

**NUCLEAR REGULATORY AUTHORITY,
GHANA**



DRAFT BASIC IONISING RADIATION CONTROL REGULATIONS

Nuclear Regulatory Authority (NRA), Ghana
Houses 1 & 2, Neutron Avenue, P.O. Box AE 50, Atomic- Kwabenya, Accra

official.mail@gnra.org.gh

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BASIC IONISING RADIATION CONTROL REGULATIONS

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The Basic Ionising Radiation Control Regulations, 2020

(Under section 91 of the Nuclear Regulatory Authority Act, Act 895, 2015)

In exercise of the power conferred on the Minister responsible for Nuclear Regulatory Authority, acting on the advice of the Board by Section 91 of the Nuclear Regulatory Authority Act, 2015 (Act 895), these Regulations are made this day of

Preliminary

Application

- 1.(1) These regulations apply to
 - (a) the introduction, conduct, discontinuance, or cessation of a practice;
 - (b) the design, manufacture, construction, assembly, acquisition, import, export, distribution, selling, leasing hiring, locating, commissioning, processing, production, possession, use and operation, maintenance or repair, transfer or decommissioning, disassembly, transport of all situations involving exposure or the potential for exposure to ionising radiation, storage; and
 - (c) disposal of a source within a practice unless exposure from the source is excluded or exempted in accordance with these regulations.
- (2) The sources within a practice to which these regulations apply include
 - (a) radioactive and nuclear material and devices that contain radioactive and nuclear material or produce ionising radiation and may be in the form of consumer products, sealed sources, unsealed sources, ionising radiation generators, and mobile radiography equipment;
 - (b) installations and facilities containing radioactive and nuclear material and devices that contain radioactive and nuclear material or produce ionising radiation which are used for industrial, medical, agricultural, research, nuclear power generation and education purposes; and
 - (c) any other source specified by the Authority.

Exposures and exposure situations

- 2.(1) the exposures to which these regulations apply include
 - (a) planned exposure situation which may be in the nature of occupational exposure, medical exposure or public exposure;
 - (b) emergency exposure situation which may be in the nature of occupational exposure or public exposure; and
 - (c) existing exposure situation which may be in the nature of occupational exposure or public exposurearising out of a relevant practice or source within a practice.

Exclusions

- 3.(1) The following exposures are excluded from these regulations:
 - (a) exposures from natural radioactivity in the body;
 - (b) exposures from cosmic radiation; and

- (c) exposure from any other source that is essentially not amenable to control as determined by the Authority.

Persons responsible for application of Regulations

4.(1) The person or organisation responsible for a facility that generates or an activity that gives rise to radiation risk shall have the prime responsibility to provide protection and safety and this responsibility cannot be delegated.

(2) The principal persons responsible for the application of and compliance with these regulations are

- (a) a person authorised by the mandated authority for the purpose of application of and compliance with these Regulations or a person or an organisation responsible for a facility and activities for which notification only is required;
- (b) in the case of occupational exposure an employer of a person employed in a facility or engaged in the activity referred to in sub regulation (1);
- (c) a radiological medical practitioner, in the case of medical exposure; and
- (d) a person or an organisation designated to deal with an emergency exposure situation or an existing exposure situation.

(3) Other persons that have specified responsibilities in relation to the application of these Regulations include

- (a) a supplier of sources, a provider of relevant equipment and software, and a provider of a relevant consumer product;
- (b) a radiation protection officer;
- (c) a referring medical practitioner;
- (d) a medical physicist;
- (e) a medical radiation technologist;
- (f) a qualified expert or any other person to whom a principal person has assigned a specific responsibility;
- (g) a worker other than a worker listed in paragraph (a) to (f) in this sub regulation;
- (h) the Ethics Committee of the Board; and
- (i) any other person specially delegated by a person referred to in sub regulation (2).

(4) A relevant principal person shall establish and implement a protection and safety programme that is appropriate for each exposure situation and which shall

- (a) adopt objectives for protection and safety in accordance with these Regulations;
- (b) apply protection and safety measures that are
 - (i) commensurate with the radiation risks associated with the exposure situation ;and
 - (ii) adequate to ensure compliance with the requirements of these Regulations.

(5) A relevant principal person shall ensure that in the implementation of the protection and safety programme,

- (a) the measures and resources that are necessary for achieving the objectives of protection and safety have been determined and are duly provided;
- (b) the programme is periodically reviewed to assess its effectiveness and its fitness for purpose;

- (c) any failure or shortcoming in protection and safety is identified and corrected, and steps are taken to prevent its recurrence;
- (d) an arrangements is made to consult with interested persons; and
- (e) appropriate records are maintained.

(6) A relevant principal person and any other person who has a specified responsibility in relation to protection and safety shall ensure that any personnel engaged in an activity relevant to protection and safety has the appropriate education, training and qualification to understand the responsibility and to perform the duty competently in accordance with the standard procedures.

(7) A relevant principal person shall ensure that qualified experts are identified and are where necessary consulted on the proper observance of these Regulations.

Right to enter and inspect

5.(1) A relevant principal person shall grant access to an authorised representative of the Authority to carry out an inspection of

- (a) the facility and activity; and
- (b) the protection and safety records,

of that person and that person shall cooperate in the conduct of inspections.

Non-compliance and accidents

6.(1) In the event of a breach of these regulations, a principal person shall

- (a) investigate the incident or accident;
- (b) take the appropriate action to remedy the circumstance and prevent a recurrence of a similar situation;
- (c) report to the Authority within twenty-four hours, on the causes of the breach, the circumstances and consequences of the breach, and on the corrective or preventive actions taken or to be taken; and
- (d) take any other action necessary under these Regulations.

(2) The relevant principal person shall within forty-eight hours communicate the occurrence of an incident or accident to the Authority after an emergency exposure situation has developed or is developing.

(3) Despite sub regulation (2), where the incident or accident involves the loss of control of a nuclear power plant or Category 1, 2 or 3 radioactive source occurs or occurring, the relevant principal person shall inform the Authority within 24 hours.

(4) Where the relevant principal person fails to take corrective or preventive action within a reasonable time in accordance with these Regulations, the Authority may modify, suspend or withdraw the authorisation granted to the principal person.

Applicability of other regulations and requirements

7.(1) These regulations are in addition to, and not in place of, other applicable regulations.

(2) Nothing in these regulations shall be construed as relieving employers from complying with applicable laws and regulations governing workplace hazards, including radiation hazards from natural sources, which are unconnected with the work.

(3) The Authority shall be notified to initiate steps towards resolution, where a conflict exists between regulations contained herein and other laws or regulations.

Enforcement

8.(1) The Authority may revoke, suspend or modify an authorisation to use a radiation source, or prohibit the possession of a radiation source, if the Authority finds that there is

- (a) an undue threat to health and safety; or
- (b) non-compliance with applicable regulatory requirements.

(2) Where the Authority takes an action under sub regulation (1), the Authority may

- (a) fine,
- (b) direct the closure or the locking up of the premises of the person who is the subject of the action; and
- (c) require the person against whom the action has been taken to take the necessary remedial measures in accordance with these Regulations.

(3) The Authority may refer a wilful violation of these Regulations to the office of the Attorney Generals for prosecution.

Additional Requirements

9. (1) The Authority may, in order to,

- (a) protect health,
- (b) protect the environment, or
- (c) minimise the risk from radiation hazards,

issue and publish additional directives, or conditions of authorisation that the Board determines to be necessary for giving effect to these Regulations.

Requirements for notice and authorisation

10. Subject to regulation 12, a person who intends to engage in a relevant practice or to be in control of a relevant source shall give notice of that intention to the Authority and apply for authorisation from the Authority in the form and manner required by the NRA Authorisation Guidelines.

Exemption of practices and sources

11. (1) A practice or source that fall within the exemption levels specified in the First Schedule of these Regulations is exempt from the requirements of these Regulations.

(2) Without prejudice to sub regulation (1) and subject to regulation 22, the Authority may exempt a practice or source from one or more of the requirements of these Regulations and shall publish the exemption in the Gazette.

Application for authorisation

12.(1) Except as provided for by Regulation 10 and Regulation 11, a person who intends to engage in a practice or possess a radiation source referred to in Regulation 1 shall apply to the Authority for an authorisation.

(2) An application for an authorisation shall contain

- (a) information on the legal status and technical competence of the applicant;
- (b) a technical description of the practice to be carried out;
- (c) the planned time of commencement and completion of the construction of installations relating to the practice;
- (d) the name of and qualifications of at least one person designated as a Radiation Protection Officer for the purposes of the practice;
- (e) an evaluation of the nature, magnitude and likelihood of the exposures that may arise from the practice and source;
- (f) reports and studies undertaken, including an environmental impact assessment and a safety assessment of the proposed practice;
- (g) a determination of the characteristics and activities of any radioactive material to be discharged into the environment, with an assessment of the resulting doses to the relevant critical group or representative person;
- (h) in case of a source meant for medical exposure, the qualifications in radiation protection of the medical practitioner who is to be designated by name and by qualification and credentials in the authorisation as the only individual permitted to administer medical exposure by means of the authorised source;
- (i) necessary steps to be taken for the protection and safety of workers, members of the public and where applicable, patients;
- (j) the impact of the proposed practice on public and private interests, including the interests of affected landowners and holders of other rights in relation to land and possible mitigation measures;
- (k) an emergency response plan for the proposed practice;
- (l) consents and permits required under any other law;

- (m) any further information that the Authority may require; and
- (n) evidence of payment of the prescribed fees.

(3) An authorised person shall submit to the Authority for review, the required safety information in the form of a safety assessment report.

(4) The Authority shall, within thirty days after receipt of an application for an authorisation, acknowledge receipt of the application in writing to the applicant and may by that correspondence inform the applicant that the application is complete or request for further information from the applicant.

(5) The Authority shall process an application for authorisation within ninety days after receipt of the application where no additional information is required.

(6) Where the Authority determines that by reason of the mount of work required for the processing of the application, the authorisation cannot be granted within the ninety days, the Authority shall, in writing, inform the applicant of that determination and specify the date for the grant.

(7) An applicant shall, where the Authority requires, submit additional information to facilitate the review and assessment of an application.

- (8) Where an application refers to
- (a) an industrial irradiation installation,
 - (b) nuclear installation,
 - (c) an installation processing radioactive substance,
 - (d) a medical or industrial radiography facility, or
 - (e) for any use of source,

which the Authority has not designated as appropriate for registration, the authorisation shall take the form of a licence.

(9) An authorisation to possess or use a source or radiation premises is for the duration specified in the authorisation and may be renewed by the Authority after fulfilment of the safety requirements.

(10) A holder of an authorisation shall submit an application for renewal of the authorisation within three months before the expiration of the authorisation.

Modifications

13.(1) Modifications such as change of ownership, transfer, sell, lease or loan of any apparatus, article, plant, installation or other material or substance shall require authorisation.

(2) An applicant for an authorisation to modify an apparatus, an article, a plant, an installation or any other material or substance shall

- (a) submit to the Authority relevant information specified by the Authority to be necessary to support the application; and

(b) provide evidence of payment of the prescribed fee.

(3) An applicant for an authorisation to transfer, sell, lease or loan of any apparatus, article, plant, installation or other material or substance shall

- (a) submit to the Authority relevant information specified by the Authority to be necessary to support the application;
- (b) state how the specific safety and security measures required by these Regulations will be met;
- (c) state a final disposal solution for generated radioactive waste and any disused sealed source; and
- (d) provide evidence of payment of the prescribed fee.

Grant and rejection of application

14.(1) The Authority shall for the purpose of granting or rejecting an application for authorisation, take into consideration, as far as is adequate for the practice applied for,

- (a) the legal status of the applicant;
- (b) the impact of the practice on the social, cultural and recreational life of the community;
- (c) the need to protect the environment and to conserve natural resources;
- (d) the land use and siting of the practice;
- (e) the ability of the applicant to operate in a manner that
 - (i) protects the health and safety of users, workers, beneficiaries and other members of the public who would be affected by the practice; and
 - (ii) ensures the security of radiation sources and installations; and
- (f) the public and private interests that are affected by the practice.

(2) An authorisation granted by the Authority is subject to these Regulations and any conditions set out in the authorisation.

(3) Where the Authority decides not to grant an authorisation, the Authority shall, in writing inform the applicant of the decision within thirty days after the decision.

(4) A person aggrieved by the decision of the Authority under sub regulation (3) may appeal to the Minister as required by Section 82 of Act 895.

(5) These Regulations do not prevent the holder of an authorisation, who has fulfilled all the obligations under the authorisation, from applying for and obtaining any other authorisation required under these Regulations.

Cessation or suspension of an authorised activity or an authorised facility

15.(1) A person who holds an authorisation shall not, without the written approval or instruction of the Authority,

- (a) cease or suspend the authorised activity or the operation of an authorised facility; or
- (b) decommission or abandon an installation or waste management system.

(2) An authorised person shall, before vacating any premises used by that authorised person for an activity which is regulated or controlled by the Act and these Regulations, decontaminate the premises in accordance with the procedures approved of the Authority.

Authorisation to import, export or transport

16.(1) A person who applies for an authorisation to import, export or transport an apparatus, article, plant, installation or other material or substance which is a source or intended to be used for the purposes of emission of radiation, shall

- (a) submit to the Authority the information that the Authority has determined to be necessary to support the application; and
- (b) provide evidence of payment of the prescribed fee.

(2) An authorisation to import, export or transport a radiation source is valid for six months from the date of grant of the authorisation or as prescribed by the Authority.

(3) The Authority shall, in granting or rejecting an application for an authorisation under sub-regulation (1), take into consideration the matters specified in Regulation 14.

Registration of technical support services

17.(1) A person who intends to carry out technical support practice that involves

- (a) calibration of equipment,
 - (b) personnel dosimetry,
 - (c) environmental monitoring, or
 - (d) any other activity in the supply chain determined by the Authority to be a technical service and that satisfies the requirements of these regulations in that regard,
- shall apply for an authorisation

(2) The application for authorisation shall contain

- (a) relevant requirements for the technical support service; and
- (b) evidence of payment of the prescribed fee

(3) The authorisation for a technical support service provider shall be valid for three years from the date of the grant of the authorisation or as prescribed by the Authority.

(4) An authorisation granted to a person under Sub regulation (2) may be suspended, revoked or modified if the person violates the conditions of the authorisation or other regulatory requirements.

General administrative requirements

18. (1) A person shall not engage in an activity required to be controlled in the Act or to be regulated in these Regulations by the Authority, if that person does not satisfy the requirements of these Regulations.

(2) An authorised person shall comply with the established regulatory system by the Authority for protection and safety that include:

- (a) notification and authorisation,

- (b) review and assessment of facilities and activities,
- (c) inspection of facilities and activities,
- (d) enforcement of regulatory requirements,
- (e) regulatory functions relevant to emergency exposures situations and existing exposure situations, and
- (f) provision of information to, and consultation with, parties affected by its decisions and, as appropriate, the public and authorised parties

in the regulatory oversight of facilities and activities.

(3) An authorised person shall comply with the implementation of the regulatory system by the Authority for protection and safety in a graded approach such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation.

(4) An authorised person shall comply with the application of the requirements for education, training, qualification and competence by the Authority in the protection and safety of all persons engaged in activities relevant to protection and safety.

(5) An authorised person shall comply with the mechanisms by the Authority in place for the timely dissemination of information on lessons learned for protection and safety from

- (a) regulatory experience and operating experience,
- (b) incidents and accidents, and
- (c) the related findings

to relevant persons including suppliers of and users of sources

(6) The mechanism established in sub regulation (5) shall, as appropriate, be used to provide relevant information to other relevant organisations at the national and international level.

(7) An authorised person shall comply with specific requirements by the Authority, in conjunction with other relevant authorities for the

- (a) acceptance, and
- (b) performance

of any manufactured or constructed source, device, equipment or facility that, when in use, has implications for protection and safety.

(8) An authorised person shall comply with the provisions made by the Authority for establishing, maintaining and retrieving adequate records relating to facilities and activities.

(9) For the purposes of sub regulation (8), records include

- (a) registers of sealed sources and radiation generators;
- (b) records of doses from occupational exposure;
- (c) records relating to the safety of facilities and activities;
- (d) records that might be necessary for the shutdown and decommissioning or closure of facilities;
- (e) records of events, including non-routine releases of radioactive material to the environment; and
- (f) inventories of radioactive waste and of spent fuel.

(10) An authorised person shall comply with the established mechanisms by the Authority in respect of protection and safety related issues for communication and discussion concerning professional and constructive interactions with relevant persons.

(11) An authorised person shall comply with provisions by the Authority, in consultation with the health authority, put in place for ensuring protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources, either as a result of radiological procedures for medical treatment of patients or as a consequence of an emergency.

(12) An authorised person shall comply with the established, implemented, assessed and continually improved management system by the Authority to ensure alignment with the Authority's goals and the achievement of those goals for the protection of facilities and activities.

(13) The authorised person shall comply with issued directives by the Authority in the implementation of the regulatory system for protection and safety.

Responsibilities of authorised persons

19.(1) An authorised person shall bear the responsibility for setting up and implementing the technical and organisational measures that are necessary for the protection and safety required for the practices and sources for which they are authorised.

(2) An authorised person may designate a suitably qualified person to carry out a task that relates to a responsibility of that authorised person, but the authorised person is ultimately responsible for protection and safety, regardless of any delegation.

(3) An authorised person shall document the personal details and the responsibility of a person designated to ensure compliance with the requirements of these Regulations.

(4) An authorised person shall give the Authority notice of any intention to introduce modifications to an authorised practice or source if the intended modification is likely to have a significant implication for protection and safety, and the authorised person shall not carry out the modification unless it is authorised by the Authority.

(5) An authorised person shall

- (a) establish clear lines of responsibility and accountability for protection and safety for the sources for which they are authorised, and shall establish organizational arrangements for protection and safety;
- (b) ensure that any delegation of responsibilities by a principal party is documented;
- (c) for the sources for which they are authorised and for which a safety assessment is required, conduct the safety assessment and keep the assessment up to date;
- (d) for the sources for which they are authorised and for which the Authority requires a prospective assessment to be made for radiological environmental impacts, conduct the assessment and keep the assessment up to date;
- (e) assess the likelihood and magnitude of potential exposures, their likely consequences and the number of individuals who may be affected by them;

- (f) have in place operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system;
- (g) establish procedures for reporting on and learning from accidents and other incidents;
- (h) establish arrangements for the periodic review of the overall effectiveness of the measures for protection and safety;
- (i) ensure that adequate maintenance, testing and servicing are carried out as necessary so that sources remain capable of fulfilling their design requirements for protection and safety throughout their lifetime;
- (j) ensure safe management of and control over all radioactive waste that is generated, and shall dispose of that waste in accordance with the regulatory requirements.
- (k) submit annual operating report for nuclear installations, and radioactive source category 1 and 2 facilities within the first quarter of the following year using the format issued by the Authority.

Clearance

20.(1) A source, including a substance, material or an object used for the purpose of authorised practices that satisfies the clearance levels specified in the First Schedule is exempt from further compliance requirements under these Regulations.

(2) A source, including a material, a substance or an object that is used in notified and authorised practice and which for the purposes of regulatory control requires clearance shall be approved by the Authority.

(3) A source that for the purposes of regulatory control has been cleared by the Authority shall not be subject to the requirements for notification, registration and licensing unless that is specifically required by these Regulations.

Radiation Protection Performance Requirements

General requirements of radiation protection

- 21. (1)** A person who, under these Regulations, has responsibility for protection and safety shall,
- (a) ensure that the principles of radiation protection are applied for all exposure situations;
 - (b) in each planned exposure situation that requires justification for any action taken, ensure that no practice is undertaken unless it is justified;
 - (c) in each emergency exposure situation and in an existing emergency situation that requires justification for any action taken, ensure that any protective action or remedial action is justified and is undertaken in a manner that achieves the objectives set out in the protection strategy;
 - (d) in all exposure situations, ensure that protection and safety is optimised; and
 - (e) in each planned exposure situation other than a medical exposure situation, ensure that, specified dose limits are not exceeded.

(2) The application of the requirements for protection and safety shall be commensurate with the radiation risks associated with the exposure situation.

Justification of practice

22. (1) An applicant for authorisation shall comply with the requirements of the Authority for the justification of any type of practice and for review of the justification, that is necessary for authorisation.

(2) The applicant shall in justification of a practice, provide sufficient evidence to show that the practice is more benefit to the individuals or to society that are exposed, than any radiation harm that it might cause, taking into account the social, economic and other relevant factors.

(3) The applicant shall provide sufficient information and evidence on the benefits to be derived from the practice to support the justification of the practice.

(4) The following practices are not considered to be justified:

- (a) a practice, other than a justified practice that involves medical exposure, that results in an increase in activity, by the deliberate addition of radioactive substances in food, feed, a beverage, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by a person, or by application to a person;
- (b) a practice that involves the unnecessary use of a radiation or a radioactive substance in a commodity or in a product including a toy, personal jewellery or adornment, which is likely to or intended to cause an increased activity as a result of the use of the commodity or product;
- (c) human imaging that uses radiation
 - (i) as a form of art or for publicity purposes;
 - (ii) for theft detection purposes;
- (d) human imaging using radiation
 - (i) that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication,
 - (ii) for the detection of concealed objects for anti-smuggling purposes, and
 - (iii) for the detection of concealed objects that can be used for criminal acts that pose a national security threatexcept in some circumstances, the Authority decides that the justification of such human imaging for specific practices is to be considered; and
- (e) any other practice determined by the Authority.

Dose limits

23.(1) An authorised person shall comply with

- (a) the established dose limits specified in the Second Schedule for occupational exposures and public exposures in planned exposure situations; and
- (b) any additional restriction that is determined by the Authority to be required to ensure that the dose limits specified in the Second Schedule are not exceeded as a result of possible combinations of doses from exposures arising from different authorised practices.

(2) An authorised person shall ensure that the exposure of an individual resulting from the practice of that authorised person does not exceed the dose limits specified in the Second Schedule with regard to effective dose or the equivalent dose to tissues or organs.

Optimisation of protection and safety

24.(1) An authorised person shall

- (a) comply with the established requirements for the optimisation of protection and safety;
- (b) provide documentation that addresses the optimisation of protection and safety; and
- (c) comply with the established or approved
 - (i) constraints on dose and on risk as appropriate; or
 - (ii) process for establishing the constraints, to be used in the optimisation of protection and safety.

(2) An authorised person shall ensure that protection and safety is optimised.

(3) The occupational exposure and public exposure measures for the optimisation of protection and safety shall range from intuitive qualitative analysis to quantitative analysis based on decision aiding techniques, that are sufficient to take into account in a coherent way all relevant factors in order to

- (a) determine optimised protection and safety measures for the prevailing circumstances, with account taken of the available protection and safety options as well as the nature, magnitude and likelihood of exposures; and
- (b) establish criteria, on the basis of the results of the optimisation, for the restriction of the magnitudes of exposures and of their probabilities by means of measures for preventing accidents and mitigating their consequences.

Dose constraints

25. (1) An authorised person shall, for the purpose of optimisation of radiation protection and safety for occupational exposure, public exposure and medical exposure, comply with the guidance provided by the Authority for the establishment of dose constraints in a manner that ensures that for

- (a) occupational exposure, the constraint on individual dose to workers that is established sets a range of options in optimising protection and safety in respect of each specified source;
- (b) public exposure, the dose constraint is a source related value that is established taking into account the doses from planned operations of all sources under the control of the authorized person; and
- (c) medical exposure, the dose constraint is a source related value that optimizes the protection of
 - (i) care givers and comforters of patients undergoing radiological procedures; and
 - (ii) volunteers subject to exposure as part of a programme of biomedical research.

(5) An authorised person shall ensure, as appropriate, that relevant constraints concerning occupational exposure and public exposure are used in the optimisation of protection and safety for any particular source within a practice.

Management for protection and safety

26.(1) An authorised person shall ensure that protection and safety is effectively integrated into the overall management of the organisation for which that authorised person is responsible.

(2) An authorised person shall in the discharge of the authorised functions demonstrate commitment to protection and safety at the highest levels within the organisation for which that person is responsible.

(3) An authorised person shall ensure that the management system of the organisation to which the authorisation relate is designed and implemented to enhance protection and safety and in this regard

- (a) applies the requirements for protection and safety coherently with other requirements, including requirements for operational performance and guidelines for security;
- (b) describes the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are fulfilled;
- (c) ensures that protection and safety is not compromised by other requirements;
- (d) provides for the regular assessment of performance for protection and safety and the application of lessons learned from experience; and
- (e) promotes safety culture.

(4) An authorised person shall ensure that protection and safety elements of the management system of the organisation to which the authorisation relate are commensurate with the complexity of and the radiation risks associated with the activity.

(5) An authorised person shall ensure the effective compliance with the requirements for protection and safety in the management system of the organisation to which the authorisation relate.

(6) An authorised person shall promote and maintain a safety culture that

- (a) promotes individual and collective commitment to protection and safety at all levels of the organisation;
- (b) ensures a common understanding of the key aspects of safety culture within the organisation;
- (c) provides the means by which the organisation supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interactions between individuals, technology and the organisation;
- (d) encourages the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures that deal with protection and safety;
- (e) ensures accountability of the organisation and of individuals at all levels for protection and safety;
- (f) encourages open communication with regard to protection and safety within the organisation and with relevant parties, as appropriate;
- (g) encourages a questioning and learning attitude and discourages complacency with regard to protection and safety; and

- (h) provides a means by which the organisation continually seeks to develop and strengthen its safety culture.

Quality assurance, quality control and quality management system

27. An authorised person shall establish a management system of the organisation to which the authorisation relate that provides

- (a) adequate assurance that the specified requirements relating to protection and safety are satisfied;
- (b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures; and
- (c) quality management mechanisms and procedures for optimisation of protection and safety.

Human factor

28. (1) An authorised person shall ensure that the personnel on whom protection and safety depend,

- (a) are appropriately trained and qualified, as specified by the Authority;
- (b) understand their responsibilities;
- (c) perform their duties with appropriate judgment according to defined procedures; and
- (d) undergo periodic retraining.

(2) An authorised person and other persons having specified responsibilities in relation to protection and safety, as appropriate shall

- (a) take into account human factors, and
- (b) support good performance and good practices

to prevent human and organisational failures.

(3) An authorised person shall for the purpose of

- (a) facilitating the safe use of equipment and minimising the contribution of human errors to accidents or incidents, and
- (b) reducing the possibility that indications of normal conditions and abnormal conditions could be misinterpreted

in co-operation with suppliers or manufactures, apply sound ergonomic principles in the possession, receipt and design of equipment and preparation of operating procedures.

(4) An authorised person shall provide appropriate equipment, safety systems and procedures to

- (a) reduce, as far as practicable, the possibility of human errors leading to unplanned exposure of any person;
- (b) provide a means to detect and prevent human errors and correct or compensate for them; and
- (c) facilitate early intervention in the event of an accident due to failure of safety systems or failure of measures for protection and safety.

Radiation Protection Officer

29.(1) An authorised person shall, in consultation with the Authority, appoint a qualified person to be appointed as a Radiation Protection Officer in relation to the operations of that authorised person.

(2) For the purposes of sub regulation (1), where the operations of an authorised person consists of practices carried on in two or more premises and involves the use of ionising radiation, a Radiation Protection Officer shall be appointed in respect of each.

(3) The qualifications of a Radiation Protection Officer shall be determined on the basis of the level of academic knowledge and professional experience that is essential for the management of the levels of risk associated with the authorised practice or source within the practice.

(4) A Radiation Protection Officer shall

- (a) advise the authorised person in matters that pertain to
 - (i) the protection of workers, patients, the public and the environment from ionising radiation; and
 - (ii) the security of radiation sources;
- (b) advise the user regarding formulation, the observance and enforcement of local rules for the protection of workers, patients, the public and the environment from ionising radiation;
- (c) advise and liaise with the Authority regarding the implementation of radiation protection measures at the work place of that Officer;
- (d) monitor the purchase and stock levels, the safe use, handling, transport and storage of radioactive materials;
- (e) inspect and monitor the facility for radiation protection and safety;
- (f) assist in the training of all relevant aspects of radiation protection;
- (g) ensure that all workers are monitored regularly with personal dosimetry badges and a record system kept of the doses received;
- (h) ensure that all reports of the work under the officer are made available to the Authority at the frequency specified by the Authority; and
- (i) assist the Authority in the enforcement of these Regulations in relation to the functions of that officer or that expert and assist the authorised person in keeping the records required by the Authority.

Radiation Safety Committee

30.(1) An authorised person shall, for each practice, in consultation with the Authority, constitute a Radiation Safety Committee, consisting of

- (a) a representative of management;
- (b) a qualified expert;
- (c) a representative of workers; and
- (d) the Radiation Protection Officer.

(2) The Radiation Safety Committee shall

- (a) review the relevant local rules and radiation protection and safety programmes;

- (b) ensure that the authorised person has an emergency response and preparedness plan which has been approved by the Authority;
 - (c) ensure that drills and exercises on emergency response for workers are organised regularly at least once a year; and
 - (d) advise the authorised person on how to achieve safety and security of sources.
- (3) An authorised person shall comply with the mechanism established by the Authority for the formal recognition and engagement of Radiation Protection Officers and qualified experts .

Safety assessments

31. (1) An applicant for authorization to operate a facility or undertake an activity that creates a radiation risk shall comply with the requirements established by the Authority for the conduct of safety assessment.

(2) The Authority shall not grant authorisation to an applicant if

- (a) that applicant has not submitted to the Authority a safety assessment report; and
- (b) the safety assessment report of the applicant has not been reviewed and assessed by the Authority.

(3) The authorised person shall conduct a safety assessment that is either generic or specific to the practice or source for which they are responsible.

(4) An authorised person shall, in order to

- (a) identify the ways through which normal exposures and potential exposures can be incurred, taking into consideration the effect of events external to the sources as well as events directly involving the sources and their associated equipment,
- (b) determine the expected magnitude of normal exposures,
- (c) estimate the probabilities and magnitude of potential exposures, and
- (d) assess the quality and extent of the protection and safety provisions

make assessments related to protection and safety measures for sources within the practice at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance, and decommissioning.

(5) The safety assessment shall include a systematic and critical review of

- (a) the operational limits and conditions for the operation of the facility or activity;
- (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 cause 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 those 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; and
- (g) any uncertainties or assumptions and their implications for protection and safety.

(6) An authorised person shall in the safety assessment take account of

- (a) factors that could precipitate a substantial release of radioactive material, the measures available to prevent or to control that 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 precipitate a smaller but continuing release of radioactive material, and the measures available to detect and to prevent or to control that 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 the use of redundant and diverse safety features, which are independent of each other and in respect of which the failure of one does not result in failure of any other, is appropriate to restrict the likelihood and the magnitude of potential exposure.
- (7) An authorised person shall
 - (a) ensure that the safety assessment is documented and, where appropriate, that it is independently reviewed under the relevant management system; and
 - (b) perform additional reviews of the safety assessment as necessary to ensure that the technical specifications or conditions of use continue to be adhered to when
 - (i) significant modifications to the facility or to the operating procedures or maintenance procedures of the facility are envisaged;
 - (ii) significant changes occur on the site that could affect the safety of the facility or of activities on the site;
 - (iii) information on operating experience, or information about accidents and other incidents that could result in exposures, indicates that the current assessment might be invalid;
 - (iv) any significant changes in activities are envisaged; and
 - (v) any relevant changes in guidelines or standards have been made or are envisaged.
- (8) Where there is the need to improve protection and safety as result of safety assessment or for any other reason and the improvement requires modifications, the modifications shall only be made after the implications of the modification for protection and safety have been assessed and found to be favourable.
- (9) An authorised person shall ensure that in the implementation of improvements, the optimisation of protection and safety is prioritised.

Monitoring and verification of compliance

- 32.** (1) An authorised person shall develop and implement a monitoring and measurement programme to monitor and measure the parameters necessary for verification of compliance with the requirements of these Regulations.
- (2) The Authority shall review and approve the monitoring and measurement programme.
- (3) An authorised person who uses the sources in Categories 1, 2 and 3 as specified in the Third Schedule and nuclear installations shall, for the purposes of monitoring and verification of compliance,
- (a) provide suitable equipment and procedures for verifying compliance;
 - (b) properly maintain, test, and calibrate equipment at appropriate intervals with reference to standards that are based on national and international standards;
 - (c) ensure that records, including records of the tests and calibrations carried out in accordance with these Regulations, and of the results of the monitoring and verification of compliance are maintained in the manner required by the Authority; and
 - (d) ensure that the results of monitoring and verification of compliance are shared with the Authority as required.

Records

33. (1) An authorised person shall keep records of the results of monitoring and verification of compliance, which shall include

- (a) records of the tests and calibrations carried out in accordance with these regulations;
- (b) radiation dose records;
- (c) cases of overexposure;
- (d) medical records;
- (e) cases of contamination of skin, hair and clothing;
- (f) area monitoring;
- (g) leakage tests of sealed radioactive sources;
- (h) lists of all sealed radiation sources and their details including
 - (i) location of each source;
 - (ii) radionuclide;
 - (iii) radio activity on a specified date;
 - (iv) serial number or unique identifier;
 - (v) chemical or physical form;
 - (vi) each source use history, including records of movements into and out of the storage location;
 - (vii) receipt, transfer or disposal of each source.
 - (viii) the radiation dose of any person undergoing treatment or diagnosis;
 - (ix) stocks of unsealed radioactive material, with dates of receipt, issue and disposal and the supplier's or manufacture's certificate;
 - (x) investigation of emergencies, accident and disposal of radioactive wastes;
 - (xi) maintenance records of apparatus; and
 - (xii) any other relevant information required by the Authority.

Prevention and mitigation of accidents

34.(1) An authorised person shall ensure that the siting, location, design, manufacture, construction, assembly, commissioning, operation, maintenance, and decommissioning of sources is based on good and appropriate engineering practice which

- (a) takes into account approved codes, standards, technical criteria, scientific developments, and feedback of information on lessons learned from experience;
- (b) is supported by reliable managerial and organisational features, with the purpose of ensuring protection and safety throughout the lifetime of the facility;
- (c) includes adequate safety margins
 - (i) in the design, construction and operation of sources and the facility, so as to ensure reliable performance in normal operation; and
 - (ii) that take into account 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; and
- (d) take account of relevant developments concerning technical criteria, as well as the results of any relevant research on protection and safety and feedback of information on lessons learned from experience.

(2) An authorised person shall ensure that the structures, systems and components, including software, that are related to protection and safety for the facility and activities are designed, constructed, commissioned, operated and maintained in a manner, that is as far as is reasonably practicable,

- (a) prevents reasonably foreseeable accidents in the facility or the activity;
- (b) mitigates the consequences of accidents that do occur;
- (c) provides workers with the information, instruction, training and equipment necessary to restrict potential exposures;
- (d) ensures that there are adequate procedures for the control of the facility and for the management of any reasonably foreseeable accidents;
- (e) ensures that the safety of significant structures, systems and components, including software, and other equipment can be inspected and tested regularly for any degradation that could lead to abnormal conditions or inadequate performance;
- (f) ensures that maintenance, inspection and testing, necessary for the preservation of the provisions for protection and safety can be carried out without undue occupational exposure;
- (g) provides, wherever appropriate, automatic systems for safely shutting off or reducing the release of radiation from facilities in the event that operating conditions are outside the stipulated ranges;
- (h) ensures 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; and
- (i) ensures that all relevant safety documentation is available in the appropriate languages that could be understood by users.

Radiation generators and radioactive sources

35.(1) An authorised person who is a manufacturer or a supplier of radiation generators and radioactive sources shall in the performance of the function specified in this sub regulation, ensure that

- (a) any radiation generator or radioactive source manufactured or supplied by that authorised person is well-designed, well-constructed and well-manufactured and that device in which the radiation generator or radioactive source is used
 - (i) provides for protection and safety in accordance with the requirements of these Regulation;
 - (ii) satisfies the engineering, performance and functional specifications;
 - (iii) satisfies the quality standards commensurate with the significance for protection and safety of the systems and components, including software; and
 - (iv) provides clear displays, gauges and instructions on operating consoles in the appropriate language that could be understood by users.
- (b) the radiation generators and radioactive sources are tested to demonstrate compliance with the relevant specifications;
- (c) information is available, in the appropriate language that could be understood by users on the proper installation and use of the radiation generator or radioactive source and on its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety; and
- (d) the protection provided by shielding and by other protective devices is optimised.

(2) An authorised person shall make suitable arrangements with suppliers of radiation generators and radioactive sources, the Authority and relevant persons for the purposes of

- (a) obtaining information on conditions of use and operating experience that may be important for protection and safety;
 - (b) providing feedback and information that may have implications for protection and safety for other users, or that may have implications for the possibility of improvements in protection and safety for radiation generators and radioactive sources.
- (3) An authorised person shall, in choosing a location to use or to store a radiation generator or radioactive source consider
- (a) factors that could affect the safe management of and control over the radiation generator or radioactive source;
 - (b) factors that could affect occupational exposure and public exposure due to the radiation generator or radioactive source; and
 - (c) the feasibility of taking the factors stated in paragraphs (a) and (b) into account in the engineering design.
- (4) An authorised person shall, in selecting a site for a facility that will contain a large amount of radioactive and nuclear material and that will have the potential for the release of significant amounts of radioactive material, take into account features that might affect
- (a) protection and safety;
 - (b) the integrity or functioning of the facility; and
 - (c) the feasibility of carrying out off-site protective actions if they become necessary.
- (5) An authorised person shall maintain an inventory that includes records of
- (a) the location and description of each radiation generator or radioactive source for which that authorised person is responsible; and
 - (b) the activity and form of each radioactive source for which that authorised person is responsible.
- (6) An authorised person shall, on request, submit to the Authority, specified information from the inventory records of radiation generators and radioactive sources kept by that authorised person.
- (7) An authorised person shall keep a radiation generator and radioactive source under control in order to prevent loss or damage and to prevent any unauthorised person from carrying out any other activity, by ensuring that
- (a) control over a radiation generator or radioactive source is relinquished only in compliance with the relevant requirements specified in the registration or licence;
 - (b) the Authority is promptly notified of information regarding a radiation generator or radioactive source that is lost, missing or not under control;
 - (c) a radiation generator or radioactive source is transferred only if the recipient possesses the necessary authorisation; and
 - (d) an inventory, as required in sub regulation (10), of radiation generators or radioactive sources is checked periodically to confirm that they are in their assigned locations and are under control.

(8) An authorised person shall ensure that sealed sources are categorized in accordance with the categorisation scheme set out in the Third Schedule, and in accordance with the requirements of the Authority.

(9) An authorised person who is a manufacturer of a radioactive source or a device containing a radioactive source shall, as far as is practicable, ensure that the source itself and its container are marked with the symbol recommended by the International Organisation for Standardisation.

(10) An authorised person shall, in cooperation with a manufacturer, ensure that where practicable, sealed sources are identifiable and traceable.

(11) An authorised person shall ensure that

- (a) a radioactive source which is not in use is stored in an appropriate manner for protection and safety;
- (b) protocols are established for the safe management of and the exercise of control over each radiation generator and each radioactive source, including appropriate financial provision, once it has been decided to take them out of use.

Feedback of operating experience

36.(1) An authorised person shall ensure that information on normal operation performance and abnormal conditions and events significant to radiation safety and security is disseminated to the Authority and other persons specified by the Authority.

(2) The information required in sub regulation (1) includes

- (a) details of doses associated with given activities;
- (b) data on maintenance;
- (c) descriptions of events and information on corrective actions; and
- (d) information on operating experience from other relevant facilities and activities.

(3) An authorised person shall, in consonance with a supplier of a source, establish and maintain a mechanism for exchange, between the authorised person and the supplier, of information on use, maintenance, disposal and malfunctioning, relevant for future improvements in the design and construction of the source supplied.

General responsibilities under occupational exposure

37.(1) An authorised person shall comply with the

- (a) established responsibilities by the Authority for authorised person and employers with regards to the application of the requirements for occupational exposure in planned exposure situations;
- (b) established requirements by the Authority for occupational exposures to ensure that protection and safety is optimised; and
- (c) dose limits for occupational exposure specified in Second Schedule except in the special circumstances specified under regulation 47.

(2) The Authority shall not grant authorisation for a new or a modified practice, unless the person who seeks the authorisation has first submitted to the Authority, for review, supporting documents that state

- (a) design criteria and design features that relate to the exposure and potential exposure of workers in all operational states and accident conditions; and
- (b) design criteria and design features of the appropriate systems and programmes for monitoring of workers for occupational exposure in all operational states and accident conditions.

(3) An authorised person shall

- (a) comply with the established requirements for monitoring, recording and control of occupational exposures in a planned exposure situation, in accordance with the requirements of these Regulations;
- (b) develop, for review by the Authority, a monitoring programme that ensures that the requirements with regard to occupational exposure in a planned exposure situation are fulfilled;
- (c) seek approval or authorisation from the Authority for providing services for individual monitoring and calibration services;
- (d) submit, for review by the Authority, periodic reports on occupational exposure including results of monitoring programmes and dose assessments ;
- (e) submit to the Authority, exposure records and results of the assessment of doses from occupational exposure; and
- (f) comply with the requirements on the control of occupational exposure for an authorised practise.

(4) An authorised person and employers shall, for workers who are engaged in activities in which they are or could be subject to occupational exposure in planned exposure situations,

- (a) provide for the protection of the workers of that person against occupational exposure;
- (b) comply with the relevant requirements on occupational exposure in planned exposure situations of these Regulations.
- (c) ensure that
 - (i) the occupational exposure is controlled to the extent that the relevant dose limits for occupational exposure specified in Second Schedule are not exceeded;
 - (ii) protection and safety are optimised in accordance with the requirements of these Regulations;

- (iii) any decision with regard to a measure for protection and safety is recorded and made available in the manner specified by the Authority to the relevant persons, through their representatives, where appropriate;
- (iv) policies, procedures and organisational arrangements for protection and safety particularly design measures and technical measures are established to implement the relevant requirements of these Regulations;
- (v) suitable and adequate facilities, equipment and services for protection and safety commensurate in type and extent with the expected likelihood and magnitude of occupational exposure are provided;
- (vi) necessary health surveillance for the workers and health services for the workers are provided;
- (vii) appropriate monitoring equipment and personal protective equipment are provided and arrangements are made for their proper use, calibration, testing and maintenance;
- (viii) suitable and adequate human resource and appropriate training in protection and safety, as well as periodic retraining as required to ensure the necessary level of competence, are provided;
- (ix) adequate records are maintained in accordance with the requirements of these Regulations;
- (x) arrangements are made to facilitate consultation of and cooperation with workers, through their representatives, where appropriate, with regard to protection and safety on all measures necessary to achieve the effective application of these Regulations; and
- (xi) necessary conditions for promoting safety culture are provided.

(5) An authorised person and employers shall

- (a) involve workers, through their representatives where appropriate, in the optimisation of protection and safety;
- (b) establish and use, constraints as part of optimisation of protection and safety;
- (c) ensure that any worker of that authorised person who is exposed to radiation from sources within the practice that are not required by or directly related to their work have the same level of protection against the exposure as a member of the public;
- (d) take the administrative actions that are necessary to ensure that each worker is informed of the need to adhere to protection and safety requirements as an integral part of a general occupational health and safety programme in which the worker has a specific obligation and responsibility for safety of sources and for self-protection and the protection of others against radiation exposure;
- (e) record any report received from a worker that identifies circumstances that could affect compliance with the requirements of these Regulations, and shall take appropriate action;
- (f) facilitate compliance by workers with the requirements of these Regulations; and
- (g) cooperate to the extent necessary for compliance by all responsible parties with the requirements for protection and safety.

(6) Where a worker is engaged in work that involves or could involve a source that is not under the control of the employer of that worker, the authorised person responsible for the source and the employer shall cooperate, to the extent necessary, to ensure compliance with the requirements of these Regulation.

- (7) Cooperation under sub regulation (6), includes
- (a) the development and use of specific restrictions on exposure and other means to institute measures for the protection and safety of the worker who is engaged in the work;
 - (b) specific assessment of the doses received by the workers; and
 - (c) a clear documentation of the responsibilities for protection and safety and the allocation of those responsibilities to the employer and to the authorised person.
- (8) As part of the cooperation under sub regulations (6) and (7), the authorised person responsible for the source or for the exposure shall
- (a) obtain from the employer, the previous occupational exposure history of the worker and any other necessary information;
 - (b) provide appropriate information to the employer, including any available information relevant for compliance with the requirements of these Regulations that the employer requests;
 - (c) provide both the worker and the employer with the relevant exposure records.

Conditions of service

- 38.(1) An authorised person or employer shall not use
- (a) the existence or possibility of occupational exposure as the basis for determining the conditions of service of a worker; and
 - (b) special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits to offset the provision of proper protection and safety measures in accordance with the requirements of these Regulations.
- (2) An authorised person or employer shall, in writing, inform each female worker who is likely to enter a controlled area or a supervised area of
- (a) the risk that exposure poses to the embryo or foetus of a pregnant woman;
 - (b) the importance of a female worker of notifying her employer as soon as that female worker suspects that she is pregnant; and
 - (c) the risk that the ingesting of a radioactive substance poses to an infant who is being breast fed.
- (3) An authorised person or employer shall not exclude a female worker from work by reason of
- (a) a notice of pregnancy given by that female worker;
 - (b) a suspicion that that female worker is pregnant; or
 - (c) that female worker breast feeding a baby.
- (4) An authorised person or employer, who
- (a) is given notice of a pregnancy by a female worker, or
 - (b) has a female worker who is breast feeding
- shall manage the working conditions in respect of occupational exposure of that female worker in a manner that ensures that the embryo or fetus or the infant is afforded the same broad level of protection as is required for members of the public.

(4) An authorised person or employer shall, where it has been determined, either by the Authority or in the framework of the health surveillance programme required by these Regulations, that a worker, for health reasons, may no longer continue in employment involving occupational exposure, make every reasonable effort to provide that worker with a suitable alternative workplace or employment.

(5) An authorised person or employer shall not, in the facility or activity in which that authorised person operates, allow

- (a) a person under the age of sixteen to be exposed to occupational exposure; or
- (b) a person under the age of eighteen years to work in a controlled area except where that person is under supervision for the purpose of
 - (i) training for employment in which that person is or could be exposed to occupational exposure; or
 - (ii) studies in which sources are used.

Classification of areas

39.(1) An authorised person shall designate an area as a controlled area in which specific measures for protection and safety are or could be required for the purpose of

- (a) controlling exposures or preventing the spread of contamination in normal operation; and
- (b) preventing or limiting the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions.

(2) An authorised person shall, in the determination of the boundaries of a controlled area, take into account

- (a) the magnitude of the exposures expected in normal operation;
- (b) the likelihood and magnitude of exposures in anticipated operational occurrences and in accident conditions; and
- (c) the type and extent of the procedures required for protection and safety.

(3) An authorised person shall

- (a) delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;
- (b) where a source is only intermittently brought into operation or energised, or is moved from place to place, delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances and that specify exposure times;
- (c) display the symbol recommended by the International Organisation for Standardisation and shall display instructions at access points to and at appropriate locations within the controlled area;
- (d) establish local rules and procedures for controlled areas and measures for protection and safety, including, as appropriate, physical measures to control the spread of contamination;
- (e) restrict access to controlled areas by means of administrative procedures including the use of work permits, and physical barriers, which may be in the nature of locks or interlocks, with the degree of restriction being commensurate with the likelihood and magnitude of exposures;
- (f) 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;

- (g) 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 any 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;
- (h) periodically review conditions to assess whether there is a need to modify the measures for protection and safety or the boundaries of controlled areas; and
- (i) provide appropriate information, instruction and training for persons working in controlled areas.

(4) An authorised person shall designate an area as a supervised area, where the area has not been designated as a controlled area but the use of the area requires occupational exposure conditions to be kept under review, even though specific measures for protection and safety are not normally needed.

(5) An authorised person shall, taking into account the nature, likelihood and magnitude of exposures or contamination in a supervised area,

- (a) delineate the supervised areas by appropriate means;
- (b) display approved signs, as appropriate, at access points to the supervised area; and
- (c) 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.

Local rules, supervision and personnel protective equipment

40.(1) An authorised person or employer shall, in consultation with workers, or the representatives of the workers,

- (a) establish in writing, local rules and procedures that are necessary for protection and safety of the workers;
- (b) include in the local rules and procedures any relevant investigation level or authorised level, and the procedures to be followed in the event that any such level is exceeded;
- (c) make the local rules and procedures and the measures for protection and safety known to the workers to whom they apply and to other persons who may be affected by them;
- (d) ensure that any work in which workers are or could be subject to occupational exposure is adequately supervised and that the rules, procedures, and measures for protection and safety are observed; and
- (e) designate, a radiation protection officer in accordance with criteria established by the Authority.

(2) An authorised person or employer shall ensure that

- (a) each worker is provided with suitable and adequate personal protective equipment that complies with relevant standards or specifications, including
 - (i) protective clothing;
 - (ii) respiratory protective equipment the characteristics of which are made known to the user;
 - (iii) protective apron, protective gloves and organ shield.

- (b) where the circumstances require, a worker is given adequate instruction in the proper use of the respiratory protective equipment, including testing for good fit;
- (c) a task that requires the use of a special personal protective equipment is assigned only to a worker, who on the basis of medical advice, is capable of safely handling the equipment;
- (d) every personal protective equipment, including equipment for use in an emergency, is maintained in proper condition and tested at regular intervals; and
- (e) where the use of personal protective equipment is required for a task, account is taken of
 - (i) any additional exposure arising from the additional time that it takes to use the protective equipment in performing the task;
 - (ii) the inconvenience that the use of that equipment may entail; and
 - (iii) any non-radiological risks that might be associated with using the personal protective equipment while performing the task.

Compliance by authorised persons and workers

41.(1) An authorised person or employer shall minimise the use of administrative controls and personal protective equipment for protection and rather apply a combination of preventive measures that are, in order of priority, based on

- (a) engineered controls;
- (b) administrative controls;
- (c) personal protective equipment; and
- (d) satisfactory working conditions.

(2) An authorised person or employer shall,

- (a) provide for each worker of that authorised person
 - (i) adequate information, instruction and training for protection and safety;
 - (ii) adequate information on health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions;
 - (i) adequate instruction and training and periodic retraining in protection and safety; and
 - (ii) adequate information on the significance and impact of their actions in respect of protection and safety;
- (b) provide for a worker who could be involved in or affected by the response to and emergency, appropriate information, adequate instruction and training, and periodic retraining, in respect of protection and safety;
- (c) maintain records of the training provided to individual workers.

(3) A worker to whom this regulation relates shall

- (a) fulfill their obligations and carry out their duties for protection and safety.
- (b) comply with the applicable rules and procedures for protection and safety as specified by the authorised person;
- (c) use appropriately, the monitoring equipment and personal protective equipment provided;
- (d) cooperate with the authorised person with regard to protection and safety, and programmes for workers' health surveillance and programmes for dose assessment;

- (e) provide to the authorised person information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for the worker and others;
- (f) abstain from any willful action that could put the worker or others in a situation that would not be in accordance with the requirements of these Regulations;
- (g) accept information, instruction and training in protection and safety that will enable the worker and others to conduct their work in accordance with the requirements of these Regulations.

(4) A worker who identifies a circumstance or a situation that could adversely affect protection and safety shall report the circumstance or situation to the authorised person as soon as possible.

Exposure assessment

42. (1) An authorised person or employer, as well as self-employed persons, shall arrange with an authorised or approved dosimetry service provider to assess the occupational exposure of workers, on the basis of individual monitoring where appropriate.

(2) An authorised person or employer shall, for each worker who works in a controlled area and is susceptible to receiving a significant dose from occupational exposure,

- (a) undertake individual monitoring where that is appropriate, adequate and feasible; or
- (b) where individual monitoring is not appropriate, adequate or feasible, assess the occupational exposure on the basis of the results of workplace monitoring and information on the locations and durations of exposure of the worker.

(3) An authorised person or employer shall, for each worker who regularly works in a supervised area or who enters a controlled area only occasionally, assess the occupational exposure on the basis of the results of workplace monitoring or individual monitoring, as is appropriate.

(4) An employer shall

- (a) ensure that any worker who could be subject to contamination are identified, including an worker who uses respiratory protective equipment; and
- (b) arrange for appropriate monitoring, to the extent necessary; to demonstrate the effectiveness of the measures for protection and safety and to assess intakes of radionuclides and the committed effective doses.

Monitoring of workplace

43. (1) An authorised person, in co-operation with employers where appropriate, shall establish, maintain and keep under review a programme for the monitoring of the workplace commensurate with the nature of the source and the risks associated with the source.

(2) The nature and frequency of monitoring of a workplace shall be

- (a) sufficient to enable
 - (i) evaluation of the radiological conditions in all workplaces;
 - (ii) assessment of the exposure of workers in controlled areas and supervised areas;
- and

- (iii) review of the classification of controlled areas and supervised areas
- (b) based on
 - (i) dose rate, activity concentration in air and surface contamination, and their expected fluctuations; and
 - (ii) the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions.
- (3) A programme for monitoring of the workplace shall specify
 - (a) the quantities to be measured;
 - (b) where and when the measurements are to be made and at what frequency;
 - (c) the most appropriate measurement method, instrument to be used and the procedure;
 - (d) reference levels and the action to be taken where the levels are exceeded; and
 - (e) calibration of equipment and frequency.
- (4) An authorised person, in co-operation with employers where appropriate, shall maintain records of the findings of the workplace monitoring programme and make the findings available to the workers, or to their representatives.

Health surveillance

- 44.** (1) An authorised person or employer shall make arrangements for appropriate health surveillance programme for the worker.
- (2) A programme for the health surveillance of workers shall be
 - (a) based on the general principles of occupational health; and
 - (b) designed to assess the initial fitness and continuing fitness of workers for their intended tasks.
- (3) If one or more workers are to be engaged in work in which they are or could be exposed to radiation from a source that is not under the control of their employer, the authorised person responsible for the source shall, as a precondition for the engagement of such workers, make with the employer any special arrangements for workers' health surveillance that are needed to comply with the rules established by the Authority.

Records of exposure of worker

- 45.**(1) An authorised person or employer shall maintain records of occupational exposure for each worker for whom assessment of occupational exposure is required under regulation 42 and 43.
- (2) An authorised person or employer shall maintain the occupational exposure of a worker during and after the working life of the worker, at least until the worker or former worker attains or would have attained the age of seventy-five years or for a period of not less than thirty years after the worker ceased being susceptible to occupational exposure, whichever occurs first.
- (3) An authorised person or employer shall
 - (a) grant each worker, access to the occupational exposure record of that worker;

- (b) grant the supervisor of the programme for health surveillance of workers and the Authority, access to the occupational exposure record of each worker;
- (c) facilitate the provision of copies of the occupational exposure record of an worker to a new employer when a worker changes employment;
- (d) establish a process for the retention of exposure records of former workers; and
- (e) in complying with paragraph (a) to (d) , give due care and attention to maintaining the confidentiality of the records.

(5) Where an authorised person or employer ceases to engage in an activity in which the workers are susceptible to occupational exposure, that authorised person or employer shall establish a process for the retention of the records of occupational exposure of the workers by the authorised person or the employer or the Authority as appropriate.

Investigation of accidental occupational exposures

46.(1) An authorised person shall promptly investigate any repeated equipment failure, accident, error, mishap or other unusual occurrence that has the potential to make an worker susceptible to occupational exposure significantly different from that anticipated.

(2) The authorised person shall, with respect to an investigation conducted under sub regulation (1),

- (a) estimate the doses received and their distribution in the worker;
- (b) indicate the corrective measures required to prevent recurrence of the accident;
- (c) implement the corrective measures for which the authorised person is responsible;
- (d) where the occurrence which is the subject of the investigation has the potential to cause or has caused serious injury or death of a worker or involves more than one worker, serve the Authority and other relevant agencies notice, by telephone or electronic mail or any other efficient means of communication, of the occurrence, as soon as practicable, but not later than twenty-four hours after the occurrence;
- (e) where the occurrence which is the subject of the investigation caused only minor injuries, serve the Authority notice by telephone or electronic mail or any other efficient means of communication as soon as possible;
- (f) submit to the Authority, within fifteen days after the occurrence, a written report which states the cause of the occurrence and that includes information on the doses received, corrective measures and any other relevant information; and
- (g) inform the worker of the findings of the investigation conducted.

Special circumstances

47. (1) Where a practice which is justified and for which radiation safety is optimised, presents special circumstances which require a temporary change in some of the dose limitation requirements of these Regulations, an authorised person shall not make the temporary change without the approval of the Authority.

(2) The request for approval shall be in the form of an application submitted to the Authority to provide evidence to demonstrate that

- (a) reasonable effort has been made to reduce exposures and optimise radiation safety provisions in accordance with these Regulations; and

(b) the employers and workers or their representatives as appropriate, have been consulted on the need for and the conditions of the temporary change in the dose limitation requirements.

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

General responsibilities under medical exposure

48.(1) The authorised person shall comply with the provisions of the Authority, in consultation with relevant health authority and professional bodies, that ensure

- (a) relevant persons identified in regulation 4(2) and (3) are
 - (i) authorised to assume their roles and responsibilities;
 - (ii) notified of their duties in relation to protection and safety for individuals undergoing medical exposures;
- (b) a set of diagnostic reference levels are established based on
 - (i) adequate image quality, and
 - (ii) as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstancesfor medical exposures incurred in medical imaging, including image guided interventional procedures.
- (c) dose constraints are established, to enable the requirements to be fulfilled respectively for
 - (i) exposures of carers and comforters; and
 - (ii) exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research;
- (d) criteria and guidelines are established for the release of a patient
 - (i) who has undergone therapeutic radiological procedures using unsealed sources; or
 - (ii) who still retains implanted sealed sources.

(2) An authorised person shall comply with the provisions of the Authority that ensures the authorisation for medical exposures to be performed at a particular medical radiation facility allows personnel such as radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients to assume the responsibilities specified in these Regulations, only if the personnel

- (a) are specialised in the appropriate area of expertise;
- (b) meet the respective requirements for education, training and competence in radiation protection;
- (c) are named in a list maintained up to date by the authorised person.

(3) An authorised person shall ensure that

- (a) a patient, whether symptomatic or asymptomatic, is not subjected to a medical exposure unless
 - (i) 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 it is part of an approved health screening programme;
 - (ii) the exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening programme;
 - (iii) a radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure; and

- (iv) the patient or the legally authorised representative of the patient has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.
- (4) An authorised person shall ensure that an individual is not subjected to a medical exposure
 - (a) as part of a programme of biomedical research unless
 - (i) the exposure has been approved by an ethics committee or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority;
 - (ii) a radiological medical practitioner has assumed responsibility; and
 - (iii) the requirements are fulfilled for the optimisation of protection and safety for persons subject to exposure as part of a programme of biomedical research.
 - (b) as a carer or comforter unless
 - (i) the person has received and has indicated an understanding of the relevant information on the radiation protection and on the radiation risks; and
 - (ii) the requirements for the optimisation of protection and safety for any radiological procedure in which an individual acts as a carer or comforter are fulfilled.
- (5) The authorised person shall ensure that
 - (a) a radiological medical practitioner who performs or oversees a radiological procedure has assumed responsibility for ensuring overall protection and safety for the patients in the planning and delivery of the medical exposure, including the justification of the radiological procedure and the optimisation of protection and safety, in cooperation with the medical physicist and the medical radiation technologist;
 - (b) a radiological medical practitioner, a medical physicist, a medical radiation technologist and any other health professional with a specific duty in relation to protection and safety for patients in a given radiological procedure has a specialty in the appropriate area;
 - (c) sufficient medical personnel and paramedical personnel are available as specified by the health authority and the Authority;
 - (d) for a therapeutic radiological procedure, the requirements of these Regulations for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment are fulfilled by or under the supervision of a medical physicist;
 - (e) for a diagnostic radiological procedure and image guided interventional procedure, the requirements of these Regulations for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment are fulfilled by or under the oversight of a medical physicist or on the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedure and the associated radiation risks; and
 - (f) any delegation of responsibilities by a principal person is documented.

Justification of medical exposure

49. (1) A medical practitioner shall justify any medical exposure prescribed by that practitioner by weighing the diagnostic or therapeutic benefit that the exposure will produce against the radiation detriment that the exposure might cause, taking into account the benefits and risks of available alternative techniques that do not involve the exposure.

- (2) Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional body, and shall be reviewed whenever necessary, taking into account advances in knowledge and technological developments.
- (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 with account being taken particularly of
- (a) patients who are pregnant or breast-feeding or are paediatric;
 - (b) the appropriateness of the request;
 - (c) the urgency of the radiological procedure;
 - (d) the characteristics of the medical exposure;
 - (e) the characteristics of the individual patient; and
 - (f) any relevant information from the previous radiological procedure of the patient.
- (4) Relevant national or international referral guidelines shall be taken into account for the justification of a medical exposure of an individual patient in a radiological procedure.
- (5) Justification for a radiological procedure to be performed as part of a health screening programme for asymptomatic populations shall be carried out by the health authority in conjunction with appropriate professional body.
- (6) An radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of the relevant professional body or the health authority.
- (7) In any procedure under sub regulation (6), the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.
- (8) The medical exposure of a volunteer as part of a programme of biomedical research is not justified unless the exposure is
- (a) in accordance with the Helsinki Declaration [1964] and takes into account
 - (i) the guidelines published by the Council for International Organization for Medical Science (CIOMS) and World Health Organisation (WHO); and
 - (ii) recommendations of International Commission on Radiological Protection (ICRP);
 - (b) subject to
 - (i) the approval of a qualified Ethical Review Committee;
 - (ii) any dose constraints that may be specified; and
 - (iii) to any other applicable laws and regulations.

Optimisation of protection for medical exposures

50.(1) In addition to satisfying the general requirements for optimisation of radiation safety specified in these Regulations, an authorised person, in co-operation with suppliers, shall ensure that medical radiological equipment and software that could influence the delivery of medical exposure are used only if they conform to the applicable standards of the International

Electrotechnical Commission and the International Organisation for Standardisation or to national standards adopted by the Authority.

(2) A radiological medical practitioner, in cooperation with a medical radiation technologist and a medical physicist, and where appropriate with a radio-pharmacist or radio-chemist, shall, for the purpose of

- (a) diagnostic radiological procedures and image guided interventional procedures, ensure the use of the following:
 - (i) appropriate medical radiological equipment and software, and, for nuclear medicine, appropriate radiopharmaceuticals; and
 - (ii) 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 being taken of relevant norms of acceptable image quality established by the relevant professional body and of relevant diagnostic reference levels established by the Authority;
- (b) therapeutic radiological procedures, ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable and consistent with the delivery of the prescribed dose to the planning target volume within the required tolerances; and
- (c) therapeutic radiological procedures in which radio-pharmaceuticals are administered, ensure that for each patient the appropriate radio-pharmaceutical with the appropriate activity is selected and administered, so that the radioactivity is primarily localised in the organ of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.

(3) The authorised person shall ensure that the particular aspects of medical exposures are considered in the optimisation process for

- (a) paediatric patients subjected to medical exposure;
- (b) individuals subjected to medical exposure as part of an approved 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 of a pregnant female patient, in particular, for radiological procedures in which the abdomen or pelvis of that pregnant female patient is exposed to the useful radiation beam or could otherwise receive a significant dose; and
- (f) exposure of a breastfed infant as a result of a lactating female patient having undergone a radiological procedure with radio-pharmaceuticals.

Calibration, clinical dosimetry and quality assurance for medical exposures

51.(1) In accordance with regulation 48 (5) (d) and (e), a Medical Physicist shall ensure that

- (a) sources that give rise to medical exposure are calibrated in terms of appropriate quantities on the basis of nationally and internationally accepted protocols;
- (b) each type of radiotherapy equipment is calibrated in terms of the relevant dosimetric quantities and irradiation conditions and subject to independent verification prior to clinical use;
- (c) unsealed sources for nuclear medicine procedures are calibrated in terms of activity of the radio-pharmaceuticals to be administered;

- (d) calibration of equipment is carried out at
 - (i) the time of commissioning of a unit prior to clinical use;
 - (ii) after any maintenance procedure that may affect the calibration;
 - (iii) at regular intervals approved by the Authority, taking into consideration the manufacturer's recommendation and risk associated with the practice; and
- (e) calibration of a dosimeters used for dosimetry of patients and for calibration of sources is traceable to a secondary standards dosimetry laboratory.

(2) The authorised person shall ensure that dosimetry of a patient is performed and documented by or under the supervision of a medical physicist, using a calibrated dosimeter and following internationally accepted or nationally accepted protocols, including dosimetry to determine in the case of

- (a) diagnostic radiological procedures, typical doses to patients for common procedures;
- (b) image guided interventional procedures, typical doses to patients;
- (c) therapeutic radiological procedures, absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and
- (d) therapeutic radiological procedures with unsealed sources, typical absorbed doses to patients.

(3) The authorised person shall, with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radio-pharmacists and radio-chemists, and in conjunction with other health professionals as appropriate, establish a comprehensive programme of quality assurance for medical exposures.

(4) In the establishment of a comprehensive programme under sub regulation (3) principles established by the World Health Organisation, the Pan American Health Organization and any other relevant professional body shall be taken into account.

(5) The authorised person shall ensure that any programme of quality assurance for medical exposure includes, 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 the acceptance and commissioning of the equipment before its clinical use on patients;
 - (ii) periodically after the acceptance and commissioning;
 - (iii) after any major maintenance procedure that could affect the protection and safety of patients; and
 - (iv) after any installation of new software or modification of existing software that could affect the protection and safety of patients;
- (b) a process for the implementation of corrective actions if measured values of the physical parameters mentioned in paragraph (a) are outside established tolerance limits;
- (c) verification of the appropriate physical and clinical factors used in radiological procedures;

- (d) maintenance of records of relevant procedures and results; and
- (e) periodic checks of the calibration and condition of operation of dosimetry equipment and monitoring equipment.

(5) The authorised person shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that the frequency of the audits is in accordance with the complexity of the radiological procedures being performed and the associated risks.

Dose constraints

- 52.(1) The authorised person shall ensure that
- (a) the relevant dose constraints are used in the optimisation of protection and safety in any radiological procedure in which an individual acts as a carer or comforter; and
 - (b) the dose constraints specified or approved by the ethics committee or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority, on a case by case basis as part of a proposal for biomedical research, are used in the optimisation of protection and safety for persons subject to exposure as part of a programme of biomedical research.

Diagnostic Reference Levels

- 53.(1) The authorised person shall ensure that
- (a) local assessment, on the basis of measurement, is made at approved intervals for those radiological procedures for which diagnostic reference levels have been established; and
 - (b) a review is conducted to determine whether the optimisation of protection and safety for patients is adequate, or whether corrective action is required where in 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.

Pregnant or breast-feeding female patients

- 54.(1) The authorised person shall ensure that
- (a) processes are established for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding;
 - (b) notices in the appropriate languages are posted
 - (i) in public places,
 - (ii) in waiting rooms for patients,
 - (iii) in cubicles and other appropriate places, and
 - (iv) through other means of communication
 to request a pregnant or a lactating female patient or a female patient who suspects she is pregnant to inform the radiological medical practitioner, medical radiation technologist or other similar personnel of that condition, where that female patient is required to undergo a radiological procedure which may include the administration of a radio-pharmaceutical;
 - (c) for the purpose of obtaining information that can be factored into the justification for a radiological procedure and in the optimisation of protection and safety, there is an established procedure for

- (i) ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or foetus where that female patient is pregnant.
- (ii) determining 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 breastfed infant.

Maximum activity for patients in therapy on discharge from hospital

55. (1) The Authorised person shall, before a patient is released following radionuclide therapy, ensure that a procedure has been established for the provision of appropriate radiation protection for members of the public and for family members.

(2) The Authorised person shall ensure that a patient who has undergone a therapeutic radiological procedure with a sealed source or an unsealed source is not discharged from a medical radiation facility 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; and
- (b) the patient or the legal guardian of the patient is provided with
 - (i) written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination; and
 - (ii) information on the radiation risks.

Investigation of accidental medical exposures

56. (1) The authorised person shall

- (a) ensure that all practicable measures are taken to minimise the likelihood of unintended or accidental medical exposures; and
- (b) promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions.

(2) The authorised person shall

- (a) ensure that all practicable measures are taken to minimise the likelihood of unintended or accidental medical exposures arising from
 - (i) flaws in design and operational failures of medical radiological equipment;
 - (ii) failures of and errors in software; or
 - (iii) human error;
- (b) promptly investigate any of the following unintended or accidental medical exposures
 - (i) a therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the value prescribed by the radiological medical practitioner or that could lead to unduly severe secondary effects;
 - (ii) a diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;
 - (iii) an exposure for diagnostic purposes that is substantially greater than was intended;

- (iv) an exposure arising from an image guided interventional procedure that is substantially greater than was intended;
- (v) an inadvertent exposure of an embryo or a foetus in the course of performing a radiological procedure; and
- (vi) any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.

(3) The authorised person shall, with respect to any investigation required under sub-regulation (2),

- (a) calculate or estimate the doses received and their distribution within the patient;
- (b) indicate the corrective actions required to prevent recurrence of that type of unintended or accidental medical exposure;
- (c) implement all the corrective actions that is under the responsibility of that authorised person;
- (d) produce and keep, as soon as possible after the investigation or otherwise required by the Authority, a written record that states the cause of the unintended or accidental medical exposure and includes the information under sub regulation (a) to (c), as relevant, and any other information as required by the Authority;
- (e) for significant unintended or accidental medical exposures or as otherwise required by the Authority, submit a written record, as soon as possible, to the Authority; and
- (f) inform the patient or the legally authorised representative of the patient and the referring medical practitioner of the patient about the unintended or accidental medical exposure.

Reviews and records

57.(1) The authorised person shall ensure that radiological reviews are performed periodically

- (a) at a medical radiation facility and that records are maintained; and
- (b) by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists.

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

(3) The authorised person shall maintain for the period specified by the Authority and make available on request

- (a) personnel records in respect of
 - (i) records of any delegation of responsibilities by a principal person; and
 - (ii) records of training of personnel in radiation protection;
- (b) records of calibration, dosimetry and quality assurance in respect of
 - (i) records of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;
 - (ii) records of dosimetry of patients;
 - (iii) records of local assessments and reviews made with regard to diagnostic reference levels; and
 - (iv) records associated with the quality assurance programme.
- (c) records for medical exposure in respect of

- (i) diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;
- (ii) image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired;
- (iii) nuclear medicine, the types of radio-pharmaceutical administered and their activity;
- (iv) external beam radiation therapy or brachytherapy, a description of the planning target volume, the absorbed dose to the centre of the planning target volume, and the maximum and minimum absorbed doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and in addition, for external beam radiation therapy, the dose fractionation and the overall treatment time;
- (v) exposure records for volunteers subject to medical exposure as part of a programme of biomedical research; and
- (vi) reports on investigations of unintended and accidental medical exposures.

General responsibilities under public exposure

58.(1) An authorised person, supplier or provider of a relevant consumer product shall comply with their responsibilities established by the Authority in relation to the application of the requirements for public exposure in planned exposure situations.

- (2) An authorised person shall comply with
 - (a) the requirements established by the Authority for the optimisation of protection and safety in situations in which individuals are or could be subject to public exposure; and
 - (b) the constraints established or approved by the Authority in respect of dose and risk for the optimisation of protection and safety for members of the public.
- (3) The constraints established or approved by the Authority under sub regulation (2), in respect of a source within a practice, shall take into account,
 - (a) the characteristics of the source and of the practice that are of relevance for public exposure;
 - (b) good practice in the operation of similar sources;
 - (c) dose contributions from other authorised practices or from possible future authorised practices, estimated at the design and planning stage, so that the total dose to members of the public does not at any time after the start of operations of the source exceed the dose limit; and
 - (d) the views of interested parties.
- (4) An authorised person shall comply with
 - (a) the established dose limits specified in the Second Schedule for public exposure; and
 - (b) the operational limits and conditions established or approved by the Authority, relating to public exposure, including authorised limits for discharges.
- (5) The operational limits and conditions shall
 - (a) be used by the authorised person as the criteria for demonstration of compliance after the commencement of operation of a source;
 - (b) correspond to doses below the dose limits with account taken of the results of optimisation of protection and safety;
 - (c) reflect good practice in the operation of similar facilities or activities;
 - (d) allow for operational flexibility;
 - (e) take into account the results of the prospective assessment for radiological environmental impacts that is undertaken in accordance with requirements of the Authority.
- (6) Where a source within a practice is likely to cause public exposure outside the territory or other area under the jurisdiction or control of the State in which the source is located, the authorised person shall
 - (a) perform assessment for radiological impacts that includes those impacts outside the territory or other area under the jurisdiction or control of the State;
 - (b) to the extent possible, comply with the requirements established by the Authority for the control of discharges;

- (c) comply with the procedures established by the Authority, in consonance with the affected State, for the exchange of information and consultations.

(7) An Authorised person shall submit to the Authority for review, the safety assessment and other design related documents that address the optimisation of protection and safety, the design criteria and the design features relating to the assessment of exposure and potential exposure of members of the public before authorisation of a new or modified practice.

(8) An authorised person in cooperation with suppliers and with providers of consumer products shall apply the requirements of these Regulations, and verify and demonstrate compliance with them, in the manner specified by the Authority, in relation to any public exposure delivered by a source for the authorised person together with the suppliers and providers has responsibility.

(9) An authorised person in cooperation with suppliers, in applying the principle of optimisation of protection and safety in the design, planning, operation and decommissioning of a source or for closure and the post-closure period for waste disposal facilities, take into account

- (a) possible changes in any conditions that could affect exposure of a member of the public, including changes in the characteristics and use of the source, changes in environmental dispersion conditions, changes in exposure pathways or changes in values of parameters used for the determination of the representative person;
- (b) good practice in the operation of similar sources or the conduct of similar practices;
- (c) possible buildup 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 in time.

(10) An authorised person, for sources under their responsibility, shall establish, implement and maintain

- (a) policies, procedures and organisational arrangements for protection and safety in relation to public exposure, in accordance with the requirements of these Regulations;
- (b) measures for ensuring:
 - (i) optimisation of protection and safety;
 - (ii) limitation of exposure of members of the public from such sources, in accordance with the authorisation; and
 - (iii) the safety of such sources;
- (c) 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 exposures;
- (d) programmes for appropriate training of personnel having functions relevant to protection and safety of members of the public, as well as periodic retraining as required, to ensure the necessary level of competence;
- (e) provision for appropriate monitoring equipment, monitoring programmes and methods for assessing public exposure;
- (f) adequate records of monitoring programmes; and
- (g) emergency plans, emergency procedures and emergency arrangements, in accordance with the nature and magnitude of the radiation risks associated with the sources.

Control of visitors

- 59.**(1) An authorised person, in cooperation with employers where appropriate shall
- (a) comply with the relevant requirements of these Regulations in respect of public exposure for visitors to a controlled area or a supervised area;
 - (b) ensure that a visitor to a controlled area is accompanied by a person who knows the measures for protection and safety for the controlled area;
 - (c) provide adequate information and instructions to a visitor before the visitor enters a controlled area or a supervised area, in order to provide for protection and safety for the visitor and any other individual who could be affected by the actions of the visitor;
 - (d) ensure that adequate control is maintained over the entry of a visitor to a controlled area or a supervised area, including the use of signs for such areas.

Source of external irradiation

- 60.**(1) An authorised person shall ensure that where a source can give rise to external exposure of a member of the public
- (a) the floor plan and positioning of equipment for each new installation that utilizes the sources, as well as every significant modification to an existing installation, is subject to review and approval by the Authority before commissioning; and
 - (b) shielding and other measures for protection and safety, including access control, are provided in order to restrict public exposure, in particular at open sites including sites for some applications of industrial radiography.
- (2) An authorised person shall ensure, as appropriate, that
- (a) specific provisions for confinement are established for the design and operation of a source that could cause the spread of contamination in areas that are accessible to members of the public;
 - (b) measures for protection and safety are implemented in order to restrict public exposure due to contamination in areas within a facility that are accessible to the public.

Radioactive waste and discharge

- 61.**(1) A person who is engaged in or is in control of an activity that is connected with radioactive waste shall ensure that the radioactive waste and discharges of the radioactive material to the environment are managed in accordance with the authorisation issued by the Authority.
- (2) An authorised person shall, in cooperation with supplier, where necessary,
- (a) ensure that
 - (i) radioactive waste generated is kept to the minimum practicable in terms of both activity and volume;
 - (ii) radioactive waste is managed in accordance with the requirements of these Regulations, *Regulation on radioactive waste management*, and other applicable International Atomic Energy Agency (IAEA) standards, and in accordance with the relevant authorisation;
 - (iii) there is separate processing of radioactive waste of different types, where warranted by differences in factors including radionuclide content, half-life, activity concentration, volume, and physical and chemical properties, taking into account the available options for storage and disposal of radioactive waste, without precluding the mixing of radioactive waste for purposes of protection and safety;

- (iv) any activity for the predisposal management of and for the disposal of radioactive waste is conducted in accordance with the requirements of the *Regulation on radioactive waste management* and applicable IAEA standards, and in accordance with the authorisation;
 - (b) maintain an inventory of radioactive waste that is generated, stored, transferred or disposed of; and
 - (c) develop and implement a strategy for radioactive waste management which includes appropriate evidence that protection and safety is optimised.
- (3) An authorised person, acting in cooperation with a supplier where necessary, shall, in applying for an authorisation for discharges,
- (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 pathway by which discharged radionuclides could give rise to exposure of a member of the public;
 - (c) assess the doses to the representative person due to the planned discharges;
 - (d) consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the Authority;
 - (e) submit to the Authority findings of paragraph (a) to (d) as an input to the establishment by the Authority of the authorised limits on discharges and conditions for their implementation.
- (4) An authorised person shall ensure that the operational limits and the conditions that relate to public exposure are met in accordance with regulation 48 (4) and (5).
- (5) Where a source within a practice could cause public exposure outside the territory or other area under the jurisdiction or control of the State in which the source is located, the Authority shall
- (a) ensure that the assessment for radiological impacts includes those impacts outside the territory or other area under the jurisdiction or control of the State;
 - (b) to the extent possible, establish requirements for the control of discharges;
 - (c) arrange with the affected State the means for the exchange of information and consultations, as appropriate.

Monitoring and reporting of public exposure

- 62.(1)** An authorised person shall put in place programmes for source monitoring and environmental monitoring and shall have the results recorded and made available.
- (2) An authorised person shall as appropriate
- (a) provide monitoring programmes for review and approval by the Authority, which shall be sufficient to
 - (i) verify compliance with the requirements of these Regulations in respect of public exposure in planned exposure situations; and
 - (ii) assess doses from public exposure;
 - (b) provide periodic reports on public exposure including results of monitoring programmes and dose assessments for review by the Authority;
 - (c) make provision for receiving from the Authority, independent monitoring and assessment of the total public exposure due to authorised sources and practices in the country on the basis of monitoring data;

- (d) provide records of discharges, results of monitoring programmes and results of assessments of public exposure to the Authority for maintenance; and
 - (e) receive officers of the Authority for verification of compliance of the authorised practice with the requirements of these Regulations for the control of public exposure.
- (3) The Authority shall publish or make available on request results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure.
- (4) An authorised person shall establish and implement monitoring programmes to ensure that public exposure due to sources under the responsibility of that authorised person is adequately assessed and that the assessment is sufficient to verify and demonstrate compliance with the authorisation.
- (5) The programmes to be established under sub regulation (4) shall include monitoring of
- (a) external exposure due to the sources;
 - (b) discharges;
 - (c) radioactivity in the environment;
 - (d) any other parameters important for the assessment of public exposure.
- (6) An authorised person shall
- (a) maintain appropriate records of the results of the monitoring programmes and estimated doses to members of the public;
 - (b) report or make available to the Authority the results of the monitoring programme at approved intervals, including, as applicable, the levels and composition of discharges, dose rates at the site boundary and in premises open to members of the public, results of environmental monitoring and retrospective assessments of doses to the representative person;
 - (c) report promptly to the Authority any levels exceeding the operational limits and conditions relating to public exposure, including authorised limits on discharges, in accordance with reporting criteria established by the Authority;
 - (d) report promptly to the Authority any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the authorised practice, in accordance with reporting criteria established by the Authority;
 - (e) establish and maintain a capability to conduct monitoring in an emergency in the event of unexpected increases in radiation levels or in concentrations of radionuclides in the environment due to an accident or other unusual event attributed to the authorised source or facility;
 - (f) verify the adequacy of the assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts; and
 - (g) publish or make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure.

Consumer products

- 63.(1)** A provider of consumer products whose services relate to any matter regulated by the Act or these Regulations shall, upon request for authorisation to provide consumer products to the public, provide
- (a) documents to demonstrate compliance with the requirements of regulation 48;
 - (b) to the Authority for consideration, an assessment report indicating the basis for selection of parameters; and
 - (c) details on the end use of consumer product for exemption if applicable;

(2) The Authority shall, where it is satisfied that the provider has complied with the requirements for authorisation, grant to the provider the authorisation to provide the consumer product to the public subject to any conditions that the Authority may specify.

(3) A provider of consumer products under this regulation shall not make a consumer product available to the public unless the use of that product by the public has been justified, and either the use of that products is exempted from the need for authorisation or the provision of that product to the public has been authorised.

(4) The provider of consumer products shall

- (a) comply with the conditions of the authorisation to provide consumer products to the public;
- (b) ensure that consumer products comply with the requirements of regulations 3;
- (c) have an established plan for the servicing, maintenance, recycling or disposal of the consumer products.

(5) A person who designs or manufactures a consumer products that is subject to this Regulation shall, with regard to features that could affect exposure during normal handling, transport and use, as well as in the event of mishandling, misuse, accident or disposal ensure the optimisation of protection and safety.

(6) In pursuance of sub regulation (5), a designer, a manufacturer and a provider of consumer products shall take into account

- (a) the various radionuclides that could be used in consumer products and their radiation types, energies, activities and half-lives;
- (b) the chemical and physical forms of the radionuclides that could be used in consumer products and their significance for protection and safety in normal conditions and abnormal conditions;
- (c) the containment and shielding of radioactive and nuclear materials in consumer products and access to these radioactive substances in normal conditions and abnormal conditions;
- (d) the need for servicing or repair of a consumer product and the ways in which this could be done; and
- (e) any relevant experience with similar consumer products.

(7) The provider of consumer products shall ensure that where practicable, a legible label that

- (a) states that the consumer product contains radioactive and nuclear substances and identifies the radionuclides and their activities,
 - (b) states that the provision of the consumer product to the public has been authorised by the Authority,
 - (c) provides information on required or recommended options for recycling or disposal
- is firmly affixed to a visible surface of each of the consumer products and also printed legibly on each of the retail packaging of the consumer product.

(8) The provider of consumer products shall, in respect of each consumer product, provide clear and appropriate information and instructions on

- (a) the correct method for installation, use and maintenance;
- (b) servicing and repair;
- (c) the radionuclides and their activities at a specified date;
- (d) dose rates in normal operation and during servicing and repair; and
- (e) required or recommended options for recycling or disposal.

(9) The provider of consumer products shall provide each retailer of the consumer product with appropriate information on safety and instructions on their transport and storage.

General responsibilities under safety and security of sources

64.(1) An authorised person shall establish safety and security procedures in a manner that integrates the safety measures and security measures and ensures that the measures do not compromise each other.

(2) For the purposes of sub regulation (1), the authorised person shall

- (a) make appropriate provisions in the design and construction of radioactive material and nuclear material, and other facilities;
- (b) establish controls on access to radioactive material and nuclear installations, and other facilities to prevent the loss of, and the unauthorised removal, possession, transfer and use of, radioactive and nuclear material;
- (c) establish procedures for mitigating the consequences of accidents and failures, which also facilitate measures for dealing with breaches in security that give rise to radiation risks; and
- (d) institute measures for the security of the management of sources.

(3) An authorised person shall ensure the safety and security of a source for which the authorised person is responsible, from the moment of the acquisition of the source and throughout the entire operational life of the source, up to the final disposal of the source.

(4) An authorised person shall ensure that a multilevel system of sequential and independent provisions for protection and safety commensurate with the magnitude and likelihood of the potential exposures is applied to sources for which the authorised person are authorised.

(5) An authorised person shall under sub regulation (4) ensure that if one level of protection were to fail, the subsequent independent level of protection would be available in a manner that such defence in depth is applied for the purposes of

- (a) preventing accidents that may cause unintended exposure;
- (b) mitigating the consequences of any accident that may occur; and
- (c) restoring a source to a safe condition after any accident.

(5) An authorised person shall, in addition to complying with the requirements on safety and security of this regulation, comply with the requirements of the *Nuclear Security Regulations*.

Storage of radiation source

65.(1) An authorised person shall, with regard to storage of radiation sources ensure that

- (a) the design of the place of storage of the source is approved by the Authority;
- (b) a radiation source which is not in use is kept in a place of storage assigned for that purpose only and that the source bears the appropriate warning symbol;
- (c) the place of storage of the source is adequately shielded in a manner that

- (i) prevents the radiation dose at the outside surface of the walls of the source or of the receptacle of the source from exceeding public exposure dose limits as specified in Second Schedule; and
 - (ii) minimises risks from fire or flood;
 - (d) the place of storage is inspected regularly and checked for possible contamination at a frequency that is approved by the Authority;
 - (e) the place of storage is sited and designed in a manner that prevents the source from giving excessive exposure to any person, both during storage and in the course of transfer of radiation sources to and from the store; and
 - (f) where the place of storage is to contain either sealed or unsealed radiation sources that are susceptible to release a radioactive gas or vapour, the store is continuously vented to the open air, or provided with a mechanical venting system that can be operated from outside the store before the store is opened.
- (2) An authorised person shall ensure that
- (a) each radiation source is clearly labelled, in a manner that gives information on their activity, nature and physical form;
 - (b) a container for beta emitting radionuclides has adequate thickness to reduce the primary radiation to a safe level and that considerable additional shielding is provided against bremsstrahlung radiation that may arise from high intensity sources;
 - (c) a gamma emitting and neutron source is stored in a manner that limits the radiation exposure from any other source when one source is being handled;
 - (d) appropriate equipment is provided for storing unsealed radiation sources to prevent external irradiation hazards and internal contamination hazards;
 - (e) records are kept of each stored radiation source and the records are in a form that gives clear information on the type of source activity, times of removal and return, and the name of the person responsible for the source during its absence from the store;
 - (f) inventories are updated periodically; and
 - (g) a bottle that contains radioactive material in liquid form is placed in a non-fragile vessel, large enough to hold the entire contents of the bottle in case of breakage.

Design and procurement of sources

- 66.**(1) An authorised person, in co-operation with a relevant supplier, shall
- (a) ensure that on procurement of new equipment containing radiation generators or sources, the equipment and sources conform to the applicable standards of the International Electrotechnical Commission (IEC) and the International Standards Organisation (ISO) or equivalent standards approved by the Authority;
 - (b) ensure that sources and equipment are tested to demonstrate compliance with the appropriate specifications;
 - (c) conduct a safety and security assessment, either generic or specific, for the sources for which the authorised person is responsible, according to the requirements of regulation 31;
 - (d) ensure that performance specifications, operating and maintenance instructions, including protection and safety instructions, are provided in English and in compliance with the relevant IEC and ISO standards with regard to accompanying documents;

- (e) ensure that, the operating terminology and operating values are displayed on operating consoles or other control systems in English and in the language of the supplier; and
- (f) where appropriate, ensure through an agreement concluded between the authorised person and the supplier that the supplier will take back the source when it is no longer in use.

Accountability and security of sources

67.(1) An authorised person shall comply with the radiation source accountability and security provided in the *Nuclear Security Regulations*.

Investigations

68. (1) An authorised person shall, as specified by the Authority, conduct an investigation where

- (a) a quantity or operating parameter relating to protection and safety exceeds the investigation level or is outside the stipulated range of operating conditions;
- (b) an equipment failure, accident, error, mishap or other unusual event or condition occurs that has the potential for causing a quantity to exceed the relevant limit or operating restriction; or
- (c) a nuclear security event occurs.

(2) An authorised person shall conduct an investigation as soon as possible after an event and shall prepare a written record of the causes, or suspected causes of the event, including a verification or determination of any doses received or committed and recommendations for preventing the recurrence of the event and the occurrence of similar events.

(3) An authorised person shall submit to the Authority and to any other relevant person, a written report of any formal investigation relating to events, in the form prescribed by the Authority, including exposures giving rise to doses that exceed a dose limit and shall also immediately report to the Authority any event in which a dose limit is exceeded.

Responsibilities under emergency exposure situations

69.(1) An authorised person shall comply with the national established integrated and coordinated emergency management system that provides for an emergency response in respect of protection of human life, preservation of health and the conservation of the environment in the event of a nuclear or radiological emergency.

(2) The established emergency management system under sub regulation (1) shall

(a) be designed to

(i) be commensurate with the results of a radiation hazard assessment conducted; and

(ii) assure an effective emergency response to reasonably foreseeable events including very low probability events in connection with facilities or activities.

(b) be integrated, to the extent practicable, into an all-hazards emergency management system.

(c) provide for essential elements at the scene of the event, at the local level, and at the national and international levels that include

(i) hazard assessment;

(ii) development and exercising of emergency plans and emergency procedures;

(iii) clear allocation of responsibilities to persons and organisations having roles in the arrangements for emergency preparedness and response;

(iv) arrangements for efficient and effective cooperation and coordination among organisations;

(v) reliable communication, including public information;

(vi) optimised protection strategies for the implementation and the termination of measures for the protection of members of the public who could be susceptible to exposure in an emergency, including relevant considerations for protection of the environment;

(vii) procedures for the protection of emergency workers;

(viii) education and training, including training in radiation protection, of persons involved in emergency response and exercising of emergency plans and emergency procedures;

(ix) preparations for the transition from emergency exposure situation to existing exposure situation;

(x) arrangements for the medical response and the public health response in an emergency;

(xi) provision for individual monitoring and environmental monitoring and for dose assessment; and

(xii) involvement of relevant persons and interested persons.

(5) An authorised person shall comply with the national arrangements and capabilities for coordination of emergency with the relevant international emergency arrangements.

(6) An authorised person shall, in addition to complying with the requirements on emergency exposure situations of this regulation, comply with the requirements of the *Regulations on Emergency Preparedness and Response for Authorised Persons*.

Preparedness and response to an emergency

70.(1) An authorised person shall comply with the justified and optimised national protection strategies developed by the Authority at the planning stage based on scenarios on hazard assessment, for avoiding deterministic effects and reducing the likelihood of stochastic effects due to public exposure.

(2) The protection strategy under sub regulation (1) shall include the following three successive steps:

- (a) the setting of a reference level expressed in terms of residual dose, typically an effective dose in the range of 20 – 100 mSv that includes dose contributions through all exposure pathways and planning for residual doses to be as low as reasonably achievable below the reference level;
- (b) the development on the basis of the outcome of the optimisation of the protection strategy, the use of the reference level, generic criteria for particular protective actions and other response actions, expressed in terms of projected dose or of dose that has been received and where the numerical values of the generic criteria are exceeded, the protective actions and other response actions, either individually or in combination that are to be implemented; and
- (c) the derivation from the generic criteria of pre-established operational criteria for initiating the different parts of the emergency plan, primarily for the initial phase, once the protection strategy has been optimised and a set of generic criteria has been developed, with the operational criteria providing for,
 - (i) on-scene conditions;
 - (ii) operational intervention levels and emergency action levels expressed in terms of parameters or observable conditions; and
 - (iii) procedures established in advance to revise these operational criteria in an emergency and that take into account the prevailing conditions as they evolve.

(3) Each protective action shall be justified in the context of the protection strategy.

(4) An authorised person shall comply with the national arrangements for emergency preparedness and response that considers

- (a) the dynamic nature of emergencies ;
- (b) the influence that subsequent actions may have on decisions taken early in the emergency response;
- (c) the different conditions that may prevail in different geographical areas; and
- (d) the different requirements that may be needed for the response.

(5) An authorised person shall comply with the national response plan and procedures for emergency exposure situations that considers timely implementation of emergency response arrangements, including arrangements that provide for

- (a) prompt protective actions and other response actions to avoid severe deterministic effects on the basis of observed conditions and, if possible, before any exposure occurs;
- (b) the use of generic criteria dose levels for preventing severe deterministic effects as specified in the fourth Schedule;
- (c) assessing the effectiveness of the protective actions and other response actions taken and modifying them as appropriate;
- (d) comparing residual doses with the applicable reference level, giving priority to those groups for whom residual doses exceed the reference level; and

- (e) implementing further protection strategies that are necessary on the basis of prevailing conditions and available information.

Protection of emergency workers

71.(1) A response organisation and employer shall implement the established programme by the Authority for the management, control and recording of doses received in an emergency by emergency workers.

(2) A response organisation and an employer responsible for ensuring compliance with this regulation shall be specified in the emergency plan.

(3) In an emergency exposure situation, the relevant requirements for occupational exposure in a planned exposure situation shall be applied to each emergency worker, in accordance with a graded approach, except as required in sub regulation (5).

(4) A response organisation and employer shall ensure that an emergency worker is not subject to an exposure in an emergency in excess of 50 mSv except

- (a) for the purposes of saving life or preventing serious injury;
- (b) when undertaking actions to prevent severe deterministic effects and action to prevent the development of catastrophic conditions that could significantly affect people and the environment; or
- (c) when undertaking actions to avert a large collective dose.

(5) In the exceptional circumstances specified in sub regulation (4), the response organisation and the employer shall

- (a) take every reasonable precaution to keep doses to the emergency worker below the values set out in the Fourth Schedule; and
- (b) ensure that an emergency worker who undertakes an action in which the doses could approach or exceed the values set out in Fourth Schedule does so only when the expected benefits to others would clearly outweigh the risks to the emergency worker.

(6) The response organisation and the employer shall ensure that the emergency worker who undertakes an actions in which the doses received might exceed 50 mSv,

- (a) does so voluntarily;
- (b) is clearly and comprehensively informed in advance of the associated health risks and the available measures for protection and safety; and
- (c) to the extent possible is trained in the actions that that emergency worker may be required to take.

(7) A response organisation and employer shall take all reasonable steps to assess and record the doses received in an emergency by each emergency worker and communicate to each of the affected emergency workers, information on the doses received and information concerning the associated health risks.

(8) A worker who receives doses in an emergency exposure situation shall not be precluded from incurring further occupational exposure, however, a qualified medical advice shall be obtained before any further occupational exposure

- (a) at the request of the worker; or
- (b) where the worker has received a dose exceeding 200 mSv.

Transition from an emergency exposure situation to an existing exposure situation

72. (1) An authorised person shall comply with the national procedures for the transition from an emergency exposure situation to an existing exposure situation and the procedures shall take into account the need to provide for different geographical areas to undergo the transition at different times.

(2) The Authority shall take the decision to effect the transition to an existing exposure situation and shall in that regard ensure that the transition is made in a coordinated and orderly manner, by making any necessary transfer of responsibilities between organisations, with the involvement of the relevant authorities and interested parties.

(3) A worker who undertakes

- (a) work, including repairs to a plant or a building,
- (b) an activity for radioactive waste management, or
- (c) remedial actions for the decontamination of the site and surrounding areas,

is subject to the relevant requirements for occupational exposure in planned exposure situations in this regulation.

Responsibility under existing exposure situation

73.(1) An authorised person shall comply with the identified existing exposure situations that has been evaluated by the Authority to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection.

- (2) An authorised person shall comply with
 - (a) the assigned responsibilities by the Authority for protection and safety concerning existing exposures;
 - (b) the appropriate reference levels established by the Authority; and
 - (c) the protection and safety provisions for the management of existing exposure situation in these Regulations and the Act 895.
- (3) The management of existing exposure situations under sub regulation (2)(c) shall include
 - (a) the exposure situations that are included in the scope of existing exposure situations;
 - (b) the general principles underlying the protection strategies developed to reduce exposure when remedial actions and protective actions have been determined to be justified;
 - (c) assignment of responsibilities for the establishment and implementation of protection strategies to the Authority and the implementation of remedial actions and protective actions to the authorised person; and
 - (d) provision for the involvement of interested parties in decisions regarding the development and implementation of protection strategies, as appropriate.
- (4) An authorised person shall comply with the established protection strategy by the Authority that specifies, for an existing exposure situation,
 - (a) the objectives to be achieved by means of the protection strategy; and
 - (b) appropriate reference levels.
- (5) An authorised person shall comply with
 - (a) the implementation of the protection strategy,
 - (b) the evaluation of the available remedial actions and protective actions for achieving the objectives, and for evaluation of the efficiency of the actions planned and implemented, and
 - (c) provision of information to individuals subject to exposure on potential health risks and on the means available for reducing their exposures and the associated risksby the Authority

Justification for protective action and optimisation of protection and safety

- 74.**(1) An authorised person shall comply with the provisions of the Authority that ensure
- (a) remedial actions and protective actions are justified, and that protection and safety is optimised;
 - (b) protection strategy for the management of existing exposure situations is commensurate with the radiation risks associated with the existing exposure situation;
 - (c) remedial actions or protective actions are expected to yield sufficient benefits to outweigh the detriments associated with taking them, including detriments in the form of radiation risks.

(2) An authorised person shall comply with the provisions of the Authority and other persons responsible for remedial actions or protective action that ensure

- (a) the form, scale and duration of such actions are optimised;
- (b) the optimisation process is intended to provide optimised protection for all individuals subject to exposure, priority shall be given to those groups for whom the dose exceeds the reference level;
- (c) taking all reasonable steps to prevent doses from remaining above the reference levels;
- (d) reference levels to be expressed as an annual effective dose to the representative person in the range of 1–20 mSv or other corresponding quantity, the actual value depending on the feasibility of controlling the situation and on experience in managing similar situations in the past.

(4) An authorised person shall comply with periodically reviewed reference levels by the Authority, to ensure that they remain appropriate in the light of the prevailing circumstances.

Remediation of areas with residual radioactive or nuclear material

75.(1) An authorised person shall comply with the processes established by the Authority for

- (a) identifying persons or organisations responsible for areas with residual radioactive or nuclear material;
- (b) establishing and implementing remediation programmes and post-remediation control measures, where appropriate; and
- (c) putting in place an appropriate strategy for radioactive waste management.

(2) An authorised person shall, for the purposes of the remediation of an area with residual radioactive or nuclear material deriving from past activity or from a nuclear or radiological emergency, comply with the provision made in the framework for protection and safety by the Authority for the following:

- (a) the identification of the person or organisation responsible for the contamination of the area and the person responsible for financing the remediation programme, and the determination of an appropriate arrangement for alternative sources of funding if the person or organisation is no longer present or is unable to meet the liability;
- (b) the designation of the person or the organisation responsible for planning, implementing and verifying the results of the remedial actions;
- (c) the establishment of restrictions on the use of or access to the area concerned before, during and, if necessary, after remediation;
- (d) an appropriate system for maintaining, retrieval and amendment of records that cover
 - (i) the nature and the extent of contamination;
 - (ii) the decisions made before, during and after remediation; and
 - (iii) information on verification of the results of the remedial actions, including the results of the monitoring programmes after completion of the remedial actions.

(3) The authorised person shall comply with the strategy by the Authority for radioactive waste management within the framework for protection and safety to deal with any waste arising from the remedial actions.

(4) The persons or organisations responsible for the planning, implementation and verification of remedial actions shall ensure that

- (a) a remedial action plan, supported by safety assessment, is prepared and is submitted to the Authority for approval;
- (b) the remedial action plan provides for the timely and progressive reduction of the radiation risks and for the possible removal of the restrictions on the use of or access to the area where the area has been determined to be safe;
- (c) any additional doses received by members of the public as a result of the remedial actions are justified on the basis of the resulting net benefit, including consideration of the consequent reduction of the annual dose
- (d) in the choice of the optimised remediation option
 - (i) any radiological impact together with any non-radiological impacts on persons and the environment, and technical, societal and economic factors are taken into consideration; and
 - (ii) the cost of the transport and management of radioactive waste, the radiation exposure of and health risks to the workers managing the radioactive waste, and any subsequent public exposure associated with its disposal are taken into account;
- (e) a mechanism for public information is established and interested parties are included in the planning, implementation and verification of the remedial actions, including any monitoring after the remediation;
- (f) a monitoring programme is established and implemented;
- (g) a system for maintaining adequate records relating to the existing exposure situation and to actions taken for protection and safety is in place; and
- (h) procedures are established for reporting of any abnormal conditions relevant to protection and safety to the Authority.

(5) The person or organisation responsible for remediation shall

- (a) submit to the Authority
 - (i) for review, a safety assessment report;
 - (ii) for approval, a remedial action plan and subsequent changes to the remedial action plan; and
 - (iii) a request for the grant of any necessary authorisation;
- (b) comply with the established criteria and methods for assessing safety;
- (c) submit work procedures, monitoring programmes and records to the Authority for review;
- (d) provide information on significant changes to procedures or equipment that may
 - (i) have radiological environmental impact, or
 - (ii) alter the exposure conditions for workers taking remedial actions or for members of the publicfor review and approval by the Authority; and
- (e) comply with the established regulatory requirements for control measures after remediation.

(6) The person or organisation responsible for carrying out the remedial action shall

- (a) ensure that the work, including management of the radioactive waste that results from the work, is carried out in accordance with the remedial action plan;

- (b) take full responsibility for protection and safety in its entirety, including the conduct of safety assessment;
 - (c) monitor the area of remedial action regularly during the remediation so as to
 - (i) verify levels of contamination;
 - (ii) verify compliance with the requirements for radioactive waste management; and
 - (iii) enable any unexpected levels of radiation to be detected and subject to the approval of the Authority, the remedial action plan to be modified accordingly;
 - (d) perform a radiological survey after completion of the remedial actions to demonstrate that the end point conditions, as established in the remedial action plan, have been met; and
 - (e) prepare and retain a final remediation report and submit a copy of that report to the Authority.
- (7) After the completion of remedial action, the person or organisation responsible for the remedial action shall
- (a) submit amended post-remediation control measures, with due consideration being given the residual radiation risks, to the Authority for review;
 - (b) submit to the Authority, for the purpose of any post-remediation control measures the details of the person or organisation responsible for the remedial action;
 - (c) comply with provisions for specific restrictions as imposed by the Authority in respect of the remediated area, regarding
 - (i) access by unauthorised persons;
 - (ii) removal of radioactive material or use of radioactive material, including the use of that material in commodities;
 - (iii) future use of the affected area, including the use of water resources and the use of that area for the production of food or feed; and
 - (iv) the consumption of food from the area.
 - (d) submit reports to the Authority for periodic review and for the amendment or removal restrictions where necessary.
- (8) A person or an organisation responsible for post-remediation control measures shall establish and maintain, for as long as required by the Authority, an appropriate programme, including any necessary provision for monitoring, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation.
- (9) For areas with long lasting residual radioactive material, in which the Authority has decided to allow habitation and the resumption of social and economic activities, the Authority shall
- (a) put in measures as necessary for the continuing control of exposure with the aim of establishing conditions for sustainable living;
 - (b) establish reference levels for protection and safety that are consistent with day to day life; and
 - (c) establish an infrastructure to support continuing ‘self-help protective actions’ in the affected areas, such as by the provision of information and advice, and by monitoring

(10) The conditions that prevail after the completion of remedial actions, shall, where the Authority has not imposed any restrictions or controls, be considered to constitute the background conditions for new facilities and activities or for habitation on the land.

Indoors radon exposure to the public

76.(1) A person or organisation responsible for indoor radon public exposure shall comply with

- (a) information provided by the Authority on levels of radon indoors and associated health risk; and
- (b) established and implemented action plan by the Authority for controlling public exposure due to radon indoors.

(2) A person or organisation responsible for indoor radon public exposure shall comply with

- (a) information gathered by the Authority on activity concentrations of radon in dwellings and other buildings with high occupancy factors for members of the public through appropriate means, such as representative radon surveys; and
- (b) relevant information provided by the Authority on exposure due to radon and the associated health risks, including the increased risks relating to smoking, is provided to the public and other interested parties.

(3) Where activity concentrations of radon that may affect public health are identified on the basis of the information gathered, the Authority shall establish an action plan comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings and the action plan shall provide for

- (a) the establishment of an appropriate reference level for ^{222}Rn for dwellings and other buildings with high occupancy factors for members of the public, with account taken of the prevailing social and economic circumstances, that in general should not exceed an annual average activity concentration due to ^{222}Rn of 300 Bq/m^3 ;
- (b) the reduction of activity concentrations of ^{222}Rn and consequent exposures to levels at which protection is optimised;
- (c) the prioritisation of actions to reduce activity concentrations of ^{222}Rn in those situations for which the action is likely to be most effective;
- (d) the inclusion in building codes of appropriate preventive measures and corrective actions to prevent the ingress of ^{222}Rn and to facilitate further actions wherever necessary.

(4) A person or organisation responsible for indoor radon public exposure shall comply with the assigned responsibilities by the Authority for

- (a) establishing and implementing the action plan for controlling public exposure due to ^{222}Rn indoors; and
- (b) determining the circumstances under which actions are to be mandatory or to be voluntary, with account taken of legal requirements and of the prevailing social and economic circumstances.

Radionuclides in commodities

77. (1) A person or organisation responsible for radionuclides in commodities shall comply with the reference levels established by the Authority for exposure arising from radionuclides in commodities including construction materials, food and animal feed and drinking water.

(2) Each of the specific reference levels established by the Authority, shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv.

(3) The reference levels established by the Authority shall take into consideration the guideline levels published by

- (a) the Joint Food and Agriculture Organisation of the United Nations and the World Health Organisation Codex Alimentarius Commission, for radionuclides in food, traded internationally, that could contain radioactive substances as a result of a nuclear or radiological emergency; and
- (b) the World Health Organisation for radionuclides contained in drinking water.

Exposure in workplaces

78.(1) A worker in a facility or engaged in an activity governed by the Act and these Regulations shall comply with the requirements established by the Authority for the protection of workers in existing exposure situations.

(2) The requirements in respect of public exposure shall be applied for the protection and safety for workers in existing exposure situations, other than in those specific situations specified in sub regulation (3) to (10).

(3) An employer shall ensure that the exposure of a worker who undertakes remedial actions for which the employer is responsible, is controlled in accordance with the relevant requirements on occupational exposure in planned exposure situations as established under occupational exposure protection in these Regulations.

(4) An employer shall comply with the strategy established by the Authority for protection against exposure due to ^{222}Rn in workplaces, including the established appropriate reference level for ^{222}Rn which shall be set at a value that does not exceed an annual average activity concentration of ^{222}Rn of 1000 Bq/m^3 , taking into account the prevailing social and economic circumstances.

(5) An employer shall ensure that activity concentrations of ^{222}Rn in workplaces are as low as reasonably achievable below the reference level established, and shall ensure that protection is optimised.

(6) Where despite reasonable efforts by the employer to reduce activity concentrations of radon, the activity concentration of ^{222}Rn in workplaces remains above the reference level established, the relevant requirements for occupational exposure in planned exposure situations provided under occupational exposure protection in these Regulations shall apply.

(7) The Authority shall determine whether an assessment of the exposure of aircrew due to cosmic radiation is warranted.

(8) Where an assessment is determined to be warranted under sub regulation (7), the Authority shall establish a framework to include a reference level of dose and a methodology for the

assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation

(9) In furtherance of sub regulation (8),

- (a) where the doses of aircrew are likely to exceed the reference level, the employer of the aircrew shall
 - (i) assess and keep records of the doses; and
 - (ii) make the records of the doses available to the aircrew.
- (b) the employer of the aircrew shall
 - (i) inform female aircrew of the risk to the embryo or foetus due to exposure to cosmic radiation and of the need for early notification of pregnancy;
 - (ii) apply the requirements of regulation 40 (4) in respect of notification of pregnancy.

(10) An employer shall comply with the requirements of the framework established by the Authority for radiation protection for an individual engaged in a space based activity that is appropriate for the exceptional conditions of space.

(11) Despite that the requirements of these Regulations in respect of dose limits do not apply to individuals in space based activities, an employer shall make reasonable efforts to optimise protection for an individual engaged in a space based activity by restricting the doses received by that individual while not unduly limiting the extent of the activity.

Human imaging for purposes other than medical exposure

79.(1) An authorised person using ionising radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research shall subject the human imaging to the system of protection and safety.

(2) The Authority may in accordance with regulation 22 (4) (d) determine that the requirements for the justification of practices shall apply to any type of human imaging procedure in which radiation is used for purposes other than for medical diagnosis or medical treatment or other than as part of a programme of biomedical research.

(3) The justification process shall include the consideration of

- (a) the benefits and detriments of implementing the type of human imaging procedure;
- (b) the benefits and detriments of not implementing the type of human imaging procedure;
- (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) A particular practise of human imaging using radiation is subject to regulatory control if that practice is determined under sub-regulation (2) to be justified.

(5) An authorised person shall comply with the requirements for regulatory control of the practice and review of justification, established by the Authority, in cooperation with other relevant authorities, agencies and professional bodies.

(6) Where a medical personnel uses radiological equipment to perform human imaging that requires the use of radiation, and the process exposes people to radiation for the purpose of employment related, legal or health insurance, without reference to clinical indications, the authorised person shall

- (a) comply with the dose constraints established by the Authority acting in accordance with the outcome of consultations with other authorities and professional bodies mandated to deal with matters concerning human imaging; and
- (b) ensure that the appropriate optimisation requirements for medical exposure are applied, using the dose constraints required in paragraph (a), instead diagnostic reference levels.

(7) Procedures with inspection imaging devices in which radiation is used to expose persons for the purpose of detection of concealed weapons, contraband or other objects on or within the body are for the purposes of these Regulations, considered to give rise to public exposure.

(8) An authorised person who is responsible for a procedure specified in sub regulation (7), shall

- (a) apply the requirements for public exposure in planned exposure situations; and

- (b) in particular, ensure that the optimisation of protection and safety is subject to any dose constraints established by the Authority for public exposure.

(9) The authorised persons shall ensure that a person who is to undergo a procedure with an inspection imaging device in which ionising radiation is used is informed of the possibility of requesting the use of an alternative inspection technique that does not use ionising radiation, where that alternative is available.

(10) The authorised person shall ensure that an inspection imaging device which is used for the detection of concealed objects on or within the body, whether manufactured in or imported into this country, conforms to the applicable standards of the International Electrotechnical Commission or the International Organisation for Standardisation or to the equivalent national standards.

Penalties

80.(1) A person who

- (a) constructs a radiological or nuclear facility without permit or approved design;
- (b) engages unauthorised or unqualified person to work in an authorised facility;
- (c) uses an authorised facility at an undesignated site;
- (d) does not formerly designate a radiation protection officer to supervise radiation safety at the facility;
- (e) does not follow written local rules, procedures and quality assurance programme during operations and maintenance;
- (f) does not update written local rules, procedures and quality assurance programme as required;
- (g) uses radiation for a purpose other than authorised;
- (h) provides irregular or no personnel monitoring service of authorised workers;
- (i) transports a nuclear or other radioactive material with unauthorised transporters;
- (j) exports a nuclear or other radioactive material without a permit;
- (k) imports a nuclear or other radioactive material without a permit;
- (l) does not notify the Authority on significant changes that bother on safety and security at the facility/installation;
- (m) does not notify the Authority of incidents or accidents of safety significance within 24 hours;
- (n) does not keep appropriate records at the facility or installation;
- (o) does not provide adequate safety and security measures;
- (p) decommissions a facility/installation without a permit;
- (q) transfers an authorisation without informing the Authority;
- (r) does not display the certificate of authorisation at a prominent public area within the facility/installation;
- (s) operates a facility or conducts an activity with an expired authorisation;
- (t) breaches the condition of authorisation;

is liable to pay the Authority a maximum administrative penalty of one million penalty units for nuclear installations or two hundred and fifty thousand penalty units for radiological facilities or activities.

(2) A person who contravenes any provisions of these Regulations for which a penalty unit has not been provided is liable to pay the Authority, a maximum administrative penalty of one

million penalty units for nuclear installations or two hundred and fifty thousand penalty units for radiological facilities or activities.

(3) An administrative penalty required to be paid under this regulation and which is not paid within the period specified in the notice shall be a debt owed to the Republic and recoverable by the Authority in court.

(4) Payment of an administrative penalty or fine pursuant to this regulation shall not be recovered as expenditure or cost incurred in conducting nuclear or radiological operations.

(5) A person who contravenes any of the provision of these Regulations that does not warrant an administrative penalty or fine as provided in Regulation 80 (1) and (2) commits an offence and is liable on a summary conviction to a fine or to a term of imprisonment or both fine and imprisonment as provided in section 23 (2), 25 (2), 50 (2), 67 (3), 77 (1-2), 78 (1-3), 79 and 80 (3-4) of the Nuclear Regulatory Authority Act, 2015 (Act 895).

Appeal

81.(1) A person who is not satisfied with a decision taken by the Authority may appeal in accordance with the procedures provided in sections 81, 82, 83, 84 and 85 of the Nuclear Regulatory Authority Act, 2015 (Act 895).

Interpretation

82. In these regulations, unless the context otherwise requires:

“Act” means the Nuclear Regulatory Authority Act, 2015;

“activity” means the design, manufacture, construction, import, export, distribution, sale, loan, commissioning, use, operation, maintenance, repair, transfer, decommissioning or possession of radiation sources for industrial, education, research, agriculture and medical purposes; the transport of radioactive material; the mining and processing of radioactive ores; the closing down of associated facilities; the clean-up of sites affected by residues from past activities; and radioactive waste management activities such as the discharge of effluents;

“administer ionising radiation” means the intentional act of subjecting ionising radiation whether internal or external to a person for the purpose of medical treatment or diagnosis by a qualified expert;

“apparatus” means equipment associated with the emission of radiation;

“article” means an item or thing or equipment associated with the emission of radiation;

“authorisation” means permission granted in writing by the Authority to a person who has submitted an application to carry out a practice or any other action described in the general obligations for practices under the Act and includes a certificate of registration, licence or permit granted by the Authority under Section 21 of the Act;

“authorised officer” means an officer appointed or authorised to perform a function in relation to the implementation of these Regulations, and this may include a police officer or any other law enforcement officer;

“authorised person” means a person who has been granted authorisation;

“carer and comforter” means a person who willingly and voluntarily helps, other than in the occupation of that person, in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment;

“clearance” means the removal of a radioactive material or a radioactive object within authorised practices from any further control by the Authority;

“committed effective dose” means the quantity $E(\tau)$, defined as: $E(\tau) = \sum_T w_T H_T(\tau)$, where $H_T(\tau)$ is the committed equivalent dose to tissue or organ T over the integration time τ elapsed after an intake of radioactive substances and w_T is the tissue weighting factor for tissue or organ T; when τ is not specified, it will be taken to be fifty years for adults and seventy years for intakes by children;

“consumer product” means a device or manufactured item in which a radionuclide has deliberately been incorporated or produced by activation, or which generates ionising radiation, and which can be sold or made available to a member of the public without special surveillance or regulatory control after sale;

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

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

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

“decommissioning” means administrative and technical action taken to allow removal of some or all of the regulatory controls from a nuclear or radiological facility except for a repository, which is closed and not decommissioned; and it includes decontamination, dismantling and removal of radioactive materials, waste, components and structures;

“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 radio-pharmaceuticals administered in a specified radiological procedure is unusually high or unusually low for that procedure;

“disposal” means the emplacement of radioactive material in an appropriate facility without the intention of retrieval;

“dose” means a measure of the radiation received or absorbed by a target;

“dose constraint” means prospective and source related value of individual dose or risk that is used in a planned exposure situation as a parameter for the optimisation of protection and safety for the source, and that serves as a boundary in defining the range of options in optimisation;

“dose equivalent” means a quantity used by the International Commission on Radiation Units and measurements, ICRU, in defining the operational quantities ambient dose equivalent, directional dose equivalent and personal dose equivalent;

“dose limit” means the value of the effective dose or the equivalent dose to an individual that is not to be exceeded in activities of controlled practices;

“dosimetry” means the science of measuring radiation doses;

“effective dose” means a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor that gives a whole body representation of radiation effect;

“emergency worker” means person having specified duties as a worker in response to an emergency.

- (i) Emergency workers may include workers employed by an authorised person, as well as personnel of response organizations, such as police officers, firefighters, medical personnel, and drivers and crews of evacuation vehicles.
- (ii) An emergency worker may or may not be designated as such in advance of an emergency. An emergency worker not designated as such in advance of an emergency is not necessarily a worker prior to the emergency.

“emergency action level” means a specific, predetermined, observable criterion used to detect, recognise and determine the emergency class;

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

“emergency management” means organisation and management of resources and responsibilities for dealing with preparedness, response, mitigation and recovery phases of an emergency;

“emergency plan” means a set of procedures to be implemented in the event of a radiation accident;

“emergency preparedness” means The capability to take actions that will effectively mitigate the consequences of an emergency for human health and safety, quality of life, property and the Environment;

“emergency procedures” means a set of instructions describing in detail the actions to be taken by response personnel in an emergency;

“emergency worker” means a person having specified duties as a worker in response to an emergency

“employee” means a person who works, whether full time, part time or temporarily, for an employer and who has recognised rights and duties in relation to occupational radiation protection.

“employer” means a person or organisation with recognised responsibilities, commitments and duties towards a worker in the employment of the person or organization by virtue of a mutually agreed relationship. A self-employed person is regarded as being both an employer and a worker.

“equivalent dose” means the measure of the radiation dose to the tissue where an attempt has been made to allow for the different relative biological effects of different types of ionising radiation and where the quantity $H_{T,R}$ defined as $H_{T,R} = \sum D_{T,R} \cdot W_R$ where $D_{T,R}$ is the absorbed dose delivered by radiation type R averaged over a tissue or organ T and W_R is the radiation weighting factor for radiation type R);

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

“exclude” means the exclusion from regulation of any exposure whose magnitude or likelihood is essentially un-amenable to control through the requirements of the Regulations;

“exempt” means the determination by the Authority that a source or practice need not to be subject to some or all aspects of regulatory control on the basis that the exposure, including potential exposure due to source or practice is too small to warrant the application of those aspects or where that is the optimum option for protection irrespective of the actual level of dose or risks;

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

“exposure” means the act or condition of being subjected to irradiation;

“external exposure” means the act or condition of being subjected to irradiation by a source outside the body;

“facility and activity” means a nuclear facility, use of all sources of ionising radiation, any radioactive waste management activity, transport of radioactive material and any other practice or circumstance in which people may be subject to exposure to radiation from a naturally occurring or an artificial source;

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

“health professional” means an individual who has been formally recognised through appropriate national procedures to practise a profession related to health in the form of medicine, dentistry, chiropractic, pediatry, nursing, medical physics, medical radiation technology, radio-pharmacy, occupational health;

“IAEA” means the International Atomic Energy Agency;

“incident” means any unintended event which under slightly different circumstances, could have resulted in harm to people, damage to property, or loss of process;

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

“internal exposure” means the act or condition of being subjected to irradiation by a source inside the body;

“intervention” means any action intended to reduce or avert exposure, or the likelihood of exposure to a source which is not part of a controlled practice or which is out of control as a consequence of an accident;

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

“ionising radiation” means electromagnetic or corpuscular radiation, consisting of photons or particles capable of producing ions, directly or indirectly, in its passage through matter;

“licence” means an authorisation granted by the Authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by an authorised person;

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

“medical exposure” means exposure incurred by patients for the purposes of medical or dental diagnosis or treatment, by carers and comforters, and by volunteers subject to exposure as part of a programme of biomedical research;

“medical practitioner” means an individual who has been accredited through appropriate national procedures as a health professional, fulfils the national requirements for training and experience of prescribing procedures involving medical exposure and is an authorised person, or a worker

who has been designated by a registered or licenced employer for the purpose of prescribing procedures involving medical exposure;

“nuclear installation” means a nuclear fuel fabrication plant, a nuclear reactor and any critical and sub critical assemblies, research reactor, nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility;

"nuclear material" means nuclear fuel, other than natural uranium capable of producing energy by a self- sustaining chain process of nuclear fission outside a nuclear reactor, either alone or in combination with some other material and radioactive products or waste;

“operational intervention level” means a set level of a measurable quantity that corresponds to a generic criterion;

“physical protection” means measures for the protection of nuclear material or an authorised facility, designed to prevent unauthorised access or removal of fissile material or sabotage with regard to safeguards;

“plant” means a machinery, facility or installation, whether affixed to land or not and which is not anything comprised or to be comprised in any means of transport, whether by land, water or air;

“practice” means a human activity that introduces additional sources of exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed;

“principal person” means a person who has the main responsibility for the application of these Regulations and who may be an authorised person or an employer;

“protection and safety” means the protection of people against exposure to ionizing radiation or due to radioactive material and the safety of sources, including and the means for achieving this and for preventing accidents and mitigating the consequences of accidents that may occur;

“qualified expert” means an individual who by virtue of certification by an appropriate legal body or society, professional licence or academic qualification and experience, is duly recognised as having expertise in a relevant field of specialisation in the nature of medical physics, radiation protection, occupational health, quality assurance or any relevant engineering or safety specialty;

“quality assurance” means planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality and may be specified in the licence;

"quality control" means a procedure or set of procedures designed to ensure that a product or service complies with a defined set of criteria with regards to quality or meets the requirements of the client or customer and meets protection and safety requirements;

"radiation protection" means a system of technical and organisational measures to reduce or limit exposure of people and the environment from ionising radiation;

"radiation protection officer" means a person technically competent in radiation protection matters relevant for a given type of practice and who is designated by the authorised person to oversee the application of requirements of these regulations and is recognised by the Authority;

"radiation safety" means measures intended to minimise the likelihood of accidents with radiation sources and where an accident occurs, to mitigate the consequences of the accident;

"radiation source" means anything that may cause radiation exposure, such as by emitting ionising radiation or releasing radioactive substances or materials;

"radioactive material" means any matter or substance containing one or more radionuclides, the activity or concentration of which is sufficiently intense to entail a significant risk or disability or disease to any person or organ on exposure, whether external or internal, and whether continuous or total;

"radioactive waste" means material for which no further use is foreseen that contains, or is contaminated with, a radionuclide at activity concentrations greater than clearance levels as established by the Authority;

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

"registration" means a form of authorisation for practices of low or moderate risks by which the legal person responsible for the practice has prepared and submitted a safety assessment of the facility and equipment to the Authority and in which the practice or use is authorised with conditions or limitations and for which the requirements for safety assessment and the conditions or limitations applied are less severe than those for licensing;

"response organisation" means an organisation designated or otherwise recognized by a State as being responsible for managing or implementing any aspect of an emergency response.

"safety culture" means the assembly of characteristics and attitudes in organisations and individuals which establishes that as an overriding priority, protection and safety issues should receive attention in accordance with their significance;

"sealed source" means a source consisting of radioactive material firmly incorporated in a solid of effectively inactive materials, or sealed in an inactive container of a strength sufficient to

prevent, under normal conditions of use, any dispersion of radioactive material and any possibility of contamination;

“security” means measures to prevent unauthorised access or damage to, and loss, theft or unauthorised transfer of radioactive materials;

“source” means an apparatus, device, material or anything capable of emitting radiation;

“storage” means the holding of a radioactive source or radioactive waste in a facility that provides for its containment with the intention of retrieval;

“supervised area” means a defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though no specific protection measures or safety provisions are normally needed;

“supplier of a source” means any person or organisation to whom an authorised person delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source;

“unsealed source” means a source that does not meet the definition of a sealed source;

“user” means a person or body of persons or institution authorised to use ionising radiation under these regulations or the Act;

“worker” means any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection.

(i) A self-employed person is regarded as having the duties of both an employer and a worker.

FIRST SCHEDULE - Exemption and Clearance Levels

Table 1.1: Levels for Exemption 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	1×10^5
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
Cl-38	1×10^1	1×10^5	Fe-52	1×10^1	1×10^6
Cl-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
Ar-39	1×10^7	1×10^4	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

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
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
Zn-72	1×10^2	1×10^6	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}

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
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
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

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	1×10^2	1×10^6	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	1×10^1	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-116m	1×10^1	1×10^5
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

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
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-123m	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	I-124	1×10^1	1×10^6
Sb-122	1×10^2	1×10^4	I-125	1×10^3	1×10^6
Sb-124	1×10^1	1×10^6	I-126	1×10^2	1×10^6
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-116	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

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
Xe-127	1×10^3	1×10^5	La-131	1×10^1	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-138	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
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

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
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
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 (24.4 h)	1×10^3	1×10^7
Sm-156	1×10^2	1×10^6	Tb-156m' (5 h)	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
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

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
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
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

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
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	1×10^1	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	1×10^6	Ir-190m (3.1 h)	1×10^1	1×10^6
W-188 ^b	1×10^2	1×10^5	Ir-190m' (1.2 h)	1×10^4	1×10^7
Re-177	1×10^1	1×10^6	Ir-192	1×10^1	1×10^4
Re-178	1×10^1	1×10^6	Ir-192m	1×10^2	1×10^7
Re-181	1×10^1	1×10^6	Ir-193m	1×10^4	1×10^7
Re-182	1×10^1	1×10^6	Ir-194	1×10^2	1×10^5
Re-182m	1×10^1	1×10^6	Ir-194m	1×10^1	1×10^6
Re-184	1×10^1	1×10^6	Ir-195	1×10^2	1×10^6
Re-184m	1×10^2	1×10^6	Ir-195m	1×10^2	1×10^6
Re-186	1×10^3	1×10^6	Pt-186	1×10^1	1×10^6
Re-186m	1×10^3	1×10^7	Pt-188 ^b	1×10^1	1×10^6
Re-187	1×10^6	1×10^9	Pt-189	1×10^2	1×10^6
Re-188	1×10^2	1×10^5	Pt-191	1×10^2	1×10^6
Re-188m	1×10^2	1×10^7	Pt-193	1×10^4	1×10^7
Re-189 ^b	1×10^2	1×10^6	Pt-193m	1×10^3	1×10^7
Os-180	1×10^2	1×10^7	Pt-195m	1×10^2	1×10^6
Os-181	1×10^1	1×10^6	Pt-197	1×10^3	1×10^6
Os-182	1×10^2	1×10^6	Pt-197m	1×10^2	1×10^6
Os-185	1×10^1	1×10^6	Pt-199	1×10^2	1×10^6
Os-189m	1×10^4	1×10^7	Pt-200	1×10^2	1×10^6

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
Au-193	1×10^2	1×10^7	Pb-201	1×10^1	1×10^6
Au-194	1×10^1	1×10^6	Pb-202	1×10^3	1×10^6
Au-195	1×10^2	1×10^7	Pb-202m	1×10^1	1×10^6
Au-198	1×10^2	1×10^6	Pb-203	1×10^2	1×10^6
Au-198m	1×10^1	1×10^6	Pb-205	1×10^4	1×10^7
Au-199	1×10^2	1×10^6	Pb-209	1×10^5	1×10^6
Au-200	1×10^2	1×10^5	Pb-210 ^b	1×10^1	1×10^4
Au-200m	1×10^1	1×10^6	Pb-211	1×10^2	1×10^6
Au-201	1×10^2	1×10^6	Pb-212 ^b	1×10^1	1×10^5
Hg-193	1×10^2	1×10^6	Pb-214	1×10^2	1×10^6
Hg-193m	1×10^1	1×10^6	Bi-200	1×10^1	1×10^6
Hg-194 ^b	1×10^1	1×10^6	Bi-201	1×10^1	1×10^6
Hg-195	1×10^2	1×10^6	Bi-202	1×10^1	1×10^6
Hg-195m ^b	1×10^2	1×10^6	Bi-203	1×10^1	1×10^6
Hg-197	1×10^2	1×10^7	Bi-205	1×10^1	1×10^6
Hg-197m	1×10^2	1×10^6	Bi-206	1×10^1	1×10^5
Hg-199m	1×10^2	1×10^6	Bi-207	1×10^1	1×10^6
Hg-203	1×10^2	1×10^5	Bi-210	1×10^3	1×10^6
Tl-194	1×10^1	1×10^6	Bi-210m ^b	1×10^1	1×10^5
Tl-194m	1×10^1	1×10^6	Bi-212 ^b	1×10^1	1×10^5
Tl-195	1×10^1	1×10^6	Bi-213	1×10^2	1×10^6
Tl-197	1×10^2	1×10^6	Bi-214	1×10^1	1×10^5
Tl-198	1×10^1	1×10^6	Po-203	1×10^1	1×10^6
Tl-198m	1×10^1	1×10^6	Po-205	1×10^1	1×10^6
Tl-199	1×10^2	1×10^6	Po-206	1×10^1	1×10^6
Tl-200	1×10^1	1×10^6	Po-207	1×10^1	1×10^6
Tl-201	1×10^2	1×10^6	Po-208	1×10^1	1×10^4
Tl-202	1×10^2	1×10^6	Po-209	1×10^1	1×10^4
Tl-204	1×10^4	1×10^4	Po-210	1×10^1	1×10^4
Pb-195m	1×10^1	1×10^6	At-207	1×10^1	1×10^6
Pb-198	1×10^2	1×10^6	At-211	1×10^3	1×10^7
Pb-199	1×10^1	1×10^6	Fr-222	1×10^3	1×10^5
Pb-200	1×10^2	1×10^6	Fr-223	1×10^2	1×10^6

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
Rn-220 ^b	1×10^4	1×10^7	U-235 ^b	1×10^1	1×10^4
Rn-222 ^b	1×10^1	1×10^8	U-236	1×10^1	1×10^4
Ra-223 ^b	1×10^2	1×10^5	U-237	1×10^2	1×10^6
Ra-224 ^b	1×10^1	1×10^5	U-238 ^b	1×10^1	1×10^4
Ra-225	1×10^2	1×10^5	U-239	1×10^2	1×10^6
Ra-226 ^b	1×10^1	1×10^4	U-240	1×10^3	1×10^7
Ra-227	1×10^2	1×10^6	U-240 ^b	1×10^1	1×10^6
Ra-228 ^b	1×10^1	1×10^5	Np-232	1×10^1	1×10^6
Ac-224	1×10^2	1×10^6	Np-233	1×10^2	1×10^7
Ac-225 ^b	1×10^1	1×10^4	Np-234	1×10^1	1×10^6
Ac-226	1×10^2	1×10^5	Np-235	1×10^3	1×10^7
Ac-227 ^b	1×10^{-1}	1×10^3	Np-236	1×10^2	1×10^5
Ac-228	1×10^1	1×10^6	Np-236m	1×10^3	1×10^7
Th-226 ^b	1×10^3	1×10^7	Np-237 ^b	1×10^0	1×10^3
Th-227	1×10^1	1×10^4	Np-238	1×10^2	1×10^6
Th-228 ^b	1×10^0	1×10^4	Np-239	1×10^2	1×10^7
Th-229 ^b	1×10^0	1×10^3	Np-240	1×10^1	1×10^6
Th-230	1×10^0	1×10^4	Pu-234	1×10^2	1×10^7
Th-231	1×10^3	1×10^7	Pu-235	1×10^2	1×10^7
Th-232	1×10^1	1×10^4	Pu-236	1×10^1	1×10^4
Th-234 ^b	1×10^3	1×10^5	Pu-237	1×10^3	1×10^7
Pa-227	1×10^1	1×10^6	Pu-238	1×10^0	1×10^4
Pa-228	1×10^1	1×10^6	Pu-239	1×10^0	1×10^4
Pa-230	1×10^1	1×10^6	Pu-240	1×10^0	1×10^3
Pa-231	1×10^0	1×10^3	Pu-241	1×10^2	1×10^5
Pa-232	1×10^1	1×10^6	Pu-242	1×10^0	1×10^4
Pa-233	1×10^2	1×10^7	Pu-243	1×10^3	1×10^7
Pa-234	1×10^1	1×10^6	Pu-244	1×10^0	1×10^4
U-230 ^b	1×10^1	1×10^5	Pu-245	1×10^2	1×10^6
U-231	1×10^2	1×10^7	Pu-246	1×10^2	1×10^6
U-232 ^b	1×10^0	1×10^3	Am-237	1×10^2	1×10^6
U-233	1×10^1	1×10^4	Am-238	1×10^1	1×10^6
U-234	1×10^1	1×10^4	Am-239	1×10^2	1×10^6

Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide ^a	Activity concentration (Bq/g)	Activity (Bq)
Am-240	1×10^1	1×10^6	Bk-247	1×10^0	1×10^4
Am-241	1×10^0	1×10^4	Bk-249	1×10^3	1×10^6
Am-242	1×10^3	1×10^6	Bk-250	1×10^1	1×10^6
Am-242m ^b	1×10^0	1×10^4	Cf-244	1×10^4	1×10^7
Am-243 ^b	1×10^0	1×10^3	Cf-246	1×10^3	1×10^6
Am-244	1×10^1	1×10^6	Cf-248	1×10^1	1×10^4
Am-244m	1×10^4	1×10^7	Cf-249	1×10^0	1×10^3
Am-245	1×10^3	1×10^6	Cf-250	1×10^1	1×10^4
Am-246	1×10^1	1×10^5	Cf-251	1×10^0	1×10^3
Am-246m	1×10^1	1×10^6	Cf-252	1×10^1	1×10^4
Cm-238	1×10^2	1×10^7	Cf-253	1×10^2	1×10^5
Cm-240	1×10^2	1×10^5	Cf-254	1×10^0	1×10^3
Cm-241	1×10^2	1×10^6	Es-250	1×10^2	1×10^6
Cm-242	1×10^2	1×10^5	Es-251	1×10^2	1×10^7
Cm-243	1×10^0	1×10^4	Es-253	1×10^2	1×10^5
Cm-244	1×10^1	1×10^4	Es-254	1×10^1	1×10^4
Cm-245	1×10^0	1×10^3	Es-254m	1×10^2	1×10^6
Cm-246	1×10^0	1×10^3	Fm-252	1×10^3	1×10^6
Cm-247	1×10^0	1×10^4	Fm-253	1×10^2	1×10^6
Cm-248	1×10^0	1×10^3	Fm-254	1×10^4	1×10^7
Cm-249	1×10^3	1×10^6	Fm-255	1×10^3	1×10^6
Cm-250	1×10^{-1}	1×10^3	Fm-257	1×10^1	1×10^5
Bk-245	1×10^2	1×10^6	Md-257	1×10^2	1×10^7
Bk-246	1×10^1	1×10^6	Md-258	1×10^2	1×10^5

^a m and m' denote metastable states of the radionuclide. The metastable state m' is of higher energy than the metastable state m.

^b Parent radionuclides and their progeny whose dose contributions are taken into account in the dose calculations (thus requiring only the exemption level of the parent radionuclide to be considered) are listed here:

Ge-68	Ga-68Rb-83	Kr-83m	Y-87	Sr-87m
Sr-82	Rb-82		Zr-93	Nb-93m
Sr-90	Y-90		Zr-97	Nb-97
Ag-108m	Ag-108		Ru-106	Rh-106
Sn-121m	Sn-121 (0.776)			
Sn-126	Sb-126m		Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Xe-122	I-122			
Xe-122	I-122		Ra-228	Ac-228
Cs-137	Ba-137m		Ac-225	Fr-221, At-217, Bi-213, Po-213 (0.978), Tl-209 (0.0216), Pb-209 (0.978)
Ba-140	La-140			
Ce-134	La-134			
Ce-144	Pr-144			
Gd-146	Eu-146		Ac-227	Fr-223 (0.0138)
Hf-172	Lu-172		Th-226	Ra-222, Rn-218, Po-214
W-178	Ta-178		Th-228	Ra-224, Rn-220, Po-216,

W-188	Re-188		Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Re-189	Os-189m (0.241) Ir-189		
	Os-189m	Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Pt-188	Ir-188		
Hg-194	Au-194	Th-234	Pa-234m
Hg-195m	Hg-195 (0.542) Pb-210	U-230	Th-226, Ra-222, Rn-218, Po-214
	Bi-210, Po-210		
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)	U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64) U-
Bi-210m	Tl-206		
Bi-212	Tl-208 (0.36), Po-212 (0.64)	235	Th-231
Rn-220	Po-216	U-238	Th-234, Pa-234m
Rn-222	Po-218, Pb-214, Bi-214, Po-214	U-240	Np-240m
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207	Np-237	Pa-233
		Am-242m	Am-242
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)	Am-243	Np-239

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)
H-3	100	Co-58	1
Be-7	10	Co-58m	10 000
C-14	1	Co-60	0.1
F-18	10	Co-60m	1 000
Na-22	0.1	Co-61	100
Na-24	1	Co-62m	10
Si-31	1 000	Ni-59	100
P-32	1 000	Ni-63	100
P-33	1 000	Ni-65	10
S-35	100	Cu-64	100
Cl-36	1	Zn-65	0.1
Cl-38	10	Zn-69	1 000
K-42	100	Zn-69m ^a	10
K-43	10	Ga-72	10
Ca-45	100	Ge-71	10 000
Ca-47	10	As-73	1 000
Sc-46	0.1	As-74	10
Sc-47	100	As-76	10
Sc-48	1	As-77	1 000
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
Mn-53	100	Sr-87m	100
Mn-54	0.1	Sr-89	1 000
Mn-56	10	Sr-90 ^a	1
Fe-52 ^a	10	Sr-91 ^a	10
Fe-55	1 000	Sr-92	10
Fe-59	1	Y-90	1 000
Co-55	10	Y-91	100
Co-56	0.1	Y-91m	100
Co-57	1	Y-92	100

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
Y-93	100	In-111	10
Zr-93	10	In-113m	100
Zr-95 ^a	1	In-114m ^a	10
Zr-97 ^a	10	In-115m	100
Nb-93m	10	Sn-113 ^a	1
Nb-94	0.1	Sn-125	10
Nb-95	1	Sb-122	10
Nb-97 ^a	10	Sb-124	1
Nb-98	10	Sb-125 ^a	0.1
Mo-90	10	Te-123m	1
Mo-93	10	Te-125m	1 000
Mo-99 ^a	10	Te-127	1 000
Mo-101 ^a	10	Te-127m ^a	10
Tc-96	1	Te-129	100
Tc-96m	1 000	Te-129m ^a	10
Tc-97	10	Te-131	100
Tc-97m	100	Te-131m ^a	10
Tc-99	1	Te-132 ^a	1
Tc-99m	100	Te-133	10
Ru-97	10	Te-133m	10
Ru-103 ^a	1	Te-134	10
Ru-105 ^a	10	I-123	100
Ru-106 ^a	0.1	I-125	100
Rh-103m	10 000	I-126	10
Rh-105	100	I-129	0.01
Pd-103 ^a	1 000	I-130	10
Pd-109 ^a	100	I-131	10
Ag-105	1	I-132	10
Ag-110m ^a	0.1	I-133	10
Ag-111	100	I-134	10
Cd-109 ^a	1	I-135	10
Cd-115 ^a	10	Cs-129	10
Cd-115m ^a	100	Cs-131	1 000

Radionuclide	Activity concentration (Bq/g)	Radionuclide	Activity concentration (Bq/g)
Cs-132	10	Er-171	100
Cs-134	0.1	Tm-170	100
Cs-134m	1 000	Tm-171	1 000
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	1 000
La-140	1	W-187	10
Ce-139	1	Re-186	1 000
Ce-141	100	Re-188	100
Ce-143	10	Os-185	1
Ce-144 ^a	10	Os-191	100
Pr-142	100	Os-191m	1 000
Pr-143	1 000	Os-193	100
Nd-147	100	Ir-190	1
Nd-149	100	Ir-192	1
Pm-147	1 000	Ir-194	100
Pm-149	1 000	Pt-191	10
Sm-151	1 000	Pt-193m	1 000
Sm-153	100	Pt-197	1 000
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	Tl-200	10
Dy-165	1 000	Tl-201	100
Dy-166	100	Tl-202	10
Ho-166	100	Tl-204	1
Er-169	1 000	Pb-203	10

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-243	1 000
Po-205	10	Pu-244 ^a	0.1
Po-207	10	Am-241	0.1
At-211	1 000	Am-242	1 000
Ra-225	10	Am-242m ^a	0.1
Ra-227	100	Am-243 ^a	0.1
Th-226	1 000	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	1 000
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
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	10 000
Pu-239	0.1	Fm-255	100
Pu-240	0.1		

^aParent radionuclides, and their progeny whose dose contributions are taken into 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,
Ru-105	Rh-105m	U-240	Tl-208
Ru-106	Rh-106		Np-240m, Np-240
Pd-103	Rh-103m	Np-237	Pa-233
Pd-109	Ag-109m	Pu-244	U-240, Np-240m, Np-240
Ag-110m	Ag-110	Am-242m	Np-238
Cd-109	Ag-109m	Am-243	Np-239
Cd-115	In-115m	Cm-247	Pu-243
Cd-115m	In-115m	Es-254	Bk-250
In-114m	In-114	Es-254m	Fm-254

Table 1.3: Levels for clearance of material: activity concentrations of radionuclides of natural origin

Radionuclide	Activity concentration (Bq/g)
^{40}K	10
All other radionuclides of natural origin	1

SECOND SCHEDULE - Dose Limits for Planned Exposure Situations

OCCUPATIONAL EXPOSURE

1. For occupational exposure of workers over the age of eighteen years, the dose limits are
 - (a) an effective dose of 20 mSv per year averaged over five consecutive years^a (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; and
 - (c) an equivalent dose to the extremities (hands and feet) or to the skin of 500 mSv in a year.

Additional restrictions apply to occupational exposure for a female worker who has given notice of pregnancy or is breast-feeding

2. For occupational exposure of apprentices of sixteen to eighteen years of age who are being trained for employment involving radiation and for exposure of students of age sixteen to eighteen years who use sources in the course of their studies, the dose limits are:
 - (a) an effective dose of 6 mSv in a year;
 - (b) an equivalent dose to the lens of the eye of 20 mSv in a year;
 - (c) an equivalent dose to the extremities (hands and feet) or to the skin^b of 150 mSv in a year.

^a The start of the averaging period shall be coincident with the first day of the relevant annual period after the date of entry into force of these Regulations, with no retrospective averaging.

^b The equivalent dose limits for the skin apply to the average dose over 1 cm² of the most highly irradiated area 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.

PUBLIC EXPOSURE

3. For public exposure, the dose limits are
 - (a) an effective dose of 1 mSv in a year;
 - (b) in special circumstances^a, a higher value of effective dose in a single year could apply, if 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.

^a For example, in authorised, justified and planned operational conditions that lead to transitory increases in exposures.

VERIFICATION OF COMPLIANCE WITH DOSE LIMITS

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 fifty years for intakes by adults and shall be up to seventy years for intakes by children.
5. For occupational exposure, the personal dose equivalent $H_p(10)^b$ may be used as an approximation of the effective dose from external exposure to penetrating radiation.
6. Values of the effective dose per unit air kerma free-in-air and per unit particle fluence are given in Tables 2.1 –2.3.
7. Doses per unit intake, dose coefficients, for the estimation of the committed effective dose for ingestion and inhalation of radionuclides shall follow as provided in the standards of the International Atomic Energy Agency (IAEA).

^b $H_p(10)$ is the personal dose equivalent $H_p(d)$ where $d = 10$ mm.

Table 2.1: Conversion coefficients from air kerma free-in-air to $H_p(10,0^\circ)$ in an International Commission on Radiation Units and measurements ICRU slab (photons)

Photon energy (MeV)	$H_p(10,0^\circ)/K$ (Sv/Gy)	Photon energy (MeV)	$H_p(10,0^\circ)/K$ (Sv/Gy)
0.010	0.009	0.150 1.607	0.150 1.607
0.0125	0.098	0.200 1.492	0.200 1.492
0.015	0.264	0.300 1.369	0.300 1.369
0.0175	0.445	0.400 1.300	0.400 1.300
0.020	0.611	0.500 1.256	0.500 1.256
0.025	0.883	0.600 1.226	0.600 1.226
0.030	1.112	0.800 1.190	0.800 1.190
0.040	1.490	1.0 1.167	1.0 1.167
0.050	1.766	1.5 1.139	1.5 1.139
0.060	1.892	3.0 1.117	3.0 1.117
0.080	1.903	6.0 1.109	6.0 1.109
0.100	1.811	10.0 1.111	10.0 1.111
0.125	1.696		

Table 2.2: Conversion coefficients from air kerma free-in-air to $h_p(0.07,0^\circ)$ in an International Commission on Radiation Units and Measurements ICRU slab (photons)

Photon energy (MeV)	$H_p(0.07,0_o)/K$ (Sv/Gy)	Photon energy (MeV)	$H_p(0.07,0_o)/K$ (Sv/Gy)
0.005	0.750	0.100	1.669
0.010	0.947	0.150	1.518
0.015	0.981	0.200	1.432
0.020	1.045	0.300	1.336
0.030	1.230	0.400	1.280
0.040	1.444	0.500	1.244
0.050	1.632	0.600	1.220
0.060	1.716	0.800	1.189
0.080	1.732	1.000	1.173

Table 2.3: Effective dose per unit neutron fluence e/ϕ for monoenergetic neutrons incident in international organisation for standardisation geometry on an adult anthropomorphic computational phantom

Neutron energy (MeV)	E/Φ (pSv·cm ²)	Neutron energy (MeV)	E/Φ (pSv·cm ²)
1.00×10^{-9}	2.40	1.50×10^{-1}	35.2
1.00×10^{-8}	2.89	2.00×10^{-1}	42.4
2.53×10^{-8}	3.30	3.00×10^{-1}	54.7
1.00×10^{-7}	4.13	5.00×10^{-1}	75.0
2.00×10^{-7}	4.59	7.00×10^{-1}	92.8
5.00×10^{-7}	5.20	9.00×10^{-1}	108
1.00×10^{-6}	5.63	1.00×10^0	116
2.00×10^{-6}	5.96	1.20×10^0	130
5.00×10^{-6}	6.28	2.00×10^0	178
1.00×10^{-5}	6.44	3.00×10^0	220
2.00×10^{-5}	6.51	4.00×10^0	250
5.00×10^{-5}	6.51	5.00×10^0	272
1.00×10^{-4}	6.45	6.00×10^0	282
2.00×10^{-4}	6.32	7.00×10^0	290
5.00×10^{-4}	6.14	8.00×10^0	297
1.00×10^{-3}	6.04	9.00×10^0	303
2.00×10^{-3}	6.05	1.00×10^1	309
5.00×10^{-3}	6.52	1.20×10^1	322

1.00×10^{-2}	7.70	1.40×10^1	333
2.00×10^{-2}	10.2	1.50×10^1	338
3.00×10^{-2}	12.7	1.60×10^1	342
5.00×10^{-2}	17.3	1.80×10^1	345
7.00×10^{-2}	21.5	2.00×10^1	343
1.00×10^{-1}	25.2		

Table 2.4: Reference conversion coefficients from fluence to directional dose equivalent for monoenergetic electrons and normal incidence

Electron energy (MeV)	$H'(0.07,0^\circ)/\Phi$ (nSv·cm ²)	$H'(3,0^\circ)/\Phi$ (nSv·cm ²)	$H'(10,0^\circ)/\Phi$ (nSv·cm ²)
0.07	0.221		
0.08	1.056		
0.09	1.527		
0.10	1.661		
0.1125	1.627		
0.125	1.513		
0.15	1.229		
0.20	0.834		
0.30	0.542		
0.40	0.455		
0.50	0.403		
0.60	0.366		
0.70	0.344	0.000	
0.80	0.329	0.045	
1.00	0.312	0.301	
1.25	0.296	0.486	
1.50	0.287	0.524	
1.75	0.282	0.512	0.000
2.00	0.279	0.481	0.005
2.50	0.278	0.417	0.156
3.00	0.276	0.373	0.336
3.50	0.274	0.351	0.421
4.00	0.272	0.334	0.447
5.00	0.271	0.317	0.430
6.00	0.271	0.309	0.389
7.00	0.271	0.306	0.360
8.00	0.271	0.305	0.341
10.00	0.275	0.303	0.330

THIRD SCHEDULE - Categories for Sealed Sources Used in Common Practices

Table 3.1: Categorisation of sealed sources

Category	Ratio of activity in the source to activity that is considered dangerous ^a (A/D)	Example of sources ^b and practices
1	$A/D \geq 1000$	• Radioisotope thermoelectric generators (RTGs) • Irradiators • Teletherapy • Fixed, multi-beam teletherapy (gamma knife)
2	$1000 > A/D \geq 10$	• Industrial gamma radiography • High/medium dose rate brachytherapy
3	$10 > A/D \geq 1$	• Fixed industrial gauges incorporating high activity sources (e.g. level gauges, dredger gauges etc.); • Well logging gauges
4	$1 > A/D \geq 0.01$	• Low dose rate brachytherapy (except eye plaques and permanent implant sources) • Industrial gauges not incorporating high activity sources (e.g. moisture/density gauges etc.); • Bone densitometers • Static eliminators
5	$0.01 > A/D$ and $A >$ level for Exemption ^c	• Low dose rate brachytherapy eye plaques and permanent implant sources • X ray fluorescence devices • Electron capture devices • Mossbauer spectrometry • Positron Emission Tomography (PET) checking

^a A is the activity of the radionuclide in a source and D is the activity of that radionuclide that is regarded as dangerous. A dangerous source is defined as one that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. Values of D for selected radionuclides are given in Table 3.2 on the basis of the quantity of radioactive material that could give rise to severe deterministic effects for given exposure scenarios and for given dose criteria. This column of the table can, thus, be used to determine the category of a source, purely on the basis of the value of A/D. This may be appropriate if, for example: 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.

^b Factors other than A/D have been taken into consideration in assigning these sources to a particular category.

^c Levels for exemption are given in Schedule 1.

Table 3.2: Activity^a corresponding to a dangerous source (D Value) 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}	Tl-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 dose criteria were used, these D values cannot be used 'in reverse' to derive possible doses from exposure due to sources of known activity.

FOURTH SCHEDULE – Criteria for use in Emergency Preparedness and Response

Table 4.1: Generic criteria for doses received within a short period of time for which protective actions and other response actions are expected to be undertaken under any circumstances to avoid or to minimise severe deterministic effects

Acute external exposure (<10 h)		If the dose is projected:
AD _{red marrow} ^a	1 Gy	- Take precautionary urgent protective actions immediately (even under difficult conditions) to keep doses below the generic criteria - Provide public information and warnings - Carry out urgent decontamination
AD _{fetus}	0.1 Gy	
AD _{tissue} ^b	25 Gy at 10.5cm	
AD _{skin} ^c	10 Gy to 100cm ²	
Acute internal exposure due to an intake ($\Delta = 30$ d)^d		If the dose has been received:
AD (Δ) _{red marrow}	0.2 Gy for radionuclides with atomic number $Z \geq 90$ 2 Gy for radionuclides with an atomic number $Z \leq 89$ ^e	- Perform immediate medical examination, consultation and indicated medical treatment - Carry out contamination control - Carry out immediate decorporation^f (if applicable) - Carry out registration for longer term medical follow-up - Provide comprehensive physiological counselling
AD (Δ) _{thyroid}	2 Gy	
AD (Δ) _{lung} ^g	30 Gy	
AD(Δ) _{colon}	20 Gy	
AD(Δ) _{fetus} ^h	0.1 Gy	

^a AD_{red marrow} represents the average relative biological effectiveness (RBE) weighted absorbed dose to internal tissues or organs (e.g. red marrow, lung, small intestine, gonads, thyroid) and to the lens of the eye from exposure in a uniform field of strongly penetrating radiation.

^b Dose delivered to 100 cm² at a depth of 0.5 cm under the body surface in tissue due to close contact with a radioactive source (e.g. source carried in the hand or pocket).

^c The dose is to the 100 cm² dermis (skin structures at a depth of 40 mg/cm² (or 0.4 mm) below the surface).

^d AD(Δ) is the RBE weighted absorbed dose delivered over a period of time Δ by the intake (I_{05}) that will result in a severe deterministic effect in 5% of exposed individuals.

^e Different generic criteria are used to take account of the significant difference in RBE weighted absorbed dose from exposure at the intake threshold values specific for these two groups of radionuclides.

^f Decorporation is the action of the biological processes, facilitated by chemical or biological agents, by means of which incorporated radionuclides are removed from the human body. The generic criterion for decorporation is based on the projected dose without decorporation.

^g For the purposes of these generic criteria, ‘lung’ means the alveolar-interstitial region of the respiratory tract.

^h For this particular case, ‘ Δ ’ means the period of in utero development of the embryo and fetus.

Table 4.2: Guidance values for restricting exposure of emergency workers

Tasks	Guidance Value ^a
Lifesaving actions	$H_p(10)^b < 500 \text{ mSv}$ 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	$H_p(10) < 500 \text{ mSv}$
Actions to avert a large collective dose	$H_p(10) < 100 \text{ mSv}$

^a 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.

^b $H_p(10)$ is the personal dose equivalent $H_p(d)$ where $d = 10 \text{ mm}$.