E+00
Gd-153	1.E+03	3.E+04	1.E+01	3.E+02	1.E+00	3.E+01
Ir-192	8.E+01	2.E+03	8.E-01	2.E+01	8.E-02	2.E+00
Pm-147	4.E+04	1.E+06	4.E+02	1.E+04	4.E+01	1.E+03
Pu-238	6.E+01	2.E+03	6.E-01	2.E+01	6.E-02	2.E+00
Pu-239[b]/Be	6.E+01	2.E+03	6.E-01	2.E+01	6.E-02	2.E+00
Ra-226	4.E+01	1.E+03	4.E-01	1.E+01	4.E-02	1.E+00
Se-75	2.E+02	5.E+03	2.E+00	5.E+01	2.E-01	5.E+00
Sr-90 (Y-90)	1.E+03	3.E+04	1.E+01	3.E+02	1.E+00	3.E+01
Tm-170	2.E+04	5.E+05	2.E+02	5.E+03	2.E+01	5.E+02
Yb-169	3.E+02	8.E+03	3.E+00	8.E+01	3.E-01	8.E+00
Au-198**	2.E+02	5.E+03	2.E+00	5.E+01	2.E-01	5.E+00
Cd-109*	2.E+04	5.E+05	2.E+02	5.E+03	2.E+01	5.E+02
Co-57*	7.E+02	2.E+04	7.E+00	2.E+02	7.E-01	2.E+01
Fe-55*	8.E+05	2.E+07	8.E+03	2.E+05	8.E+02	2.E+04

[a] The primary values to be used are given in TBq. Curie values are provided for practical usefulness and are rounded after conversion.

[b] Criticality and safeguards issues will need to be considered for multiples of D

Radionuclide	Category 1 1000 x D		Category 2 10 x D		Category 3 D	
	(TBq)	(Ci)[a]	(TBq)	(Ci)[a]	(TBq)	(Ci)[a]
Ge-68*	7.E+02	2.E+04	7.E+00	2.E+02	7.E-01	2.E+01
Ni-63*	6.E+04	2.E+06	6.E+02	2.E+04	6.E+01	2.E+03
Pd-103*	9.E+04	2.E+06	9.E+02	2.E+04	9.E+01	2.E+03
Po-210*	6.E+01	2.E+03	6.E-01	2.E+01	6.E-02	2.E+00
Ru-106 (Rh-106)*	3.E+02	8.E+03	3.E+00	8.E+01	3.E-01	8.E+00
Tl-204*	2.E+04	5.E+05	2.E+02	5.E+03	2.E+01	5.E+02

The category of a source can be determined by dividing the activity of the source ('A' in TBq) by the D-value for the relevant radionuclide, and comparing the A/D value with those given in column 2 of table IV-2.

In some situations it may be appropriate to categorize a source on the basis of A/D alone for example, when the practice for which the source may be used is unknown or not confirmed, as may happen at the time of import or export of the source. However, when the circumstances of use of the source are known, the regulatory body may make a judgement to modify this initial categorization using other information about the source or its use. In some circumstances it may, therefore, be convenient to assign a category on the basis of the practice in which the source is used, as shown in column 3 in table IV-2).

Note: The categorization system set is composed of five categories, as shown in Table IV-2 below. This number of categories is considered sufficient to enable the practical application of the scheme, without unwarranted precision. Within this categorization system, sources in Category 1 are considered to be the most 'dangerous' because they can pose a very high risk to human health if not managed safely and securely. An exposure of only a few minutes to an unshielded Category 1 source may be fatal. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled, and therefore need to be kept under appropriate regulatory control. Categories should not be subdivided as this would imply a degree of precision that is not warranted and would lead to a loss of international harmonization.

* These radionuclides are very unlikely to be used in individual radioactive sources with activity levels that would place them within Categories 1, 2 or 3 and would, therefore, not be subject to those paragraphs of the Code relating to national registries or to import and export controls.

Table IV–2. Categories for radioactive sources and some typical sources and practices with those categories

Category	Activity ratio (A/D)[a]	Source[b] and practice
1	A/D ≥ 1000	Radioisotope thermoelectric generators (RTGs) Irradiators Teletherapy sources Fixed, multi-beam 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 that incorporate high activity sources[c] Well logging gauges
4	1 > A/D ≥ 0.01	Low dose-rate brachytherapy sources (except eye plaques and permanent implants) Industrial gauges that do not incorporate high activity sources Bone densitometers Static eliminators
5	0.01 > A/D and A > Exempt[d]	Low dose-rate brachytherapy eye plaques and permanent implant sources X ray fluorescence devices Electron capture devices Mossbauer spectrometry sources Positron Emission Tomography (PET) check sources

Unlisted Practices

For radioactive sources used in practices not listed in Table 3, the regulatory body may assign a category to the source based on the A/D ratio.

Short Half-life Radionuclides and Unsealed Sources

In some practices, such as nuclear medicine, radionuclides with a short half-life are used in a source form that is unsealed. Examples of such applications include 99mTc in radiodiagnosis and 131I in radiotherapy. In such situations, the principles of the categorization system may be applied to determine a category for the source, but a judgement should be made in choosing the activity on the basis of which to calculate the ratio A/D. These situations should be considered case by case.

[a] Some D-values are given in Ref. [21,29].

[b] Factors other than A/D alone have been taken into consideration in assigning the sources to a category as indicated in Annex I of Ref. [22].

Aggregation of Sources

For an aggregation of sources of a single radionuclide in a single storage or use location where sources are in close proximity, such as in storage facilities or manufacturing processes, the total activity shall be treated as one source for the purposes of assigning a category. If sources with several radionuclides are aggregated, then the sum of the A/D ratios shall be used to determine the category in accordance with the formula:

$$\text{Aggregate A/D} = \sum_{n} \frac{\Sigma i A_{i,\,n}}{D_n}$$

Where:

Ai,n = activity of each individual source i of radionuclide n.
Dn = D value for radionuclide *n*.

FIFTH SCHEDULE

Fees (regs 14, 17, 64,)

A person who intends to engage in any activity or practice involving a radiation source, nuclear material or any other radioactive material must ensure that such activity or practice is licensed in accordance with Section 23 of the Atomic Energy Act.

Fees to engage in any activity or practice	**K**	**t**
1. Application Fee (Non-Refundable)	20,000	00
2. Renewal Fee (Non-Refundable)	20,000	00
3. Annual Licence to Possess and Use a radiation source (Number of radiation sources in the same location to be dealt with under one license)		
For less than 3 radiation sources		
Category 1	500,000	00
Category 2	450,000	00
Category 3	400,000	00
Category 4	350,000	00
Category 5	300,000	00
For more than 3 radiation sources but less than 6		
Category 1	1,200,000	00
Category 2	950,000	00
Category 3	850,000	00
Category 4	750,000	00
Category 5	600,000	00

For more than 6 radiation sources		
Category 1	2,400,000	00
Category 2	1,900,000	00
Category 3	1,700,000	00
Category 4	1,500,000	00
Category 5	1,200,000	00
4. License to mine and/or process radioactive minerals		
1 year	3,000,000	00
2 years	5,500,000	00
5. Licence to transport radioactive material or radioactive minerals (Per consignment)	400,000	00
6. Licence to import category 1 and category 2 radioactive source (per import for one source)	400,000	00
7. Licence to export category 1 and category 2 radioactive source (per import for one source)	400,000	00
8. Licence to generate, keep or manage radioactive waste (Annual)	2,000,000	00
9. Licence to operate Radioactive waste storage facility (Annual)	2,000,000	00
10. Licence to decommission a mining facility	8,000,000	00

NOTE:—The categorization system set is composed of five categories, as shown in Table IV-2 below. This number of categories is considered sufficient to enable the practical application of the scheme, without unwarranted precision. Within this categorization system, sources in Category 1 are considered to be the most 'dangerous' because they can pose a very high risk to human health if not managed safely and securely. An exposure of only a few minutes to an unshielded Category 1 source may be fatal. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled, and therefore need to be kept under appropriate regulatory control. Categories should not be subdivided as this would imply a degree of precision that is not warranted and would lead to a loss of international harmonization.

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[a] Some D-values are given in Ref. [21,29]

Made this 31st day of July, 2012.

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