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THE NUCLEAR SAFETY AND RADIATION PROTECTION ACT

THE NUCLEAR SAFETY AND RADIATION PROTECTION REGULATIONS, 2019

In exercise of the power conferred upon the Minister by section 139 of the Nuclear Safety and Radiation Protection Act, and every other power hereunto enabling, the following Regulations are hereby made:—

Citation and commencement.

1.—(1) These Regulations may be cited as the Nuclear Safety and Radiation Protection Regulations, 2019.

(2) These Regulations shall come into operation on the 6th day of September, 2019.

PART I.—*Preliminary*

Interpretation.

2.—(1) In these Regulations—

"broker" means a person who acts on behalf of one or more other persons to negotiate or arrange contracts, purchases, sales, or other means

of transfer, of radioactive material, nuclear material, nuclear technology, ionizing radiation apparatus or radiation sources;

"bulk authorization" means an authorization granted in a single document in respect of multiple activities, or multiple facilities, for a specified period, and the scope of any such authorization shall be construed having regard to the provisions of regulation 7;

"carers and comforters" means persons who, other than in connection with their paid occupation, volunteer the provision of care, support or comfort to patients undergoing radiological procedures for medical diagnosis or medical treatment;

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

"contamination" means—

(a) the presence of any unintended or undesirable radioactive substance—

(i) on a surface or within a solid, liquid, or gas; or

(ii) within the human body; or

(b) the process giving rise to the presence of a substance as mentioned in paragraph (a);

"controlled area" means an area defined pursuant to regulation 31 (2);

"defence in depth" means the application of more than a single protective measure for a given safety objective, in order to achieve the objective even if one of the protective measures fails;

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

"disused radiation source" means a radiation source which is no longer used, or intended to be used, for the activity for which an authorization has been granted under these Regulations;

"dose constraint" means a prospective and source related value of individual dose or risk that is used in planned exposure situations

as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization;

"emergency" means a non-routine situation that necessitates prompt action in order to mitigate a hazard (whether occurring or perceived to be imminent) or adverse consequences for human health, safety, quality of life, property or the environment, and examples include—

(a) a nuclear or radiological emergency; and

(b) conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes;

"emergency exposure situation" means exposure arising as a result of an accident, a malicious act, or any other unexpected event, and which requires prompt action in order to avoid or reduce adverse consequences;

"emergency plan" means a description of—

(a) the objectives, policy and concept of operations, for a systematic and effective response to an emergency; and

(b) the structure and responsibilities for coordinating that response;

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

"ethics committee" means a committee appointed by the Authority to review and approve levels of exposure for individuals participating in biomedical research;

"equivalent dose" means the product of the mean absorbed dose, in a tissue or organ of the body, from a particular type of ionizing radiation and the respective radiation weighting factor;

"GSR" means General Safety Regulations;

"health professional" means an individual who meets all the requirements imposed by the laws of Jamaica for lawful practice in the health related area concerned (which area may include, for example, medicine, dentistry, chiropractice, podiatry, nursing, medical physics, medical radiation technology, radiopharmacy, allied health, or occupational health);

"health screening programme" means a programme which includes the performance of a health test or medical examination, for the purpose of the early detection of disease;

"inspection imaging device" means an imaging device designed specifically for imaging—

(a) persons, for the purpose of detecting concealed objects on or within the human body; or

(b) a vehicle or cargo, for the purpose of detecting concealed objects within the vehicle or cargo (as the case may be);

"investigation level" means a specified quantity in relation to a value item (such as effective dose, intake of radionuclides or contamination) at or above which an investigation should be conducted for protection and safety;

"justified" means justified as permitted under regulation 6 or 41;

"licensee" for the purposes of Part V means a person or organization licensed under regulation 65;

"management system" means the administrative and operational activities involved in the manufacture,

supply, receipt, possession, storage, use, transfer, import, export, transport, maintenance, recycling or disposal, of radiation sources;

"medical exposure" means exposure incurred by—

(a) patients for the purpose of medical or dental diagnosis or treatment;

(b) carers and comforters; or

(c) an individual who volunteers to be subjected to exposure as part of a programme of biomedical research;

"medical physicist" means a health professional, with specialist education and training in the concepts and techniques of applying physics in medicine, who is competent to practice independently in one or more of the specialties of medical physics;

"medical radiation facility" means a medical facility in which radiological procedures are carried out;

"medical radiation technologist" means a health professional—

(a) with specialist education and training in medical radiation technology; and

(b) who is competent to carry out radiological procedures, as delegated by a radiological medical practitioner, in

one or more of the specialties of medical radiation technology;

"medical radiological equipment" means radiological equipment—

(a) used in medical radiation facilities to perform radiological procedures; and

(b) that either delivers exposure to a person or directly controls or influences the extent of such exposure,

for example, radiation generators (such as X-ray machines or medical linear accelerators), devices containing sealed sources (such as cobalt-60 teletherapy units), devices used in medical imaging to capture images (such as gamma cameras, image intensifiers, flat panel detectors and positron emission tomography scanners);

"member of the public", when used in relation to protection and safety, does not include a person subjected to occupational exposure or medical exposure;

"operational stage", in relation to an activity, means the stage during which the activity is being undertaken;

"optimization of protection and safety" means—

(a) the process of determining the level of protection and safety that would result in the lowest reasonably achievable level (when economic and social factors are taken into account) of exposure incurred by individuals (whether occupationally or as members of the public); and

(b) in relation to medical exposure patients, the management of the radiation dose to the patient commensurate with the medical purpose;

"planned exposure situation" means exposure arising from—

(a) the planned operation of a source; or

(b) a planned activity that results in an exposure from a source;

"protection", when used in conjunction with "safety", means—

(a) the prevention of accidents and the mitigation of the consequences of accidents if accidents do occur;

(b) the protection of persons against exposure to ionizing radiation; and

(c) the safety of sources,

including the means for achieving such protection and safety;

"protection and safety requirements" means the requirements of Part III;

"radiation source" includes—

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

(b) radioactive material, being material designated by the Act, or by the Authority pursuant to any power under the Act, as being subject to regulatory control because of its radioactivity;

(c) any radioactive source, being—

(i) radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form, and which is not exempt from regulatory control; or

(ii) the use of radioactive material released from a leaking or broken radiation source,

but excluding material encapsulated for disposal, or nuclear material within the nuclear fuel cycles of research and power reactors;

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

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

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

"reference level" means the level of dose, risk or activity concentration—

(a) above which it is not appropriate to plan to allow exposures to occur; and

(b) below which optimization of protection and safety would continue to be implemented, in an emergency situation or an existing exposure situation;

"referring medical practitioner" means a health professional who refers individuals to a radiological medical practitioner for medical exposure;

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

"representative person" means an individual who receives a dose that is representative of the doses received by the more highly exposed individuals in the population of Jamaica;

"risk constraint" means a source related value that is a function of the probability of an unintended event causing a dose, and the probability of the detriment due to the dose;

"safety case" means the scientific, technical, administrative and managerial arguments and evidence supporting the safety of a disposal facility, with reference to—

(a) the suitability of the site of the facility and its design;

(b) the construction and operation of the facility;

(c) the assessment of radiation risks; and

(d) the assurance of the adequacy and quality of all safety related work associated with the facility;

"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;

"single authorization" means an authorization issued for a single activity, or single facility, for a specified period;

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

"storage" means the holding of radiation sources or radioactive waste in a facility that provides for their containment with the intention to retrieve them;

"supervised area" means an area defined pursuant to regulation 31(4) (classification of areas);

"supplier", in relation to a source, means any person or organization to whom an authorization holder delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source.

(2) For the purposes of these Regulations—

(a) where reference is made to action required to be taken if or where "appropriate", the question whether a particular action is "appropriate" in a given case shall be determined having regard to what is reasonable according to established protection and safety standards for the industry concerned; and

First Schedule.

(b) reference to a source by category means the source as categorised in the First Schedule.

Applications of Regulations.

3.—(1) These Regulations apply to—

(a) the adoption, introduction, conduct, discontinuance, or cessation of a practice in a planned exposure situation, emergency exposure situation and existing exposure situation;

(b) the design, manufacture, construction, assembly, acquisition, importation or exportation, distribution, sale, loan, hire, location, commissioning, disassembly, transportation, storage, and recycling or disposal, of a radiation source within a practice; and

(c) the following practices in planned exposure situations—

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

(ii) the use of sources and consumer products;

(iii) the production and supply of devices that generate radiation, including linear accelerators, cyclotrons and fixed and mobile radiography equipment;

(iv) the use of radiation or radioactive material for medical, industrial, veterinary, agricultural, legal or security purposes and the use of associated equipment, software or devices in circumstances where such use could affect exposure to radiation;

(v) the use of radiation or radioactive material for education, training or research, including any activity relating to such use that involves or could involve exposure to radiation or exposure due to radioactive material; and

(vi) any other practice specified by the Minister by order published in the Gazette, after consultation with the Authority.

(2) The sources within any practice to which the requirements of these Regulations, relating to practices, shall apply include—

(a) facilities that contain radioactive material and facilities that contain radiation generators, including medical radiation facilities and irradiation facilities;

(b) individual sources of radiation, including sources within the types of facility mentioned in paragraph (a), as specified by the Authority in writing published on its official website;

(c) exposure due to material in any practice, where the activity concentration in the material of any radionuclide in the uranium decay chain or thorium decay chain is greater than 1 Bq/g or the activity concentration of 40K is greater than 10 Bq/g;

(d) subject to subparagraph (3), radioactive waste resulting from use of sources;

(e) subject to paragraph (3), 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 radiation sources;

(f) any other radiation source specified by the Authority in writing published on its official website, and which may include sources in the environment (such as radon).

(3) Sub-paragraphs (d) and (e) are limited to waste arising from medical, agricultural, industrial, research and education applications, mining and milling activities and associated radioactive waste activities such as collection, segregation, characterization, classification, treatment, conditioning and storage.

(4) For the avoidance of doubt, these Regulations also apply to—

(a) intervention by persons lawfully authorized to possess radiation sources in the event of radiological emergencies involving their source; and

(b) all activities and practices for which authorization is required under the Second Schedule of the Act.

(5) The exposures to which the protection and safety requirements of these Regulations apply are any occupational exposure, medical exposure, or exposure incurred by a member of the public, due to any practice or radiation source within the practice.

(6) These Regulations do not apply to the following exposures—

(a) exposures from natural radioactivity in the body;

(b) cosmic radiation;

(c) such other radiation sources that are essentially not amenable to control, as may be specified by the Authority in writing published on its official website.

PART II.—*Procedure for, and Management of, Authorization Applications*

Applications for authorization.

4.—(1) Every application for authorization under the Act shall comply with the procedure set out in this regulation.

Second and Third Schedules.

(2) The application shall be made by completing an authorization application in the appropriate form set out in the Second Schedule and submitting the completed application form to the Authority together with—

(a) subject to paragraph (5), the relevant fee specified in the Third Schedule; and

(b) all supporting documents required by the Authority for the purpose of determining the application, and which may include—

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

Fourth Schedule.

(ii) a safety assessment in accordance with GSR Part 3 requirement 13 section 3.29-3.36 of the IAEA Safety Standards, as set out in the Fourth Schedule;

(iii) an appropriate prospective assessment made for radiological environmental impact, commensurate with the radiation risks associated with the facility or activity;

(iv) an emergency plan, if applicable, in accordance with GSR Part 7 of the IAEA Safety Standards;

(v) a determination of the characteristics and activity of any radioactive material to be discharged into the environment, with an assessment of the resulting doses to the representative person;

(vi) a final disposal solution for generated radioactive waste and disused sealed sources according to the *Radioactive Waste Management Policy* or any other policy document specified to be applicable, by the Authority on its official website;

First Schedule.

(vii) where the application concerns authorizations involving any category falling within category 1, 2 or 3 of the radiation sources set out in the First Schedule, a description of the arrangements for the safe management of the sources once they become disused, including financial provisions where appropriate;

(viii) the qualifications in radiation protection, held by the medical practitioners who are to be designated (by name or by qualification credentials) in the licence as the only individuals permitted to prescribe medical exposure by means of the authorized source, which qualifications shall include training in the medical uses of radiation technology, medical physics, or any other relevant field;

(ix) the draft decommissioning plan in respect of the facility or activity concerned, in accordance with regulation 85; and

Second Schedule.

(x) a notification of practices and sources, completed in the form set out in Annex 1 of the Second Schedule.

(3) For the purposes of paragraph (2), the application form, supporting documents, and the relevant fee, shall be submitted to the Authority by such means, and in such manner, as may be notified by the Authority from time to time (which may include submission by registered post or by electronic means).

(4) Where an application for authorization includes information which the applicant desires the Authority to hold as confidential, that information shall clearly be so identified in the application.

(5) The Minister may, by order published in the Gazette, provide that the fee referred to in paragraph (2)(a) or regulation 5(8) or 10(a) shall not be

required in the case of medical practitioners (within the meaning of the Medical Act) or registered dentists (within the meaning of the Dental Act), in full time employment in the public service.

Grant or refusal of authorization.

5.—(1) Within fourteen days after receiving an application made in accordance with regulation 4, the Authority shall, in accordance with this regulation and the provisions of section 39 of the Act, consider and determine the application.

(2) The Authority shall approve the application, subject to such terms and conditions as the Authority considers appropriate, if the Authority is satisfied that—

(a) the activity in respect of which the authorization is sought is activity in respect of which authorization may be granted under the Act by the Authority; and

(b) none of the grounds for refusal set out in regulation 6 (justification of practices) or in section 43 of the Act apply to the application, and nothing in the Act or any other law otherwise precludes the grant of the authorization.

(3) For the purposes of determining any matter referred to in paragraph (2), the Authority may conduct such background checks, and require the applicant to produce such documents, as may be reasonably necessary.

(4) Unless otherwise specified by the Act or these Regulations, the authorization issued by the Authority shall take the form of—

(a) a permit or registration; or

(b) a licence, in any case where the application for authorization relates to an industrial irradiation installation, an installation processing radioactive materials, a medical or industrial radiography facility, the transportation of radioactive material, or to the use of a source in respect of which the Authority has determined that a permit or registration is not a suitable format for the authorization.

(5) For the purposes of paragraph (4), a permit or registration is the suitable format for an authorization if the activity concerned poses low or moderate risk to safety and protection, as determined by the Authority after considering a safety assessment, of the facility concerned, submitted to it by the applicant.

(6) Where the Authority approves an application, it shall—

Fifth Schedule.

(a) issue a grant of authorization, of the appropriate type pursuant to paragraph (4), to the applicant in the form set out in the Fifth Schedule; and

(b) enter the particulars of the authorization in the Register of Authorizations in accordance with section 49 of the Act.

(7) The grant of authorization referred to in paragraph (6)(a) shall—

(a) specify the type of activity authorized;

(b) state the date of its issue and the date of its expiration;

(c) specify whether the authorization is a single authorization or a bulk authorization;

(d) specify the terms and conditions (if any) to which the authorization is subject; and

(e) bear a unique identification number.

(8) Where the Authority intends to refuse an application for authorization, the Authority shall forthwith inform the applicant in writing, giving the reasons therefor and specifying a reasonable period within which the applicant may—

(a) address the matters raised in the reasons given by the Authority; and

Third Schedule.

(b) subject to regulation 4(5) pay the relevant reconsideration fee specified in the Third Schedule and request that the Authority reconsider the application.

(9) The applicant may make a request for reconsideration pursuant to paragraph (8)(b) and, where the applicant makes such a request, the Authority shall reconsider the application and if the Authority is satisfied—

(a) that the reasons given for the proposed refusal still apply to the applicant, the Authority shall proceed with the refusal in accordance with section 39(4) of the Act; or

(b) as to the matters set out in paragraph (2), the Authority shall approve the application.

Justification of practices.

6.—(1) In determining whether a practice is justified in the public interest, for the purposes of section 43(1)(a) of the Act, the Authority shall consider whether the practice is likely to produce sufficient benefit to the exposed individuals or to society to offset the radiation harm that the practice might cause, taking into account all relevant social, economic and other relevant factors.

(2) For the purposes of section 43(1)(a) of the Act, the following factors shall be considered as indicating that authorizing a practice would not be justified in the public interest—

(a) the practice is not a justified practice involving medical exposure, and is likely to result in an increase in activity, by the deliberate addition of radioactive substances or by activation, in food, feed, beverages, cosmetics, or any other product intended for ingestion, inhalation or percutaneous intake by, or application to, a person;

(b) the practice involves the frivolous use of radiation or radioactive substances in commodities or in products such as toys or personal jewellery or other adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation;

(c) the practice involves human imaging using radiation—

(i) that is performed as a form of art or for publicity purposes;

(ii) that is performed for occupational, legal, or health insurance, purposes without reference to clinical indication, unless the Authority is satisfied that exceptional circumstances exist which justify such human imaging for specific practices;

(iii) for theft detection purposes;

(iv) for the detection of concealed objects for antismuggling purposes, unless the Authority is satisfied that exceptional circumstances exist which justify such human imaging for specific practices;

(v) for the detection of concealed objects that can be used for criminal acts or to pose a threat to national security, unless the Minister responsible for national security certifies in writing to the Authority that the imaging is justified.

(3) In determining whether the practice of any type of human imaging procedure in which radiation is used, other than for medical diagnosis or medical treatment or as part of a programme of biomedical research, is justified in the public interest, the Authority shall have regard to—

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

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

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

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

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

(4) If it is determined by the Authority that a particular practice of human imaging using radiation is justified, then the Authority may only authorize the practice subject to specific regulatory controls.

Scope of bulk authorization.

7.—(1) Where the type of authorization specified in a grant of authorization is a bulk authorization the authorization holder shall, for the duration of the period of validity of the grant, be deemed to have authorization to carry out the activity described in the grant, without the need for any further specific authorization from the Authority.

(2) Notwithstanding paragraph (1), as part of the terms and conditions of the grant, the authorization holder may be required to notify the Authority prior to the international transfer of any item that is the subject of the grant of authorization.

Deemed terms and conditions.

8. It shall be deemed to be a term and condition of every authorization granted under these Regulations that the authorization holder shall—

(a) comply with the provisions of the Act and all applicable regulations made under the Act and , in the case of a licence for the transportation of radioactive material, comply with the IAEA Regulations for the Safe Transport of Radioactive Material, 2012 Edition, Specific Safety Requirements No. SSR-6 and any revisions thereto as specified by the Authority, on its official website, to be applicable;

(b) take all necessary steps for the protection and safety of its employees, its patients and members of the public; and

(c) ensure the availability of human and financial resources for decommissioning the facility and managing radioactive waste, as necessary.

General responsibilities of authorization holders.

9. An authorization holder shall establish information management systems, commensurate with the size and nature of the authorized activity, which ensure that—

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

(b) information received in confidence from another party is only disclosed to a third party with the consent of the first party.

Renewal or variation of authorization.

10. An application for renewal of an authorization or for the variation of an authorization shall be accompanied by—

(a) subject to regulation 4(5), the relevant fee specified in the Third Schedule; and

(b) a copy of the grant of authorization sought to be renewed or varied,

and shall be submitted by such means and in such manner as may be notified by the Authority from time to time (which may include submission by registered post or by electronic means).

Exemptions.

11. The following practices and sources are automatically exempted from the requirement to obtain authorization under any provision of the Act—

(a) radioactive materials in a moderate amount for which the total activity of a given nuclide present on the premises at any one time or its activity concentration does not exceed the levels specified in the Sixth Schedule;

Sixth Schedule.

(b) radioactive material in a bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value specified in the Seventh Schedule;

Seventh Schedule.

(c) equipment containing radioactive material exceeding the quantities or concentrations specified in sub-paragraph (a) or (b), if—

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

(ii) the equipment is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage;

(iii) the equipment is in the form of an unsealed source in a small amount, such as sources used for radioimmunoassay;

(iv) in normal operating conditions, the equipment does not cause an ambient dose equivalent rate or a directional dose equivalent rate, as the case may be, exceeding 1 μSv/h at a distance of 0.1 metres from any accessible surface of the equipment; or

(v) necessary conditions for disposal of the equipment have been specified by the Authority;

(d) radiation generators of a type approved by the regulatory body, or in the form of an electronic tube, such as a cathode ray tube for the display of visual images, if—

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

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

Management of exemption applications.

12.—(1) The Authority shall establish such internal procedures as it considers appropriate to manage the determination of exemptions under the Act and the regulations.

(2) In keeping with procedures established pursuant to paragraph (1), the Authority may, upon an application under paragraph (3), in writing exempt from the requirement to obtain authorization under any provision of the Act, any activity specified in paragraph (3) for which such authorization would otherwise be required under the Act.

(3) An application for exemption from any provision of the Act requiring the obtaining of authorization may be made in respect of—

(a) the international transfer of any material or technology pursuant to an agreement entered into between the Government of Jamaica and a foreign State or international organization;

(b) activity carried out by the Ministry responsible for national security or the Ministry responsible for defence;

(c) the transfer of material or technology for the purpose of providing humanitarian aid in the case of a disaster or as a donation in the case of a national or international emergency; or

(d) any case where the Minister certifies that the exemption is desirable in the public interest.

(4) An application for exemption on any of the grounds specified in paragraph (3) may be made to the Authority in accordance with paragraph (5).

(5) An application under this regulation shall be in writing accompanied by such supporting documents as the Authority may reasonably require for the purpose of determining the application.

(6) Upon receiving an application in accordance with paragraph (5), the Authority shall forthwith consider and determine the application and notify the applicant in writing of the decision and the reasons therefor.

Exemptions from protection and safety requirements.

13.—(1) The practices and sources exempted under regulation 11 from authorization requirements are automatically exempted from the protection and safety requirements.

(2) Upon the written application of the authorization holder, the Authority may exempt a radiation source (which may include substances, materials, radioactive waste and objects within the authorized practice) from the protection and safety requirements if satisfied that the source meets the criteria for clearance set out in the Eighth Schedule.

Eighth Schedule.

Registration of brokers.

14.—(1) A person shall not operate as a broker unless that person is registered as a broker under these Regulations.

(2) An application to be registered as a broker may be made to the Authority in writing accompanied by the relevant application fee specified in the Third Schedule.

Third Schedule.

(3) Upon receiving an application in accordance with paragraph (2), the Authority shall approve the application if the Authority is satisfied that the applicant is a fit and proper person, or deny the application if not so satisfied.

(4) For the purposes of paragraph (3), in determining whether a person is fit and proper, the Authority may take into account any one or more of the matters set out in section 3(a) to (i) of the Act, with the necessary modifications.

(5) The Authority shall keep, in the Register of Authorizations, a list of the brokers registered under this regulation, including particulars as to the name and address of each broker and the date of registration.

(6) A person who contravenes paragraph (1) commits an offence and shall be liable on conviction in a Parish Court to a fine not exceeding one million dollars or to imprisonment for a term not exceeding six months.

PART III.—*Protection and Safety*

Scope.

15.—(1) In respect of the activity or practice which is the subject of an authorization, the authorization holder shall have the primary responsibility for the implementation of, and adherence to the protection and safety requirements.

(2) The scope of an authorization holder's responsibility for compliance with these Regulations extends to all activities carried on by or on behalf of the authorization holder, for which authorization is, or may be, required under the Act.

(3) Notwithstanding paragraph (1), an entity on whom a specific responsibility is imposed under this Part may be held liable, and proceeded

against accordingly, in respect of any offence which applies upon breach of the obligation.

(4) Entities to which liability may attach pursuant to paragraph (3) may include, for example—

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

(b) radiation protection officers;

(c) referring medical practitioners;

(d) medical physicists;

(e) medical radiation technologists;

(f) qualified experts;

(g) any other party to whom a party principally responsible has delegated specific responsibilities;

(h) ethics committees;

(i) employers whose workers carry out activities in respect of activities or practices requiring authorization.

(5) Nothing in these Regulations shall be construed as limiting any other power under any other law dealing with occupational health and safety or with any building requirements.

General responsibilities of authorization holders regarding protection and safety.

16.—(1) In respect of the practices and sources which are the subject of an authorization, the authorization holder shall have the responsibility for—

(a) compliance with this Part;

(b) establishing and implementing the technical and organizational measures that are necessary to ensure protection and safety;

(c) establishing organizational arrangements for protection and safety and defining the accountability therefor; and

(d) ensuring that any delegation of responsibility is documented.

(2) In addition to any other responsibilities imposed on an authorization holder by the Act or the regulations, an authorization holder shall be responsible for—

(a) establishing radiation protection and safety objectives in conformity with these Regulations;

(b) developing, implementing, and keeping appropriate records in respect of, a protection and safety programme commensurate with the radiation risks associated with the exposure situation of the

activity or practice which is the subject of the authorization, and which is sufficient to ensure compliance with these Regulations, and such a programme shall include the following actions—

(i) determining and keeping continually under review the measures needed to achieve the radiation safety objectives, ensuring that the resources needed for their implementation are provided, and verifying on a regular basis that the radiation safety objectives are being achieved;

(ii) identifying, preventing, and promptly correcting, as appropriate, any failures or shortcomings in the radiation safety measures;

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

(iv) keeping appropriate records regarding the discharge of the authorization holder's responsibilities under this Part;

(c) ensuring that –

(i) radiation sources are managed in accordance with the authorization;

(ii) when radiation sources are not in use, they are promptly stored;

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

(iv) arrangements are made for the safe management of the radiation sources set out in categories 1, 2 and 3 of the First Schedule, including financial provisions (where appropriate), once they become disused;

First Schedule.

(v) the import and export of the radiation sources set out in category 1 of the First Schedule is done in accordance with these Regulations;

(vi) sources are shipped and received in accordance with the regulations; and

(vii) such assistance is provided, to local law enforcement authorities and to law enforcement authorities in other States, as may be lawfully required, in recovering any lost or stolen source;

(d) ensuring, in co-operation with other parties having specified responsibilities in relation to protection and safety, that all personnel engaged in activities relevant to protection and safety have the appropriate education, training and qualifications to enable such personnel to understand their responsibilities and perform their duties competently, with sound judgement and in accordance with established procedures;

(e) ensuring that arrangements for protection and safety are reviewed periodically and updated as necessary;

(f) establishing procedures for reporting on, and learning from, accidents and other incidents;

(g) ensuring safe management of, and control over, all radioactive waste that is generated, and disposing of such waste in accordance with these regulations;

(h) ensuring that the appropriate safety measures are taken during the entire life cycle of radiation sources, from the moment of their manufacture up to their final disposal;

(i) ensuring that a multilevel, or defence in depth, system of sequential, independent, provisions for protection and safety that is commensurate with the likelihood and the magnitude of potential exposures is applied to sources, with a view to—

(i) preventing accidents;

(ii) mitigating the consequences of any accidents that do occur; and

(iii) restoring the sources to safe conditions after such accidents;

(j) ensuring that structures, systems and components, including software, that are related to protection and safety for facilities and activities, are designed, constructed, commissioned, operated and maintained, so as to prevent accidents as far as reasonably practicable;

(k) making suitable arrangements to—

(i) prevent reasonably foreseeable accidents in the facility or the activity (as the case may be);

(ii) mitigate the consequences of those accidents that do occur;

(iii) provide radiation workers with the information, instructions, training and equipment necessary to restrict potential exposures;

(iv) ensure that there are adequate procedures for the control of the facility and for the management of any reasonably foreseeable accidents;

(v) ensure that safety significant structures, systems and components, including software and other equipment, are inspected and tested regularly for any degradation that could lead to abnormal conditions or inadequate performance;

(vi) ensure that maintenance, inspection, and testing, appropriate to the preservation of the protection and safety measures are able to be carried out and are carried out, without undue occupational exposure;

(vii) provide, wherever appropriate, automatic systems for safely shutting off or reducing the release of radiation from facilities in the event that operating conditions are outside of the stipulated ranges;

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

(ix) ensure that all relevant safety documentation is available in the English language;

(l) ensuring that the safety of the facility, or of any waste, is not jeopardised by any action taken, or omission made, for the purpose of complying with the provisions of any other law;

(m) ensuring that levels of public exposure are continuously monitored.

(3) An authorization holder shall ensure that protection and safety is optimized and, in particular, in respect of occupational exposure and public exposure, shall ensure that all relevant factors are taken into account in a coherent way to achieve the following objectives—

(a) the determination of measures for protection and safety that are optimized for the prevailing circumstances, with account taken of the available options for protection and safety as well as the nature, likelihood and magnitude of exposures;

(b) the establishment of criteria, based on the results of the optimization referred to in paragraph (a), for the restriction of the likelihood and

magnitude of exposures by means of measures for preventing accidents and for mitigating the consequences of those accidents that do occur; and

(c) the use of dose constraints in the optimization of protection and safety for sources within a practice.

(4) An authorization holder shall ensure that protection and safety is effectively integrated into an overall management system that is commensurate with the size and nature of the activity or practice authorized and the complexity of, and radiation risks associated with, the activity or practice.

(5) The management system referred to in paragraph (4) shall ensure that—

(a) policies and procedures are established that identify safety as being of 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, within the organization, who has a responsibility for safety are clearly identified and each such individual is suitably trained and qualified to discharge the responsibility;

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

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

(6) An authorization holder shall ensure that the management system referred to in paragraph (4) is designed and implemented in a manner that enhances protection and safety by—

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

(b) describing the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are fulfilled;

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

(d) providing for the regular assessment of performance for protection and safety and the application of lessons learned from experience; and

(e) promoting a safety culture.

(7) An authorization holder shall promote and maintain a safety culture by—

(a) promoting individual and collective commitment to protection and safety at all levels of the organization;

(b) ensuring a common understanding of the key aspects of safety culture within the organization;

(c) providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, with account taken of the interactions between individuals, technology and the organization;

(d) encouraging the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety;

(e) ensuring accountability of the organization, and of individuals, at all levels, for protection and safety;

(f) encouraging open communication with regard to protection and safety within the organization and with relevant parties as appropriate;

(g) encouraging a questioning and learning attitude and discouraging complacency with regard to protection and safety; and

(h) providing means by which the organization continually seeks to develop and strengthen its safety culture.

(8) An authorization holder shall provide the Authority with such information with respect to the authorization holder's employees as the Authority may reasonably require for the purposes of this regulation.

(9) The Authority shall treat as confidential all information obtained under paragraph (8) and shall not disclose that information except as absolutely necessary for the purposes of this regulation.

Notifications.

17.—(1) Where a breach of the protection and safety requirements is committed in respect of any source or activity that is the subject of an authorization, the authorization holder shall forthwith upon becoming, or having reason to become, aware of the breach, and in any event within twenty-four hours after the occurrence of the breach—

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

(b) take appropriate action to remedy the breach and prevent a reoccurrence;

(c) report its findings under subparagraph (a) to the Authority; and

(d) take any other action that may be required under these Regulations, or as directed by the Authority, in respect of the breach.

(2) An authorization holder shall notify the Authority of the authorization holder's intention to introduce modifications to any practice or source which is the subject of the authorization, if the modification could have significant implications for protection and safety, and shall not carry out the modification unless the Authority approves the modification.

(3) In respect of the practice or source (as the case may be) which is the subject of an authorization, the authorization holder shall notify the Authority—

(a) immediately, of any event in which a dose limit is exceeded;

(b) forthwith, but in any event not later than twenty-four hours after discovery, of any emergency exposure situation;

(c) as soon as is reasonably practicable, of any lost sources and any theft or attempted theft of sources;

(d) immediately, of any discharges of radioactive waste exceeding the limits specified in the authorization;

(e) immediately, of any releases of radioactive material into the environment above the clearance criteria set out in the Eighth Schedule; and

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(f) immediately, of any unusual events or incidents such as—

(i) loss of control over a radiation source;

(ii) unauthorized use of any source; or

(iii) discovery of an orphan source.

(4) A notification under this regulation shall be in such manner as shall be determined by the Authority from time to time and published on its official website, and may include use of telephone, facsimile, electronic mail or any other means the Authority considers appropriate.

Reports.

18. An authorization holder shall provide the Authority with the following written reports in respect of the authorization holder's sources, facilities, activities and practices—

(a) a summary of the results of its public exposure monitoring conducted pursuant to regulation 16(2)(m), at such intervals as may be determined by the Authority from time to time and published on its official website, and promptly report any abnormal results which lead or could lead to an increase of public exposure;

(b) within thirty days after becoming aware of a significant medical exposure that is accidental, a report stating the cause of the exposure and the doses incurred, the corrective measures taken, and any other relevant information with respect thereto;

(c) a report as to all authorized discharges of radioactive waste into the environment, within thirty days of the discharge;

(d) a detailed written report on the release of radioactive material referred to in regulation 17(3)(e), within thirty days after the release;

(e) at six month intervals, report of its radiation source inventory data, showing any changes to those data, except for routine movements of the source allowed in the authorization;

(f) a report as to the relevant parts of any contract or acceptance document concerning the return of radiation sources intended to be exported or imported under regulation 62 or 63 at least thirty days before the proposed date for export or import (as the case may be);

(g) at such intervals as may be specified by the Authority from time to time on its official website, a report on the authorization holder's radioactive waste management activities; and

(h) a report as to all material cleared from regulatory control pursuant to regulation 81, within thirty days after the removal.

Investigation and report on abnormal events.

19.—(1) The authorization holder shall conduct an investigation, in accordance with such guidelines as may be issued by the Authority, in the event that—

(a) a quantity or operating parameter relating to protection and safety exceeds an investigation level or is outside the range of operating conditions stipulated in the authorization; or

(b) any equipment failure, accident, error, or other mishap or unusual event occurs that has the potential to cause a quantity to exceed any applicable limit or operating restriction.

(2) The investigation referred to in paragraph (1) shall be conducted as soon as possible after the event, and the authorization holder shall forthwith—

(a) prepare a written report of the findings, including the causes (or suspected causes) of the event, a verification or determination of any doses received or committed, and recommendations for preventing a reoccurrence of the event or the occurrence of a similar event; and

(b) give a copy of the report to the Authority and any affected parties.

Feedback on operating experiences.

20. An authorization holder shall—

(a) ensure that information on normal operation performance as well as abnormal conditions and events significant to radiation safety is disseminated or made available (as the case may require) to the Authority and other relevant parties (including other users) as specified by the Authority in the authorization and on its official website;

(b) make suitable arrangements, with suppliers of sources, to establish and maintain mechanisms for giving to those suppliers any information, on the use, maintenance, disposal or malfunctioning of the sources supplied that may contribute to the development of improvements in the design and fabrication of the sources.

Dose constraints.

21. In the case of a source that can release radioactive material into the environment, the authorization holder shall establish dose constraints such that the prospective annual doses—

(a) to members of the public, including people distant from the source and people of future generations; and

(b) summed over all exposure pathways, including contributions by other practices and sources,

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are unlikely to exceed the dose limits specified in the Ninth Schedule.

Dose limits.

22. An authorization holder shall ensure that the exposure of individuals due to the practices authorized is restricted so that neither the effective dose nor the equivalent dose to tissues or organs exceeds any relevant dose limit specified in the Ninth Schedule.

Human factors.

23.—(1) An authorization holder, and any parties having specified responsibilities in relation to protection and safety shall take into account human factors and shall support good performance and good practices to prevent human and organizational failures, by ensuring that—

(a) sound ergonomic principles are followed in the design of equipment and the development of operating procedures, so as to facilitate the safe operation and use of equipment to minimise the possibility that operator errors will lead to accidents, and to reduce the possibility that indications of normal conditions and abnormal conditions will be misinterpreted;

(b) appropriate equipment, safety systems and procedural requirements are provided and other necessary provisions are made—

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

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

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

(2) An authorization holder shall—

(a) inform its employees at least once annually of the importance of effective measures for protection and safety, and ensure that the employees receive appropriate training in the implementation of those measures; and

(b) routinely update the training measures adopted pursuant to paragraph (a).

Qualified experts and radiation protection officers.

24.—(1) An authorization holder shall arrange for qualified experts to be identified and made available for the purpose of providing advice on the observance of these Regulations, when so required by the Authority.

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

(3) An authorization holder shall keep the Authority informed of the arrangements made with respect to paragraphs (1) and (2).

(4) An authorization holder may, with the consent of the Authority, appoint a radiation protection officer in lieu of a qualified expert in radiation safety, in any case where the Authority is satisfied that the authorized activity concerned is of relatively low risk.

(5) An authorization holder shall not appoint a person to be a radiation protection officer pursuant to paragraph (4) unless that person is technically competent in radiation protection matters relevant to the authorized activity concerned.

Safety Assessment.

25.—(1) Whenever required to do so by the Authority, or to meet management system requirements, an authorization holder shall prepare safety

assessments that are either generic or specific to the practices or sources for which the authorization holder is responsible, including radioactive waste management activities, so as to—

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

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

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

(2) The safety assessments referred to in paragraph (1) shall include, as appropriate, a systematic critical review of—

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

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

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

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

(e) the implications, for protection and safety, of any modifications to safety standards;

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

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

(3) In making the safety assessments referred to in paragraph (1), an authorization holder shall take into account—

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

(b) factors that could give rise to a smaller but continuing release of radioactive material, and the measures available to detect and to prevent or control such a release;

(c) factors that could give rise to unintended operation of any radiation generator or a loss of shielding, and the measures available to detect and to prevent or control such occurrences; and

(d) the extent to which defence in depth is appropriate to restrict the likelihood and magnitude of potential exposure.

(4) An authorization holder shall ensure that the safety assessments conducted pursuant to this section are documented and, where appropriate, independently reviewed under the authorization holder's management system.

(5) An authorization holder shall cause to be performed additional reviews of the safety assessments, to ensure that the technical specifications and conditions of use continue to be met, whenever—

(a) any significant modification to the facility or to its operating procedures or maintenance procedures are proposed to be made;

(b) any significant change occurs on the site of the authorized activities, that could affect the safety of the facility or of activities on the site;

(c) information on operating experience, or information about accidents and other incidents that could result in exposures, indicates that the current safety assessments might be invalid;

(d) any significant changes in activities are proposed to be made; or

(e) changes in applicable guidelines or standards have been made or proposed to be made.

(6) An authorization holder shall ensure that if, as a result of a safety assessment or for any other reason, opportunities to improve protection and safety appear to be available and such improvement seems desirable, that—

(a) any consequential modifications are made cautiously and only after favourable assessment of all the implications for protection and safety; and

(b) the implementation of all such improvements is prioritized so as to optimize protection and safety.

Monitoring and testing to verify compliance.

26. An authorization holder shall ensure that—

(a) monitoring and measurements of parameters are performed as necessary for the verification of compliance with the regulations and the terms and conditions of the authorization;

(b) suitable equipment is provided for the monitoring and verification referred to in sub-paragraph (a), and that the procedures for verification are complied with;

(c) the equipment referred to in paragraph (b) is properly maintained, tested, and calibrated, at appropriate intervals with reference to standards traceable to national or international standards;

(d) records are maintained of the results of the monitoring and verification, in such form as may be required by the Authority in writing published on its official website, including records of the tests and calibrations carried out in accordance with the regulations and the terms and conditions of the authorization; and

(e) the results of the monitoring and verification are supplied to the Authority upon request.

Inventory and records.

27.—(1) Authorization holders shall maintain, and be able to supply to the Authority upon request, records in respect of—

(a) inventory of sealed sources and radiation generators;

(b) doses from occupational exposures;

(c) facilities and activities;

(d) inventory of radioactive waste;

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

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

(g) the transfer of radiation sources; and

(h) the testing of equipment and safety systems, and calibrations carried out in accordance with the regulations.

(2) For the purposes of paragraph (1), records in respect of sealed sources shall include information as to—

(a) the location of the source;

(b) radionuclide;

(c) radioactivity on a specified date;

(d) the serial number or other unique identifier;

(e) its chemical and physical form;

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

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

(h) the name and job classification of each person employed at a facility of the authorization holder,

and such other information as may be appropriate to enable the source to be identifiable and traceable.

(3) An authorization holder shall conduct regular inventory checks to confirm that radiation generators are in their assigned locations and are under control.

Optimization of safety as regards human imaging using radiation.

28.—(1) In the case of human imaging using radiation conducted by medical personnel using medical radiological equipment, which exposes humans to radiation for employment related, legal, or health insurance purposes, without reference to clinical indications, the authorization holder shall ensure that the appropriate optimization requirements for medical exposure set out in regulation 42 (optimization of protection for medical exposures) are applied, with the dose constraints specified by the Authority, on its official website, used instead of diagnostic reference levels.

(2) Procedures using inspection imaging devices in which radiation is used to expose persons for the purpose of detecting concealed weapons, contraband, or other objects within the body are deemed as giving rise to public exposure, and authorization holders shall—

(a) meet the requirements set out in regulations 53 to 57; and

(b) ensure that optimization of protection and safety is subject to the dose constraints to public exposure specified by the Authority on its official website.

(3) Authorization holders shall ensure that all persons who undergo procedures involving inspection imaging devices in which ionizing radiation is used are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionizing radiation, where such an alternative is available.

(4) An authorization holder who uses an inspection imaging device for the detection of objects on or within the body (whether or not the device is manufactured in or imported into Jamaica) shall ensure that the device conforms to all applicable standards of the International Electrotechnical Commission or the International Organization for Standardization, or to equivalent national standards.

Occupational Exposure

General responsibilities relating to occupational exposure.

29.—(1) In respect of workers who are engaged in activities which subject, or could subject, them to occupational exposure in planned exposure situations, the authorization holder in respect of the activities shall be responsible for—

(a) the protection of those workers against occupational exposure; and

(b) compliance with the relevant requirements of the regulations and the terms and conditions of the authorization.

(2) In particular, in discharging its responsibilities under paragraph (1), the authorization holder shall ensure that—

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(a) occupational exposures are controlled so that the relevant dose limits specified in the Ninth Schedule are not exceeded;

(b) protection and safety is optimized in accordance with regulation 16(3);

(c) decisions with regard to measures for protection and safety are recorded and made available;

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

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

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

(g) appropriate monitoring equipment and personal protective equipment are provided and arrangements are made for its proper use, calibration, testing and maintenance;

(h) suitable and adequate human resources and appropriate training in protection and safety are provided, as well as periodic training as required to ensure the necessary level of competence;

(i) adequate records are maintained in accordance with the requirements of the regulations and the terms and conditions of the authorization;

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

(k) necessary conditions for promoting a safety culture are maintained.

(3) An authorization holder shall ensure that workers exposed to radiation from sources within a practice that are not required by, or directly related to, their work have the same level of protection against such exposure as members of the public.

(4) An authorization holder shall—

(a) involve workers, through their representatives where appropriate, in the optimization of protection and safety;

(b) establish and use, as appropriate, constraints as part of the optimization of protection and safety;

(c) take such administrative actions as are necessary to ensure that workers are informed that ensuring protection and safety is an integral part of a general occupational health and safety programme in which they have specific obligations and responsibilities for their own protection and the protection of others against radiation exposure and for the safety of sources;

(d) 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 take such remedial action as may be appropriate; and

(e) facilitate compliance by workers with the requirements of these Regulations.

Co-operation between employers and authorization holders.

30.—(1) In any case where workers are engaged in work that involves, or that could involve, a source that is not under the control of their employer, the employer and the authorization holder responsible for the source shall co-operate to ensure compliance with the requirements of this Part.

(2) The co-operation referred to in paragraph (1) shall include, where appropriate—

(a) the development and use of specific restrictions on exposure and other means of ensuring that the measures for protection and safety of workers who are engaged in work that involves or could involve a source that is not under the control of their employer are at least as good as those for employees of the authorization holder who controls the source;

(b) specific assessments of the doses received by workers referred to in sub-paragraph (a);

(c) clear allocation and documentation of the responsibilities of the employer, and those of the authorization holder in control of the source, for protection and safety.

(3) The authorization holder in control of the source and the employer shall co-operate in the exchange of information as follows—

(a) the employer shall supply to the authorization holder the past occupational exposure records, of the workers referred to in paragraph (2)(a), and any other information relevant thereto;

(b) the authorization holder shall provide to the employer any available information, relevant for compliance with these Regulations, that the employer requests; and

(c) the authorization holder shall provide both the worker and the employer with the relevant occupational exposure records in respect of the work involving the source.

(4) In this regulation, "occupational exposure records" means the records referred to in regulation 35.

Classifications of areas.

31.—(1) An authorization holder shall designate areas as controlled areas or supervised areas, as the case may require, in accordance with this regulation.

(2) An authorization holder shall designate as controlled areas all areas in which specific measures for protection and safety are, or could be, required for—

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

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

(3) For the purposes of paragraph (2), an authorization holder shall—

(a) determine the boundaries of each controlled area on the basis of the likelihood and magnitude of expected exposures and the type and extent of the procedures required for protection and safety;

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

(c) where a source is only intermittently brought into operation or energized, or is moved from place to place—

(i) delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances; and

(ii) specify exposure times;

(d) display a warning symbol, in accordance with the international standards published by the International Organization for Standardization in respect of warning signs, and display suitable instructions and access points to, and at appropriate locations within, controlled areas;

(e) establish measures for occupational protection and safety, including (as appropriate) physical measures to control the spread of contamination, and rules and procedures for controlled areas;

(f) restrict access to controlled areas by means of—

(i) administrative procedures, such as the use of work permits; and

(ii) physical barriers, which may include locks or interlocks, such that the degree of restriction is commensurate with the likelihood and magnitude of exposures;

(g) provide, as appropriate, at entrances to controlled areas—

(i) personal protective equipment;

(ii) equipment for individual monitoring and workplace monitoring; and

(iii) suitable storage for personal clothing;

(h) provide, as appropriate, at exits from controlled areas—

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

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

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

(iv) suitable storage for contaminated personal protective equipment;

(i) periodically review conditions to assess whether there is any need to modify the measures for protection and safety or the boundaries of controlled areas;

(j) provide appropriate information, instructions, and training, for persons working in controlled areas.

(4) An authorization holder shall—

(a) designate as supervised areas all areas not required to be designated as controlled areas under paragraph (2);

(b) delineate the supervised areas by appropriate means;

(c) display approved signs, at appropriate access points to supervised areas;

(d) periodically review conditions to assess whether there is any need for further measures for protection and safety or any need for changes to the boundaries of supervised areas.

(5) In determining whether an area is suitable to be designated as a supervised area pursuant to paragraph (4), an authorization holder shall have regard to whether or not the specific protection and safety measures set out in these Regulations are needed in the area in order to comply with these Regulations, and if it is determined that they are not normally needed, the area may be designated as a supervised area, but the authorization holder shall still ensure that occupational exposure conditions in the area are kept under review.

Engineered controls as the prioritized means for protection and safety.

32.—(1) An authorization holder shall provide protection and safety by means of well engineered controls and satisfactory working conditions prioritized in accordance with the following hierarchy—

(a) firstly, engineered controls;

(b) secondly, administrative controls; and

(c) thirdly, personal protective equipment.

(2) An authorization holder shall, in consultation with workers through their representatives, in a language appropriate to the audience addressed—

(a) establish in writing site specific rules and procedures that are necessary for protection and safety for workers and other persons;

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

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

(d) ensure that any work in which workers are, or could be, subjected to occupational exposure is adequately supervised, and take all reasonable steps to ensure that the site rules and the protection and safety measures are complied with;

(e) designate, if appropriate, a radiation protection officer in accordance with such criteria as is specified in these Regulations.

(3) Authorization holders shall ensure that—

(a) workers are provided with suitable and adequate personal protective equipment that meets the standards developed by the IAEA, including, where appropriate—

(i) protective clothing;

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

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

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

(c) tasks requiring the use of certain personal protective equipment are assigned only to workers who, on the basis of medical advice are capable of safely sustaining the extra effort necessary;

(d) all personal protective equipment, including equipment for use in any emergency, is maintained in proper condition and, if appropriate, is tested at regular intervals; and

(e) if the use of personal protective equipment is considered for any given task, account is taken of any additional exposure that could result owing to the additional time taken or the inconvenience, and of any non-radiological risks that might be associated with using personal protective equipment while performing the task.

Workplace monitoring.

33.—(1) Authorization holders shall establish, maintain and keep under review, a programme for monitoring the work sites of the authorized activity, which programme shall be—

(a) commensurate with a graded approach; and

(b) supervised by a qualified expert or radiation protection officer, as the case may require.

(2) A programme established pursuant to paragraph (1) shall—

(a) be of such type and frequency as enables—

(i) evaluation of radiological conditions in all workplaces;

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

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

(b) be based on the dose rate, activity concentration in air and surface contamination and their expected fluctuations, and on the likelihood and magnitude of exposures in anticipated occupational occurrences and accident conditions; and

(c) specify—

(i) the quantities to be measured;

(ii) where and when the measurements are to be made and with what frequency;

(iii) the most appropriate measurement methods and procedures; and

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

(3) An authorization holder shall maintain records of the findings of its workplace monitoring programme and shall make those findings available to workers, where appropriate, through the workers' representatives.

Occupational exposure assessment.

34.—(1) Authorization holders and employers whose workers are engaged in work that involves, or that could involve, a source that is not under the control of their employer, shall make appropriate arrangements for the assessment of the occupational exposure of each worker, including on the basis of individual monitoring where required under this regulation, and shall ensure that arrangements are made with dosimetry service providers approved by the Authority on a list of approved providers published on its official website that operate under a quality management system.

(2) In the case of workers who—

(a) usually work in a controlled area; or

(b) occasionally work in a controlled area and who may receive a significant dose from occupational exposure,

individual monitoring shall be undertaken where appropriate, adequate and feasible, and in cases where individual monitoring is inappropriate, inadequate or not feasible, occupational exposure shall be assessed on the basis of workplace monitoring and information on the locations and duration of exposure.

(3) In the case of workers who regularly work in a supervised area, or who enter controlled areas only occasionally, occupational exposure shall be assessed on the basis of the results of workplace monitoring, or individual monitoring, as appropriate.

(4) An employer whose workers are engaged in work that involves, or that could involve, a source that is not under the control of that employer, shall—

(a) ensure that workers who could be subjected to exposure due to contamination are identified (including workers who use respiratory protective equipment); and

(b) arrange for appropriate monitoring to the extent necessary to—

(i) demonstrate the effectiveness of the protection and safety measures; and

(ii) assess the intakes of radionuclides and the committed effective doses.

Records of worker exposure.

35.—(1) Authorization holders and employers who are required to assess occupational exposure pursuant to regulation 34, shall –

(a) keep records of those assessments (hereinafter referred to as the records of occupational exposure), in accordance with this regulation;

(b) provide each worker with access to the records of occupational exposure in respect of that worker;

(c) provide the person responsible for the supervision of workers' health surveillance pursuant to regulation 36 and the Authority, with access to the records of occupational exposure;

(d) provide each other with access to the records of occupational exposure of workers of the employer, where those workers have engaged in work in relation to activities of the authorization holder;

(e) provide a copy of a worker's records of occupational exposure to the worker's new employer upon change of employment;

(f) in complying with paragraphs (b) to (e), give due care and attention to maintaining the confidentiality of the records of occupational exposure; and

(g) upon ceasing to conduct activities in which workers are subject to occupational exposure, arrange for the transfer of the records of occupational exposure to the Authority.

(2) The records of occupational exposure shall include—

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

(b) information on dose assessments, exposures and intakes at or above the relevant recording levels and the data upon which the dose assessments were based;

(c) when a worker is, or has been, exposed while in the employ of more than one employer, information on the dates of employment with each employer and on the doses, exposures and intakes in each such employment; and

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

Arrangments for workers' health surveillance and services.

36.—(1) Authorization holders and employers whose workers are engaged in work that involves, or that could involve, a source and services. That is not under the control of their employer, shall ensure that appropriate arrangements are in place for—

(a) health surveillance of their workers, in keeping with general principles of occupational health, in order to assess the initial fitness, and continuing fitness, of workers for their assigned tasks; and

(b) the provision of health services to their workers, inclusive of the following—

(i) health assessments;

(ii) measures targeted at ensuring continuing compatibility between the health of their workers and the working conditions of those workers;

(iii) the keeping of records of occupational exposure in accordance with regulation 35; and

(iv) the provision to their workers of advisory and treatment services in the event of personal contamination or exposure.

(2) Before engaging any worker for a task in which that worker is to be, or could be, exposed to radiation from a source that is not under the control of the employer, the employer and the authorization holder in respect of the source shall make an agreement as to which of them shall be responsible for the conduct of the workers' health surveillance for the purpose of these Regulations.

Information, instructions and training.

37. Authorization holders and employers whose workers are engaged in work that involves, or that could involve, a source that is not under the control of their employer, shall—

(a) provide their workers with—

(i) adequate information on the health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions;

(ii) adequate instruction and training in protection and safety, which shall be updated periodically; and

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

(b) provide those workers who could be involved in, or affected by, the response to an emergency with appropriate information, and adequate instruction and training in relation thereto, which shall be updated periodically; and

(c) maintain records of the training provided to workers pursuant to this regulation.

Conditions of Service.

38.—(1) Authorization holders, and employers whose workers are engaged in work that involves or could involve a radiation source that is not under the control of that employer, shall ensure that the conditions of service of their workers are independent of whether the workers are, or could be, subjected to occupational exposure, such that special compensatory arrangements and preferential considerations with respect to salary, insurance coverage, working hours, length of vacation, additional holidays and retirement benefits, shall neither be granted, nor used, as substitutes for protection and safety in accordance with the requirements of these Regulations.

(2) Authorization holders and employers shall make all reasonable efforts to provide their workers with suitable alternative employment in circumstances where it is determined, whether by the Authority or in accordance with health surveillance requirements, that those workers should, for health reasons, no longer continue in employment in which they are, or could be, subjected to occupational exposure.

Special arrangements for female workers and persons under the age of eighteen years.

39.—(1) Employers whose workers are engaged in work that involves, or that could involve, a source that is not under the control of their employer shall, in co-operation with the authorization holder in respect of the source, provide female workers who are likely to enter control areas or supervised areas, or who may undertake emergency duties, as part of their work, with appropriate information on—

(a) the risks to an embryo or foetus due to exposure of a pregnant woman;

(b) the importance, for a female worker who suspects that she is pregnant or who is breastfeeding, of notifying her employer as soon as possible; and

(c) the health risks, for a breast-fed infant, posed by ingestion of radioactive substances.

(2) An employer shall—

(a) not exclude a female worker from work solely on the basis that the worker is pregnant or breast-feeding;

(b) if notified of a female worker's pregnancy or suspected pregnancy, or that she is breastfeeding, adapt the working conditions of that worker, in respect of occupational exposure, so as to ensure that the embryo, foetus or infant (as the case may be) is afforded the same broad level of protection as is required for members of the public.

(3) Authorization holders, and employers whose workers are engaged in work that involves, or that could involve, a source that is not under the control of their employer, shall ensure that no person under the age of sixteen years is subjected to occupational exposure.

(4) Authorization holders, and employers whose workers are engaged in work that involves, or that could involve, a source that is not under the control of their employer, shall ensure that persons who have attained the age of sixteen years but are below the age of eighteen years are allowed access to controlled areas only—

(a) under supervision; and

(b) for the purpose of—

(i) training for employment in which they are, or could be, subjected to occupational exposure; or

(ii) studies in which sources are used.

Medical Exposure

General responsibilities of authorization holders.

40.—(1) An authorization holder shall ensure that no patient, whether symptomatic or asymptomatic, undergoes medical exposure unless—

(a) the exposure is a radiological procedure that has been requested by a referring medical practitioner and information on the clinical context has been provided, or the exposure is part of an approved health screening programme;

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

(c) a radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in paragraph (4)(a); and

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

(2) An authorization holder shall ensure that no individual incurs a medical exposure as part of a programme of biomedical research unless—

(a) the exposure is approved by an ethics committee, or other institutional body that the Authority has assigned functions similar to those of an ethics committee;

(b) a radiological medical practitioner has assumed responsibility as mentioned in paragraph (4)(a); and

(c) protection and safety is optimized.

(3) An authorization holder shall ensure that—

(a) no individual incurs a medical exposure as a carer or comforter unless that individual has received, and has indicated an understanding of, relevant information on radiation protection and information on the risks prior to providing care and comfort to a patient undergoing a radiological procedure; and

(b) the requirements specified in regulation 47 are fulfilled for the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

(4) An authorization holder shall ensure that—

(a) where a radiological procedure is performed, the procedure is performed or overseen by a radiological medical practitioner who assumes responsibility for ensuring overall protection and safety for patients in the planning and delivery of the medical exposure, including—

(i) justifying the procedure, as required by regulation 41; and

(ii) optimizing protection and safety in co-operation with the medical physicist and medical radiation technologist;

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

(c) sufficient medical personnel and paramedical personnel are available as specified by the Minister responsible for health and—

(i) are specialized in the appropriate area; and

(ii) meet such requirements for education and training as are established in guidelines issued by the Authority after consultation with the Minister responsible for health;

(d) an up to date list is maintained of the names and qualifications of all medical and paramedical personnel involved in the performance of radiological procedures on behalf of the authorization holder;

(e) in the case of therapeutic radiological procedures, the requirements of these Regulations in respect of calibration, dosimetry, and quality assurance (including the acceptance and commissioning

of medical radiological equipment) are conducted as specified in regulations 43, 44, 45 and 46 by or under the supervision of a medical physicist;

(f) in the case of diagnostic radiological procedures and image guided interventional procedures, the requirements of these Regulations for medical imaging, dosimetry, and quality assurance (including the acceptance and commissioning of medical radiological equipment) as specified in regulations 43, 44, 45 and 46 are fulfilled by or under the oversight, or with the documented advice, of a medical physicist whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks; and

(g) any delegation of responsibilities for compliance with this regulation is documented.

Justification of medical exposure.

41.—(1) This regulation concerns justification for the purposes of regulation 40.

(2) A medical exposure shall be justified by weighing the diagnostic or therapeutic benefits that the exposure is expected to yield against the radiation detriment that the exposure might cause, with account taken of the benefits and risks of available alternative techniques that do not involve medical exposure.

(3) The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken (in particular for patients who are pregnant, breast-feeding or paediatric) of—

(a) the appropriateness of the request;

(b) the urgency of the radiological procedure;

(c) the characteristics of the medical exposure;

(d) the characteristics of the individual patient; and

(e) all relevant information from the patient's previous radiological procedures.

(4) For the purposes of this regulation, all applicable national and international referral guidelines shall be taken into account in the justification of the medical exposure of an individual patient in a radiological procedure.

(5) Justification of radiological procedures that are to be performed as part of a health screening programme for asymptomatic populations shall be carried out by the ministry responsible for health after consultation with appropriate professional bodies.

(6) An authorization holder shall ensure that—

(a) no radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, other than as part of an approved health screening programme, is carried out unless specifically justified for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines issued by the Minister responsible for health after consultation with appropriate professional bodies; and

(b) the individual is informed in advance of the expected benefits, risks and limitations of the radiological procedure.

(7) For the purposes of these Regulations, the exposure of volunteers as part of a programme of biomedical research is deemed not to be justified unless—

(a) the research is conducted in accordance with—

(i) the provisions of the *World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects*; and

(ii) the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* for the application of the Declaration referred to in sub-paragraph (i), prepared by the World Health Organization; and

(b) the research is approved by an ethics committee (or other institutional body to whom the Authority assigns functions similar to those of an ethics committee) and is subject to such dose constraints as may be specified pursuant to regulation 47 and all applicable regulations.

Optimization of protection for medical exposures.

42.—(1) In respect of medical exposures, an authorization holder and the radiological medical practitioner concerned shall ensure that protection and safety is optimized.

(2) In respect of medical radiological equipment, and software that could influence the delivery of medical exposure, an authorization holder and the supplier of the equipment or software shall ensure that the equipment or software (as the case may be) conforms to the applicable standards of the International Electrochemical Commission and the International Organization for Standardization, or such other standards as may be specified by the Authority for that purpose on its official website.

(3) In respect of a radiological procedure or image guided interventional procedure, the radiological medical practitioner, in co-operation with the medical radiation technologist, and the medical physicist and, if

appropriate, the radiopharmacist or radiochemist, shall ensure that the following are used—

(a) appropriate medical radiological equipment and software and, for nuclear medicine, appropriate pharmaceuticals; and

(b) appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the radiological procedure, with account taken of the relevant norms of acceptable image quality established by relevant professional bodies and of relevant diagnostic reference levels established in accordance with regulation 45.

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

(5) In respect of therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner, in co-operation with the medical physicist, and the medical radiation technologist, shall ensure that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered so that the radioactivity is primarily localized in the organs of interest, while the radioactivity in the rest of the body is kept as low as is reasonably achievable.

(6) An authorization holder shall ensure that the particular aspects of medical exposures are considered in the optimization process for—

(a) paediatric patients subjected to medical exposure;

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

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

(d) relatively high doses to the patient;

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

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

Calibration.

43. For the purposes of regulations 40(4)(e) and (f), the medical physicist concerned shall ensure that—

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

(b) calibrations are carried out—

(i) at the time of commissioning a unit prior to clinical use;

(ii) after any maintenance procedure that could affect the dosimetry; and

(iii) at intervals approved by the Authority;

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

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

Dosimetry of patients.

44. An authorization holder shall ensure that dosimetry of patients is performed and documented, by or under the supervision of a medical physicist, using calibrated dosimeters and in accordance with internationally accepted or nationally accepted protocols, including dosimetry to determine—

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

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

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

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

Diagnostic reference levels.

45. An authorization holder shall ensure that—

(a) local assessments, on the basis of the measurements required under regulation 44 are made at intervals approved by the Authority, after consultation with the Minister responsible for health, for those radiological procedures for which diagnostic reference levels have been established by the Authority and published on its official website; and

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

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

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

Quality assurance for medical exposures.

46.—(1) Authorization holders shall establish a comprehensive programme of quality assurance for medical exposures, with the active participation of—

(a) medical physicists, radiological medical practitioners, and medical radiation technologists; and

(b) for complex nuclear medicine facilities, radiopharmacists and radiochemists,

and in conjunction with other health professionals as appropriate.

(2) An authorization holder in respect of a medical radiation facility shall ensure that programmes of quality assurance for medical exposures include, as appropriate to the medical radiation facility—

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

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

(ii) at regular intervals after the making of the measurements referred to in sub-paragraph (i);

(iii) after any major maintenance procedure that could affect protection and safety for patients; and

(iv) after any installation of new software, or modification of existing software, that could affect protection and safety for patients;

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

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

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

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

(3) An authorization holder shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks.

Dose constraints.

47. An authorization holder shall ensure that—

(a) relevant dose constraints are used in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter; and

(b) dose constraints specified or approved—

(i) by the ethics committee, or any other institutional body to which the Authority assigns functions similar to those of an ethics committee; and

(ii) on a case by case basis as part of a proposal for biomedical research in accordance with regulation 41(7),

are used in the optimization of protection and safety for persons subjected to exposure as part of a programme of biomedical research.

Pregnant or breast-feeding female patients.

48. In respect of a radiological medical practice, the authorization holder shall ensure that—

(a) there are arrangements in place for appropriate radiation protection in cases where a female patient is, or might be, pregnant or is breast-feeding;

(b) appropriate signs are placed in the public areas, waiting rooms for patients, examination cubicles and other appropriate places of the practice, and that other means of communication are also used, as appropriate, to request that female patients who are to undergo a radiological procedure notify the radiological medical practitioner, medical radiation technologist or other personnel involved in the practice, that the patient is, or might be, pregnant or is breast-feeding; and

(c) there are procedures in place for—

(i) ascertaining the pregnancy status, of female patients of reproductive capacity, before the performance of any radiological procedure that could result in a significant dose to the embryo or foetus; and

(ii) establishing that a female patient is not currently breast-feeding, before the performance of any

radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breast-fed infant,

in order for that information to be considered in the justification process for the radiological procedure and in the optimization of protection and safety therefor.

Release of patients after radionuclide therapy.

49.—(1) Before a patient is released after radionuclide therapy, the authorization holder shall ensure that arrangements are in place for appropriate radiation protection for members of the public and family members of the patient.

(2) The radiological medical practitioner concerned shall ensure that a patient is not discharged from a medical radiation facility, after undergoing a therapeutic radiological procedure, until it has been established by either a medical physicist or the facility's radiation protection officer that—

(a) the activity of radionuclides in the patient is such that doses that could be received by members of the public and family members would be in compliance with the requirements set by the Authority after consultation with the Minister responsible for health; and

(b) the patient, or the legal guardian of the patient (if appropriate), is provided with—

(i) written instructions for keeping doses to persons in contact with, or in the vicinity of, the patient as low as is reasonably achievable, and for avoiding the spread of contamination; and

(ii) information on the radiation risks involved.

Unintended and accidental medical exposures.

50.—(1) An authorization holder shall, in accordance with regulations 16(2)(j) and (k), 16(7), 59 and 87, ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.

(2) An authorization holder shall promptly investigate the following unintended or accidental medical exposures—

(a) medical treatment—

(i) delivered to the wrong individual or to the wrong tissue or organ of the patient;

(ii) using the wrong radiopharmaceutical;

(iii) with an activity, a dose or dose fraction differing substantially from the values prescribed by the radiological medical practitioner; or

(iv) that could lead to unduly severe secondary effects;

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

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

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

(e) inadvertent exposure of an embryo or foetus, in the course of performing a radiological procedure, or any failure of medical radiological equipment, software or systems, or any incident, error or mishap or other unusual occurrence, which has the potential to subject the patient to a medical exposure that is substantially different from what was intended.

(3) An authorization holder shall, in respect of an investigation required under paragraph (2)—

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

(b) identify and implement, as far as is within the authorization holder's control, the corrective action required to prevent recurrence;

(c) make, and submit to the Authority and the Minister responsible for health, within such time as is specified by the Authority or, if no time is specified, as soon as possible after the completion of the investigation, a written report stating—

(i) the cause of the exposure, failure, accident, error, mishap or other unusual occurrence;

(ii) the information referred to in sub-paragraphs (a) and (b); and

(iii) any other relevant information requested by the Authority; and

(d) in a case of unintended or accidental exposure, ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient, or the patient's legal representative (if appropriate), of the exposure.

Radiological reviews.

51.—(1) In respect of a facility conducting medical radiation, the authorization holder shall ensure that radiological reviews are performed periodically by the facility's radiological medical practitioners in co-operation with its medical radiation technologists and medical physicists.

(2) For the purposes of paragraph (1), the radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed by the facility.

Records related to medical exposures.

52.—(1) An authorization holder shall—

(a) maintain for not less than seven years, or such longer period as may be specified by the Authority and published on its official website; and

(b) make available to the Authority upon request, the records referred to in paragraph (2).

(2) The records referred to are—

(a) records of any delegation of responsibility by the authorization holder required to be kept under regulation 40(4)(g);

(b) records of training of personnel in radiation protection;

(c) the following records of calibration, dosimetry and quality assurance—

(i) records of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during the treatment of patients;

(ii) records of dosimetry of patients, as required by regulation 44;

(iii) records of local assessments and reviews made with regard to diagnostic reference levels, as required by regulation 45; and

(iv) records associated with the quality assurance programme required to be observed under regulation 46(2);

(d) in respect of diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;

(e) in respect of image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired;

(f) in respect of nuclear medicine, the types of radiopharmaceutical administered and their activity;

(g) in respect of external beam radiation therapy or brachytherapy—

(i) a description of the planning target volume, the absorbed dose to the centre of the planning target volume, or equivalent alternative information on absorbed doses to relevant tissues and organs as determined by the radiological medical practitioner; and

(ii) the dose fractionation and the overall treatment time;

(h) exposure records for volunteers subjected to medical exposure as part of a programme of biomedical research;

(i) reports on investigations of unintended and accidental medical exposures as required by regulation 50(3).

Public Exposure

General responsibilities in respect of public exposure.

53.—(1) In respect of public exposure delivered by a source, the authorization holder, in co-operation with suppliers and with providers of consumer products, shall—

(a) apply the requirements of this Part; and

(b) verify and demonstrate compliance therewith whenever requested to do so by the Authority.

(2) In applying the principle of optimization of protection and safety in the design, planning, operation and decommissioning of a source and the closure and post-closure procedures for waste disposal facilities, the authorization holder in co-operation with suppliers shall take into account—

(a) possible changes in any conditions that could affect exposure of members of the public, such as changes in the characteristics and use of the source, changes in environmental dispersion conditions, changes in exposure pathways and changes in values of parameters used for the determination of the representative person;

(b) good practice in the operation of similar sources or the conduct of similar practices (as the case may be);

(c) possible build-up and accumulation in the environment of radioactive substances from discharges during the lifetime of the source;

(d) uncertainties in the assessment of doses, especially uncertainties in contributions to doses if the source and the representative person are separated in space or time.

(3) In relation to a source, the authorization holder shall establish, implement and maintain—

(a) policies, procedures and organizational arrangements for protection and safety in relation to public exposure, in accordance with the requirements of these Regulations;

(b) measures for ensuring—

(i) optimization of protection and safety;

(ii) limitation of exposure of members of the public from the source, so that the total exposure is not higher than the dose limits for members of the public as specified in the Ninth Schedule;

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(c) measures for ensuring the safety of the source;

(d) provision for suitable and adequate resources (including facilities, equipment and services) for the protection and safety of members of the public, commensurate with the likelihood and magnitude of the exposures;

(e) programmes for appropriate training of personnel having functions relevant to the protection and safety of the public, as well as periodic retraining as necessary, to ensure the appropriate level of competence;

(f) provisions for appropriate monitoring equipment, monitoring programmes and methods for assessing public exposure;

(g) emergency plans, emergency procedures and emergency response arrangements, in accordance with the nature and magnitude of the radiation risks associated with the sources; and

(h) adequate records of monitoring programmes.

Control of visitors.

54. An authorization holder shall, in co-operation with employers where appropriate—

(a) apply the relevant requirements of these regulations in respect of public exposure for visitors to a controlled area or supervised area;

(b) ensure that visitors, when in a controlled area, are accompanied by a person who knows the measures for protection and safety for the controlled area;

(c) provide adequate information and instruction to visitors before the visitors enter a controlled area or supervised area, so as to provide protection and safety for visitors, and other individuals who could be affected by the actions of visitors;

(d) ensure that adequate control is maintained over the entry of visitors to a controlled area or a supervised area (as the case may be), including the use of appropriate signage for such areas.

Sources of external irradiation.

55. If a source can give rise to external exposure of members of the public, the authorization holder shall ensure that—

(a) the floor plans and arrangements of equipment for all new installations utilizing the source, as well as significant modifications to any existing installation, are subjected to review and approval by the Authority prior to being commissioned;

(b) shielding and other measures for protection and safety, including access controls, are provided, as appropriate, for restricting public exposure, in particular at open sites (such as some applications of industrial radiography).

Contamination in areas accessible to members of the public.

56. The authorization holder concerned shall ensure that—

(a) in the design and operation of a source that could cause the spread of contamination in areas that are accessible to members of the public, specific provisions for containment are established; and

(b) measures for protection and safety are implemented for restricting public exposure due to contamination in areas, within a facility, that are accessible to members of the public.

Monitoring of public exposure.

57. The authorization holder concerned shall, as appropriate—

(a) establish and implement monitoring programmes, which include, as appropriate, monitoring of—

(i) external exposure from the source;

(ii) discharges;

(iii) radioactivity in the environment; and

(iv) other appropriate parameters for the assessment of public exposure;

(b) maintain appropriate records of the results of the monitoring programmes referred to in paragraph (a) and estimated doses to members of the public;

(c) report or make available the records of the results of the monitoring programmes to the Authority at approved intervals, including—

(i) the levels and composition of discharges;

(ii) dose rates at the site boundary and in premises open to members of the public;

(iii) results of environmental monitoring; and

(iv) retrospective assessments made of doses to the representative person;

(d) report promptly to the Authority, in a form approved by the Authority, any levels exceeding the operational limits and conditions relating to public exposure, including limits on discharges specified in the authorization;

(e) report promptly to the Authority, in a form approved by the Authority, any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the practice or activity authorized;

(f) establish and maintain a capability to carry out monitoring in an emergency in the event of unexpected increases in radiation levels or concentrations of radionuclides in the environment due to accidents or other unusual events attributed to the source, or the facility concerned;

(g) verify the adequacy of the assumptions made for the assessment of public exposure and radiological environmental impacts;

(h) publish or make available to any member of the public on request, as appropriate, the results of the monitoring programmes and assessment of public exposure for each year.

Consumer products.

58.—(1) A provider of a consumer product shall ensure that the consumer product is not made available to the public unless the justification for the use of the consumer product is approved by the Authority and—

(a) the use of the consumer product falls within an exemption specified in regulation 13; or

(b) the provision of the consumer product to the public is the subject of an authorization.

(2) Where the use of a consumer product falls within an exemption specified in regulation 13, a provider of the consumer product who imports the consumer product for the purpose of sale or distribution shall—

(a) apply to the Authority for authorization to sell or distribute (as the case may require) the consumer product, and shall include with the application a copy of the export authorization issued by the appropriate regulatory body in the State from which the provider has imported the consumer product;

(b) ensure that, where practicable, a legible label is firmly affixed to a visible surface of the retail package containing the consumer product, which label shall—

(i) state that the product contains radioactive substances, and identify the radionuclides and their activities;

(ii) state that the provision of the consumer product to the public is authorized by the Authority; and

(iii) provide information about required or recommended options for recycling or disposal;

(c) provide with each consumer product, clear and appropriate information and instructions on—

(i) correct installation, use and maintenance of the product;

(ii) servicing and repair;

(iii) the radionuclides and their activities;

(iv) dose rates in normal operation and during servicing and repair; and

(v) required or recommended options for recycling or disposal.

(3) Where the provider of a consumer product provides the product to retailers, the provider shall give to each retailer appropriate information on safety and instructions on the transportation and storage of the consumer product.

Radiation Generators and Other Radiation Sources

General responsibilities in respect of radiation generators and other radiation sources.

59.—(1) In respect of radiation generators and other radiation sources, the authorization holder concerned, in co-operation with all other relevant parties, shall ensure that the location, design, construction, assembly, commissioning, operation, maintenance, and decommissioning, of facilities, and parts relating thereto, are based on good engineering practice which shall, as appropriate—

(a) take account of international and national standards;

(b) be supported by managerial and organizational features, with the purpose of ensuring protection and safety throughout the lifetime of the facility;

(c) include adequate safety margins in the design and construction of the facility, and in operations involving the facility, so as to ensure reliable performance in normal operation and take account of the necessary quality, redundancy and capability for inspection, with

emphasis on preventing accidents, mitigating the consequences of those accidents that do occur and restricting any possible future exposures;

(d) take account of—

(i) relevant developments concerning technical criteria;

(ii) the results of any relevant research on protection and safety; and

(iii) feedback received on lessons learned from prior experiences.

(2) An authorization holder in respect of a radiation generator or other radiation source shall make appropriate arrangements with the supplier of the radiation generator or other radiation source (as the case may be), the Authority and all other relevant parties, for the purposes of—

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

(b) providing feedback and information that may have implications for protection and safety for other users, or that may be relevant for the purpose of making improvements in protection and safety for radiation generators or other radiation sources.

Design of radiation generators and other radiation sources.

60.—(1) An authorization holder who is a manufacturer or supplier of radiation generators or other radiation sources shall ensure that the authorization holder meets its responsibilities to—

(a) supply well-designed, well-manufactured and well-constructed radiation generators or other radiation sources (as the case may be) that—

(i) provide for protection and safety in accordance with these Regulations;

(ii) meet engineering, performance and functional specifications in accordance with International Electrotechnical Commission and International Organization for Standardization technical standards, or such other standards as are specified for that purpose by the Authority and published on its official website;

(iii) meet quality standards commensurate with the significance for protection and safety of systems and components, including software; and

(iv) provide clear displays, gauges and instructions, in the English language, on operating consoles;

(b) test those radiation generators or other radiation sources (as the case may be) to demonstrate compliance with all relevant specifications;

(c) make information available, in the English language, on the proper installation and use of those radiation generators or other radiation sources (as the case may be), and the associated radiation risks, including performance specifications, instructions for operation and maintenance, and instructions for protection and safety, in compliance with all relevant International Electrotechnical Commission and International Organization for Standardization *l* standards for accompanying documents; and

(d) ensure that the protection provided by shielding and by other protective devices is optimized.

First Schedule.

(2) An authorization holder in respect of a sealed radiation source shall ensure that the source is categorized in accordance with the categorization scheme set out in the First Schedule, and as required by the Authority.

(3) The manufacturer of a radiation source or a device containing a radiation source shall ensure that, where practicable, the source itself and the container of the source are each marked with appropriate symbols.

(4) In respect of a sealed source, the authorization holder, in co-operation with the manufacturer, shall ensure that, where practicable, the source is identifiable and traceable.

(5) In respect of a radiation source, the authorization holder shall ensure that, when those sources are not in use, they are stored in an appropriate manner for protection and safety.

(6) An authorization holder in respect of a radiation generator or other radiation source shall ensure that arrangements are made promptly for the safe management of, and control over, the radiation generator or other radiation source, including appropriate financial provision, upon making a decision to take the radiation generator or other radiation source out of use.

Supply and procurement of radiation sources.

61.—(1) An authorization holder who supplies or distributes a radiation source shall ensure that the person to whom the source is supplied is authorized to receive the source.

(2) Before purchasing or otherwise acquiring a radiation source, an authorization holder shall—

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

(b) submit to the Authority the details of the arrangements referred to in paragraph (1), including copies of any contractual arrangements relating thereto.

(3) An authorization holder who supplies a radiation source or a device that incorporates a radiation source shall provide the recipient of the source or device (as the case may be) with all relevant technical information required for the safe management of that source or device.

PART IV.—*Import and Export of Category 1 and 2 Radiation Sources*

Exportation of category 1 or 2 radiation source.

62.—(1) An authorization holder shall, before exporting a category 1 or 2 radiation source, apply to the Authority for an export authorization.

Tenth Schedule.

(2) An application made under paragraph (1) shall be in the form set out in the Tenth Schedule and shall be accompanied by—

(a) a copy of the document issued by the appropriate authority in the State to which the source is to be exported, authorizing the intended recipient of the source to receive the source, which document shall include—

(i) the name of the recipient;

(ii) the address of the recipient's principal place of business;

(iii) the relevant radionuclides and radioactivity;

(iv) the uses of the source, if appropriate; and

(v) the expiration date (if any) of the recipient's authorization;

(b) where there is an agreement for the re-importation of the source, a copy of that agreement;

(c) the justification or explanation of the need to use the "exceptional circumstances" provisions set out in the *IAEA Guidance on the Import and Export of Radioactive Sources, Code of Conduct on the Safety and Security of Radioactive Sources: Guidance on the Import and Export of Radioactive Sources*, and any revisions thereto specified by the Authority on its official website to be applicable; and

(d) any other document or information which the Authority may require for the purpose of determining the application.

(3) An authorization holder who receives authorization under this regulation to export a source, shall ensure that—

(a) the export of the source is conducted in compliance with all applicable transport requirements of the IAEA Regulations for the Safe Transport of Radioactive Material and any revisions thereto as specified by the Authority, on its official website, to be applicable; and

(b) the State to which the source is to be exported is notified in writing in advance, at least seven days in advance if practicable, of the exportation, including adequate information as to the following—

(i) the estimated date of export;

(ii) the exporting facility;

(iii) the recipient;

(iv) radionuclides and radioactivity;

(v) aggregate activity level; and

(vi) the number of radiation sources being exported and, if available, their unique identifiers,

and in respect of a category 1 source, that notification is accompanied by a copy of the consent of the importing State to import the source, if applicable.

Importation of category 1 or 2 radiation source.

63.—(1) An authorization holder shall, prior to importing any category 1 or 2 radiation source, apply to the Authority for an import authorization.

Tenth Schedule.

(2) An application under paragraph (1) shall be in the form set out in the Tenth Schedule and shall include the following information—

(a) the name of the exporter;

(b) the address of the exporter's principal place of business;

(c) the name of the recipient;

(d) the address of the recipient's principal place of business;

(e) relevant radionuclides and radioactivity;

(f) uses of the source, if appropriate;

(g) the details of the arrangements made for the safe management of the source, including financial provisions where appropriate, once the source becomes disused, and any contractual agreements relating thereto; and

(h) the justification or explanation of the need to use the "exceptional circumstances" provision set out in the IAEA Guidance on the Import and Export of Radioactive Sources, Code of Conduct on the Safety and Security of Radioactive Sources: Guidance on the Import and Export of Radioactive Sources, and any revisions thereto specified by the Authority on its official website to be applicable.

(3) An authorization holder who receives authorization under this regulation to import a source shall, to the extent applicable, ensure that the importation of the source is in compliance with all applicable transport requirements of the IAEA Regulations for the Safe Transport of Radioactive Material and the IAEA Safety Standards Series No. SSR-6, and any revisions thereto as determined by the Authority to be applicable.

PART V.—*Management of Radioactive Waste*

General responsibilities in respect of radioactive waste.

64.—(1) An authorization holder shall be responsible for the safety of predisposal waste management in connection with the activity which is the subject of the authorization, and shall ensure an adequate level of protection and safety by the utilization of various means, including—

(a) demonstration of safety by means of the safety case and, for an existing facility or activity, by means of periodic safety reviews;

(b) preparation and implementation of appropriate operating procedures, including monitoring;

(c) application of good engineering practice;

(d) establishment and implementation of a management system;

(e) ensuring that staff are trained, qualified and competent;

(f) establishing and implementing an overall strategy for management of radioactive waste that is generated, including waste that has arisen from past practices, and for providing financial security therefor, taking into account interdependencies among all steps in waste management, the available options, the *Radioactive Waste Management Policy* and any other policy document specified to be applicable, by the Authority on its official website;

(g) establishing and maintaining mechanisms to provide and ensure adequate financial resources to discharge its responsibilities;

(h) derivation of operational limits, conditions and controls, including waste acceptance criteria, to assist with ensuring that the predisposal radioactive waste management facility is operated in accordance with the safety case;

(i) ensuring that generation of radioactive waste is kept to the minimum practicable, and that radioactive waste is managed by appropriate

classification, segregation, treatment, conditioning, storage and disposal;

(j) ensuring that there are no unavoidable delays in processing waste and that each stage of the process is proceeded with as soon as practicable; and

(k) using relevant international experience to ensure that operations are as safe as practicable.

(2) An authorization holder shall be responsible for the safe management of radioactive waste generated by the activity which is the subject of the authorization, and shall take all necessary measures to ensure that—

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

(b) the radioactive waste is managed by appropriate classification, segregation, treatment, conditioning, storage and disposal, and the maintenance of records with respect thereto;

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

(d) all required reports are made to the Authority within the intervals specified in the authorization, including reports relating to changes in ownership of the waste.

Licence applications.

65.—(1) No person or organization shall generate, keep or manage radioactive waste, except in accordance with a licence issued by the Authority.

(2) An application for a licence under paragraph (1) shall set out all the elements of management of radioactive waste in respect of which the licence is sought, which may include, for example—

(a) waste generation;

(b) predisposal, pre-treatment, characterization, treatment, conditioning, storage, clearance or transport, of radioactive waste;

(c) the control of discharges;

(d) packaging strategies;

(e) the design and manufacture of containers;

(f) the handling of waste packages;

(g) the site evaluation, design, construction, operation, closure and the post-closure stages, of the waste management facility concerned.

(3) An application for a licence under paragraph (1) shall—

(a) be accompanied by a safety case and supporting safety and environmental assessments, in a form satisfactory to the Authority, and which is commensurate with the complexity of the activities for which the licence is sought and their potential impact;

(b) include a description of how all the safety aspects of the facility, the design, operation, shut down and decommissioning, and the managerial controls, satisfy the requirements of the Radioactive Waste Management Policy and any other applicable policy document and, in particular, the measures for reducing hazards posed to workers, members of the public, and the environment, during normal operation and in possible accident conditions; and

(c) demonstrate the level of protection provided, and supply such assurances, as the Authority may require, that the requirements of these Regulations and the *Radioactive Waste Management Policy*, and any other policy document specified by the Authority on its website to be applicable, will be met.

(4) The safety case mentioned in paragraph (3) shall be progressively developed and refined by a licensee, or prospective licensee (as the case may be), as the waste management facility in respect of which the licence is issued or sought develops, and, in particular, shall be updated when—

(a) there is any significant change that may affect the safety of the facility or activity;

(b) there is any significant development in knowledge and understanding of the process (such as developments arising from research or operational experience feedback);

(c) there is an emerging safety issue owing to a regulatory concern or an incident; or

(d) there is any significant improvement in assessment techniques, such as computer codes or input data used in the safety analysis.

(5) An applicant for a licence to operate a radioactive waste storage facility shall demonstrate that the design and cost of the facility—

(a) ensures sufficient storage capacity to account for uncertainties in the availability of facilities for treatment, conditioning and disposal, and taking into account the possible need to process waste arising from incidents or accidents;

(b) is suitable for the expected period of storage, preferably using passive safety features, and taking into account—

(i) the potential for degradation; and

(ii) natural site characteristics that could impact performance (such as geology, hydrology and climate);

(c) allows for waste to be inspected, monitored and preserved in a condition suitable for release or transportation, as appropriate;

(d) ensures appropriate containment of waste (for example, on the integrity of the facility's structures and equipment, and the integrity of the waste forms and containers over the expected duration of storage), with consideration given to interactions between the waste, the containers and their environment; and

(e) makes provision for the retrieval of the waste whenever required,

and in the case of disposal of radioactive waste from mining and mineral processing, shall specify the proposed options to be followed in respect of the siting, design, construction, operation, closure and post-closure activities of the facility.

(6) The Authority shall grant an application for a licence under this regulation if the Authority is satisfied, having regard to the information submitted to the Authority under this Regulation, that the conception of the facility is consistent with the *Radioactive Waste Management Policy*, and any other applicable policy document.

(7) Where the Authority is not satisfied as mentioned in subsection (6), the Authority shall refuse the application and shall advise the applicant, in writing, of the refusal, giving the reasons therefor.

Management system for radioactive waste.

66.—(1) A licensee shall establish and submit to the Authority for approval and, upon obtaining such approval, implement, a management system for the facility concerned, which system shall contain at least the following elements—

(a) policy and procedures that identify safety as being of the highest priority;

(b) clear lines of authority for decisions on safety and compliance with procedures and processes;

(c) organizational arrangements and lines of communication that result in the appropriate flow of information on safety at and between the various levels in respect of the entire facility;

(d) clear specification of safety responsibilities for each individual;

(e) responsibilities for compliance with system requirements;

(f) clear requirements that problems affecting safety must be promptly identified and corrected in a manner commensurate with their importance;

(g) provision requiring each individual to be suitably trained and qualified;

(h) a quality assurance programme that—

(i) provides information on the performance of the radioactive waste management system and equipment;

(ii) establishes a review regime in respect of the system; and

(iii) ensures that all necessary records are maintained and are readily retrievable when required;

(i) provisions to ensure that where information is received in confidence from another party, the confidentiality of the information is preserved and the information is only disclosed to a third party with the consent of the other party; and

(j) provisions to ensure that the facility has sufficient capacity to process and store radioactive waste, having regard to the technological requirements of the facility and the requirements of the *Radioactive Waste Management Policy*, and any other applicable policy document.

(2) The Authority shall approve a management system submitted for its approval under paragraph (1), if the Authority is satisfied that the system contains the elements set out in paragraph (1) and provides—

(a) adequate assurance that the protection and safety measures will be met; and

(b) assurance that the components of the safety systems are quality sufficient for their tasks.

(3) A licensee shall—

(a) promote and maintain a strong safety culture;

(b) take account of interdependencies in all steps in the predisposal management of radioactive waste and the impact of the anticipated disposal options, and manage those interdependencies so far as is practicable so that disposal is affected in an integrated manner that does not compromise safety;

(c) ensure that the facility is operated in accordance with—

(i) documented procedures;

(ii) the regulations and all terms and conditions of the licence.

Radioactive Waste Management Officers.

67.—(1) If required by the Authority to do so, or the licensee thinks the appointment of an officer under this paragraph to be appropriate having regard to its management system, the licensee shall appoint a technically competent person with the appropriate independence and authority to be a Radioactive Waste Management Officer.

(2) The function of a Radioactive Waste Management Officer shall be to assist the licensee in the safe and efficient on-site management of radioactive waste.

Radioactive waste records and reports.

68.—(1) In respect of all radioactive waste management activities under its responsibility, a licensee shall develop an appropriate and comprehensive recording system that includes discharges and allows for traceability of radioactive waste from the point of its collection through to its long term storage and its disposal.

(2) A licensee shall ensure that all records related to radioactive waste inventory (including disused sources) and radioactive waste management activities (including changes to waste characteristics during processing) are—

(a) maintained up to date; and

(b) retained in such a way as to ensure that relevant information is accessible as necessary; and

(c) supplied to the Authority upon request.

(3) Where a licensee transfers waste, the licensee shall ensure that the transfer is done under an arrangement which provides for the licensee to be furnished with records as to the steps taken in respect of the waste after transfer.

Emergency preparedness.

69.—(1) A licensee shall prepare and submit to the Authority for approval an emergency plan, in accordance with regulation 87, that—

(a) includes arrangements for the licensee's radioactive waste management and inventory;

(b) defines on-site responsibilities and takes into account off-site responsibilities of other organizations with respect to implementation of the plan;

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

(d) identifies the various operating and other conditions of radioactive waste inventory, which could lead to the need for intervention;

(e) describes the methods and instruments for assessing the accident and its consequences on and off the site;

(f) provides for protective actions and mitigation actions, and assigns responsibilities for initiating and discharging those actions;

(g) provides for rapid and continuous assessment of the accident as it proceeds, and determines the need for protective actions;

(h) allocates responsibilities for notifying the relevant authorities and for initiating intervention;

(i) provides procedures, including communication arrangements, for contacting and obtaining assistance from any relevant organizations, such as fire-fighters, police and medical personnel;

(j) provides for training personnel involved in implementing emergency plans to engage in rehearsals at appropriate intervals; and

(k) provides for the periodic review and updating of the plan.

(2) The Authority shall approve a plan submitted to it under this regulation if satisfied that the plan complies with paragraph (1).

Security.

70. A licensee shall take appropriate measures to ensure the physical security of its radioactive waste management facilities, and, in particular, to prevent the unauthorized access by individuals and the removal of radioactive materials.

Nuclear safeguards.

71. In the design and operation of its waste management facilities, a licensee shall consider nuclear safeguard requirements, and shall implement those requirements in such a way as not to compromise the safety of the facility.

Pre-disposal Management of Radioactive Waste

Control of radioactive waste generation.

72.—(1) An authorization holder who generates radioactive waste shall ensure that appropriate measures are taken to keep the generation of radioactive waste to the minimum practicable.

(2) The measures contemplated by paragraph (1) may include—

(a) applying care to the planning of the design, construction, administration, operation and decommissioning of facilities;

(b) reusing and recycling materials, as far as appropriate;

(c) the authorized discharge of effluent and clearance of materials after appropriate processing or a sufficiently long period of storage, so as to reduce the amount of radioactive waste that needs further processing or storage;

(d) minimizing the activity and volume of waste by using the minimum quantity of radioactive material needed;

(e) whenever possible, when purchasing sealed sources, establishing contractual arrangements for the return of sealed sources to the manufacturer, or a pre-determined waste manager, after use;

(f) implementing a comprehensive management system for all activities potentially generating radioactive waste; and

(g) maintaining consistency with the radioactive management policy and strategy.

Radioactive waste characterization and classification.

73. An authorization holder shall categorize radioactive waste in terms of its physical, mechanical, chemical, radiological and biological properties, in accordance with the *Radioactive Waste Management Policy* and any other policy document specified by the Authority to be applicable, on its official website.

Acceptance criteria for radioactive waste.

74.—(1) A licensee shall identify, set out in a list, and submit to the Authority, as part of the safety case required under regulation 65, the licensee's waste acceptance criteria for each step of the waste management process.

(2) For the purposes of this regulation, the waste acceptance criteria shall—

(a) take into account the other steps within the waste management process;

(b) for each step of the waste management process, specify the characteristics of waste packages and unpackaged waste, under normal and abnormal conditions to be processed, stored or disposed of in that step;

(c) specify the known or likely requirements for subsequent disposal of the radioactive waste; and

(d) be in accordance with IAEA Guideline SSR 5.

(3) A licensee shall ensure that—

(a) an appropriate control system is established to provide confidence that the waste under its responsibility meets its waste acceptance criteria;

(b) radioactive waste to be transferred to other installations or to other waste management steps meets the waste acceptance criteria established by the authorization holder of the installation;

(c) the licensee's procedures for receiving waste contain provisions for safely identifying, assessing and dealing with waste that fails to meet the acceptance criteria, for example by taking remedial actions or by returning the waste.

Processing radioactive waste.

75.—(1) A licensee shall comply with the provisions of this regulation in processing radioactive waste.

(2) Radioactive material for which no further use is foreseen, and having characteristics that make it unsuitable for authorized discharge, authorized use or clearance from regulatory control, shall be processed as radioactive waste.

(3) A licensee shall ensure that—

(a) radioactive waste is collected, characterized and segregated, at the point of origin, in accordance with—

(i) established criteria;

(ii) a defined waste management strategy; and

(iii) the waste acceptance criteria defined for the next step in the waste management process;

(b) radioactive waste is rendered into a safe and passive form for storage or disposal as soon as possible;

(c) radioactive waste is processed in such a way that the safety of the operations is appropriately ensured during normal operations, that measures are taken to prevent the occurrence of incidents or accidents and that provisions are made to mitigate the consequences if accidents occur;

(d) the processing of radioactive waste is consistent with the type of waste, the possible need for its storage, the anticipated disposal method, and the limits, conditions and controls established in the safety case and in the assessment of environmental impacts;

(e) radioactive waste is processed in such a way that the resulting waste form can be safely stored and retrieved from the storage facility until its ultimate disposal; and

(f) consideration is given to the consequences of dealing with any secondary waste (whether radioactive or nonradioactive) that is created during processing.

Conditioning.

76.—(1) In selecting a conditioning process for radioactive waste, a licensee shall consider—

(a) whether safety would be improved from the use of a matrix material;

(b) compatibility of the radioactive waste with the selected materials and processes; and

(c) the minimization of the generation of secondary radioactive waste.

(2) A licensee shall ensure that—

(a) waste packages are designed and produced so that radionuclides are confined under both normal conditions and accident conditions that may occur during handling, storage or disposal; and

(b) each package of conditioned waste is provided with an appropriate label bearing the identification number and other relevant information and that a proper record of each package is kept under the management system.

Storage of radioactive waste.

77. An authorization holder shall—

(a) prior to generating radioactive waste that may require subsequent management, ensure the availability of an appropriate storage facility within their own organization, or in another authorized facility;

(b) in arrangements for the storage of radioactive waste, comply with the Radioactive Waste Management Policy and any other policy document specified by the Authority, on its official website, to be applicable;

(c) implement measures to ensure that radioactive waste and disused sealed sources are stored in containers, packages and facilities that meet the specifications set out in the safety case approved by the Authority;

(d) ensure that radioactive waste is stored in a manner that ensures—

(i) proper segregation;

(ii) protection of workers, the public and the environment;

(iii) enables inspection, monitoring, retrieval and preservation in a condition suitable for movement, handling, transportation and disposal;

(e) ensure that full traceability of waste packages by means of record keeping and adequate labelling is maintained during the different stages of storage;

(f) ensure that the integrity of stored waste packages is maintained until they are retrieved for further treatment, conditioning or disposal and is such as permits—

(i) retrieval at the end of the storage period;

(ii) enclosure in an overpack if necessary;

(iii) transport to, and handling at, a disposal facility; and

(iv) compliance with relevant waste acceptance criteria;

(g) where the Radioactive Waste Management Policy or any other policy document specified by the Authority, on its official website, to be applicable requires that radioactive waste be stored in a centralized facility, ensure that waste is promptly transferred to that facility; and

(h) ensure that the adequacy of its storage capacity is periodically reviewed, with account taken of—

(i) the predicted waste arising both from normal operation and from possible incidents;

(ii) the expected lifetime of the storage facility; and

(iii) the availability of disposal options.

Management of disused radiation sources.

78. Authorization holders shall—

(a) at least annually, review their radiation source inventory to identify any sources that have become disused;

(b) include disused sources on their inventory of radioactive material;

(c) ensure that all regulatory requirements in respect of disused sources are complied with;

(d) make all reasonable efforts to return a disused radiation source to its supplier before determining that the source is radioactive waste;

(e) ensure that the continuity of control is maintained once a radiation source becomes disused;

(f) periodically review the status of control of their disused radiation sources; and

(g) unless the authorization otherwise allows, promptly transfer their disused radiation sources to a centralized, or other approved, radioactive waste management facility.

Recycling and reuse.

79. Whenever the exercise of an option to recycle and reuse radioactive material or radiation sources requires the transfer of ownership of the radioactive material or radiation source to another organization, the authorization holder shall ensure compliance with regulation 61 (supply and procurement of radiation sources).

Discharge of radioactive materials into the environment.

80.—(1) An authorization holder shall, before discharging any radioactive materials into the environment—

(a) determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge;

(b) determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;

(c) assess doses to the representative person due to the planned discharges;

(d) consider the radiological environment impacts in an integrated manner with features of the system of protection and safety, in accordance with the requirements of the Authority;

(e) submit the authorization holder's findings in respect of the matters set out in sub-paragraphs (a) to (d) to the Authority in writing and obtain authorization for the discharge.

(2) The Authority shall utilize submissions made to it under paragraph (1)(e) as a basis for establishing authorized limits on discharges and conditions on their implementation and take those limits into account in determining whether to authorize a discharge pursuant to that paragraph.

(3) During the operational stage, the authorization holder shall—

(a) keep all radioactive discharges as far below the authorized limits established by the Authority as is reasonably achievable;

(b) monitor and record the discharges of radionuclides with sufficient detail and accuracy to demonstrate compliance with the authorized discharge limits and to permit estimation of the exposure of the representative person;

(c) maintain an appropriate management system for the activities related to effluent and environmental monitoring;

(d) report its discharges of radioactive material into the environment to the Authority at such intervals as are specified in the authorization and forthwith report all discharges that exceed the authorized limits established by the Authority; and

(e) review the authorization holder's operating experiences in respect of discharges of radioactive material and, with the approval of the Authority, adjust the authorization holder's discharge control measures to ensure optimization of protection and safety.

Clearance and control of clearance.

81.—(1) Where an applicant for authorization intends to clear radioactive material from regulatory control during the operational stage, that applicant shall disclose that intention to the Authority in the application.

(2) In respect of clearance and the control of clearance, the authorization holder shall adopt provisions that ensure that—

(a) the clearance of radioactive waste complies with clearance levels approved by the regulatory body;

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

(c) deliberate dilution of material, other than the dilution that takes place in normal operations, is not carried out;

(d) radiation markings are removed from material in respect of which regulatory controls no longer apply, and such information as the Authority requires, regarding material to which regulatory controls no longer apply, is recorded and supplied to the Authority.

Development and Operation of Radioactive Waste Management Facilities

Location and design of radioactive waste management facilities.

82. A licensee shall ensure that the facilities at which the licensee carries on radioactive waste management are—

(a) located and designed so as to ensure safety for their expected operating lifetime, under both normal and possible accident conditions, and for their decommissioning; and

(b) tested, examined and inspected periodically to ensure safety as mentioned in paragraph (a).

Construction and commissioning of radioactive waste management facilities.

83.—(1) A licensee shall ensure, in respect of the radioactive waste management facilities at which the licensee carries on radioactive waste management, that—

(a) the facilities are constructed in accordance with the design as described in the safety case and approved by the Authority;

(b) commissioning of the facility is carried out to verify that the equipment, structures, systems and components of the facility, and the facility as a whole, performs as planned;

(c) in cases where commissioning is carried out in several stages, the commissioning is reviewed and approved at every stage by the Authority; and

(d) upon the completion of commissioning, a final commissioning report is submitted to the Authority along with the safety case updated, as necessary, to reflect the "as-built" status of the facility and the conclusions of the commissioning report.

(2) Where any modification of the facility is undertaken, that has significant safety implications that require a revision of the safety case, the provisions of this Part in respect of reporting and approval requirements shall apply as if the facility was a new facility.

Review of safety, and storage capacity.

84. A licensee shall periodically review—

(a) the storage capacity of the facilities at which it stores radioactive waste, and assess the adequacy of that capacity, taking into account the predicted waste arising, the expected lifetime of the facilities and the availability of disposal options;

(b) the safety of its facilities in order to verify compliance with regulatory controls and shall make such upgrades in respect thereof as shall ensure compliance.

PART VI.—*Decommissioning of Facilities and Activities*

Decommissioning.

85.—(1) In this regulation, "end state" means a state where the facility, or all materials connected with an activity, as the case may be, is in a state fit for release from regulatory control.

(2) In respect of the decommissioning of a facility or activity, the authorization holder concerned shall be responsible for—

(a) ensuring the safety of workers and the public, and the protection of the environment during and after the decommissioning;

(b) establishing a decommissioning strategy and preparing and maintaining a decommissioning plan, in accordance with paragraph (4);

(c) establishing a waste management strategy for decommissioning facilities, including the identification of an acceptable destination for all wastes arising from decommissioning;

(d) performing safety assessments and environmental impact assessments related to decommissioning;

(e) preparing and implementing appropriate safety procedures, including emergency preparedness, and applying good engineering practices;

(f) ensuring that properly trained, qualified and competent staff are available for the decommissioning project;

(g) performing appropriate radiological surveys in support of decommissioning;

(h) keeping such records and submitting such reports as are required by the Authority;

(i) establishing a management system which provides for organizational and administrative controls, staffing and qualifications, project management, documentation and record keeping, definition of the parameters for the involvement of sub-contractors, and safety management;

(j) ensuring that end state criteria have been met by performing a final survey; and

(k) notifying the Authority prior to permanent shut down of the facility, or termination of the activity, as the case may be.

(3) An authorization holder shall apply a graded approach to the planning, conduct and completion of decommissioning.

(4) The decommissioning plan referred to in paragraph (2) (b) shall be maintained throughout the lifetime of the facility or activity (as the case may be), unless the Authority otherwise directs, and the authorization holder shall—

(a) periodically review and update the decommissioning plan, as appropriate; and

(b) within twenty-one days before commencing decommissioning, submit to the Authority a finalized version of the decommissioning plan that—

(i) reflects all reviews and updates made pursuant to these Regulations;

(ii) states the methodology and criteria that will be used to demonstrate that the proposed end state has been achieved;

(iii) states how the decommissioning will be managed, including decontamination and dismantling techniques that optimize the protection of workers, the public and the environment and minimize the generation of waste;

(iv) specifies the estimated decommissioning cost and indicates the financial provisions in place for the decommissioning, including the management of the resulting waste, even in the event that a premature shutdown is necessary;

(v) is accompanied by a supporting optimization analysis satisfactory to the Authority; and

(vi) where any new or untried methods for decommissioning are proposed to be used, demonstrates

that the use of such methods is justified and is addressed within the optimization analysis supporting the decommissioning plan.

(5) An authorization holder shall not begin decommissioning until the finalized decommissioning plan submitted under paragraph (4) is approved by the Authority.

(6) The Authority shall approve a decommissioning plan if satisfied as to the matters set out in this regulation.

(7) The authorization holder shall adhere to the approved decommissioning plan and, on completion of the decommissioning, shall demonstrate to the Authority that the end state criteria as defined in the decommissioning plan and all other acceptable requirements under these Regulations have been met.

(8) Regulatory controls shall continue to apply to a facility or activity, as the case may be, until the Authority certifies that the facility or activity is decommissioned in accordance with these regulations.

PART VII.—*Transportation of Radioactive Material*

Transportation requirements.

86. An authorization holder who transports , (whether domestically or internationally) a radiation source, radioactive waste, or any other radioactive material, shall comply with all applicable transport requirements of the IAEA Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. SSR-6, IAEA, Vienna (2012), and any revisions thereto specified by the Authority, on its official website, to be applicable.

PART VIII.—*Emergency Preparedness and Response*

Emergency plan.

87.—(1) Where an activity, source, or radioactive waste, has the potential for creating an emergency affecting either workers or members of the public, the authorization holder shall prepare and submit to the Authority for approval an emergency plan for the protection of people and the environment.

(2) The emergency plan referred to in paragraph (1) shall—

(a) include arrangements for the prompt identification of an emergency and for determining the appropriate level of the emergency response;

(b) provide for individual monitoring and area monitoring, and arrangements for medical treatment;

(c) include arrangements for assessing and mitigating the consequences of an emergency;

(d) characterise the content, features and extent of a potential emergency, taking into account the results of any hazard assessment

and the lessons learned from operating experience and from accidents that have occurred with activities, sources or waste (as the case may be) of a similar type;

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

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

(g) provide for protective actions and mitigation actions, and assign the responsibilities for initiating and discharging those actions;

(h) provide for rapid and continuous assessment of accidents, as they proceed, in determining the need for protective actions;

(i) allocate responsibility for notifying the relevant authorities and for initiating intervention;

(j) provide procedures, including communication arrangements for contacting and obtaining assistance from the relevant response organizations (such as fire-fighters, medical personnel and the police);

(k) provide for the training of personnel involved in implementing emergency plans and for rehearsal of emergency responses at appropriate intervals.

(3) Authorization holders shall be responsible for obtaining approval for, and implementing, the emergency plan required under this regulation, and shall, in accordance with the plan—

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

(b) make available for use in an emergency all equipment, instrumentation and diagnostic aids that may be needed; and

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

Implementation of intervention.

88.—(1) An authorization holder shall ensure that the protective actions or remedial actions taken by or on behalf of the authorization holder to reduce or avert 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 intervention pursuant to paragraph (1) shall be optimized so as to produce the maximum net benefit under the prevailing social and economic circumstances.

(3) An authorization holder shall forthwith notify the Authority when an accident requiring intervention has arisen, or is expected to arise, and shall keep the Authority informed as to—

(a) the state of affairs and their 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 emergency workers in an emergency exposure situation.

89.—(1) The employer of an emergency worker shall ensure that the worker is not subject to exposure in excess of 50 mSv other than—

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

(b) when undertaking actions to avert a large collective dose;

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

(2) In any of the circumstances referred to in paragraph (1)(a), (b) or (c), the employer shall make all reasonable efforts to—

Eleventh Schedule.

(a) keep doses to emergency workers below the values set out in the Eleventh Schedule; and

(b) subject to paragraph (3), ensure that workers who undertake actions due to which their doses could approach or exceed the values set out in the Eleventh Schedule do so only when the expected benefits to others would clearly outweigh the risks to those workers.

(3) No employer shall require an emergency worker to undertake any action in which the doses received might exceed 50 mSv, and shall ensure that a worker who undertakes such action—

(a) understands that the worker does so voluntarily;

(b) is informed, clearly and comprehensively, in advance, of the health risks involved, as well as the available measures for protection and safety; and

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

(4) Employers shall take all reasonable steps to assess and record the doses received in an emergency by emergency workers, and shall communicate all relevant information concerning the doses received and the associated health risks to the workers concerned.

(5) Where, in an emergency exposure situation, a worker—

(a) receives a dose exceeding 200 mSv; or

(b) requests medical advice,

the worker shall not be required to undertake any activity in which the worker could incur further occupational exposure unless a qualified medical practitioner clears the worker for further activities involving occupational exposure.

PART IX.—*Existing Exposure Situations*

Remediation of areas having residual radioactive material.

90.—(1) The authorization holder shall submit to the Authority for approval a remedial action plan, supported by a safety assessment, in respect of any facility in respect of which remediation is required regarding residual radioactive material.

(2) The remedial action plan referred to in paragraph (1) shall have as its objective the timely and progressive reduction of the radiation risks and the eventual removal, if possible, of the facility from regulatory control, and in particular shall contain provisions aimed at ensuring that—

(a) any additional dose received by members of the public as a result of the remedial actions is justified on the basis of the resulting net benefit, including consideration of the consequent reduction of the annual dose;

(b) the choice of optimized remediation option takes into account—

(i) the radiological impacts on people and the environment together with non-radiological impacts on people and the environment, and technical, societal and economic factors; and

(ii) the costs of the transport and management of radioactive waste, and any subsequent public exposure associated with its disposal;

(c) a mechanism for public information is in place and the interested parties affected by the existing exposure situation are involved in the planning, implementation and verification of the remedial actions, including any monitoring and surveillance following remediation;

(d) a monitoring programme is established and implemented;

(e) a system for maintaining adequate records relating to the existing exposure situation, and actions taken for protection and safety, is in place; and

(f) procedures are in place for reporting to the Authority any abnormal conditions relevant to protection and safety.

(3) In carrying out any remedial action referred to in this regulation, the authorization holder shall—

(a) ensure that the remedial action, including management of any radioactive waste, is conducted in accordance with the remedial action plan;

(b) take responsibility for all aspects of protection and safety, including the performance of a safety assessment;

(c) monitor and perform a radiological survey of the area regularly during the carrying out of the remedial action, so as to verify levels of contamination, verify compliance with these regulations, and enable any unexpected levels of radiation to be detected and the remedial action plan modified accordingly;

(d) perform a radiological survey after completion of the remedial action plan in order to verify that the end state conditions, as established in the plan, have been met;

(e) prepare a final remediation report and submit a copy thereof to the Authority.

(4) Where a modification is made to the remedial action plan, an authorization holder shall establish and maintain, for so long as required by the Authority, an appropriate programme of post-remedial control measures, which shall include appropriate provisions for—

(a) monitoring and surveillance of the facility concerned; and

(b) verifying the long-term effectiveness of the completed remedial actions, in respect of facilities for which regulatory control remains applicable after the remediation is completed.

PART X.—*General*

Management systems and electronic database.

91. The Authority may utilize an electronic database and implement such internationally acceptable quality control systems as are necessary, for the efficient management of its functions.

Use of international safety standards and other publications.

92. Where no specific provision of the regulations applies, the Authority may give such directions to an authorization holder as are appropriate to ensure compliance with the International Safety Standards of the IAEA.

Retention of records.

93. Unless otherwise specifically provided in these regulations, where a provision of these regulations requires any record or document or other information to be kept, that record or document or other information shall be retained for a period of not less than four years.

FIRST SCHEDULE (Regulations 2, 4, 16 and 60)

Recommended Categories for Sources Used in Common Practices

Category	Source[a] and practice	Activity ratio[b] (A/D)	Risk
1	Radioisotope thermoelectric generators (RTGs) Irradiators Teletherapy sources Fixed, multi-beam teletherapy (gamma knife) sources	A/D $\geq$ 1000	HIGH
2	Industrial gamma radiography sources High/medium dose rate brachytherapy sources	1000 > A/D $\geq$ 10	HIGH
3	Fixed industrial gauges that incorporate high activity sources[c] Well logging gauges	10 > A/D $\geq$ 1	MEDIUM
4	Low dose rate brachytheraphy sources (except eye plaques and permanent implants) Industrial gauges that do not incorporate high activity sources[c] Bone densitometers Static eliminators	1 > A/D $\geq$ 0.01	LOW
5	Low dose rate brachytheraphy eye plaques and permanent implant sources Xray fluorescence (XRF) devices Electron capture devices Mossbauer spectrometry sources Positron emission tomography (PET) check sources	0.01 > A/D and A > exempt[d]	LOW

FIRST SCHEDULE, *contd.*

[a] Factors other than A/D alone have been taken into consideration in assigning the sources to a category (see Annex I – "Rationale and Method for the Categorization of Radiological Sources" of the IAEA Safety Standards Categorization of Radioactive Sources, Safety Guide, No. RS-G-1.9).

[b] This column can be used to determine the category of a source purely on the basis of A/D.

This may be appropriate, for example, if the practice is not known or is not listed, if sources have a short half-life and/or are unsealed, or if sources are aggregated (see Chapter 3 "Implementation of the Categorization System" para. 3.5 of the IAEA Safety Standards Categorization of Radioactive Sources, Safety Guide, No. RS-G-1.9).

[c] Examples are given in Appendix I of IAEA Safety Standards Categorization of Radioactive Sources, Safety Guide, No. RS-G-1.9.

[d] Exempt quantities are given in Schedule I of the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Series No. 115, Vienna 1996.

A is the activity of the radionuclide in the source

D is the activity of the radionuclide in the source that is considered dangerous.

FIRST SCHEDULE, *contd.*

Radionuclide Activity Values

	Radionuclide	Activity Value (GBq)
1.	Americium-241	60
2.	Americium-241/Beryllium	60
3.	Cadmium-109	2×10^4
4.	Caesium-137	100
5.	Californium-252	20
6.	Cobalt-57	700
7.	Cobalt-60	30
8.	Curium-244	50
9.	Gadolinium-153	1×10^3
10.	Germanium-68	700
11.	Gold-198	200
12.	Iodine-125	200
13.	Iodine-131	200
14.	Iridium-192	80
15.	Iron-55	8×10^5
16.	Krypton-85	3×10^4
17.	Molybdenum-99	300
18.	Nickel-63	6×10^4
19.	Palladium-103	9×10^4
20.	Phosphorus-32	1×10^4
21.	Plutonium-238	60
22.	Plutonium-239/Beryllium	60
23.	Polonium-210	60
24.	Promethium-147	4×10^4
25.	Radium-226	40
26.	Ruthenium-106 (Rhodium-106)	300

FIRST SCHEDULE, *contd.*

Radionuclide	Activity Value (GBq)
27. Selenium-75	200
28. Strontium-90 (Yttrium-90)	1×10^3
29. Technetium-99m	700
30. Thallium-204	2×10^4
31. Thulium	2×10^4
32. Tritium (H-3)	2×10^6
33. Ytterbium-169	300
34. All other radioisotopes	20

SECOND SCHEDULE (Regulation 4)

Nuclear Safety and Radiation Protection Application Form

Section 38 of the NSRP Act states that every person who engages or proposes to engage in a prescribed activity shall apply, subject to subsection (4) in the prescribed form and manner to the Authority for the appropriate authorization. Subsection (3) states that the Authority may require the applicant to provide further information that it considers necessary to determine the application.

INSTRUCTIONS: Kindly answer all relevant sections. All first time and renewal applicants are required to complete a Fit and Proper Questionnaire and submit along with a completed application form. For amendments, where there is a change in the legal operator, a new Fit and Proper Questionnaire is also to be submitted with the application form. For places leased, a Declaration form is to be completed and submitted along with application.

For construction of new facilities that will use sources of Categories 1 and 2, an Environmental Impact Assessment is required.

For the purposes of this application;

"Radiation Source" means a radiation generator, a radioactive source or other radioactive material.

"Nuclear Substance" means thorium, uranium or an element with an atomic number greater than 92; a derivative or compound of thorium, uranium or of an element with an atomic number greater than 92.

"Low Risk" in relation to any activity or practice means that the possibility of suffering harm from or loss due to exposure to ionizing radiation is low. See categorization and classification of sources.

NOTE: Applicants will receive response from the Authority within 14 days of receipt of all required documents. Processing of Applications will not commence until all relevant and required documents have been submitted to the Authority along with a valid national ID and proof of payment.

SECTION I: TYPE OF APPLICATION

This is an Application For:

Licence ☐ A Permit ☐

Registration ☐ Renewal ☐

Amendment ☐

Current Licence Number:_____

Reason for Amendment: _____

SECOND SCHEDULE, *contd.*

SECTION II: DETAILS OF APPLICANT

(a) Name: _____

(b) Mailing address: _____

_____

(c) Email address: _____

(d) Telephone: _____ (e) Fax number: _____

SECTION III: DETAILS OF BUSINESS

(a) Type of Business: _____

(b) Proof of Legal Status:

These supporting documents should be submitted with the application form - Certified Copy of Certificate of Incorporation or Certificate of Registration of Business or charter and Certified Copy of Valid Photo Identification for Authorized Signatories.

Business Number: _____

Corporation Number: _____

For public institutions, specify the enabling legislation (Act):

_____

(c) Financial Contact Person

Name: _____

Address: _____

Telephone: _____ Fax number: _____

Email address _____

(d) Financial guarantee

(Provide information regarding the value and form of the financial guarantee, if required by the authority).

_____

_____

SECOND SCHEDULE, *contd.*

SECTION IV: PURPOSE OF PROPOSED REGISTRATION/LICENCE

(a) Registration/License Activities
(This application covers Import/Export activities for sources of categories 3-5 only)

Possess/Store	☐	Transfer	☐
Use	☐	Import/Export	☐
Service	☐	Manufacture	☐
Construction	☐	Operation/ Decommissioning	☐

(b) Location:

i. Address of place of business

_____

_____

ii. Main address of storage and/or use/or any other activity

_____

_____

Used at ☐ Stored at ☐ Both ☐

(c) Additional information regarding other locations of storage and/or use.

_____

(d) Unsealed Sources (Append copy of all standard certificates)

Append additional source details where required. For sources to be added to existing licence and/or requests for removal from regulatory control, complete and append Amendment of Inventory Form.

Radionuclide Activity in possession of any one time	Maximum Activity to be acquired per year	Total	Use

SECOND SCHEDULE, *contd.*

(e) Sealed Sources (Not included in radiation device)

(Append copy of all standard certificates)

Append additional source details where required. For sources to be added to existing licence and/or requests for removal from regulatory control, complete and append Amendment of Inventory Form.

Radionuclide	Maximum Activity to be contained in any single source	Activity Date	Number of sealed sources-Categories 1, 2 and 3 to be acquired	Use

(f) Radiation devices (Append copy of all standard certificates)

Append additional source details where required. For sources to be added to existing licence and/or requests for removal from regulatory control, complete and append Amendment of Inventory Form.

Radio-nuclide	Maximum `Activity	Manufacturer	Type and Name of device	Model Number	No. of devices	Use

SECTION V: RADIATION SAFETY PROGRAM
(Please note: Do not complete low-risk use-types.)

(a) Radiation Safety Officer (RSO) Details
(Append copy of CV of the Radiation Safety Officer)

RSO Name: _____

Title: _____

Telephone: _____ Ext. _____ Fax. _____

Email: _____

SECOND SCHEDULE, *contd.*

(i) Append details and of alternate RSO

(b) Qualified Expert Details (where applicable)

(Where there are more than one QE, append details and append a copy of the CV of the Qualified Expert(s))

Name: _____

Title: _____

Telephone: _____ Ext. _____ Fax. _____

Email: _____

(c) Other Representative(s) of applicant

Name: _____

Title: _____

Limitations of authority (if applicable)

_____

Signature of representative _____

(d) Classification of Workers

(Append a list of all job categories for workers using or working in the vicinity of nuclear substances, radiation sources and radiation devices)

_____

_____

(e) Personal Protective Equipment and Safety Appliances:

Tick all that applies:

Lab coats ☐

Gloves ☐

Safety glasses ☐

Splash guards ☐

Lucite (plexiglass, perspex) beta guards ☐

Respiratory protection

Please specify here: _____

SECOND SCHEDULE, *contd.*

Fume hood(s) ☐

Removable table covering(s) ☐

Lead sheet/block for gamma shielding, (appropriate to photon energies.) ☐

Tongs/forceps/other remote manipulation appliances: ☐

specify _____

(f) Append Radiation Protection Program to include the following. Please refer to Application Guide for further details.

(i) Scope of activities:

(Append tasks and operations to be performed by staff, frequency and duration of these activities as well as radiological risks associated with the work)

_____

_____

(ii) Management System:

(Append details of roles and responsibilities of different management levels including Directors in charge, Radiation Safety Officers and workers. Include organizational chart showing radiation protection lines of responsibility as well as quality assurance program)

_____

(iii) Monitoring Occupational Exposure:

Ascertaining and recording doses to workers

(Append procedures for ascertaining, monitoring and recording radiation doses received by all workers. Include dose to the extremities (hands and feet) and intakes of radioactive material)

_____

For new licences, provide dose estimates for all categories of workers.

_____

For renewals, provide a summary of the annual radiation doses for each worker

_____

Dose Limits, dose constraints and optimization

SECOND SCHEDULE, *contd.*

(Append the dose limits for planned exposure situation, the established dose constraints that will be used as part of the organization's optimization of protection and safety)

_____

Acquisition and maintenance of radiation monitoring equipment

(Append the list of radiation monitoring equipment that will be used, including the policy and procedure for use, maintenance and storage, including the policy for calibration and the calibration service provider)

_____

(iv) Workplace Monitoring

Append procedures for workplace monitoring, include the following details:

Classification of Areas (control and supervised areas) and Local Rules

(Append the policy and procedures for classifying areas, rooms or enclosures as controlled or supervised areas, including floor plans, arrangement of equipment, shielding and other measures for protection and safety. Include access control, posting of radiation warning signs. Append the local (site) rules and/policies to be followed by workers and work supervision as well as procedures for contamination control)

_____

Control of radioactive contamination (where unsealed radiation sources are handled)

(Append the policy and procedures for maintaining contamination control, including the procedure for monitoring contamination where unsealed radiative sources are used and stored and describe the actions to be taken if contamination limits are exceeded)

_____

(v) Health Surveillance of workers

Append policies and procedures for monitoring the health of workers

_____

_____

SECOND SCHEDULE, *contd.*

(vi) Investigation Levels and feedback of Operating experience

(Append details of investigation levels and the procedures to be taken if they are reached and/or exceeded. Procedure to provide HSRA and suppliers with information regarding normal operating procedures, abnormal conditions and events)

(vii) Record and Reporting System

(Appended details of the policy and procedures for the reporting of accidents, incidents as well as any event in which the authority should be notified (eg. investigations conducted, release of radioactive material into the environment etc.)

(viii) Access control and security

(Append the policy and procedures for restricting access to radiation sources to authorized and trained persons, as well as the policy and procedure for alerting the applicant to the loss, theft or unauthorized use of/ access to radiation sources)

Controlling possession of radiation sources

(Append the policy and procedure to account for radiation sources and to ensure that they do not exceed the licence limit)

(ix) Worker training and authorization

(Append a detailed description of the proposed (theoretical and practical) radiation safety training program for each job category, as well as for contractors and subcontractors).

SECOND SCHEDULE, *contd.*

(x) Control of Public Exposure

Append the policy and procedures for controlling and monitoring discharge to the environment)

_____

_____

(xi) Management of Radioactive Waste and Disused Sources

Append details of the policy and procedures for handling and disposing of waste containing radioactive and/or nuclear substances namely waste generation; predisposal, pre-treatment, characterization, treatment, conditioning, storage, control of discharges, clearance, packaging strategies, transport, design and manufacturing of container, handling of waste packages, site evaluation, design, construction, closure and the post-closure stage of estate management facility. For disused sources provide details the safe management of the sources as well as means of disposal. Include financial provisions where appropriate, and any contractual agreements regarding repatriation, disposal etc.

_____

_____

(xii) Emergency Procedures

(Append a summary of the policy and procedures that will be used in incidents, accidents and other events that involve radiation source(s) and/nuclear substances. Include procedures for notification and response to events as well as policies and prevention and mitigation of accidents)

_____

_____

(xiii) Decommissioning

(Append the policy and procedures that are related to decommissioning or remediation of licensed locations).

_____

_____

SECOND SCHEDULE, *contd.*

(xiv) Radiation Protection Program Policies

As Low As Reasonably Achievable (ALARA) Program

(Summary of the policies and procedures of the ALARA program)

_____

Leak testing of sealed sources

(Append the policy and procedure for leak testing of sealed sources, including the name of the leak test service provider to be used (if applicable).)

_____

Transfer of Radiation Sources

(Append policy and procedure for the transfer of radioactive sources)

_____

Transfer of Radiation Sources and/Nuclear Substances (for renewal)

(Append a summary of the annual activity of each radiation source and/ nuclear substance transferred during the previous licensing period)

_____

Packaging and transport of Radiation Sources and/Nuclear Substances

(Append the policy and procedures for packaging and transporting radiation source and/nuclear substances, as well as the policy and procedure for receiving such shipments.)

_____

Internal Review

(Append arrangements for supervising and auditing the Radiation Protection Programme)

_____

(g) Append Safety Assessment for facilities of activities involving sources of Categories 1 and 2.

_____

_____

SECOND SCHEDULE, *contd.*

SECTION VI: RADIATION SAFETY PROGRAM-LOW RISK SOURCES

See appendix for classification of sources

(a) Radiation Safety Officer (RSO) Details

(Append copy of CV of the Radiation Safety Officer)

RSO Name: _____

Title: _____

Telephone: _____ Ext. _____ Fax. _____

Email: _____

(ii) Append details and of alternate RSO

(b) Qualified Expert Details (where applicable)

(Where there are more than one QE, append details along with a copy of the CV of the Qualified Expert(s))

Name: _____

Title: _____

Telephone: _____ Ext. _____ Fax. _____

Email: _____

(c) Record and Reporting System

(Appended details of the policy and procedures for the reporting of accidents, incidents as well as any event in which the authority should be notified (eg. investigations conducted, release of radioactive material into the environment etc.)

_____

_____

(d) Access control and security

(Append the policy and procedures for restricting access to radiation sources and/nuclear substances to authorized and trained persons, as well as the policy and procedure for alerting the applicant to the loss, theft or unauthorized use of/ access to radiation sources)

_____

_____

SECOND SCHEDULE, *contd.*

(e) Leak testing of sealed sources

(Append the policy and procedure for leak testing of sealed sources, including the name of the leak test service provider to be used (if applicable).

_____

_____

(f) Emergency Procedures

(Append a summary of the policy and procedures that will be used in incidents, accidents and other events that involve radiation source(s) and/nuclear substance. Include procedures for notification and response to events as well as policies and prevention and mitigation of accidents)

_____

_____

(g) Management of Radioactive Waste and Disused Sources

Append details of the policy and procedures for handling and disposing of waste containing radioactive and/or nuclear substances namely waste generation; predisposal, pre-treatment, characterization, treatment, conditioning, storage, control of discharges, clearance, packaging strategies, transport, design and manufacturing of container, handling of waste packages, site evaluation, design, construction, closure and the post-closure stage of estate management facility. For disused sources provide details the safe management of the sources as well as means of disposal. Include financial provisions where appropriate, and any contractual agreements regarding repatriation, disposal etc.

_____

_____

SECTION VII – SPECIFIC REQUIREMENTS BASED ON PROPOSED LICENCE ACTIVITY

(Kindly complete and append documents for all applicable sections)

(a) MEDICAL PRACTICES

Medical practitioner

Name: _____

Address: _____

Telephone: _____

SECOND SCHEDULE, *contd.*

Fax number: _____

Email: _____

Signature of Applicant to indicate designation of medical practitioner (s)

Date: _____

Signature: _____

Acknowledgement of Medical Practitioner:

Date: _____

Signature: _____

Licence No.:_____

Administration of radiation doses for therapeutic treatment

(Provide policy and procedures for delivering radiation doses to patients for therapeutic reasons during the activities to be licensed. Include protocols and procedures for administering radiation doses to pregnant patients)

_____

_____

Append Quality Assurance Programme for medical exposure

(Quality assurance programme shall provide as appropriate: adequate assurance that the specified requirements relating to protection and safety are satisfied) Append quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures. Include where applicable: protocol and procedures for calibration, acceptance and commissioning testing and reports, quality control testing of all equipment and software used for medical exposure.

_____

_____

Instructions to caregivers

(Provide instructions that are to be given to persons who will care for a patient who has undergone nuclear medicine therapy)

_____

_____

SECOND SCHEDULE, *contd.*

Instructions to patients and their families

(Provide instructions that are to be given to patients who have recently received nuclear medicine therapy in order to control radioactive contamination effects and radiation exposures to others)

_____

_____

Release of patients

(Provide procedures for determining when patients that have received nuclear medicine therapy must be isolated and when they may be released from isolation)

_____

_____

Decontamination and release of treatment rooms

(The procedures for returning rooms that have been used for nuclear medicine therapy to a condition where they can be safely released for other purposes)

_____

_____

Medical emergencies

(The policy and procedures for responding to medical emergencies that involve patients treated with radiation sources during the activities to be licensed, as well as investigations of unintended and accidental medical exposures)

_____

_____

For Therapeutic Nuclear Medicine;

Assignment of nuclear medicine therapy rooms

(The procedures used to assure that patients undergoing nuclear therapy will be assigned to a specifically designated private room with a private washroom)

_____

_____

SECOND SCHEDULE, *contd.*

Diagnostic Studies Protocols and Procedures

Append protocols and procedures for conducting diagnostic studies

For Biomedical Research;

Append research studies protocol and procedures.

Include a statement of the proposed research studies and their proposed radiation dose constraints. Append the policy and criteria for selecting human research volunteers. Append the policy and procedures for obtaining and assuring informed consent of volunteers

Research Review Committee

(Append information regarding the proposed human research review committee or its equivalent)

(b) INDUSTRIAL RADIOGRAPHY

Emergency and operating procedures

(Summary of the Emergency and Operating Procedures)

_____

_____

Application for registration of use of packages (one per certificate)

(Please provide a copy of the Registration of Use of Packages application for each package)

_____

_____

Maintenance and use of exposure devices (for renewals only)

(Sample copies of records of the quarterly and annual maintenance of exposure devices and associated equipment and of camera use records)

_____

_____

Safety and emergency equipment

(All safety and emergency equipment which is used as part of the daily radiography operations.

SECOND SCHEDULE, *contd.*

List any additional shielding materials)

_____

_____

(c) VETRINARY NUCLEAR MEDICINE:

Administering treatment to animals

(Append policies and procedures used to administer radiation sources to animals. Owners of animals should provide a (written) consent before radionuclides are used on animals. Append a copy of the treatment consent form)

_____

_____

Animal housing

(The policy and procedures regarding the housing controls imposed on animals undergoing veterinary nuclear medicine)

_____

_____

Disposal of animal waste

(Policy and procedures for management of animal waste arising from veterinary nuclear medicine)

_____

_____

Monitoring and release of animal housing

(Policy and procedures for monitoring and release of animal housing)

_____

_____

Release of animals

(Criteria used by the applicant to decide when animals treated with radiation sources can be released to their owners)

_____

_____

SECOND SCHEDULE, *contd.*

(d) Other industries that use Nuclear material:

(This section is only applicable for industries where nuclear material is used but the industry or use is not otherwise specified in this application form)

Procedures:

(Procedures regarding the controls of the use of nuclear medicine)

_____

_____

Disposals:

(Policy and procedures for management of waste arising from the use of nuclear material)

_____

_____

Monitoring:

(Policy and procedures for monitoring the use of nuclear material)

_____

_____

(e) FIXED GAUGES

Where application is for fixed and/or portable gauges, kindly append the following:

Procedures:

Append the policy and procedures that detail the handling of fixed gauges

_____

_____

Rules for entry into the vessels or hoppers:

Append the policy and procedures to enter vessels or hoppers fitted with gauges

_____

_____

SECOND SCHEDULE, *contd.*

Installation and dismounting of fixed gauges:

Append the policy and procedures for the installing and dismounting of fixed gauges

_____

_____

Operation of insertion-type fixed gauges:

Append the policy and procedure to handle the insertion-type fixed gauges

_____

_____

Emergency procedures for fixed gauges:

In addition to the information provided above, append procedures specific to dealing with fire.

_____

_____

(if no radiation survey meter is available on site, append information to demonstrate that the survey meter will be available during an emergency in less than four hours)

(f) PORTABLE GAUGES

Emergency Procedures:

In addition to the information provided in item (e) above, append the procedures specific responding to and managing situations involving crushed or damaged portable gauges.

_____

_____

(If no radiation survey meter is available on site, append information to demonstrate that the survey meter will be available during an emergency in less than two hours)

(g) PETROLEUM EXPLORATION (Well logging)

Where application is for Petroleum Exploration, kindly append the following:

Release of radiation sources and/nuclear substances to the environment:

SECOND SCHEDULE, *contd.*

Append the policy for monitoring release of radiation source(s) and/ nuclear substances to the environment.

_____

_____

Fishing for stuck tools/sources

Append the policy and procedure that will be used during an emergency that involves fishing for stuck tools and sources

_____

_____

Abandonment of sealed sources

Append the policy and procedure for the proposed abandonment of sealed source

_____

_____

Abandonment of unsealed sources:

Append the policy and procedures for the abandonment of unsealed radiation sources and nuclear substances following sub-surface zone location or sub-surface tracer studies

_____

_____

(h) SERVICING

Append a copy of servicing procedures, specific to each radiation device identified in the application for this activity.

_____

_____

(i) MANUFACTURING

Append a copy of all manufacturing or development procedures, specific to each sealed source or radiation device identified in the application for this activity.

_____

_____

SECOND SCHEDULE, *contd.*

Declaration: I hereby declare that the information contained herein and any supplemental pages appended to this application are correct to the best of my knowledge and belief.

Name:.....

Title: .....

Signature:.....Date:.....

If company. Affix Company Seal

.....

To submit the completed application:

Mail the completed application form, together with all relevant documentation to:

Hazardous Substance Regulatory Authority

Address:.....

Email:.....

Fax: .....

The application form, together with all relevant documentation may also be submitted electronically.

.....

For official Use Only:

Approved by Hazardous Substance Regulatory Authority

Date:

Licence No.

Registration No.

Permit No.

Renewal No.

Remarks:

Signature:

SECOND SCHEDULE, *contd.*

Annex 1: Form for Notification of Practices and Sources Hazardous Substances Regulatory Authority

INSTRUCTIONS: Use ONE form for each source to be notified. If four (4) or more sources are to be declared, complete Section 1 below and a "Supplemental Form for Notification of Practices and Sources." All forms MUST be duly signed by the legal operator and subsequently submitted to HSRA.

Section 1. ADDRESS AND CONTACT INFORMATION

1. Name and address of the legal person.

_____

_____

2. Name and address of the organization.

_____

_____

3. Contact Number: _____ Email Address: _____

4. Nature of the practice in which the source is used:

_____

_____

Section 2. DETAILS OF SOURCE

("Source" means a radiation generator, a radioactive source or other radioactive material.)

5. Identification of source:

_____

6. Location:

_____

7. State field of application and purpose of the activity in which the radiation source is or will be used:

_____

_____

_____

SECOND SCHEDULE, *contd.*

Section 3. RADIONUCLIDE

Activity (Bq): _____

Activity Date: _____

Chemical form: _____

Serial No: _____

Sealed source: YES/NO

If yes, Manufacturer: _____

Model No: _____

If no, Identification no./code: _____

Status (In Use/Out of use): _____

Section 4. RADIATION GENERATING EQUIPMENT

Manufacturer: _____

Model No: _____

Serial No: _____

Max. Operating Potential: _____

Nature of the equipment in which the source is installed (Medical, Industrial etc.):

_____

Model (if appropriate): _____

Status (In Use/Out of Use): _____

Date: _____ Signature of legal person: _____

THIRD SCHEDULE (Regulations 4, 5, 10 and 14)

Fees

1.	Authorization in the Form of a Licence	
	(a) Authorization application fee	… $50,000.00
	(b) Authorization reconsideration fee	… $20,000.00
	(c) Application renewal fee	… $30,000.00
	(d) Authorization variation fee	… $10,000.00
2.	Authorization in the Form of Permit	
	(a) Authorization application fee	… $50,000.00
	(b) Authorization reconsideration fee	… $20,000.00
	(c) Application renewal fee	… $30,000.00
	(d) Authorization variation fee	… $10,000.00
3.	Authorization in the Form of a certificate of Registration	
	(a) Authorization application fee	… $25,000.00
	(b) Authorization reconsideration fee	… $15,000.00
	(c) Application renewal fee	… $20,000.00
	(d) Authorization variation fee	… $10,000.00
	(e) Broker registration fee	… $20,000.00

FOURTH SCHEDULE (Regulation 4)

IAEA GSR PART 3—Requirement 13: Safety Assessment

The regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity.

3.29. The regulatory body shall establish requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct an appropriate safety assessment. [1]Prior to the granting of an authorization, the responsible person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body.

3.30. The person or organization, applying for authorization shall, if there is a possibility of an exposure greater than a level specified by the Authority, cause a safety assessment to be made and submitted to the Authority with the application. Registrants and licensees, as appropriate, shall conduct a safety assessment that is either generic or specific to the practice or source for which they are responsible.[2]

3.31. Safety assessments shall be conducted at different stages, including the stages of siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof, as appropriate, so as:

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

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

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

3.32. The Safety assessment shall include, as appropriate, a systematic critical review of:

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

(b) The ways in which structures, systems and components, including software, and procedures relating to protection and safety might fail,

[1] Requirements on safety assessment for facilities and activities are established in the IAEA Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4, IAEA, Vienna (2009) and any amendments thereto.

[2] A generic safety assessment is usually sufficient for types or source with a high degree of uniformity in design. A specific safety assessment is usually required in other cases; however the specific safety assessment need not include those aspects covered by a generic safety assessment, if generic safety assessment has been conducted for the type of source.

FOURTH SCHEDULE, *contd.*

singly or in combination, or might otherwise give rise to exposures, and the consequences of such events;

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

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

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

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

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

3.33. The registrant or licensee shall take into account in the safety assessment:

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

(b) Factors that could give rise to a smaller but continuing release of radioactive material, and the measures available to detect and to prevent or to control such a release;

(c) Factors that could give rise to unintended operation of any radiation generator or a loss of shielding, and the measures available to detect and to prevent or to control such occurrences;

(d) The extent to which the use of redundant and diverse safety measures that are independent of each other, so that failure of one does not result in failure of another, is appropriate to restrict the likelihood and magnitude of potential exposures.

3.34. Registrants and licensees shall ensure that the safety assessment is documented and, where appropriate, that it is independently reviewed under the relevant management system.

3.35. Registrants and licensees shall perform additional reviews of the safety assessment as necessary to ensure that the technical specifications or conditions of use continue to be met when:

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

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

FOURTH SCHEDULE, *contd.*

(c) Information on operating experience, or information about accidents and other incidents that could result in exposures, indicates that the current assessment might be invalid;

(d) Any significant changes in activities are envisaged;

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

3.36. If as a result of a safety assessment, or for any other reason, opportunities to improve protection and safety appear to be available and improvement seems desirable, any consequential modifications shall be made cautiously and only after favourable assessment of all implications for protection and safety. The implementation of all improvements shall be prioritized so as to optimize protection and safety.

FIFTH SCHEDULE (Regulation 5)

Grant of Authorization

NUCLEAR SAFETY AND RADIATION PROTECTION ACT
GOVERNMENT OF JAMAICA

AUTHORIZATION FOR PRACTICES AND SOURCES WITHIN PRACTICES

AUTHORIZATION HOLDER:

Name: _____ Fax number: _____

Address: _____

E-mail: _____ Telephone number: _____

RADIATION PROTECTION OFFICER:

QUALIFIED EXPERT:

TYPE OF ACTIVITY AUTHORIZED:

SINGLE AUTHORIZATION ☐ BULK AUTHORIZATION ☐

LOCATION OF THE PREMISES:

Note: In this part the address of the premises where the practices and sources within the practices are located should be provided

RADIOACTIVE SOURCES AND APPARATUS CONTAINING RADIOACTIVE SUBSTANCES (i.e. approved for use)

Manufacturer	Model	Serial Number	Radio-nuclide	Activity (Becquerels)	Activity Date	Use	Location

FIFTH SCHEDULE, *contd.*

ELECTRICAL DEVICES PRODUCING IONIZING RADIATION (i.e. ionizing radiation generators)

Manufacturer	Model	Serial Number	Maximum Power [e.g. max radiographic kVp mA]	Use	Location

LICENCE CONDITIONS

The authorization holder shall—

(a) comply with all regulations under the Nuclear Safety and Radiation Protection Act;

(b) ensure that any person who subsequently may be engaged to operate, install, maintain or otherwise conduct activities with the practices and sources within the practices on the premises has received approved training in accordance with the criteria stated in the Radiation Protection Programme;

(c) provide prior written notification to the Authority of any intention to sell, relocate, install, or dispose of radiation sources (i.e. by any means) or of plans to modify the structure of the premises in any way that may significantly impact on radiation safety; nominate a replacement of the Qualified Expert(s) or Radiation Protection Officer (RPO);

(d) ensure that the installation, service or maintenance of the practices and the use of sources within practices on the premises is performed only by personnel authorized by the Authority; and

(e) ensure any other specific conditions that the Authority will require, are complied with;

FIFTH SCHEDULE, *contd.*

Other: (List any additional conditions)

_____

_____

The authorization holder is approved: _____
Note: Not valid unless signed by an authorized officer of the Authority

Date of issue: _____

Hazardous Substance Regulatory Authority

Address:

Email:

Fax:

NUMBER:	EXPIRY DATE:

Note: This authorization must be displayed in a prominent public location in the authorized premises for the practices and use of sources within the practice.

SIXTH SCHEDULE (Regulation 11)

Exemption Levels

TABLE I.1. LEVELS FOR EXEMPTIONS OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
H-3	1×10^{6}	1×10^{9}	Sc-45	1×10^{2}	1×10^{7}
Be-7	1×10^{3}	1×10^{7}	Sc-46	1×10^{1}	1×10^{6}
Be -10	1×10^{4}	1×10^{6}	Sc-47	1×10^{2}	1×10^{6}
C -11	1×10^{1}	1×10^{6}	Sc-48	1×10^{1}	1×10^{5}
C- 14	1×10^{4}	1×10^{7}	Sc-49	1×10^{3}	1×10^{5}
N-13	1×10^{2}	1×10^{9}	Ti-44	1×10^{1}	1×10^{5}
Ne-19	1×10^{2}	1×10^{9}	Ti-45	1×10^{1}	1×10^{6}
O-15	1×10^{2}	1×10^{9}	V-47	1×10^{1}	1×10^{5}
F-18	1×10^{1}	1×10^{6}	V-48	1×10^{1}	1×10^{5}
Na-22	1×10^{1}	1×10^{6}	V-49	1×10^{4}	1×10^{7}
Na -24	1×10^{1}	1×10^{5}	Cr-48	1×10^{2}	1×10^{6}
Mg -28	1×10^{1}	1×10^{5}	Cr -49	1×10^{1}	1×10^{6}
Al-26	1×10^{1}	1×10^{5}	Cr-51	1×10^{3}	1×10^{7}
Si-31	1×10^{3}	1×10^{6}	Mn-51	1×10^{1}	1 x 105
Si-32	1×10^{3}	1×10^{6}	Mn-52	1×10^{1}	1×10^{5}
P-32	1×10^{3}	1×10^{5}	Mn-52m	1×10^{1}	1×10^{5}
P-33	1×10^{5}	1×10^{8}	Mn-53	1×10^{4}	1×10^{9}
S-35	1×10^{5}	1×10^{8}	Mn-54	1×10^{1}	1×10^{6}
Cl-36	1×10^{4}	1×10^{6}	Mn-56	1×10^{1}	1×10^{5}
CI-38	1×10^{1}	1×10^{5}	Fe-52	1×10^{1}	1×10^{6}
CI-39	1×10^{1}	1×10^{5}	Fe-55	1×10^{4}	1×10^{6}
Ar-37	1×10^{6}	1×10^{8}	Fe-59	1×10^{1}	1×10^{6}

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Ar-39	1×10^{7}	1×10^{4}	4 Fe-60	1×10^{2}	1×10^{5}
Ar-41	1×10^{2}	1×10^{9}	Co-55	1×10^{1}	1×10^{6}
K-40	1×10^{2}	1×10^{6}	Co-56	1×10^{1}	1×10^{5}
K-42	1×10^{2}	1×10^{6}	Co-57	1×10^{2}	1×10^{6}
K-43	1×10^{1}	1×10^{6}	Co-58	1×10^{1}	1×10^{6}
K-44	1×10^{1}	1×10^{5}	Co-58m	1×10^{4}	1×10^{7}
K-45	1×10^{1}	1×10^{5}	Co-60	1×10^{1}	1×10^{5}
Ca-41	1×10^{5}	1×10^{7}	Co-60m	1×10^{3}	1×10^{6}
Ca-45	1×10^{4}	1×10^{7}	Co-61	1×10^{2}	1×10^{6}
Ca-47	1×10^{1}	1×10^{6}	Co-62m	1×10^{1}	1×10^{5}
Sc-43	1×10^{1}	1×10^{6}	Ni-56	1×10^{1}	1×10^{6}
Sc-44	1×10^{1}	1×10^{5}	Ni-57	1×10^{1}	1×10^{6}
Ni-59	1×10^{4}	1×10^{8}	As-72	1×10^{1}	1×10^{5}
Ni-63	1×10^{5}	1×10^{8}	As-73	1×10^{3}	1×10^{7}
Ni-65	1×10^{1}	1×10^{6}	As-74	1×10^{1}	1×10^{6}
Ni-66	1×10^{4}	1×10^{7}	As-76	1×10^{2}	1×10^{5}
Cu-60	1×10^{1}	1×10^{5}	As-77	1×10^{3}	1×10^{6}
Cu-61	1×10^{1}	1×10^{6}	As-78	1×10^{1}	1×10^{5}
Cu-64	1×10^{2}	1×10^{6}	Se-70	1×10^{1}	1×10^{6}
Cu-67	1×10^{2}	1×10^{6}	Se-73	1×10^{1}	1×10^{6}
Zn-62	1×10^{2}	1×10^{6}	Se-73m	1×10^{2}	1×10^{6}
Zn-63	1×10^{1}	1×10^{5}	Se-75	1×10^{2}	1×10^{6}
Zn-65	1×10^{1}	1×10^{6}	Se-79	1×10^{4}	1×10^{7}
Zn-69	1×10^{4}	1×10^{6}	Se-81	1×10^{3}	1×10^{6}
Zn-69m	1×10^{2}	1×10^{6}	Se-81m	1×10^{3}	1×10^{7}
Zn-71m	1×10^{1}	1×10^{6}	Se-83	1×10^{1}	1×10^{5}

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Zn-72	1×10^{2}	1×10^{4}	Br-74	1×10^{1}	1×10^{5}
Ga-65	1×10^{1}	1×10^{5}	Br-74m	1×10^{1}	1×10^{5}
Ga-66	1×10^{1}	1×10^{5}	Br-75	1×10^{1}	1×10^{6}
Ga-67	1×10^{2}	1×10^{6}	Br-76	1×10^{1}	1×10^{5}
Ga-68	1×10^{1}	1×10^{5}	Br-77	1×10^{2}	1×10^{6}
Ga-70	1×10^{2}	1×10^{6}	Br-80	1×10^{2}	1×10^{5}
Ga-72	1×10^{1}	1×10^{5}	Br-80m	1×10^{3}	1×10^{7}
Ga-73	1×10^{2}	1×10^{6}	Br-82	1×10^{1}	1×10^{6}
Ge-66	1×10^{1}	1×10^{6}	Br-83	1×10^{3}	1×10^{6}
Ge-67	1×10^{1}	1×10^{5}	Br-84	1×10^{1}	1×10^{5}
Ge-68[b]	1×10^{1}	1×10^{5}	Kr-74	1×10^{2}	1×10^{9}
Ge-69	1×10^{1}	1×10^{6}	Kr-76	1×10^{2}	1×10^{9}
Ge-71	1×10^{4}	1×10^{8}	Kr-77	1×10^{2}	1×10^{9}
Ge-75	1×10^{3}	1×10^{6}	Kr-79	1×10^{3}	1×10^{5}
Ge-77	1×10^{1}	1×10^{5}	Kr-81	1×10^{4}	1×10^{7}
Ge-78	1×10^{2}	1×10^{6}	Kr-81m	1×10^{3}	1×10^{10}
As-69	1×10^{1}	1×10^{5}	Kr-83m	1×10^{5}	1×10^{12}
As-70	1×10^{1}	1×10^{5}	Kr-85	1×10^{5}	1×10^{4}
As-71	1×10^{1}	1×10^{6}	Kr-85m	1×10^{3}	1×10^{10}
Kr-87	1×10^{2}	1×10^{9}	Y-94	1×10^{1}	1×10^{5}
Kr-88	1×10^{2}	1×10^{9}	Y-95	1×10^{1}	1×10^{5}
Rb-79	1×10^{1}	1×10^{5}	Zr-86	1×10^{2}	1×10^{7}
Rb-81	1×10^{1}	1×10^{6}	Zr-88	1×10^{2}	1×10^{6}
Rb-81m	1×10^{3}	1×10^{7}	Zr-89	1×10^{1}	1×10^{6}
Rb-82m	1×10^{1}	1×10^{6}	Zr-93[b]	1×10^{3}	1×10^{7}
Rb-83[b]	1×10^{2}	1×10^{6}	Zr-95	1×10^{1}	1×10^{6}

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Rb-84	1×10^{1}	1×10^{6}	Zr-97[b]	1×10^{1}	1×10^{5}
Rb-86	1×10^{2}	1×10^{5}	Nb-88	1×10^{1}	1×10^{5}
Rb-87	1×10^{3}	1×10^{7}	Nb-89	1×10^{1}	1×10^{5}
Rb-88	1×10^{2}	1×10^{5}	Nb-89m	1×10^{1}	1×10^{5}
Rb-89	1×10^{2}	1×10^{5}	Nb-90	1×10^{1}	1×10^{5}
Sr-80	1×10^{3}	1×10^{7}	Nb-93m	1×10^{4}	1×10^{7}
Sr-81	1×10^{1}	1×10^{5}	Nb-94	1×10^{1}	1×10^{6}
Sr-82[b]	1×10^{1}	1×10^{5}	Nb-95	1×10^{1}	1×10^{6}
Sr-83	1×10^{1}	1×10^{6}	Nb-95m	1×10^{2}	1×10^{7}
Sr-85	1×10^{2}	1×10^{6}	Nb-96	1×10^{1}	1×10^{5}
Sr-85m	1×10^{2}	1×10^{7}	Nb-97	1×10^{1}	1×10^{6}
Sr-87m	1×10^{2}	1×10^{6}	Nb-98	1×10^{1}	1×10^{5}
Sr-89	1×10^{3}	1×10^{6}	Mo-90	1×10^{1}	1×10^{6}
Sr-90[b]	1×10^{2}	1×10^{4}	Mo-93	1×10^{3}	1×10^{8}
Sr-91	1×10^{1}	1×10^{5}	Mo-93m	1×10^{1}	1×10^{6}
Sr-92	1×10^{1}	1×10^{6}	Mo-99	1×10^{2}	1×10^{6}
Y-86	1×10^{1}	1×10^{5}	Mo-101	1×10^{1}	1×10^{6}
Y-86m	1×10^{2}	1×10^{7}	Tc-93	1×10^{1}	1×10^{6}
Y-87[b]	1×10^{1}	1×10^{6}	Tc-93m	1×10^{1}	1×10^{6}
Y-88	1×10^{1}	1×10^{6}	Tc-94	1×10^{1}	1×10^{6}
Y-90	1×10^{3}	1×10^{5}	Tc-94m	1×10^{1}	1×10^{5}
Y-90m	1×10^{1}	1×10^{6}	Tc-95	1×10^{1}	1×10^{6}
Y-91	1×10^{3}	1×10^{6}	Tc-95m	1×10^{1}	1×10^{6}
Y-91m	1×10^{2}	1×10^{6}	Tc-96	1×10^{1}	1×10^{6}
Y-92	1×10^{2}	1×10^{5}	Tc-96m	1×10^{3}	1×10^{7}
Y-93	1×10^{2}	1×10^{5}	Tc-97	1×10^{3}	1×10^{8}

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Tc-97m	1×10^3	1×10^7	Ag-106m	1×10^1	1×10^6
Tc-98	1×10^1	1×10^6	Ag-108m	1×10^1	1×10^6
Tc-99	1×10^4	1×10^7	Ag-110m	1×10^1	1×10^6
Tc-99m	1×10^2	1×10^7	Ag-111	1×10^3	1×10^6
Tc-101	1 x l0[2]	1 x l0[6]	Ag 112	1×10^1	1×10^5
Tc-104	1×10^1	1×10^5	Ag-115	1×10^1	1×10^5
Ru-94	1×10^2	1×10^6	Cd-104	1×10^2	1×10^7
Ru-97	1×10^2	1×10^7	Cd-107	1×10^3	1×10^7
Ru-103	1×10^2	1×10^6	Cd-109	1×10^4	1×10^6
Ru-105	1×10^1	1×10^6	Cd-113	1×10^3	1×10^6
Ru-106[b]	1×10^2	1×10^5	Cd-113m	1×10^3	1×10^6
Rh-99	1×10^1	1×10^6	Cd-115	1×10^2	1×10^6
Rh-99m	1×10^1	1×10^6	Cd-115m	1×10^3	1×10^6
Rh-100	1×10^1	1×10^6	Cd-117	1×10^1	1×10^6
Rh-101	1×10^2	1×10^7	Cd-117m	1×10^1	1×10^6
Rh-101m	1×10^2	1×10^7	In- 109	1×10^1	1×10^6
Rh-102	1×10^1	1×10^6	In-110	1 x l0[1]	1×10^6
Rh-102m	1×10^2	1×10^6	In-110m	1×10^1	1×10^5
Rh-103m	1×10^4	1×10^8	In-111	1×10^2	1×10^6
Rh-105	1×10^2	1×10^7	In-112	1×10^2	1×10^6
Rh-106m	1×10^1	1×10^5	In-113m	1×10^2	1×10^6
Rh-107	1×10^2	1×10^6	In- 114	1×10^3	1×10^5
Pd- 100	1×10^2	1×10^7	In- 114m	1×10^2	1×10^6
Pd-101	1×10^2	1×10^6	In-115	1×10^3	1×10^5
Pd-103	1×10^3	1×10^8	In-115m	1×10^2	1×10^6
Pd- 107	1×10^5	1×10^8	In-1l6m	1×10^1	1×10^5

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Pd-109	1×10^3	1×10^6	In-117	1×10^1	1×10^6
Ag-102	1×10^1	1×10^5	In-117m	1×10^2	1×10^6
Ag-103	1×10^1	1×10^6	In-119m	1×10^2	1×10^5
Ag-104	1×10^1	1×10^6	Sn-110	1×10^2	1×10^7
Ag-104m	1×10^1	1×10^6	Sn-111	1×10^2	1×10^6
Ag-105	1×10^2	1×10^6	Sn-113	1×10^3	1×10^7
Ag-106	1×10^1	1×10^6	Sn-117m	1×10^2	1×10^6
Sn-119m	1×10^3	1×10^7	Te-123m	1×10^2	1×10^7
Sn-121	1×10^5	1×10^7	Te-125m	1×10^3	1×10^7
Sn-121m[b]	1×10^3	1×10^7	Te-127	1×10^3	1×10^6
Sn-123	1×10^3	1×10^6	Te-127m	1×10^3	1×10^7
Sn-1 23m	1×10^2	1×10^6	Te-129	1×10^2	1×10^6
Sn-125	1×10^2	1×10^5	Te-129m	1×10^3	1×10^6
Sn-126[b]	1×10^1	1×10^5	Te-131	1×10^2	1×10^5
Sn-127	1×10^1	1×10^6	Te-131m	1×10^1	1×10^6
Sn-128	1×10^1	1×10^6	Te-132	1×10^2	1×10^7
Sb-115	1×10^1	1×10^6	Te-133	1×10^1	1×10^5
Sb-116	1×10^1	1×10^6	Te-133m	1×10^1	1×10^5
Sb-116m	1×10^1	1×10^5	Te-134	1×10^1	1×10^6
Sb-117	1×10^2	1×10^7	I-120	1×10^1	1×10^5
Sb-118m	1×10^1	1×10^6	I-120m	1×10^1	1×10^5
Sb-119	1×10^3	1×10^7	I-121	1×10^2	1×10^6
Sb-120	1×10^2	1×10^6	I-123	1×10^2	1×10^7
Sb-120m	1×10^1	1×10^6	1-124	1×10^1	1×10^6
Sb-122	1×10^2	1×10^4	1-125	1×10^3	1×10^6
Sb-124	1×10^1	1×10^6	1-126	1×10^2	1×10^6

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Sb-124m	1×10^{2}	1×10^{6}	I-128	1×10^{2}	1×10^{5}
Sb-125	1×10^{2}	1×10^{6}	I-129	1×10^{2}	1×10^{5}
Sb-126	1×10^{1}	1×10^{5}	I-130	1×10^{1}	1×10^{6}
Sb-126m	1×10^{1}	1×10^{5}	I-131	1×10^{2}	1×10^{6}
Sb-127	1×10^{1}	1×10^{6}	I-132	1×10^{1}	1×10^{5}
Sb-128	1×10^{1}	1×10^{5}	I- 132m	1×10^{2}	1×10^{6}
Sb-128m	1×10^{1}	1×10^{5}	I-133	1×10^{1}	1×10^{6}
Sb-129	1×10^{1}	1×10^{6}	I-134	1×10^{1}	1×10^{5}
Sb-130	1×10^{1}	1×10^{5}	I-135	1×10^{1}	1×10^{6}
Sb-131	1×10^{1}	1×10^{6}	Xe-120	1×10^{2}	1×10^{9}
Te-161	1×10^{2}	1×10^{7}	Xe-121	1×10^{2}	1×10^{9}
Te- 121	1×10^{1}	1×10^{6}	Xe-122[b]	1×10^{2}	1×10^{9}
Te-121m	1×10^{2}	1×10^{6}	Xe-123	1×10^{2}	1×10^{9}
Te-123	1×10^{3}	1×10^{6}	Xe-125	1×10^{3}	1×10^{9}
Xe-127	1×10^{3}	1×10^{5}	La- 131	$I \times 10^{1}$	1×10^{6}
Xe-129m	1×10^{3}	1×10^{4}	La- 132	1×10^{1}	1×10^{6}
Xe-131m	1×10^{4}	1×10^{4}	La-135	1×10^{3}	1×10^{7}
Xe-133m	1×10^{3}	1×10^{4}	La-137	1×10^{3}	1×10^{7}
Xe-133	1×10^{3}	1×10^{4}	La-133	1×10^{1}	1×10^{6}
Xe-135	1×10^{3}	1×10^{10}	La- 140	1×10^{1}	1×10^{5}
Xe-135m	1×10^{2}	1×10^{9}	La-141	1×10^{2}	1×10^{5}
Xe-138	1×10^{2}	1×10^{9}	La- 142	1×10^{1}	1×10^{5}
Cs-125	1×10^{1}	1×10^{4}	La- 143	1×10^{2}	1×10^{5}
Cs-127	1×10^{2}	1×10^{5}	Ce-134	1×10^{3}	1×10^{7}
Cs-129	1×10^{2}	1×10^{5}	Ce-135	1×10^{1}	1×10^{6}
Cs-130	1×10^{2}	1×10^{6}	Ce-137	1×10^{3}	1×10^{7}

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Cs-131	1×10^3	1×10^6	Ce-137m	1×10^3	1×10^6
Cs-132	1×10^1	1×10^5	Ce-139	1×10^2	1×10^6
Cs-134m	1×10^3	1×10^5	Ce-141	1×10^2	1×10^7
Cs-134	1×10^1	1×10^4	Ce-143	1×10^2	1×10^6
Cs-135	1×10^4	1×10^7	Ce-144[b]	1×10^2	1×10^5
Cs-135m	1×10^1	1×10^6	Pr-136	1×10^1	1×10^5
Cs-136	1×10^1	1×10^5	Pr-137	1×10^2	1×10^6
Cs-137[b]	1×10^1	1×10^4	Pr-138m	1×10^1	1×10^6
Cs-138	1×10^1	1×10^4	Pr-139	1×10^2	1×10^7
Ba-126	1×10^2	1×10^7	Pr-142	1×10^2	1×10^5
Ba-128	1×10^2	1×10^7	Pr-142m	1×10^7	1×10^9
Ba-131	1×10^2	1×10^6	Pr-143	1×10^4	1×10^6
Ba-131m	1×10^2	1×10^7	Pr-144	1×10^2	1×10^5
Ba-133	1×10^2	1×10^6	Pr-145	1×10^3	1×10^5
Ba-133m	1×10^2	1×10^6	Pr-147	1×10^1	1×10^5
Ba-135m	1×10^2	1×10^6	Nd-136	1×10^2	1×10^6
Ba- 137m	1×10^1	1×10^6	Nd-138	1×10^3	1×10^7
Ba-139	1×10^2	1×10^5	Nd-139	1×10^2	1×10^6
Ba-140[b]	1×10^1	1×10^5	Nd-139m	1×10^1	1×10^6
Ba-141	1×10^2	1×10^5	Nd-141	1×10^2	1×10^7
Ba-142	1×10^2	1×10^6	Nd-147	1×10^2	1×10^6
Nd-149	1×10^2	1×10^6	Eu-155	1×10^2	1×10^7
Nd-151	1×10^1	1×10^5	Eu-156	1×10^1	1×10^6
Pm-141	1×10^1	1×10^5	Eu-157	1×10^2	1×10^6
Pm-143	1×10^2	1×10^6	Eu-158	1×10^1	1×10^5
Pm-144	1×10^1	1×10^6	Gd-145	1×10^1	1×10^5

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Pm-145	1×10^3	1×10^7	Gd-146[b]	1×10^1	1×10^6
Pm-146	1×10^1	1×10^6	Gd-147	1×10^1	1×10^6
Pm-147	1×10^4	1×10^7	Gd-148	1×10^1	1×10^4
Pm-148	1×10^1	1×10^5	Gd-149	1×10^2	1×10^6
Pm-148m	1×10^1	1×10^6	Gd-151	1×10^2	1×10^7
Pm-149	1×10^3	1×10^6	Gd-152	1×10^1	1×10^4
Pm-150	1×10^1	1×10^5	Gd-153	1×10^2	1×10^7
Pm-151	1×10^2	1×10^6	Gd-159	1×10^3	1×10^6
Sm-141	1×10^1	1×10^5	Tb-147	1×10^1	1×10^6
Sm-141m	1×10^1	1×10^6	Tb-149	1×10^1	1×10^6
Sm-142	1×10^2	1×10^7	Tb-150	1×10^1	1×10^6
Sm-145	1×10^2	1×10^7	Tb-151	1×10^1	1×10^6
Sm-146	1×10^1	1×10^5	Tb-153	1×10^2	1×10^7
Sm-147	1×10^1	1×10^4	Tb-154	1×10^1	1×10^6
Sm-151	1×10^4	1×10^8	Tb-155	1×10^2	1×10^7
Sm-153	1×10^2	1×10^6	Tb-156	1×10^1	1×10^6
Sm-155	1×10^2	1×10^6	Tb-156m (24.4h)	1×10^3	1×10^7
Sm-156	1×10^2	1×10^6	Tb-156m' (5h)	1×10^4	1×10^7
Eu-145	1×10^1	1×10^6	Tb-157	1×10^4	1×10^7
Eu-146	1×10^1	1×10^6	Tb-158	1×10^1	1×10^6
Eu-147	1×10^2	1×10^6	Tb-160	1×10^1	1×10^6
Eu-148	1×10^1	1×10^6	Tb-161	1×10^3	1×10^6
Eu-149	1×10^2	1×10^7	Dy-155	1×10^1	1×10^6
Eu-150	1×10^1	1×10^6	Dy-157	1×10^2	1×10^6
Eu-150m	1×10^3	1×10^6	Dy-159	1×10^3	1×10^7
Eu-152	1×10^1	1×10^6	Dy-165	1×10^3	1×10^6

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Eu-152m	1×10^{2}	1×10^{6}	Dy-166	1×10^{3}	1×10^{6}
Eu-154	1×10^{1}	1×10^{6}	Ho-155	1×10^{2}	1×10^{6}
Ho-157	1×10^{2}	1×10^{6}	Lu-172	1×10^{1}	1×10^{6}
Ho-159	1×10^{2}	1×10^{6}	Lu-173	1×10^{2}	1×10^{7}
Ho-161	1×10^{2}	1×10^{7}	Lu-174	1×10^{2}	1×10^{7}
Ho-162	1×10^{2}	1×10^{7}	Lu-174m	1×10^{2}	1×10^{7}
Ho-162m	1×10^{1}	1×10^{6}	Lu-176	1×10^{2}	1×10^{6}
Ho-164	1×10^{3}	1×10^{6}	Lu-176m	1×10^{3}	1×10^{6}
Ho-164m	1×10^{3}	1×10^{7}	Lu-177	1×10^{3}	1×10^{7}
Ho-166	1×10^{3}	1×10^{5}	Lu-177m	1×10^{1}	1×10^{6}
Ho- 166m	1×10^{1}	1×10^{6}	Lu-178	1×10^{2}	1×10^{5}
Ho-167	1×10^{2}	1×10^{6}	Lu-178m	1×10^{1}	1×10^{5}
Er-161	1×10^{1}	1×10^{6}	Lu-179	1×10^{3}	1×10^{6}
Er-165	1×10^{3}	1×10^{7}	Hf-170	1×10^{2}	1×10^{6}
Er-169	1×10^{4}	1×10^{7}	Hf-172[b]	1×10^{1}	1×10^{6}
Er-171	1×10^{2}	1×10^{6}	Hf-173	1×10^{2}	1×10^{6}
Er-172	1×10^{2}	1×10^{6}	Hf-175	1×10^{2}	1×10^{6}
Tm-162	1×10^{1}	1×10^{6}	Hf-177m	1×10^{1}	1×10^{5}
Tm-166	1×10^{1}	1×10^{6}	Hf-178m	1×10^{1}	1×10^{6}
Tm-167	1×10^{2}	1×10^{6}	Hf-179m	1×10^{1}	1×10^{6}
Tm-170	1×10^{3}	1×10^{6}	Hf-180m	1×10^{1}	1×10^{6}
Tm-171	1×10^{4}	1×10^{8}	Hf-181	1×10^{1}	1×10^{6}
Tm-172	1×10^{2}	1×10^{6}	Hf-182	1×10^{2}	1×10^{6}
Tm-173	1×10^{2}	1×10^{6}	Hf-182m	1×10^{1}	1×10^{6}
Tm-175	1×10^{1}	1×10^{6}	Hf-183	1×10^{1}	1×10^{6}
Yb-162	1×10^{2}	1×10^{7}	Hf-184	1×10^{2}	1×10^{6}

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Yb-166	1×10^{2}	1×10^{7}	Ta-172	1×10^{1}	1×10^{6}
Yb-167	1×10^{2}	1×10^{6}	Ta-173	1×10^{1}	1×10^{6}
Yb-169	1×10^{2}	1×10^{7}	Ta-174	1×10^{1}	1×10^{6}
Yb-175	1×10^{3}	1×10^{7}	Ta-175	1×10^{1}	1×10^{6}
Yb-177	1×10^{2}	1×10^{6}	Ta-176	1×10^{1}	1×10^{6}
Yb-178	1×10^{3}	1×10^{6}	Ta-177	1×10^{2}	1×10^{7}
Lu-169	1×10^{1}	1×10^{6}	Ta-178	1×10^{1}	1×10^{6}
Lu-170	1×10^{1}	1×10^{6}	Ta-179	1×10^{3}	1×10^{7}
Lu-171	1×10^{1}	1×10^{6}	Ta-180	1×10^{1}	1×10^{6}
Ta-180m	1×10^{3}	1×10^{7}	Os-191	1×10^{2}	1×10^{7}
Ta-182	1×10^{1}	1×10^{4}	Os-191m	1×10^{3}	1×10^{7}
Ta-182m	1×10^{2}	1×10^{6}	Os- 193	1×10^{2}	1×10^{6}
Ta-183	1×10^{2}	1×10^{6}	Os-194[b]	1×10^{2}	1×10^{5}
Ta-184	1×10^{1}	1×10^{6}	Ir-182	1×10^{1}	1×10^{5}
Ta-185	1×10^{2}	1×10^{5}	Ir-184	1×10^{4}	1×10^{6}
Ta-186	1×10^{1}	1×10^{5}	Ir-185	1×10^{1}	1×10^{6}
W-176	1×10^{2}	1×10^{6}	Ir-186	1×10^{1}	1×10^{6}
W-177	1×10^{1}	1×10^{6}	Ir-186m	1×10^{1}	1×10^{6}
W-178[b]	1×10^{1}	1×10^{6}	Ir-187	1×10^{2}	1×10^{6}
W-179	1×10^{2}	1×10^{7}	Ir-188	1×10^{1}	1×10^{6}
W-181	1×10^{3}	1×10^{7}	Ir-189[b]	1×10^{2}	1×10^{7}
W-185	1×10^{4}	1×10^{7}	Ir-190	1×10^{1}	1×10^{6}
W-187	1×10^{2}	1×10^{5}	Ir-190m (3.1h)	1×10^{1}	1×10^{6}
W-188[b]	1×10^{2}	1×10^{5}	Ir-190m' (1.2h)	1×10^{4}	1×10^{7}
Re- 177	1×10^{1}	1×10^{6}	Ir-192	1×10^{1}	1×10^{4}

SIXTH SCHEDULE, *contd.*

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Re- 178	1 x 10^{1}	1 x 10^{6}	Ir-192m	1 x 10^{2}	1 x 10^{7}
Re-181	1 x 10^{1}	1 x 10^{6}	Ir-193m	1 x 10^{4}	1 x 10^{7}
Re- 182	1 x 10^{1}	1 x 10^{6}	Ir-194	1 x 10^{2}	1 x 10^{5}
Re- 182m	1 x 10^{1}	1 x 10^{6}	Ir-194m	1 x 10^{1}	1 x 10^{6}
Re- 184	1 x 101	1 x 10^{6}	Ir-195	1 x 10^{2}	1 x 10^{6}
Re- 184m	1 x 10^{2}	1 x 10^{6}	Ir-102	1 x 10^{2}	1 x 10^{6}
Re- 186	1 x 10^{3}	1 x 10^{6}	Pt-186	1 x 10^{1}	1 x 10^{6}
Re- 186m	1 x 10^{3}	1 x 10^{7}	Pt-188[b]	1 x 10^{1}	1 x 10^{6}
Re- 187	1 x 10^{6}	1 x 10^{9}	Pt-189	1 x 10^{2}	1 x 10^{6}
Re- 188	1 x 10^{2}	1 x 10^{5}	Pt-191	1 x 10^{2}	1 x 10^{6}
Re- 18 8m	1 x 10^{2}	1 x 10^{7}	Pt-193	1 x 10^{4}	1 x 10^{7}
Re-189[b]	1 x 10^{2}	1 x 10^{6}	Pt-193m	1 x 10^{3}	1 x 10^{7}
Os-180	1 x 10^{2}	1 x 10^{7}	Pt-195m	1 x 10^{2}	1 x 10^{6}
Os-181	1 x 10^{1}	1 x 10^{6}	Pt-197	1 x 10^{3}	1 x 10^{6}
Os-182	1 x 10^{2}	1 x 10^{6}	Pt-197m	1 x 10^{2}	1 x 10^{6}
Os-185	1 x 10^{1}	1 x 10^{6}	Pt-199	1 x 10^{2}	1 x 10^{6}
Os-189m	1 x 10^{4}	1 x 10^{7}	Pt-200	1 x 10^{2}	1 x 10^{6}

SEVENTH SCHEDULE (Regulation 11)

Exemptions for Bank Amounts

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
H-3	100	Co-58	1
Be-7	10	Co-58m	10000
C-14	1	Co-60	0.1
F-18	10	Co-60m	1000
Na-22	0.1	Co-61	100
Na-24	1	Co-62m	10
Si-32	1000	Ni-59	100
P-32	1000	Ni-63	100
P-33	1000	Ni-65	10
S-35	100	Cu-64	100
CI-36	1	Zu-65	0.1
CI-38	10	Zu-69	1000
K-42	100	Zn-69m[a]	10
K-43	10	Ga-72	10
Ca-45	100	Ge-71	10000
Ca-47	10	As-73	1000
Sc-46	0.1	As-74	10
Sc-47	100	As-76	10
Sc-48	1	As-77	1000
V-48	1	Se-75	1
Cr-51	100	Br-82	1
Mn-51	10	Rb-86	100
Mn-52	1	Sr-85	1
Mn-52m	10	Sr-85m	100

SEVENTH SCHEDULE, *contd.*

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
Mn-53	100	Sr-87m	100
Mn-54	0.1	Sr-89	1000
Mn-56	10	Sr-90[a]	1
Fe-52[a]	10	Sr-91[a]	10
Fe-55	1000	Sr-92	10
Fe-59	1	Y-90	1000
Co-55	10	Y-91	100
Co-56	0.1	Y-91m	100
Co-57	1	Y-92	100
Y-93	100	In-111	10
Zr-93	10	In-113m	100
Zr-95a	1	In-114ma	10
Zr-97a	10	In-115m	100
Nb-93m	10	Sn-113a	1
Nb-94	0.1	Sn-125	10
Nb-95	1	Sb-122	10
Nb-97a	10	Sb-124	1
Nb-98	10	Sb-125a	0.1
Mo-90	10	Te-123m	1
Mo-93	10	Te-125m	1000
Mo-99a	10	Te-127	1000
Mo-101a	10	Te-127ma	10
Tc-96	1	Te-129	100
Tc-96m	1000	Te-129ma	10
Tc-97	10	Te-131	100
Tc-97m	100	Te-131ma	10

SEVENTH SCHEDULE, *contd.*

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
Tc-99	1	Te-132a	1
Tc-99m	100	Te-133	10
Ru-97	10	Te-133m	10
Ru-103a	1	Te-134	10
Ru-105a	10	I-123	100
Ru-106a	0.1	I-125	100
Rh-103m	10000	I-126	10
Rh-105	100	I-129	0.01
Pd-103a	1000	I-130	10
Pd-109a	100	1-131	10
Ag-105	1	1-132	10
Ag-110ma	0.1	1-133	10
Ag-111	100	1-134	10
Cd-109a	1	1-135	10
Cd-115a	10	Cs-129	10
Cd-115ma	100	Cs-131	1000
Cs-132	10	Er-171	100
Cs-134	0.1	Tm-170	100
Cs-134m	1000	Tm-171	1000
Cs-135	100	Yb-175	100
Cs-136	1	Lu-177	100
Cs-137[a]	0.1	Hf-181	1
Cs-138	10	Ta-182	0.1
Ba-131	10	W-181	10
Ba-140	1	W-185	1000
La- 140	1	W-187	10

SEVENTH SCHEDULE, *contd.*

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
Ce-139	1	Re- 186	1000
Ce-141	100	Re-188	100
Ce-143	10	Os-185	1
Ce-144[a]	10	Os-191	100
Pr-142	100	Os-191m	1000
Pr-143	1000	Os-193	100
Nd-147	100	Ir-190	1
Nd-149	100	Ir-192	1
Pm-147	1000	Ir-194	100
Pm-149	1000	Pt-191	10
Sm-151	1000	Pt-193m	1000
Sm-153	100	Pt-197	1000
Eu-152	0.1	Pt-197m	100
Eu-152m	100	Au-198	10
Eu-154	0.1	Au-199	100
Eu-155	1	Hg-197	100
Gd-153	10	Hg-197m	100
Gd-159	100	Hg-203	10
Tb-160	1	TI-200	10
Dy-165	1000	TI-201	100
Dy-166	100	TI-202	10
Ho- 166	100	TI-204	1
Er-169	1000	Pb-203	10

SEVENTH SCHEDULE, *contd.*

ACTIVITY[a] CORRESPONDING TO A DANGEROUS SOURCE (D VALUE[b]) FOR SELECTED RADIONUCLIDES

Radionuclide	D Value (TBq)	Radionuclide	D Value (TBq)
Am-241	6×10^{-2}	Mo-99	3×10^{-1}
Am-241/Be	6×10^{-2}	Ni-63	6×10^{1}
Au-198	2×10^{-1}	P-32	1×10^{1}
Cd-109	2×10^{1}	Pd-103	9×10^{1}
Cf-252	2×10^{-2}	Pm-147	4×10^{1}
Cm-244	5×10^{-2}	Po-210	6×10^{-2}
Co-57	7×10^{-1}	Pu-238	6×10^{-2}
Co-60	3×10^{-2}	Pu-239/Be	6×10^{-2}
Cs-137	1×10^{-1}	Ra-226	4×10^{-2}
Fe-55	8×10^{2}	Ru-106(Rh-106)	3×10^{-1}
Gd-153	1×10^{0}	Se-75	2×10^{-1}
Ge-68	7×10^{-2}	Sr-90 (Y-90)	1×10^{0}
H-3	2×10^{3}	Tc-99m	7×10^{-1}
I-125	2×10^{-1}	TI-204	2×10^{1}
I-131	2×10^{-1}	Tm-170	2×10^{1}
Ir-192	8×10^{-2}	Yb-169	3×10^{-1}
Kr-85	3×10^{1}		

a. Since this table does not state which doses criteria were used, these D values cannot be used 'in reverse' to derive possible doses from exposure due to sources of known activity.

b. Full details of the derivation of the D values and D values for additional radionuclides are provided in "International Commission on Radiological Protection, Conversion Coefficients for Use in Radiological Protection against External Radiation", ICRP Publication 74, Annals of the ICRP Vol. 26/3 (1997) and any amendments thereto.

SEVENTH SCHEDULE, *contd.*

TABLE 1.2. LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION AND FOR CLEARANCE OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
Bi-206	1	Pu-241	10
Bi-207	0.1	Pu-242	0.1
Po-203	10	Pu-242	1000
Po-205	10	Pu-244[a]	0.1
Po-207	10	Am-241	0.1
At-211	1000	Am-242	1000
Ra-225	10	Am-242m[a]	0.1
Ra-227	100	Am-243[a]	0.1
Th-226	1000	Cm-242	10
Th-229	0.1	Cm-243	1
Pa-230	10	Cm-244	1
Pa-233	10	Cm-245	0.1
U-230	10	Cm-246	0.1
U-231	100	Cm-247[a]	0.1
U-232[a]	0.1	Cm-248	0.1
U-233	1	Bk-249	100
U-236	10	Cf-246	1000
U-237	100	Cf-248	1
U-239	100	Cf-249	0.1
U-240[a]	100	Cf-250	1
Np-237[a]	1	Cf-251	0.1
Np-239	100	Cf-252	1
Np-240	10	Cf-253	100

SEVENTH SCHEDULE, *contd.*

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
Pu-234	100	Cf-254	1
Pu-235	100	Es-253	100
Pu-236	1	Es-254[a]	0.1
Pu-237	100	Es-254m[a]	10
Pu-238	0.1	Fm-254	10000
Pu-239	0.1	Fm-255	100
Pu-240	0.1		

[a.] Parent radionuclides, and their progeny whose dose contributions are taken to account in the dose calculations (thus requiring only the exemption level of the parent radionuclide to be considered), are listed here:

Fe-52	Mn-52m	Sn-113	In-113m
Zn-69m	Zn-69	Sb-125	Te-125m
Sr-90	Y-90	Te-127m	Te-127
Sr-91	Y-91m	Te-129m	Te-129
Zr-95	Nb-95	Te-131m	Te-131
Zr-97	Nb-97m, Nb-97	Te-132	I-132
Nb-97	Nb-97m	Cs-137	Ba-137m
Mo-99	Tc-99m	Ce-144	Pr-144, Pr-144m
Mo-101	Tc-101	U-232	Th-228,Ra-224, Rn-220
Ru-103	Rh-103m		Po-216,Pb-212, Bi-212,TI-208
Ru-105	Rh-105m	U-240	Np-240m, Np-240
Ru-106	Rh-106	Np-237	Pa-233
Pd-103	Rh-103m	Pu-244	U-240, Np-240m, Np-240
Pd-109	Ag-109m	Am-242m	Np-238
Ag-110m	Ag-110	Am-243	Np-239

SEVENTH SCHEDULE, *contd.*

Cd-109	Ag-109m	Cm-247	Pu-243
Cd-115	In-115m	Es-254	Bk-250
Cd-115m	In-115m	Es-254m	Fm-254
In-114m	In-114		

Note: In accordance with Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards Schedule I, General Safety Requirements Part 3, the exemption levels set out in Table I.1 and the exemption and clearance levels set out in this table are subject to the following considerations: (a) they were derived using a conservative model based on (i) the criteria of paras I.2 and I.I 1, respectively, and (ii) a series of limiting (bounding) scenarios for use and disposal (see European Commission, Principles and Methods for Establishing Concentrations and Quantities (Exemption Values) Below which Reporting is not Required in the European Directive, Radiation Protection 65, Office for Official Publications of the European Communities, Luxembourg (1993) National Radiological Protection Board, Exempt Concentrations and Quantities for Radionuclides not included in the European Basic Safety Standards Directives, Mobbs S.F. Harvey, M.P. NRPB - R306, Chilton (1998) and IAEA, Derivation of Activity Concentration Values for Exclusion Exemption and Clearance, Safety Reports Series No. 44, IAEA, Vienna (2005) in the case of Table 1.1, and IAEA Dangerous Quantities of Radioactive Material (D-values), EPR-D-Values 2006, Vienna (2006) in the case of this Table); (b) if there is more than one radionuclide, the derived exemption level or derived clearance level for the mixture is determined as specified in paras I.7 and I.14.

EIGHTH SCHEDULE (Regulations 13 and 17)

Clearance Criteria

I.10. The general criteria for clearance are that:

(a) Radiation risks arising from the cleared material are sufficiently low as not to warrant regulatory control, and there is no appreciable likelihood of occurrence for scenarios that could lead to a failure to meet the general criterion for clearance; or

(b) Continued regulatory control of the material would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or reduction of health risks.

I.11. Material maybe cleared without further consideration under the terms of para. I.10 (a) provided that in reasonably foreseeable circumstances the effective dose expected to be incurred by any individual owing to the cleared material is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion can be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv year.

I.12. Radioactive material within a notified practice or an authorized practice may be cleared without further consideration provided that:

(a) The activity concentration of an individual radionuclide of artificial origin in solid form does not exceed the relevant level given in Table I.2 of Schedule 1 of the GRS Part 3 of the IAEA Safety Standards; or

(b) The activity concentrations of radionuclides of natural origin do not exceed the relevant level given in Table I.3; or

(c) For radionuclides of natural origin in residues that might be recycled into construction materials, or the disposal of which is liable to cause the contamination of drinking water supplies, the activity concentration in the residues does not exceed specific values derived so as to meet a dose criterion of the order of 1 mSv in a year, which is commensurate with typical doses due to natural background levels of radiation.

I.13. Clearance may be granted by the regulatory body for specific situations, on the basis of the criterion of paras I.10 and I.11, with account taken of the physical or chemical form of the radioactive material, and its use or the means of its disposal. Such clearance level as may be specified in terms of activity concentration per unit mass or activity concentration per unit surface area.

EIGHTH SCHEDULE, *contd.*

I.14. For clearance of radioactive material containing more than one radionuclide of artificial origin, on the basis of the levels given in Table I.2 of Schedule 1 of the GSR Part 3 of the IAEA Safety Standards, the condition for clearance is that the sum of the activity concentrations for individual radionuclides is less than the derived clearance level for the mixture (Xm), determined as follows:

$$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}} \qquad \text{(I. 2)}$$

where

f(i) is the fraction of activity concentration of radionuclide i in the mixture;

X(i) is the applicable level for radionuclide i as given in Table I.2;

And n is the number of radionuclides present.

I.15. For clearance of bulk quantities of material containing a mixture of radionuclides of natural origin, and radionuclides of artificial origin, the conditions given in para. I. 12(b) and I.14 both have to be satisfied.

TABLE I.3: Levels for Clearance of Material: Activity Concentrations of Radionuclides of Natural Origin

Radionuclide	Activity Concentration (Bq/g)
K – 40	10
Each radionuclide in the uranium and thorium decay chains	1

NINTH SCHEDULE (Regulations 21, 22, 29 and 53)

DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS

OCCUPATIONAL EXPOSURE

III. 1. For occupational exposure of workers over the age 18 years, the dose limits are:

(a) An effective dose of 20 mSv per year[1] averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;

(b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;

(c) An equivalent dose to the extremities (hands and feet) or to the skin[2] of 500 mSv in a year.

Additional restrictions apply to occupational exposure for female worker who has notified pregnancy or is breast – feeding (para. 3.114).

III. 2. For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are:

(a) An effective dose of 6 mSv per year;

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

(c) An equivalent dose to the extremities (hands and feet) or to the skin[3] of 150 mSv in a year.

PUBLIC EXPOSURE

III. 3. For public exposure, the dose limits are:

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

---

[1] The start of averaging period shall be coincident with the first day of the relevant annual period after the date of entry into force of these Standards, with no retrospective averaging.

[2] The equivalent dose limits for the skin apply to the average dose over 1 cm^2 of the most highly irradiated are of the skin. The dose to the skin also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.

[3] The equivalent dose limits for the skin apply to the average dose over 1 cm^2 of the most highly irradiated are of the skin. The dose to the skin also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.

NINTH SCHEDULE, *contd.*

(b) In special circumstances[4], a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;

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

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

VERIFICATION OF COMPLIANCE WITH DOSE LIMITS

III.4. The effective dose limits specified in this schedule apply to the sum of the relevant doses from external exposure in the specified period and the relevant committed doses from intakes in the same period; the period for calculating the committed dose shall normally be 50 years for intakes by adults and shall be up to age 70 years for intakes by children.

III.5. For occupational exposure, the personal dose equivalent Hp(10)1 may be used as an approximation of the effective dose from external exposure to the penetrating radiation.

III.6. Values of the effective dose per unit air kerma free-in-air and per unit particle fluence are given in Tables III. 1A-III. 1.D Schedule III of the Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, 2014, and any amendments thereto.

III.7. Dose per unit intake (dose coefficients) for the estimation of the committed effective dose for ingestion and inhalation of radionuclides are given in Tables III.2A- III.2H (p.137) Schedule III of the Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, 2014, and any amendments thereto.

[4] For example, in authorized, justified and planned operational conditions that lead to transitory increases in exposures.

TENTH SCHEDULE (Regulations 62 and 63)

NUCLEAR SAFETY AND RADIATION PROTECTION ACT

Jamaica

Form of application for an Export or Import Authorization

Section 38 of the NSRP Act states that every person who engages or proposes to engage in a prescribed activity shall apply, subject to subsection (4) in the prescribed form and manner to the Authority for the appropriate authorization. Subsection (3) states that the Authority may require the applicant to provide further information that it considers necessary to determine the application.

INSTRUCTIONS: Kindly complete this application form and submit to the HSRA along with a copy of receipt for fees paid and all supporting documents as stipulated in the guidance document. Please note that HSRA may require additional information to fully consider the application prior to issuing the permit.

1. Type of Authorization:

   Please tick the appropriate √

   ☐ Import

   ☐ Export

2. Type of Application

   Please tick the appropriate

   New

   Renewal—valid or previous permit number: _____

   _____

3. HSRA Authorization Holder Number:

   _____

4. Applicant (Importer/Exporter) Details

   Name _____

   Title _____

   Principal place of business (Importer/Exporter) _____

   Telephone Cell: _____ Work: _____

   Email address: _____

[1] Hp(10) is the personal dose equivalent Hp(d) where *d*=10mm

TENTH SCHEDULE, *contd.*

5. Recipient and/or Final Consignee Details (*Additional consignees such as intermediate consignees may be listed on a separate sheet*)

Recipient Name	Place of Business	Contact name and email

Final Consignee Name	Place of Business	Contact name and email

6. Type of radioactive material (Additional information may be provided on a separate sheet)

i. For sealed radioactive material NOT incorporated in radiation equipment/ devices, give the following:—

(a) Radionuclide _____

(b) Serial No./Identifier No. _____

(c) Maximum activity _____

(d) Activity Date _____

(e) Physical form _____

(f) Chemical form _____

(g) Manufacturer _____

(h) Name and address of Supplier _____

(i) Use and method of application _____

(j) Radioactive waste management and method of disposal ____

_____

ii. For unsealed radioactive materials, give the following:—

(a) Radionuclide _____

TENTH SCHEDULE, *contd.*

(b) Serial No. /Identifier No. _____

(c) Maximum activity _____

(d) Physical form _____

(e) Chemical form _____

(f) Initial containment of the radionuclide(s) _____

(g) Manufacturer _____

(h) Name and address of Supplier _____

(i) Use and method of application _____

(j) Radioactive waste management and method of disposal ____

_____

7. For equipment with sealed sources(s) incorporated, give the following details:—

(*Additional information may be provided on a separate sheet*)

(a) If the device is to be used in the industrial sector, state the type of application (i.e. well logging, portable/fixed gauging, detection or analytical *etc*.)

_____

State the technical details of the sealed source device above:

i. Manufacturer _____

ii. Name and address of Supplier _____

iii. Serial No. _____

iv. Model No. _____

v. Radiation type _____

vi. Radionuclide _____

vii. Maximum activity _____

viii. Model No. of apparatus _____

ix. Type of installation (fixed/mobile) _____

x. Cost of the equipment _____

(b) If it is radiotherapy equipment, then give the details of the equipment as appropriate:—

i. Manufacturer _____

TENTH SCHEDULE, *contd.*

ii. Model number and name _____

iii. Country of manufacture _____

iv. Year of manufacture

v. Radionuclide _____

vi. Model no. of the source(s) _____

vii. Initial activity of the sources(s) _____

viii. Number of sources installed _____

ix. Maximum design activity _____

x. Total activity installed _____

xi. Name and address of Supplier _____

xii. Type of installation (fixed/mobile) _____

xiii. Cost of the equipment _____

8. Give a list and the corresponding technical details of radiation generator(s) to be imported or exported (attach relevant parts of manuals if available), including—

(*Additional information may be provided on a separate sheet*)

(a) Model name and number _____

(b) Serial number _____

(c) Maximum voltage _____

(d) Maximum current _____

(e) Radiation type _____

(f) Name and address of supplier _____

(g) Manufacturer _____

(h) Year of manufacture _____

(i) Radiation device certificate number (attach copy

_____

(j) Type of installation (fixed/mobile) _____

(k) Cost of the radiation generator(s) _____

TENTH SCHEDULE, *contd.*

9. State, giving details, the purpose for which the radiation sources will be used. (i.e. practice: treatment, diagnostic; non-destructive testing; gauging; biological irradiation etc.):

_____

_____

_____

10. Means of transport out of/into Jamaica (i.e. air, road, rail, sea, etc.) _____

_____

11. (a) For importation, expected date of receipt _____

(b) For exportation, expected date of shipment _____

12. Point of entry into/exit out of Jamaica _____

13. Arrangements made for transport from establishment to exit point or entry point to establishment: (you will be required to inform HSRA of arrival/transfer details for the monitoring of clearance and inland transport) _____

_____

_____

14. Preparations made for premises at which the radiation source will be used:

_____

_____

_____

15. Available qualified experts who will use the radiation source (names and qualifications):

i. _____

ii. _____

iii. _____

TENTH SCHEDULE, *contd.*

16. Give relevant details of any contract(s) with supplier particularly with regards to:—

    (a) Installation and training of operators _____

    _____

    (b) Repair and maintenance including warranty _____

    (c) Return or change of source after useful life: _____

17. Please provide details of arrangements for safe management of disused sources (Including financial provisions)

    _____

18. Kindly provide justification or explanation of the need to use 'exceptional circumstances'.

    _____

DECLARATION:

I, ... , (name of legal person) certify that all the information given herein and any supplemental pages appended to this application are true and correct to the best of my knowledge.

Signature of Applicant: ..... Date: .....

(If Company, Affix Company Seal)

For Official Use Only			
Permit No.:			
	By	Date	Signature
Received:			
Evaluated:			
General remarks			
and/or comments:			

ELEVENTH SCHEDULE (Regulation 89)

Guidance Values for Restricting Exposure of Emergency Workers

Tasks	Guidance Value*
Life saving actions	Hp(10)** < 500 mSv This value may be exceeded under circumstances in which the expected benefits to others clearly outweigh the emergency worker's own health risks, and the emergency worker volunteers to take the action and understands and accepts these health risks.
Actions to prevent severe deterministic effects and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment	Hp(10) < 500 mSv
Actions to avert a large collective dose	Hp(10) < 100 mSv

*These values apply only for the dose from external exposure to strongly penetrating radiation.Doses from external exposure to weakly penetrating radiation and from intake or skin contamination need to be prevented by all possible means. If this is not feasible, the effective dose and the equivalent dose to a tissue or organ that are received have to be limited to minimize the health risk to the individual in line with the risk associated with the guidance values given here.

** Hp(10) is the personal dose equivalent Hp(d) where d= 10mm

Dated the 29th day of August, 2019.

AUDLEY SHAW
Minister of Industry, Commerce, Agriculture and Fisheries.

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