PART 1: GENERAL PROVISIONS

Title

1. Radiation Protection (Safety and Security of Radioactive Sources), Regulations, Ammendmet

Purpose

2. (1)These Regulations specify the basic requirements:

(a) For protection of people against exposure to ionizing radiation, for the safety of radiation sources, for the safety of radioactive waste management, and for protection of the environment, hereinafter termed ‘protection and safety’;

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

(c) To implement the Country’s international commitments relevant to radiation safety.

(2) They are not intended to relieve an authorized legal person from the duty to take any additional actions as may be appropriate and necessary to protect the health and safety of people.

Scope

3. (1) These Regulations apply to the adoption, introduction, conduct, discontinuance, or cessation of a practice in a planned exposure situation and to the design, manufacture, construction or assembly, acquisition, import or export, distribution, selling, loaning or hiring, locating, commissioning, processing, possession, use and operation, maintenance or repair, transfer or decommissioning, disassembly, transport, storage and recycling or disposal of a radiation source within a practice other than in accordance with these Regulations.

(2) These regulations apply in particular to:

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

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

(c) human activities which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:

(i) the operation of aircraft, in relation to the exposure of crews;

(ii) the processing of materials with naturally-occurring radionuclides;

(d) the exposure of workers or members of the public to indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past human activity.

(e) the preparedness for, the planning of response to and the management of emergency exposure situations that are deemed to warrant measures to protect the health of members of the public or workers.

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

(g) The use of radiation or radioactive material for education, training or research, including any activities relating to such use that involve or could involve exposure to radiation or exposure due to radioactive material;

(3) The sources within any practice to which the requirements for practices of these Regulations shall apply include:

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

(b) Individual sources of radiation, including sources within the types of facility mentioned in para. (a), as appropriate, in accordance with the requirements of the Authority;

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

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(d) Radioactive waste resulting from applications and to radioactive waste management facilities and activities including:

(i) Effluent discharges;

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

(iii) Disused radioactive sources.

(e) Any other radiation source specified by the regulatory body, including sources in the environment such as radon.

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

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

Interpretation

4. In these regulations –

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

"Act" means the Radiation protection Act [Chapter 15:15] No.5/2004;

"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;

“authority” means the Radiation Protection Authority of Zimbabwe;

“authorization” means a permission granted by the regulatory body to a person, natural or juridical, who has submitted an application to carry out an activity or practice. An authorization may take the form of a licence or registration;

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

“Civil Protection Organisation” means the Civil Protection organization as defined in the Civil Protection Act [*Chapter 10:06];*

“clearance” means the removal of radioactive materials or radioactive substances within authorized practices from any further control by the Authority;

"clearance levels" means values established by the Authority, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of these regulations;

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

“defence in depth” means the application of more than a single protective measure for a given safety objective, such that the objective is achieved even if one of the protective measures fails.

“decommissioning plan” means a detailed document containing detailed information on the proposed decommissioning of a facility;

“decommissioning” means administrative and technical actions taken to allow the removal of all the regulatory controls from the facility (except for a repository which is closed which is closed and not decommissioned);

“emergency” means a non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear or radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes. It includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard;

“emergency exposure situation” means an emergency exposure situation is 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 plan” means a description of the objectives, policy and concept of operations for the response to an emergency and of the structure, authorities and responsibilities for a systematic, coordinated and effective response. The emergency plan serves as the basis for the development of other plans, procedures and checklists;
“exemption” means a determination by the Authority that a source or practice need to be subject to some or all aspects of regulatory control on the basis that the exposure (including potential exposure) due to the source or practice is too small to warrant the application of those aspects;

“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 of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure);

“facility” means irradiation installations, mining and milling facilities, waste management facilities and any other place where radioactive materials are produced,

processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required;

“guidance levels” shall mean a level of specified dose limit quantity, above which appropriate actions should be considered;

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

“intervention” means any action intended to reduce or avert exposure or the likelihood of exposure to sources which are part of controlled practices;

“legal person” means Any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action taken under these Regulations. This includes natural persons;

“licensee” means the holder of a current licence granted for an activity or practice, which has recognized rights and duties for the activity or practice, particularly in relation to protection and safety;

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

"medical exposure" means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;

“medical practitioner” means a health professional, with specialist education and training in the concepts and techniques of applying physics in medicine, and competent

to practise independently in one or more of the subfields (specialties) of medical physics;

“monitoring” means the measurement of dose or contamination for the assessment or control of exposure to radiation or radioactive substances , and the interpretation of the results;

“normal exposure” means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including minor incidents that can be kept under control, i.e. during normal operation and anticipated operational occurrences;

“notification” means a document submitted to the Authority by the legal person to notify an intention to carry out an activity or practice;

"occupational exposure" means exposure of workers, apprentices and students, incurred in the course of their work;

“planned exposure situation” means a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure from a source;

“practice” means any human activity that introduces additional sources of exposure or 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;

“potential exposure” means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors;

“public exposure” means exposure of individuals, excluding any occupational or medical exposure;

"Public Protector" has the same meaning as in the Public Protector's Act [*Chapter 10:18*]

"quality assurance" means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance;

"radiation protection officer" means a person technically competent in radiation protection matters and who has been granted a certificate of authorization and is an employee of the Authority;

"radiation safety officer" means a person who is technically competent in radiation protection and safety matters for a given type of practice designated by a registrant or licensee to oversee the application of the requirements of these regulations;

"radioactive discharges" means radioactive substances arising from a source within a practice discharged as gases, aerosols, liquids or solid to the environment, generally with the purpose of dilution and dispersion;

"radioactive material" means any substance consisting of, or containing any radioactive nuclide, whether natural or artificial , including but not limited to, radioactive waste;

"radioactive waste disposal" means disposal of waste in an approved and specified facility without the intention of retrieving and including the approved direct discharge or airborne or liquid effluents into the environment for subsequent diversion;

"radioactive waste management" means all activities, administrative and operational, including decommissioning activities involved in the handling, pretreatment, conditioning, storage and disposal of waste from facility;

"radioactive waste" means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered , and which is regulated as radioactive waste by the Authority ;

“registrant” means an applicant who is granted registration of a practice or source and has recognized rights and duties of such a practice or source, particularly to protection and safety

“registration” means a form of authorization for practices of low or moderate risks whereby the legal person responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facility and equipment to the regulatory body. The practice or use is authorized with conditions or limitations as appropriate. The requirements for safety assessment and the conditions or limitations applied to the practice should be less severe than those for licensing;

“safety assessment” shall mean a review of the aspects of design and operation of a source relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations;

“safety culture” means The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance;

“security” means measure to prevent unauthorized access or damage to, loss, theft or unauthorized transfer of radioactive sources;

“Storage” means the holding of radioactive sources or radioactive waste in a facility that provides for their/its containment with the intention of retrieval;

“Supervised area” means an area subject to supervision for the purpose of protection against ionising radiation;

Exposures

5.The exposures to which the safety requirements of these Regulations apply are any occupational exposure, medical exposure or public exposure due to any relevant practice or radiation source within the practice, as specified in Articles 3 (2) and 3 (3).

Exclusion

6. These regulations shall not apply to:

(a) exposure to the natural level of radiation, such as radio- nuclides contained in the human body and cosmic radiation prevailing at ground level;

(b) exposure of members of the public or workers other than air crew to cosmic radiation in flight;

(c) above ground exposure to radionuclides present in the undisturbed earth's crust.

Responsibilities

7 (1) The person or organization responsible for any facility or activity that gives rise to radiation risks shall have the prime responsibility for protection and safety, which cannot be delegated.

(2) The principal parties having the main responsibilities for the application of these

Regulations shall be:

(a) Registrants or licensees, or persons or organizations responsible for notified or

authorized practices or sources within practices;

(b) Employers of workers, in relation to occupational exposure;

(c) Radiological medical practitioners, in relation to medical exposure;

(d) Those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.

(3) Other parties shall have specified responsibilities for the application of these Regulations. These parties may include, as appropriate:

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

(b) Radiation protection officers;

(c) Referring medical practitioners;

(d) Medical physicists;

(e) Medical radiation technologists;

(f) Qualified experts or any other party to whom a principal party has assigned specific responsibilities;

(g) Workers other than workers listed in (a)-(f);

(h) Ethics committees.

(4) The general responsibilities of the principal parties include the following:

(a) To establish radiation protection and safety objectives in conformity with the relevant requirements of these Regulations;

(b) To develop, implement and document a protection and safety programme commensurate with the radiation risks associated with the exposure situation under their responsibility (graded approach) and sufficient to ensure compliance with the requirements of these Regulations. In particular, this programme shall include the following actions:

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

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

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

(iv) To keep appropriate records regarding the discharge of their responsibilities.

(c) To ensure that:

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

(ii) When radioactive sources are not in use, they are promptly stored;

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

(iv) Arrangements are made for the safe management of radioactive sources (minimum Category 1, 2 and 3), including financial provisions where appropriate, once they have become disused;

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

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

(vii) Assistance is provided to State authorities or local law enforcement authorities in recovering any lost or stolen source.

(d) The relevant principal parties and other parties having specified responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification so that they understand their responsibilities and can perform their duties ompetently, with appropriate judgement and in accordance with procedures.

Regulatory Inspection of Premises and Information

8. The relevant principal parties shall permit access by authorized representatives of the regulatory body to carry out inspections of their facilities and activities and of their protection and safety records, and shall cooperate in the conduct of inspections.

Non-Compliance and Accidents

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

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

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

(c) Report to the Authority within 24 hours, or as required, on the causes of the breach, its circumstances and consequences, and on the corrective or preventive actions taken or to be taken (see Article 16);

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

(2). The communication of such a breach to the regulatory body shall be timely and it shall be immediate whenever an emergency exposure situation has developed or is developing.

(3). Whenever a situation involving the loss of control (e.g. loss, theft) of a Category 1, 2 or 3 radioactive source has occurred, or is occurring (see Article 16) the regulatory body shall be informed as soon as practicable.

4. Failure to take corrective or preventive actions within a reasonable time in accordance with these Regulations shall be grounds for enforcement in accordance with the provisions of these Regulations.

Additional Requirements

10. The licensee shall comply with additional requirements imposed by the regulatory body by regulation, order, or conditions of an authorization, in addition to those established in these Regulations, as deemed appropriate or necessary to:

(a) Protect health;

(b) Protect the environment; or

(c) Minimize risk from radiation hazards.

PART 2

Administrative Requirements

General Obligations

11. No person shall engage in activities, which involve practices, radiation sources, or radioactive waste, as specified in Article 3 of these Regulations, unless the requirements in the Act and these Regulations, including requirements of notification and authorization, are met.

Notification Requirements

12. Except for sources and practices exempted from regulatory control referred to in section 13, any person-

(a) who, on the effective date of these regulations, is responsible for a practice or is in possession of a radiation source referred to in section 2, shall submit a notification of such to the Authority.

(b) intending to initiate a practice or to possess a radiation source referred to in section 2, shall submit a prior notification to the Authority by such an intention.

(c) Sources and practices requiring notification only shall be prescribed in the directive issued there under by the Authority.

Exemption of Practices and Sources

13. (1) Practices and sources within a practice may be exempted from the requirements of these regulations including those for notification, registration or licensing if the authority is satsfied that the sources meet the exemption criteria or the exemption levels specified in Schedule I or other exemption levels specified by the Authority on the basis of the exemption criteria.

(2). Exemptions shall not be granted for practices deemed not to be justified as specified in Articles 19 and 45.

(3). A practice or a source within a practice may be exempted without further consideration provided that the following criteria are met in all feasible situations:

(a) effective dose expected to be incurred by any individual owing to the exempt practice or the exempt source within the practice after conducting a safety

assessment is of the order of 10 μSv or less in a year.

(b) effective dose expected to be incurred by any individual for low probability scenarios does not exceed 1 mSv in a year.

(4). The following practices and sources within a practice are automatically exempted from the specific safety requirements of these Regulations, including the requirements for notification, registration or licensing (see Articles 12 and 14):

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

(b) Radioactive material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Table I-2 of Schedule I of GSR Part 3;

(c) Equipment containing radioactive material exceeding the quantities or concentrations specified above, provided that:

(i) The equipment containing radioactive material is of a type approved by the Authority;

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

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

(iv) In normal operating conditions the equipment does not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the apparatus; or

(v) Necessary conditions for disposal of the equipment have been specified by the Authority.

(d) Radiation generators of a type approved by the Authority, or in the form of an electronic tube, such as a cathode ray tube for the display of visual images, provided that:

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

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

Requirements for Authorization by Registration or License

14. (1) Except as provided in Article 12 and Article 13 of these Regulations, any person or organization intending to engage in a practice or possess a radiation source referred to in Article 3 shall apply to the regulatory body for an authorization which shall take the form of either a registration or a licence.

(2) Any legal person applying for an authorization shall:

(a) Submit to the Authority relevant information necessary to support the application, including:

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

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

(iii) An appropriate prospective assessment made for radiological environmental impact, commensurate with the radiation risks associated with the facility or activity, where prescribed by the Authority;

(iv) An emergency plan;

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

(vi) A final disposal solution for generated radioactive waste and disused sealed sources;

(b) Take all necessary steps for the protection and safety of:

(i) Workers;

(ii) Members of the public;

(iii) Patients;

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

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

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

Responsibilities of Licensees

15(1)Licensees shall bear the primary responsibility for-

(i) establishing and implementing the technical and administrative measures that are needed for ensuring protection, and safety for the practices and sources for which they are authorized; and

(ii) compliance with all applicable requirements of these Regulations.

(2). Licensees may designate suitably qualified persons to carry out actions and tasks related to these responsibilities, but they shall retain the prime responsibility for protection and safety. Licensees shall document the names and responsibilities of persons designated.

(3). Licensees shall notify the regulatory body of any intention to introduce modifications to any practice or source for which they are licensed whenever the modifications could have significant implications for protection and safety, and they shall not carry out any such modification unless specifically authorized by the regulatory body.

(4). Licensees shall establish clear lines of responsibility and accountability for protection and safety for the sources for which they are authorized, and shall establish organizational arrangements for protection and safety.

(5). Licensees shall ensure that any delegation of responsibilities by a principal party is documented.

(6). Licensees shall ensure that the relevant principal parties and other parties having specified responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification so that they understand their responsibilities and

can perform their duties competently, with appropriate judgement and in accordance with procedures.

(7). Licensees shall have in place operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system.
(8). Licensees shall establish procedures for reporting on and learning from accidents and other incidents.
(9). Licensees shall ensure safe management of and control over all radioactive waste that is generated, and shall dispose of such waste in accordance with the regulatory requirements.
(10). During the entire lifecycle of radiation sources, from the moment of their manufacturing up to their final disposal, the respective licensees shall ensure that the appropriate safety measures are taken.
(11). For this purpose, licensees shall ensure that a multilevel (defence in depth) system of sequential, independent provisions for protection and safety that is commensurate with the likelihood and the magnitude of the potential exposures is applied to sources for which the licensees are authorized. Licensees shall ensure that if one level of protection were to fail, the subsequent independent level of protection would be available. Such defence in depth shall be applied for the purposes of:
(a) Preventing accidents;
(b) Mitigating the consequences of any accidents that do occur;
(c) Restoring the sources to safe conditions after any such accidents.
(12). Licensees shall ensure that structures, systems and components, including software, that are related to protection and safety for facilities and activities are designed, constructed, commissioned, operated and maintained so as to prevent accidents as far as reasonably practicable.
(13). The licensee for any facility or activity shall make suitable arrangements:
(a) To prevent reasonably foreseeable accidents in the facility or the activity;
(b) To mitigate the consequences of those accidents that do occur;
(c) To provide workers with the information, instruction, training and equipment necessary to restrict potential exposures;
(d) To ensure that there are adequate procedures for the control of the facility and for the management of any reasonably foreseeable accidents;

(e) To ensure that safety 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) To ensure that maintenance, inspection and testing appropriate to the preservation of the provisions for protection and safety can be carried out without undue occupational exposure;
(g) To provide, wherever appropriate, automatic systems for safely shutting off or reducing the release of radiation from facilities in the event that operating conditions are outside the stipulated ranges;
(h) To ensure that abnormal operating conditions that could significantly affect protection and safety are detected by systems that respond quickly enough to allow for corrective action to be taken in a timely manner;
(i) To ensure that all relevant safety documentation is available in the appropriate languages.
(14). The licensee shall ensure that the safety of the facility or of the waste shall not be jeopardized by any provision made for the purpose of complying with national or international requirements concerning safeguards of the material.

Requirements for Reporting to the Authority
16(1). Licensees shall:
(a) Notify the regulatory body by {telephone or other method e.g. facsimile, e-mail, etc. as determined by the regulatory body} facsimile immediately of any event in which a dose limit is exceeded;
(b) Notify the regulatory body by telephone or facsimile as soon as practicable, but not later than 24 hours after discovery, of any significant unintended or accidental medical exposures (see Article 55);
(c) Submit to the regulatory body, within 30 days after discovery of any significant unintended or accidental medical exposures, a written report which states the cause of the any significant unintended or accidental medical exposures and includes information on the doses, corrective measures and any other relevant information;
(d) Report a summary of the public exposure monitoring results to the regulatory body at approved intervals and promptly inform the regulatory body of any abnormal results which lead or could lead to an increase of public exposure (see Article 56);

(e) Report discharges of radioactive waste to the environment to the regulatory body at intervals as may be specified in the licence and promptly report any discharges exceeding the authorized limits.
(f) Report promptly and within 30 days submit a written report to the regulatory body any releases of radioactive material to the environment above the clearance criteria established by the regulatory body.

(2). In addition to the radiation safety related reports above, licensees shall make the following reports to the regulatory body:
(a) Radioactive source inventory data (see Article 30) and subsequent changes to those data, except for routine movements of the source allowed in the authorization;
(b) Unusual events or incidents, such as:
(i) Loss of control over a radioactive source;
(ii) Unauthorized access to, or unauthorized use of, a source;
(iii) Discovery of any orphan sources;
(c) Any intentions to introduce modifications to any practice with a radioactive source whenever the modifications could have significant implications for safety;
(d) A copy of relevant parts of any contract or acceptance document relating to the return of radioactive sources intending to be imported (see Articles 66, 67 and 68);

(3). Breaches of these Regulations shall be communicated to the regulatory body within 24 hours, and shall include the information required by Article 9;

(4). For radioactive sources in Category 1, 2 and 3, the Zimbabwe Republic Police shall be informed immediately and the Authority shall be informed as soon as practicable for:
(a) Lost sources;
(b) Actual or attempted theft of sources;

(5). Additional reports regarding radioactive waste shall be made in accordance with the directives issued by the Authority.
(6). Unless otherwise specified, all reports required by this Article shall be made in writing within 30 days.

Investigations and Feedback of Operating Experience

17(1). Licensees shall ensure that information on normal operation performance as well as abnormal conditions and events significant to radiation safety is disseminated or made available, as appropriate, to the regulatory body and other relevant parties, including other users, as specified by the regulatory body.

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

(3). Licensees shall conduct an investigation as specified by the regulatory body in the event that:

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

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

(4). The licensee shall conduct an investigation as soon as possible after an event and shall prepare a written record of its causes, or suspected causes, 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.

(5). The licensee shall communicate to the regulatory body and to any other relevant parties, as appropriate, a written report of any formal investigation relating to events prescribed by the regulatory body, including exposures giving rise to doses exceeding a dose limit. The licensee also shall immediately report to the regulatory body any event in which a dose limit is exceeded

Clearance

18. Radiation sources, including substances, materials, radioactive waste and objects within authorized practices can be released from further compliance with the radiation protection and safety requirements of these Regulations provided that they comply with criteria for clearance or clearance levels established by the Authority.

PART 3

RADIATION PROTECTION REQUIREMENTS

Justification of Practices

19.(1) No practice shall be authorized unless it is likely to produce sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause, taking into account social, economic and other relevant factors.

(2). If requested by the Authority, the applicant for an authorization shall provide sufficient information and evidence on the benefits and the harm to support the justification of the practice or source. The Authority may deny authorization of the proposal in the application on the basis that it is not justified.

(3).The following practices are deemed to be not justified:
(a) Practices, except for justified practices involving medical exposure, that result in an increase in activity, by the deliberate addition of radioactive substances or by activation[2] , in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person;
(b) Practices involving the frivolous use of radiation or radioactive substances in commodities or in products such as toys and personal jewellery or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation;
(c) Human imaging using radiation that is performed as a form of art or for publicity purposes.

(4). This requirement is not intended to prohibit those practices that may involve the short term activation of commodities or products, for which there is no increase in radioactivity in the commodity or product as supplied.

(5). Human imaging using radiation that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication, shall normally be deemed to be not justified. If, in exceptional circumstances, the government or the Authority decides that the justification of such human imaging for specific practices is to be considered, Articles 31(1), 31(2), 32(1) and 32(3) shall apply.

(6). Human imaging using radiation for theft detection purposes shall be deemed to be not justified.

(7). Human imaging using radiation for the detection of concealed objects for antismuggling purposes shall normally be deemed to be not justified. If, in exceptional circumstances, the government or the Authority decides that the justification of such human imaging is to be considered, Articles 34 and 35 shall apply.

(8). Human imaging using radiation for the detection of concealed objects that can be used for criminal acts or to pose a national security threat shall be justified only by the government. If the government decides that the justification of such human imaging is to be considered, Articles 31 and 32 shall apply.

Optimization of Protection and Safety

20. Licensees shall ensure that protection and safety is optimized. For occupational exposure and public exposure[3], licensees shall ensure that all relevant factors are taken into account in a coherent way in the optimization of protection and safety to contribute to achieving the following objectives:

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

(b) To establish criteria, on the basis of the results of the optimization, for the restriction of the likelihood and magnitudes of exposures by means of measures for preventing accidents and for mitigating the consequences of those that do occur.

Dose Constraints

(21) Dose constraints shall be established for the purpose of optimization of protection:

(a) for occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking under the general supervision of the competent authority. In the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking.

(b) for public exposure, the dose constraint shall be set for the individual dose that members of the public receive from the planned operation of a specified radiation source. The competent authority shall ensure that the constraints are consistent with the dose limit for the sum of doses to the same individual from all authorised practices.

(c) for medical exposure, dose constraints shall apply only with regard to the protection of carers and comforters and volunteers participating in medical or biomedical research.

Dose Limits

(22) Licensees shall ensure that the exposures of individuals due to the practices for which the licensees are authorized are restricted so that neither the effective dose nor the equivalent dose to tissues or organs exceeds any relevant dose limit specified in Annex II.

Management Requirements

23(1).The principal parties shall ensure that protection and safety is effectively integrated into the overall management system of the organizations for which they are responsible.

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

(3). Licensees shall establish a management system, commensurate with the size and nature of the authorized activity, which ensures that:

(a) Policies and procedures are established that identify safety as being of the highest priority;

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

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

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

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

(4). The principal parties shall ensure that the management system is designed and implemented to enhance protection and safety by:

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

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

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

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

(e) Promoting safety culture.

(5). The principal parties shall ensure that the protection and safety elements of the management system are commensurate with the complexity of and the radiation risks associated with the activity.

Safety Culture

24. The principal parties shall promote and maintain a safety culture by:

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

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

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

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

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

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

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

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

Confidentiality of Information

25. Licensees shall establish information management systems, commensurate with the size and nature of the authorized activity, which ensure:

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

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

Human Factors

26(1).The principal parties and other parties having specified responsibilities in relation to protection and safety, as appropriate, shall take into account human factors and shall support good performance and good practices to prevent human and organizational failures, by ensuring that:

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

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

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

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

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

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

(3).Training programmes shall be routinely evaluated and updated as necessary.

Radiation Safety Officers and Qualified Experts

27. (1) Licensees shall arrange for qualified experts to be identified and made available for providing advice on the observance of these Regulations when so required by the Authority.

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

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

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

(5). Licensees shall keep the regulatory body informed of the arrangements made with respect to paragraphs 1 and 2 above.

Security of Sources

28. Sources shall be kept secure so as to prevent theft or damage, by ensuring that –

(a) control of a source not be relinquished without compliance with all relevant requirements specified in the registration or licence, and without immediate communication to the Authority

(b) a source is not to be transferred unless receiver possesses valid authorizations ; and

(c) a periodic inventory of movable sources be conducted at appropriate intervals to confirm that they are in their assigned locations and are secure

PART 4 : VERIFICATION OF SAFETY

Safety Assessment

29(1). The Authority may require the licensee shall prepare safety assessments that are either generic or specific to the practices or sources for which they are responsible, including radioactive waste management activities, so as:

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

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

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

(2). The safety assessment shall include, as appropriate, a systematic critical review of:
(a) The operational limits and conditions for the operation of a facility;
(b) The ways in which structures, systems and components, including software, and procedures relating to protection and safety might fail, singly or in combination, or might otherwise give rise to exposures, and the consequences of such events;
(c) The ways in which external factors could affect protection and safety;
(d) The ways in which operating procedures relating to protection and safety might be erroneous, and the consequences of such errors;
(e) The implications for protection and safety of any modifications;
(f) The implications for protection and safety of security measures or of any modifications to security measures;
(g) Any uncertainties or assumptions and their implications for protection and safety.

(3). The licensee shall take into account in the safety assessment:
(a) Factors that could give rise to a substantial release of radioactive material, the measures available to prevent or to control such a release, and the maximum activity of radioactive material that, in the event of a major failure of the containment, could be released to the environment;
(b) Factors that could give rise to a smaller but continuing release of radioactive material, and the measures available to detect and to prevent or to control such a release;
(c) Factors that could give rise to unintended operation of any radiation generator or a loss of shielding, and the measures available to detect and to prevent or control such occurrences;
(d) The extent to which the use of redundant and diverse safety features, that are independent of each other so that failure of one does not result in failure of any other, is appropriate to restrict the likelihood and magnitude of potential exposure.

(4). Licensees shall ensure that the safety assessment is documented and, where appropriate, that it is independently reviewed under the relevant management system.

(5). Licensees shall perform additional reviews of the safety assessment as necessary to ensure that the technical specifications or conditions of use continue to be met when:

(a) Significant modifications to the facility or to its operating procedures or maintenance procedures are envisaged;
(b) Significant changes occur on the site that could affect the safety of the facility or of activities on the site;
(c) Information on operating experience, or information about accidents and other incidents that could result in exposures, indicates that the current assessment might be invalid;
(d) Any significant changes in activities are envisaged;
(e) Any relevant changes in guidelines or standards have been made or are envisaged.

(6). If as a result of a safety assessment, or for any other reason, opportunities to improve protection and safety appear to be available and improvement seems desirable, any consequential modifications shall be made cautiously and only after favourable assessment of all the implications for protection and safety. The implementation of all improvements shall be prioritized so as to optimize protection and safety.

Monitoring, Testing and Verification of Compliance

29. Licensees and employers shall ensure that:
(a) Monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of regulations and licence conditions;
(b) Suitable equipment is provided and procedures for verification are implemented;
(c) Equipment is properly maintained, tested and calibrated at appropriate intervals with reference to standards traceable to national or international standards;
(d) Records are maintained of the results of monitoring and verification of compliance, as required by the regulatory body, including records of the tests and calibrations carried out in accordance with regulations and licence conditions;
(e) The results of monitoring and verification of compliance are shared with the regulatory body as required.

Inventory and Records

30.(1) Licensees shall establish, maintain and be able to retrieve records relating to:
(a) Inventory of sealed sources and radiation generators;
(b) Records of doses from occupational exposures;
(c) Records relating to facilities and activities;

(d) Inventory of radioactive waste;

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

(f) Records that might be necessary for decommissioning or closure of facilities;

(g) The transfer of radioactive sources;

(h) The testing of instruments and safety systems, and calibrations carried out in accordance with the requirements of the Regulations

(2). Individual sealed source records shall include the:

(a) Location of the source;

(b) Radionuclide;

(c) Radioactivity on a specified date;

(d) Serial number or unique identifier;

(e) Chemical and physical form;

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

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

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

(3). Licensees shall provide the regulatory body as required with appropriate information from their inventory records of radiation generators and radioactive sources. Licensees shall check inventory periodically to confirm that radiation generators are in their assigned locations and are under control.

PART 5: HUMAN IMAGING FOR PURPOSES OTHER THAN MEDICAL DIAGNOSIS

Justification of practices of any type of human imaging using radiation

31(1). The justification process applied to the practice of any type of human imaging procedure in which radiation is used for purposes other than for medical diagnosis or medicaltreatment or as part of a programme of biomedical research 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;

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

(2). If it has been determined through the process specified in (1) that a particular practice of human imaging using radiation is justified, then, such a practice shall be subject to regulatory control.

Optimization of protection and safety

32(1). For human imaging using radiation conducted by medical personnel using medical radiological equipment, which exposes humans to radiation for employment related, legal or health insurance4 purposes without reference to clinical indications, the licensee shall ensure that the appropriate optimization requirements for medical exposure in Article 46 of these Regulations are applied, with dose constraints used instead of diagnostic reference levels.

(2). 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 shall be considered to give rise to public exposure. Licensees shall apply the requirements for public exposure (Articles 57-63). In particular, licensees shall ensure that optimization of protection and safety is subject to any dose constraints for public exposure set by the government or the regulatory body.

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

(4). The licensee shall ensure that any inspection imaging device used for the detection of concealed objects on or within the body, whether it is manufactured in or imported into the State in which it is used, conforms to applicable standards of the International Electrotechnical Commission (IEC) or the International Organization for Standardization (ISO) or to equivalent national standards.

PART 6: OCCUPATIONAL EXPOSURE

General Responsibilities

33(1). For workers who are engaged in activities in which they are or could be subject to occupational exposure in planned exposure situations, licensees and employers shall be responsible for:

(a) Protection of workers against occupational exposure;

(b) Compliance with relevant requirements of regulations and licence conditions.

(2). Licensees and employers shall ensure, for all workers engaged in activities in which they are or could be subject to occupational exposure, that:

(a) Occupational exposures is controlled so that the relevant dose limits for occupational exposure specified in Annex II are not exceeded;

(b) Protection and safety is optimized in accordance with Articles 21 and 22;

(c) Decisions with regard to measures for protection and safety are recorded and made available to relevant parties, through their representatives where appropriate, as specified by the Authority;

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

(e) Suitable and adequate facilities, equipment and services for protection and safety are provided, the type and extent of which are commensurate with the expected likelihood and magnitude of the occupational exposure;
(f) Necessary workers' health surveillance and health services for workers are provided;
(g) Appropriate monitoring equipment and personal protective equipment are provided and arrangements are made for its proper use, calibration, testing and maintenance;
(h) Suitable and adequate human resources and appropriate training in protection and safety are provided, as well as periodic retraining as required to ensure the necessary level of competence;
(i) Adequate records are maintained in accordance with the requirements of regulations and licence conditions;
(j) Arrangements are made to facilitate consultation and cooperation with workers, with regard to protection and safety, through their representatives where appropriate, on all measures to achieve effective application of these Regulations;
(k) Necessary conditions for promoting a safety culture are provided.

(3). Licensees and employers shall:
(a) Involve workers, through their representatives where appropriate, in optimization of protection and safety;
(b) Establish and use, as appropriate, constraints as part of optimization of protection and safety.
(4). Licensees and employers shall ensure that workers exposed to radiation from sources within a practice that are not required by or directly related to their work have the same level of protection against such exposure as members of the public.
(5). Licensees and employers shall take such administrative actions as are necessary to ensure that workers are informed that ensuring protection and safety is an integral part of a general occupational health and safety programme in which they have specific obligations and responsibilities for their own protection and the protection of others against radiation exposure and for the safety of sources.
(6). Licensees and employers shall record any report received from a worker that identifies any circumstances that could affect safety conditions or compliance with the requirements of these Regulations, and shall take appropriate remedial actions.
(7). Employers and licensees shall facilitate compliance by workers with the requirements of these Regulations.

Cooperation between Employers and Licensees

34(1). Employers and licensees shall cooperate to the extent necessary for compliance by all responsible parties with the requirements of the Regulations.

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

(3).Cooperation between the employer and the licensee shall include, where appropriate:

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

(b) Specific assessments of the doses received by workers as specified in (a);

(c) A clear allocation and documentation of the responsibilities of the employer and those of the licensee for protection and safety.

(4). As part of the cooperation between parties, the licensee responsible for the source or for the exposure shall, as appropriate:

(a) Obtain from the employers, including self-employed individuals, the previous occupational exposure history of workers as specified in Article 39(1), and any other necessary information;

(b) Provide appropriate information to the employer, including any available information relevant for compliance with the requirements of these Standards that the employer requests;

(c) Provide both the worker and the employer with the relevant exposure records

Classification of Areas

35(1). Controlled Areas

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

(i) Controlling exposures or preventing the spread of contamination in normal operations;

(ii) Preventing or limiting the likelihood and magnitude of exposures in anticipated

operational occurrences and accident conditions.

(b) Licensees shall:

(i) Determine the boundaries of any controlled area on the basis of the likelihood and magnitude of expected exposures and the type and extent of the procedures required for protection and safety;

(ii) Delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;

(iii) Where a source is only intermittently brought into operation or energized or is moved from place to place, delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances and specifiy exposure times;

(iv) Display a warning symbol, recommended by the ISO, and display instructions at access points to and at appropriate locations within controlled areas;

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

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

(vii) Provide, as appropriate, at entrances to controlled areas:

a. Personal protective equipment;

b. Equipment for individual monitoring and workplace monitoring;

c. Suitable storage for personal clothing;

(viii) Provide, as appropriate, at exits from controlled areas:

a. Equipment for monitoring for contamination of skin and clothing;

b. Equipment for monitoring for contamination of any objects or material being removed from the area;

c. Washing or showering facilities and other personal decontamination facilities;

d. Suitable storage for contaminated personal protective equipment;

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

(i) Provide appropriate information, instruction and training for persons working in controlled areas.

(2). Supervised Areas

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

(b) Licensees, taking into account the nature, likelihood and magnitude of exposures or contamination in the supervised areas, shall:

(i) Delineate the supervised areas by appropriate means;

(ii) Display approved signs, as appropriate, at access points to supervised areas;

(iii) Shall 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 and Procedures and Personal Protective Equipment

36(1). Employers and licensees shall minimize the need to rely on administrative controls and personal protective equipment for protection and safety by providing well engineered controls and satisfactory working conditions, in accordance with the following hierarchy:

(a) Engineered controls;

(b) Administrative controls;

(c) Personal protective equipment.

(2). Licensees and employers shall, in consultation with workers, through their representatives, in a language appropriate to the audience addressed:

(a) Establish in writing local rules and procedures that are necessary for protection and safety for workers and other persons;

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

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

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

(e) Designate, as appropriate, a radiation protection officer in accordance with criteria established by the regulatory body.

(3). Licensees and employers shall ensure that:

(a) If necessary, workers are provided with suitable and adequate personal protective equipment that meets relevant standards or specifications, including as appropriate:

(i) Protective clothing;

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

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

(b) Where appropriate, workers receive adequate instruction in t

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

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

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

Monitoring of Workplace

37(1). Licensees, in cooperation with employers if appropriate, shall establish, maintain and keep under review a programme for the monitoring at the workplace under the supervision of a radiation protection officer or qualified expert, commensurate with the graded approach.

(2). The type and frequency of monitoring of workplaces shall:

(a) Be sufficient to enable:

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

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

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

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

(3). Licensees, in cooperation with employers where appropriate, shall maintain records of the findings of the workplace monitoring programme. The findings of the workplace monitoring programme shall be made available to workers, where appropriate through their representatives.

(4) The programmes for monitoring of the workplace shall specify:

(a) The quantities to be measured;

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

(c) The most appropriate measurement methods and procedures;

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

Occupational Exposure Assessment

38(1). Licensees and employers shall be responsible for making arrangements for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that arrangements are made with appropriate or approved dosimetry service providers that operate under a quality management system.

(2). For any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible. In cases where individual monitoring of the worker is inappropriate, inadequate or not feasible, the occupational exposure shall be assessed on the basis of the results of workplace monitoring and information on the locations and duration of exposure of the worker.

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

(4). Employers shall ensure that workers who could be subject to exposure due to contamination are identified, including workers who use respiratory protective equipment. Employers shall 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.

Records of Worker Exposure

39(1). Employers and licensees shall maintain records of occupational exposure for each worker for whom assessment of occupational exposure is required under Article 38.

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

(3). Records of occupational exposure shall include:

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

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

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

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

(4). Employers and licensees shall:

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

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

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

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

(e) In complying with (a)–(d) above, give due care and attention to maintaining the confidentiality of records.

(5). If employers and licensees cease to conduct activities in which workers are subject to occupational exposure, they shall make arrangements for the retention of workers' records of occupational exposure by the Authority or by relevant employer or licensee.

Workers' Health Surveillance

(40)1. Employers and licensees, in accordance with the rules established by the Authority, shall make arrangements for appropriate health surveillance based on the general principles of occupational health and designed to assess the initial fitness and continuing fitness of workers for their intended tasks.

2. If one or more workers are to be engaged in work in which they are or could be exposed to radiation from a source that is not under the control of their employer, the licensee 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 regulatory body or other relevant authority.

Information, Instructions and Training

41. Employers, in cooperation with licensees:

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

(b) Shall provide those workers who could be involved in or affected by the response to an emergency with appropriate information, and adequate instruction and training and periodic retraining, for protection and safety;

(c) Shall maintain records of the training provided to individual workers.

Conditions of Service

42(1). The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for measures for protection and safety in accordance with the requirements of these Regulations.

(2). Employers shall make all reasonable efforts to provide workers with suitable alternative employment in circumstances for which it has been determined, either by the regulatory body or in the framework of the programme for workers' health

surveillance in accordance with the requirements of these Regulations, that workers, for health reasons, may no longer continue in employment in which they are or could be subject to occupational exposure.

Special Arrangements for female workers and for persons under 18 years of age undergoing training

43(1). Employers, in cooperation with licensees, shall provide female workers who are liable to enter controlled areas or supervised areas or who may undertake emergency duties with appropriate information on:

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

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

(c) The risk of health effects for a breast-fed infant due to ingestion of radioactive substances.

(2). Notification of the employer by a female worker if she suspects that she is pregnant or if she is breast-feeding shall not be considered a reason to exclude a female worker from work. The employer of a female worker, who has been notified of her suspected pregnancy or that she is breast-feeding, shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus or the infant is afforded the same broad level of protection as is required for members of the public.

(3). Employers and licensees shall ensure that no person under the age of 16 years is or could be subject to occupational exposure.

(4). Employers and licensees shall ensure that persons under the age of 18 years are allowed access to a controlled area only under supervision and only for the purpose of training for employment in which they are or could be subject to occupational exposure or for the purpose of studies in which sources are used

PART 7:MEDICAL EXPOSURE CONTROL

General Responsibilities

44. (1) Unless administered by a medical practitioner, the delivery of diagnostic or therapeutic services and machines is prohibited.

(2) Licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:

(a) It 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;

(b) The medical 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;

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

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

(2). Licensees shall ensure that no individual incurs a medical exposure as part of a programme of biomedical research unless 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) as required in para. 5 of this Article and a radiological medical practitioner has assumed responsibility as specified in para. 4(a) of this Article. Licensees shall ensure that the requirements are met for the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research.

(3). Licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. Licensees shall ensure that the requirements specified in Article 54(1) are fulfilled for the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

(4). Licensees shall ensure that

(a) The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall protection and safety for patients in the planning and delivery of the medical exposure, including the justification of the radiological procedure as required in Article 45 and the optimization of protection and safety, in cooperation with the medical physicist and the medical radiation technologist;

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

(c) Sufficient medical personnel and paramedical personnel are available as specified by the health authority;

(d) Medical personnel and paramedical personnel are specialized in the appropriate area and meet the respective requirements for education, training and competence in radiation protection (*as specified by the Authority*);

(e) The names of all medical and paramedical personnel are named in a list maintained upto-date;

(f) For therapeutic radiological procedures, the requirements of these Regulations for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Articles 47, 48(c), 50(1) and 49(2), are conducted by or under the supervision of a medical physicist;

(g) For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Articles 47, 48(a), 48(b), 49, 50(1) and 50(2), are fulfilled by or under the oversight of or with the documented advice of a medical physicist,

whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks;

(h) Any delegation of responsibilities by a principal party is documented

Justification of Medical Exposure

45(1). Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.

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

(a) The appropriateness of the request;

(b) The urgency of the radiological procedure;

(c) The characteristics of the medical exposure;

(d) The characteristics of the individual patient;

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

(3). Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.

(4). Justification for radiological procedures 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 bodies.

(5). Any 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 relevant professional bodies or the health authority. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

(6). The exposure of volunteers as part of a programme of biomedical research is deemed to be not justified unless:

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

(b) It is subject to approval by an ethics committee

, subject to any dose constraints that may be specified (as required in Article 51(2)), and subject to applicable national regulations and local regulations.

Optimization of Protection for Medical Exposures

46(1). Licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

Design considerations

(2). In addition to ensuring that the responsibilities stated in Article 65 (1) are discharged, as applicable, licensees, in cooperation with suppliers, shall ensure that medical radiological equipment, and software that could influence the delivery of medical exposure are used only if they conforms to the applicable standards of the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) or to national standards adopted by the regulatory body.

Operational considerations

(3). For diagnostic radiological procedures and image guided interventional procedures, the radiological medical practitioner, in cooperation with the medical radiation technologist and the medical physicist, and if appropriate with the radiopharmacist or radiochemist, shall ensure that the following are used:

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

(b) Appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable image quality established by relevant professional bodies and of relevant diagnostic reference levels established in accordance with Article 49.

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

(5). For therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, and if appropriate with the radiopharmacist or radiochemist, shall ensure that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered so that the radioactivity is primarily localized in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.

(6). Licensees shall ensure that the particular aspects of medical exposures are considered in the optimization process for:

(a) Paediatric patients subject to medical exposure;

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

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

(d) Relatively high doses to the patient;

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

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

Calibration of equipment

47. In accordance with Articles 44(4f) and 44(4g), Licensees shall ensure that:

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

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

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

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

Dosimetry of Patients

(48) Licensees shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:

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

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

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

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

Diagnostic Reference Levels

49. Licensees shall ensure that:

(a) Local assessments, on the basis of the measurements required in Article 48, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established by the Authority;

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

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

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

Quality Assurance for Medical Exposure

50(1). Licensees shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate.

(2). Licensees shall ensure that programmes of quality assurance for medical exposures include, as appropriate to the medical radiation facility:

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

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

(ii) Periodically thereafter;

(iii) After any major maintenance procedure that could affect protection and safety of patients;

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

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

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

(d) Maintaining records of relevant procedures and results;

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

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

Dose Constraints

51(1). Licensees shall ensure that relevant dose constraints are used in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter.

(2). Licensees shall ensure that dose constraints specified or approved by the ethics committee, or by another 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 (Article 45(6)) are used in the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research.

Pregnant or breast-feeding female patients

52(1). Licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding.

(2). Licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that:

(a) She is or might be pregnant;

(b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.

(3). Licensees shall ensure that there are procedures in place for 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 fetus, so that this information can be considered in the justification for the radiological procedure (Article 45(1)) and in the optimization of protection and safety (Article 46(6)).

(4). Licensees shall ensure that there are arrangements in place for establishing that a female patient is not currently breast-feeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breast-fed infant, so that this information can be considered in the justification for the radiological procedure (Article 45(1)) and in the optimization of protection and safety (Article 46(6))

Discharge of Patients from hospital

53(1). Licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.

(2). The radiological medical practitioner shall ensure that no patient who has undergone a therapeutic radiological procedure with sealed sources or unsealed sources is 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 ;

(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;

(ii) Information on the radiation risks.

Unintended and Accidental Medical Exposures

54. Licensees, in accordance with the relevant requirements of Articles 15(11), 15(12), 24, 64(2) and 70, shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.

Investigation of Unintended and Accidental Medical Exposures

55(1). Licensees responsible for a source to be used for medical exposure shall promptly investigate any of the following unintended or accidental medical exposure:

(a) Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;

(b) Any 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;
(c) Any exposure for diagnostic purposes that is substantially greater than was intended;
(d) Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;
(e) Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;
(f) Any failure of medical radiological equipment, failure of software or system failure, accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.
(2). Licensees shall, with regard to any unintended or accidental medical exposures investigated as required above:
(a) Calculate or estimate the doses received and the dose distribution within the patient;
(b) Indicate the corrective actions required to prevent recurrence of such an unintended or accidental exposure;
(c) Implement all the corrective actions that are under their own responsibility;
(d) Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a) to (c) above,as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by the Authority, submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate;
(e) Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure.

Records Related to Medical Exposures

56(1). Licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records:
(a) Records of any delegation of responsibilities by principal parties (as required in Article 44(4h);
(b) Records of training of personnel in radiation protection.

(2). Licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance:

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

(b) Records of dosimetry of patients, as required in Article 48;

(c) Records of local assessments and reviews made with regard to diagnostic reference levels, as required in Article 49;

(d) Records associated with the quality assurance programme, as required in Article 50(2d).

(3). Licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records for medical exposure:

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

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

(c) For nuclear medicine, the types of radiopharmaceutical administered and their activity;

(d) For 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;

(e) Exposure records for volunteers subject to medical exposure as part of a programme of biomedical research;

(f) Reports on investigations of unintended and accidental medical exposures (as required in Article 55(2d).

PART 8: PUBLIC EXPOSURE

General Responsibilities

57(1). Licensees in cooperation with suppliers and with providers of consumer products shall apply the requirements of these Regulations and shall verify and demonstrate compliance with them, as specified by the regulatory body, in relation to any public exposure delivered by a source for which they have responsibility.

(2). Licensees in cooperation with suppliers, in applying the principle of optimization 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), shall take into account:

(a) Possible changes in any conditions that could affect exposure of members of the public, such as changes in the characteristics and use of the source, changes in environmental dispersion conditions, changes in exposure pathways 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.

(3). Licensees, for sources under their responsibility, shall establish, implement and maintain:

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

(b) Measures for ensuring:

(i) Optimization of protection and safety;

(ii) Limitation of exposure of members of the public from such sources, in order that the total exposure is not higher than the dose limits for members of the public as specified in Annex II;

(c) Measures for ensuring the safety of such sources;
(d) Provision for suitable and adequate resources (including facilities, equipment and services) for the protection and safety of members of the public, commensurate with the likelihood and magnitude of the exposures;
(e) Programmes for appropriate training of personnel having functions relevant to the protection and safety of the public, as well as periodic retraining as required, to ensure the necessary level of competence;
(f) Provision for appropriate monitoring equipment, monitoring programmes and methods for assessing public exposure;
(g) Emergency plans, emergency procedures and emergency response arrangements, in accordance with the nature and magnitude of the radiation risks associated with the sources;
(h) Adequate records of monitoring programmes.

Control of Visitors

58. Licensees, in cooperation with employers where appropriate, shall:
(a) Apply the relevant requirements of these Regulations in respect of public exposure for visitors to a controlled area or a supervised area;
(b) Ensure that visitors are accompanied in any controlled area by a person who knows the measures for protection and safety for the controlled area;
(c) Provide adequate information and instructions to visitors before they enter a controlled area or a supervised area so as to provide protection and safety for visitors and other individuals who could be affected by their actions;
(d) Ensure that adequate control is maintained over the entry of visitors to a controlled area or a supervised area, including the use of signs for such areas.

Sources of External Irradiation

59. Licensees shall ensure that if a source can give rise to external exposure of members of the public:
(a) The floor plans and arrangements of equipment for all new installations utilizing such sources, as well as all significant modifications to existing installations, are subject, as appropriate, to review and approval by the regulatory body prior to commissioning;

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

Contamination in Areas Accessible to Members of the Public

(60). Licensees shall ensure that:

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

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

Monitoring of Public Exposure

(61)Licensees shall, as appropriate:

(a) Establish and implement monitoring programmes to ensure that public exposure due to sources under their responsibility is adequately assessed and that the assessment is sufficient to verify and demonstrate compliance with the authorization. These programmes shall include monitoring of the following, as appropriate: external exposure from such sources; discharges; radioactivity in the environment, other parameters for the assessment of public exposure;

(b) Maintain appropriate records of the results (b) Maintain appropriate records of the results of the monitoring programmes and estimated doses to members of the public;

(c) Report or make available the results of the monitoring programme to the regulatory body 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 made of doses to the representative person;

(d) Report promptly to the regulatory body any levels exceeding the operational limits and conditions relating to public exposure, including authorized limits on discharges, in accordance with reporting criteria established by the regulatory body;

(e) Report promptly to the regulatory body any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the

authorized practice, in accordance with reporting criteria established by the regulatory body;

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

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

(h) Publish or make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments made of doses from public exposure.

Consumer Products

62(1). Providers of consumer products shall ensure that such products are not made available to the public unless the justification of their use by members of the public has been approved by the government or regulatory body, and either their use has been exempted on the basis of the criteria specified in Article 13 or their provision to the public has been authorized.

(2). Providers of consumer products, who import consumer products, as exempt products, for subsequent sale and distribution shall include in the application to the regulatory body for authorization to distribute, a copy of the exporter's or other legal persons' authorization (i.e. licence) issued by the regulatory body in the country of manufacture or origin which authorizes distribution to members of the public in that country.

(3). Providers of consumer products, who import consumer products for sale and distribution as exempt products shall ensure that:

(a) Where practicable, a legible label is firmly affixed to a visible surface of each consumer product that:

(i) States that the product contains radioactive substances and identifying the radionuclides and their activities;

(ii) States that the provision of the product to the public has been authorized by the regulatory body;

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

(b) The information specified in (a) above is printed legibly on the retail packaging of the consumer product.

(4) Providers of consumer products shall provide clear and appropriate information and instructions with each such consumer product on:
(a) Correct installation, use and maintenance of the product;
(b) Servicing and repair;
(c) The radionuclides and their activities;
(d) Dose rates in normal operation and during servicing and repair;
(e) Required or recommended options for recycling or disposal.
(5). Providers of consumer products shall provide the product retailers with appropriate information on safety and instructions on transport and storage.

Import of food stuffs
63. The Authority shall collaborate with the Food Standards Advisory Board and other relevant bodies in the establishment of a system for the control of radioactivity in foodstuff.

PART 9: RADIATION GENERATORS AND RADIOACTIVE SOURCES

General Responsibilities

64(1). The licensee, in cooperation with other responsible parties, shall ensure that the siting, location, design, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof are based on good engineering practice which shall, as appropriate:

(a) Take account of international and national standards;

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

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

(d) Take account of 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). Where applicable, licensees shall make suitable arrangements with suppliers of radiation generators and radioactive sources, the regulatory body and relevant parties for the purposes of:

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

(b) providing feedback and information that may have implications for protection and safety for other users, or that may have implications for the possibility for improvements in protection and safety for radiation generators and radioactive sources.

Design of Radiation Generators and Radioactive Sources

65(1). Licensees who are manufacturers or other suppliers of radiation generators and radioactive sources shall ensure that the following responsibilities are discharged, as applicable:

(a) Supplying a well-designed, well manufactured and well-constructed radiation generator or radioactive source and device in which the radiation generator or radioactive source is used that:

(i) Provides for protection and safety in accordance with the requirements of these Standards;

(ii) Meets engineering, performance and functional specifications.

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

(iv) Provides clear displays, gauges and instructions on operating consoles in English and local languages within that area.

(b) Ensuring that radiation generators and radioactive sources are tested to demonstrate compliance with the relevant specifications;

(c) Making information available, in English and the local languages within that area , on the proper installation and use of the radiation generator or radioactive source and its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety.

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

(2). Licensees shall ensure that sealed sources are categorized in accordance with the categorization scheme set out in ….. {*Schedule II of GSR Part 3 [3]*}, and in accordance with the requirements of the regulatory body.

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

(4). Licensees, in cooperation with manufacturers, shall ensure that, where practicable, sealed sources are identifiable and traceable.

(5). Licensees shall ensure that when radioactive sources are not in use they are stored in an appropriate manner for protection and safety.

(6). Licensees shall ensure that arrangements are made promptly for the safe management of and control over radiation generators and radioactive sources, including appropriate financial provision, once it has been decided to take them out of use.

Supply and Procurement of Radioactive Sources (69)

66(1). Licensees who supply or distribute radioactive sources shall ensure that those persons to whom the sources are being supplied are authorized to receive the sources.

(2). Before purchasing, or otherwise acquiring, radioactive sources, licensees shall:

(a) Make arrangements are made for the safe management of the source(s) including financial provisions where appropriate once they have become disused;

(b) Submit to the regulatory body details of those arrangements, including copies of any contractual arrangements.

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

PART 10: IMPORT AND EXPORT OF CATEGORY 1 AND 2 RADIOACTIVE SOURCES

Export of Category 1 or 2 Radioactive Sources

67(1). Licensees intending to export Category 1 or 2 radioactive sources shall apply to the Authority for an export authorization.

(2). The application for authorization to export a source or sources shall include a copy of the recipient authorization to receive and possess the source or sources to be exported that includes at least the following information:

(a) Name of the recipient;

(b) Recipient location and legal address or principal place of business;

(c) Relevant radionuclides and radioactivity;

(d) Uses of the source, if appropriate;

(e) Recipient authorization expiration date (if any).

(3). Other information to be submitted as part of the application for authorization to export may include, as applicable:

(a) Copies of relevant parts of any contractual agreements to re-import the source;

(b) Justification or explanation of any need to use the 'exceptional circumstances' provisions in …… *{reference [5]}*, if applicable

(4). After receiving authorization to export the source(s), licensees shall ensure that:

(a) The export of the source(s) is conducted in compliance with all applicable transport requirements of the IAEA Regulations for the Safe Transport of Radioactive Material ; and

(b) The importing State is notified in advance (at least 7 days to the extent practicable) of each shipment with the following information in writing:

(i) The estimated date of export;

(ii) Exporting facility;

(iii) Recipient;

(iv) Radionuclide(s) and radioactivity;

(v) Aggregate activity level;

(vi) The number of radioactive sources and, if available, their unique identifiers.

(c) For Category 1 sources only, the notification described above should be accompanied by a copy of the importing States consent to import the sources, if applicable.

Import of Category 1 or 2 Radioactive Sources

68(1). Licensees intending to import Category 1 or 2 radioactive sources shall apply to the regulatory body for an import authorization.

(2). The application for authorization to import a source or sources shall include the following information:

(a) Name of the exporter;

(b) Exporter location and legal address or principal place of business;

(c) Name of the recipient;

(d) Recipient location and legal address or principal place of business;

(e) Relevant radionuclides and radioactivity;

(f) Uses of the source(s), if appropriate;

(g) Details of the arrangements for the safe management of the source(s), including financial provisions where appropriate, once they have become disused, including copies of any contractual agreements;

(h) Justification or explanation of any need to use the 'exceptional circumstances' provisions in …… *{reference [5]},* if applicable.

(3). After receiving authorization to import the source(s), licensees shall, to the extent possible, ensure that the import of the source(s) is in compliance with all applicable transport requirements of the IAEA Regulations for the Safe Transport of Radioactive Material .

PART 11: REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

Transport Requirements

69. Licensees transporting radioactive sources, radioactive waste or any other radioactive material, either domestically or internationally shall do so in compliance with all applicable transport requirements of the IAEA Regulations for the Safe Transport of Radioactive Material.

PART 12: REQUIREMENTS FOR EMERGENCY PREPAREDNESS AND RESPONSE

Responsibilities of Licensees

70(1). If an authorized practice or source including radioactive waste within a practice has a potential for an emergency affecting either workers or members of the public, the licensee shall prepare an emergency plan for the protection of people and the environment. As part of this emergency plan, the licensee shall include arrangements for the prompt identification of an emergency, and for determining the appropriate level of the emergency response. In relation to the arrangements for the emergency response at the scene by the licensee, the emergency plan shall include, in particular:

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

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

(2). Licensees shall be responsible for the implementation of their emergency plans and shall be prepared to take any necessary action for effective response. To prevent the occurrence of conditions that could lead to a loss of control over a source or to the escalation of such conditions, licensees shall, as appropriate:

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

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

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

Responsibilities of the Authority

71. The Authority shall-

a) Periodically evaluate the contents and adequacy of emergency plans prepared in terms of these Regulations and ensure their regular review and revision to the required standard
b) Facilitate the undertaking of rehearsals among collaborators
c) When an emergency situation requiring intervention arises, ensure that licensees and registrants take action and measures necessary for the public

interest in order to prevent, eliminate and ameliorate the adverse effects of radiation and to restore the environment

d) Promptly mobilize an emergency squad and notify the Department of Civil Protection .

Emergency Preparedness and Response

72. Each licensee responsible for sources, including radioactive waste, for which prompt intervention may be required, shall ensure that the emergency plan defines at the scene responsibilities and takes account of off-site responsibilities of response organizations appropriate for implementation of the emergency plan. Such emergency plans shall, as appropriate:

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

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

(c) Describe the methods and instruments for assessing the accident and its consequences on and off the site;

(d) Provide for protective actions and mitigation actions, and assignment of responsibilities for initiating and discharging such actions;

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

(f) Allocate responsibilities for notifying the relevant authorities and for initiating intervention;

(g) Provide procedures, including communication arrangements for contacting any relevant response organization and for obtaining assistance from firefighting, medical, police and other relevant organizations;

(h) Provide for training personnel involved in implementing emergency plans and be rehearsed at suitable intervals based on requirements defined in Article 26(2) in conjunction with designated authorities;

(i) Provide for periodic review and updating of the plan.

Implementation of Intervention

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

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

(3). Licensees shall promptly notify the regulatory body when an accidental situation requiring intervention has arisen or is expected to arise and shall keep the regulatory body informed of:

(a) The current situation and its expected evolution;

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

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

Protection of Emergency Workers in an Emergency Exposure Situation

74(1). The response organization and employers responsible for ensuring compliance with the requirements in paragraphs (2) – (8) below shall be specified in the emergency plan

(2). In an emergency exposure situation, the relevant requirements for occupational exposure in planned exposure situations (Articles 33-43) shall be applied for emergency workers, in accordance with a graded approach, except as required in para. (3) of this Article.

(3). Response organizations and employers shall ensure that no emergency worker is subject to exposure in excess of 50 mSv other than:

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

(b) When undertaking actions to avert a large collective dose; or

(c) When undertaking actions to prevent severe deterministic effects and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment.

(4). In the exceptional circumstances of para. (3) of this Article, response organizations and employers shall make all reasonable efforts to keep doses to emergency workers below the values set out in …..{*Schedule IV, Table IV-2 of GSR Part 3 [3]*}. In addition, emergency workers undertaking actions due to which their doses could approach or exceed the values set out in …..{*Schedule IV, Table IV-2 of GSR Part 3 [3]*} shall do

so only when the expected benefits to others would clearly outweigh the risks to the emergency workers.

(5). Response organizations and employers shall ensure that emergency workers who undertake actions in which the doses received might exceed 50 mSv do so voluntarily; that they have been clearly and comprehensively informed in advance of the associated health risks, as well as of available measures for protection and safety; and that they are, to the extent possible, trained in the actions that they may be required to take.

(6). Workers undertaking work such as repairs to plant and buildings or activities for radioactive waste management or remedial work for the decontamination of the site and surrounding areas, shall be subject to the relevant requirements for occupational exposure specified in these Regulations.

(7). Response organizations and employers shall take all reasonable steps to assess and record the doses received in an emergency by emergency workers. Information of the doses received and information concerning the associated health risks shall be communicated to the workers involved.

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

PART 13: EXISTING EXPOSURE SITUATIONS

Remediation of areas with residual radioactive material

75(1). The persons or organizations responsible for the planning, implementation and verification of remedial actions shall, as appropriate, ensure that:

(a) A remedial action plan, supported by a safety assessment, is prepared and is submitted to the regulatory body or other relevant authority for approval;

(b) The remedial action plan is aimed at the timely and progressive reduction of the radiation risks and eventually, if possible, the removal of restrictions on use of or access to the area;

(c) Any additional dose received by members of the public as a result of the remedial actions is justified on the basis of the resulting net benefit, including consideration of the consequent reduction of the annual dose;

(d) In the choice of the optimized remediation option:

(i) The radiological impacts on people and the environment are considered together with non-radiological impacts on people and the environment, and technical, societal and economic factors;

(ii) The costs of the transport and management of radioactive waste, the radiation exposure of and health risks to the workers managing the waste, and any subsequent public exposure associated with its disposal are all taken into account;

e) A mechanism for public information is in place and the interested parties affected by the existing exposure situation are involved in the planning, implementation and verification of the remedial actions, including any monitoring and surveillance following remediation;

(f) A monitoring programme is established and implemented;

(g) A system for maintaining adequate records relating to the existing exposure situation and actions taken for protection and safety is in place;

(h) Procedures are in place for reporting to the regulatory body on any abnormal conditions relevant to protection and safety.

(2). The person or organization responsible for carrying out the remedial actions shall:

(a) Ensure that the work, including management of the radioactive waste arising, is conducted in accordance with the remedial action plan;

(b) Take responsibility for all aspects of protection and safety, including the performance of a safety assessment;

(c) Monitor and perform a radiological survey of the area regularly during the remediation work so as to verify levels of contamination, to verify compliance with the

requirements for waste management, and to enable any unexpected levels of radiation to be detected and the remedial action plan to be modified accordingly, subject to approval by the regulatory body or other relevant authority;

(d) Perform a radiological survey after completion of remedial actions to demonstrate that the end point conditions, as established in the remedial action plan, have been met;

(e) Prepare and retain a final remediation report and shall submit a copy to the regulatory body or other relevant authority.

(3). The person or organization responsible for post-remediation control measures shall establish and maintain for as long as required by the regulatory body or other relevant authority an appropriate programme, including any necessary provisions for monitoring and surveillance, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation has been completed.

Liability for damage incurred by emergency exposure

76(1). Registrants and licensees shall be liable for any damage caused by an emergency exposure from a practice authorised by the Authority

(2) a damage caused by emergency exposure from the sources by any person without authorisation or during the time the licence given was not renewed or was suspended or revoked , the person who possesses the source shall be strictly liable for the damage

(3) where damage is made by exposure to the environment , or to any property, which is not the subject of private ownership , the Public Protector may claim compensation for damages incurred against a person who is responsible, on behalf of the public or the Government.

PART 14: ENFORCEMENT OF THE REGULATIONS

Administrative actions

46. (1) Any person, who imports a radiation source under regulatory control without obtaining authorization from the Authority after the coming in to force of these

regulations, commits an offence and based on the extent of the risk expected from the source, shall be fined equivalent to level eight after which-

a) the source may get authorization, if the requirements prescribed in the regulations and directives are complied with; or
b) at the expense of the person who possesses the source, it can be sent back to the country of origin; or
c) may be kept or disposed of by the Authority so that it causes no damage to the health of the society, property and the environment.

(2) Unless a person, who has been possessing and using a radiation source under regulatory control prior to the coming into force of these regulations, notifies the Authority and acquires authorization within three months as of the coming into force of these regulations commits an offence and based on the extent of the risk expected from the source, shall be fined a fine equivalent to level eight.

(3) Persons referred to in subsection (2) may-

a) get authorization if the requirements prescribed and directives are complied with; or
b) at the expense of the person who possesses the source, have the source sent back to the country of origin or may be kept or disposed of by the authority so that it causes no damage to the health of the society, property and the environment.

(4) If any person who timely applies for a license for a radiation source under possession, fails to fully comply with the requirements requirements set by the Authority to obtain a license within three months from the date of his or her application, at the expense of the person who possesses the source, the source may be sent back to the country of origin or may be kept or disposed of by the Authority so that it causes no damage to the health of the society, property and the environment.

(5) Without prejudice to the liability provisions of other relevant laws, if any person engaged in an authorized practice, fails to comply with the requirements set in this Act, these regulations and directives issued there under for radiation protection and safety for the security of radioactive materials or substances or to take radiation protection measures and causes damage to a person, property or the environment, commits an offence and shall be fined a fine equivalent to level eight.

(6) If a person who engages in controlled practice without authorization, commits the offence prescribed under subsection (3), in addition to the penalty set under

subsection (3) he or she shall be punished for being engaged in a controlled practice without authorization as appropriate in terms of subsections (1) and (2).

(7) If a person who is authorized to use radiation sources for different practices fails to comply with the requirements prescribed in these regulations and directives issued for the implementation of the regulations, the Authority may-

a) give one month written notice to the registrant or licensee to comply with the requirements; or

b) suspend the license and notify the registrant or licensee to comply with all the requirements specified in the regulations and directives within two months; or

revoke the license and bring the case to the competent court, so that at the expense of the registrant o licensee the source may be sent back to the country of origin or may be kept or disposed of by the Authority so that it causes no damage to the health of the society, property and the environment.

PART 15

PETITION OR APPEAL PROCEDURES

Lodging application against decision

78. A person who is aggrieved by a decision of the Chief Executive Officer or Employee of the Authority may-

a) make an application to the Chief Executive Officer of the Authority to review the decision;
b) if a person is not satisfied with the decision of the Chief Executive Officer, he or she may appeal to the Radiation Protection Board.

Application to the Chief Executive Officer

79(1). Any person adversely affected by any action or decision of a radiation protection officer may petition to the Chief Executive Officer against that action or decision within thirty days from the date of the action or date upon which the decision was made known, as the case may be or such later date as the Chief Executive Officer may permit with good cause.

(2) The application to the Chief Executive Officer shall be in writing and the cause shall be clearly stated.

(3) After considering the ground for the application, the Chief Executive Officer shall within 30 days confirm in writing that he or she upholds, rejects or vary the action or decision and shall take the necessary measure to rectify the action taken by the radiation protection officer if he or she rejects it.

Application to the Radiation Protection Board

80.(1) Application to the Board shall be submitted within sixty days from the date on which that decision was made known to the applicant or such later date as the Board may permit on the basis of good cause.

(2) The application to the Board shall be in writing and the cause shall be clearly stated.

(3) After considering the grounds for the application, the Board shall within sixty days confirm in writing that it upholds, rejects or varies the decision.

PART 16

MISCELLANEOUS PROVISIONS

Access to the information and obligation to cooperate

81.(1) Registrants and licensees, radiation safety officers and any person involved in the practice shall maintain data and information in relation to their respective activities, and avail such information to the Authority upon request.

(2) Every person shall have the obligation to cooperate in matters relating to these regulations and to notify the Authority of any suspected sources of radiation exposure.

Directives

82. The Authority shall issue directives necessary for the proper implementation of these regulations