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Republic of the Philippines
Department of Science and Technology
PHILIPPINE NUCLEAR RESEARCH INSTITUTE
Commonwealth Avenue, Diliman, Quezon City

CPR Part 3. STANDARDS FOR PROTECTION AGAINST RADIATION, Rev. 02

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CPR Part 3. STANDARDS FOR PROTECTION AGAINST RADIATION, Rev. 02

I. GENERAL PROVISIONS

Section 1. Purpose

(a) This Part prescribes the basic standards for protection of people, radiation workers and the environment against the harmful effects of ionizing radiation resulting from activities conducted under licenses issued by the Philippine Nuclear Research Institute, pursuant to Section 16-a of Republic Act 2067, and Section 4 (a) of Republic Act 5207.

(b) This Part provides for the requirements to control the utilization of licensed materials and facilities by the licensee in such a manner that the total dose to an individual does not exceed the dose limits prescribed in this Part.

(c) This Part prescribes the requirements for the safety in the construction and operation of any atomic energy facility.

(d) Nothing in this Part shall be construed as limiting actions that may be necessary to protect health and safety.

Section 2. Scope

(a) The requirements in this Part apply to planned exposure situations arising from the following practices:

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

(2) The production of radioisotopes and supply of devices that generate radiation, including particle accelerators;

(3) The generation of nuclear power, including any activities within the nuclear fuel cycle that involve or that could involve exposure to radiation or exposure due to radioactive material;

(4) The use of 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;

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

(6) The mining and processing of raw materials that involve exposure due to radioactive material; and

(7) Any other practices as specified by the PNRI through the issuance of regulations and orders.

(b) The requirements in this Part do not deal with –

(1) Exposures from x-rays and other electrically-generated ionizing radiation, non-ionizing radiation sources, and related facilities which are currently within the responsibilities of the Department of Health – Food and Drug Administration;

(2) Exposures where the magnitude or likelihood is essentially not amenable to control;

(3) Exposures from natural radioactivity in the body;

(4) Cosmic radiation and other sources of background radiation;

(5) Security measures for radioactive sources and physical protection of facilities; and

(6) Practices and sources involving radioactive materials that meet the exemption levels given in Appendix A as adopted by virtue of Administrative Order No. 1 Series of 2015.

(c) While these requirements do not specifically address the control of non-radiological aspects of health, safety and the environment, these aspects also need to be considered.

Section 3. Definitions

As used in this Part:

(a) **"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;

(b) **"Annual dose"** means the dose from external exposure in a year plus the committed dose from intakes of radionuclides in that year;

(c) **"Bioassay"** means any procedure used to determine the nature, activity, location or retention of radionuclides in the body by direct measurement or by in vitro analysis of material excreted or otherwise removed from the body;

(d) **"Carers and comforters"** means persons who willingly and voluntarily help in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment.

(e) **"Clearance"** means the removal of regulatory control by the PNRI from radioactive material or radioactive objects within licensed facilities and activities;

(f) **"Clearance level"** means a value, established by the PNRI and expressed in terms of activity concentration, at or below which regulatory control may be removed from a source of radiation within a notified or authorized practice;

(g) **"Committed dose"** means the lifetime dose expected to result from an intake;

(h) **"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;

(i) **"Containment"** means methods or physical structures designed to prevent or control the release and the dispersion of radioactive substances;

(j) **"Contamination"** means radioactive substances on surfaces, or within solids, liquids or gases, including the human body, where their presence is unintended or undesirable, or the process giving rise to their presence in such places;

(k) **"Controlled area"** means a defined area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing the spread of contamination in normal working conditions, and preventing or limiting the extent of potential exposures;

(l) **"Decontamination"** means the complete or partial removal of contamination by a deliberate physical, chemical or biological process;

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

(n) **"Disposal"** means the emplacement of spent fuel or radioactive waste in an appropriate facility without the intention of retrieval;

(o) **"Dose"** means a measure of the energy deposited by radiation in a target;

(p) **"Dose Assessment"** means the assessment of dose(s) to an individual or group of people;

(q) **"Dose constraint"** means a prospective and source related value of individual dose (dose constraint) or risk (risk constraint) that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization.

(1) For occupational exposure, a constraint on individual dose to workers established and used by licensees to set the range of options in optimizing protection and safety for the source;

(2) For public exposure, the dose constraint is a source related value established or approved by the PNRI, with account taken of the doses from planned operations

of all sources under control. The dose constraint for each particular source is intended, among other things, to ensure that the sum of doses from planned operations for all sources under control remains within the dose limit;

(3) The risk constraint is a source related value that provides a basic level of protection for the individuals most at risk from a source. This risk is a function of the probability of an unintended event causing a dose, and the probability of the detriment due to the dose. Risk constraints correspond to dose constraints but apply to potential exposure;

(4) For medical exposure, the dose constraint is a source related value used in optimizing the protection of carers and comforters of patients undergoing radiological procedures, and the protection of volunteers subject to exposure as part of a program of biomedical research.

(r) "**Dose limit**" means the value of the effective dose or the equivalent dose to individuals that shall not be exceeded in planned exposure situations other than medical exposures;

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

(t) **"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;

(u) **"Emergency preparedness"** means the capability to take actions that will effectively mitigate the consequences of an emergency for human health and safety, quality of life, property and the environment;

(v) **"Emergency procedures"** means a set of instructions describing in detail the actions to be taken by emergency workers in an emergency;

(w) **"Event"** means any occurrence unintended by the operator, including operating error, equipment failure or other mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of protection and safety;

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

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

(z) **"Facilities"** means nuclear installations; irradiation installations; some mining and raw material processing facilities such as uranium mines; radioactive waste management facilities; and any other places where radioactive material is produced, processed,

used, handled, stored or disposed of on such a scale that consideration of protection and safety is required;

(aa) **"Graded approach"** means a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control;

(bb) **"Hazard assessment"** means an assessment of hazards associated with facilities, activities or sources within or beyond the borders of a country in order to identify:

(1) Those events and the associated areas for which protective actions and other response actions may be required within the country;

(2) Actions that would be effective in mitigating the consequences of such events.

(cc) **"Health screening program"** means a program in which health tests or medical examinations are performed for the purpose of early detection of disease;

(dd) **"Human factors"** means factors that could influence human performance and that could affect safety;

(ee) **"Incident"** means any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection and safety;

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

(gg) **"Justification"** means the process of determining for a planned exposure situation whether a practice is, overall, beneficial; i.e. whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm resulting from the practice;

(hh) **"Licensee"** means the holder of such PNRI license who shall have the prime responsibility for protection and safety which cannot be delegated;

(ii) **"Management System"** means a set of interrelated or interacting elements for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner;

(jj) **"Medical physicist"** means a health professional, with specialist education and training in the concepts and techniques of applying physics in medicine, and competent to practice independently in one or more of the subfields or specialties of medical physics;

(kk) **"Medical radiological equipment"** means equipment used in medical radiation facilities to perform radiological procedures that either delivers an exposure of an individual or directly controls or influences the extent of such exposure. The term applies to radiation generators; to devices containing sealed sources, such as ^{60}Co

teletherapy units; to devices used in medical imaging to capture images, such as gamma cameras, image intensifiers or flat panel detectors, and to hybrid systems such as positron emission tomography–computed tomography scanners;

(ll) **“Monitoring”** means the measurement of dose, dose rate or activity for reasons relating to the assessment or control of exposure to radiation or exposure due to radioactive substances, and the interpretation of the results;

(mm) **“Occupancy factor”** means a typical fraction of the time for which a location is occupied by an individual or group;

(nn) **“Optimization of protection and safety”** means the process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being “as low as reasonably achievable” (ALARA), economic and social factors being taken into account”;

(oo) **“Planned exposure situation”** means a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source;

(pp) **“Protection and safety”** means the protection of people against exposure to ionizing radiation or exposure due to radioactive material and the safety of sources, including the means for achieving this, and the means for preventing accidents and for mitigating the consequences of accidents if they do occur;

(qq) **“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;

(rr) **“Qualified Expert”** means an individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety specialty;

(ss) **“Quality assurance”** means the function of a management system that provides confidence that specified requirements will be fulfilled;

(tt) **"Radiation"** or **"Ionizing radiation"** means alpha particles, beta particles, gamma-rays, neutrons, high-speed electrons, high-speed protons and other particles that are capable of producing ions. As used in this Part, radiation does not include ionizing radiation that are electrically generated and non-ionizing radiation, such as radio or microwaves, or visible, infrared or ultra-violet light;

(uu) **“Radiation Protection Officer”** means a person technically competent in radiation protection matters relevant for a given type of practice who is designated by the licensee to oversee the application of regulatory requirements;

(vv) "**Radiation risks**" means detrimental health effects of exposure to radiation, including the likelihood of such effects occurring, and any other safety related risks, including those to the environment, that might arise as a direct consequence of:

(1) Exposure to radiation;

(2) The presence of radioactive material, including radioactive waste, or its release to the environment;

(3) A loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation.

(ww) **"Radioactive material"** means material designated by the Act as being subject to regulatory control because of its radioactivity and hence subject to the requirements of this Part;

(xx) **"Radioactive source"** means a source containing radioactive material that is used as a source of radiation, or a radioactive material that is permanently sealed in a capsule or closely bonded and in a solid form and which is not exempt from regulatory control;

(yy) **"Safety assessment"** means the process, and the result, of analyzing systematically and evaluating the hazards associated with facilities and activities that are relevant to protection and safety;

(zz) **"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;

(aaa) **"Source"** means anything that may cause radiation exposure — such as by emitting ionizing radiation or by releasing radioactive substances or radioactive material — and can be treated as a single entity for purposes of protection and safety;

(bbb) **"Supervised Area"** means any area not designated as a controlled area but for which occupational exposure conditions are kept under review even though specific protective measures and safety provisions are not normally needed;

(ccc) **"Waste or Radioactive waste"** means any material that contains or is contaminated with radionuclides at concentrations or activities greater than the clearance levels as established by PNRI, and for which no use is foreseen;

(ddd) **"Worker"** means any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection; and

(eee) **"Workers' health surveillance"** means medical supervision intended to ensure the initial and continuing fitness of workers for their intended tasks.

Section 4. Interpretation.

Except as specifically authorized by the PNRI Director in writing, no interpretation of the meaning of the requirements in this Part shall be recognized to be binding upon PNRI.

Section 5. Communication.

All communication and reports concerning the Standards in this Part shall be addressed to:

Office of the Director
Philippine Nuclear Research Institute
Commonwealth Avenue, Diliman, Quezon City

Section 6. Applicability of other Regulations and Requirements, and Resolution of Conflicts.

(a) The requirements in this Part are in addition to, and not in substitution for, other applicable requirements of the CPR and those of relevant binding conventions and national laws and regulations.

(b) Specific provisions of the IAEA General Safety Requirements Part 3 No. GSR Part 3, "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (IBSS)" (2014) which are applicable in this Part, may be addressed pursuant to PNRI Administrative Order No. 01, Series of 2015.

(c) In cases of conflict between this Part and other applicable requirements, the PNRI shall determine which requirements are to be enforced.

(d) Nothing in this Part shall be construed as restricting any actions that may otherwise be necessary for protection and safety.

Section 7. Additional Requirements.

Additional requirements may be imposed by the PNRI by regulation, order, or conditions of an authorization, in addition to those established in this Part, as deemed appropriate or necessary to protect health and the environment or to minimize risk from radiation hazards.

II. ADMINISTRATIVE REQUIREMENTS

Section 8. General Obligations

No person shall engage in activities, which involve practices, radiation sources, or radioactive waste, as specified in I.Section 2 unless the requirements of this Part are met.

Section 9. Exemption of Practices and Sources

(a) Practices and sources within a practice may be exempted from the specific safety requirements of this Part provided that they comply with criteria for exemption or any exemption levels defined by the PNRI.

(b) Exemptions shall not be granted for practices deemed not to be justified as specified in Section 13.1.

(c) The following practices and sources within a practice are automatically exempted from the specific safety requirements of this Part:

(1) 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;

(2) 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 APPENDIX A Table I-2;

(3) 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 PNRI;

(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 PNRI.

Section 10. Clearance

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 this Part provided that they comply with criteria for clearance or clearance levels as specified in Appendix A and Appendix C.

Section 11. Graded Approach

The application of the requirements set forth in this Part shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures and shall also conform to any requirement specified by the PNRI.

Section 12. General Responsibilities of Licensees.

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

(b) The licensee shall establish and implement a radiation protection and safety program that is commensurate with the scope and extent of authorized activities in accordance

with Section 14 and sufficient to ensure compliance with the requirements of this Part and the conditions of the license.

(c) The licensee shall ensure the safety of radioactive sources or devices containing a radioactive source.

(d) The licensee shall use, to the extent practical, procedures and technical controls based upon sound radiation safety principles to achieve occupational doses and doses to the members of the public that are as low as reasonably achievable (ALARA).

(e) The licensee shall notify the PNRI of any intention to introduce modifications to any practice or source for which they are authorized, whenever the modifications could have significant implications for protection and safety, and the licensee shall not carry out any such modification unless it is specifically authorized by the PNRI.

(f) The licensee 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.

(g) The licensee 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.

(h) The licensee shall, for the sources for which they are authorized and for which a safety assessment is required, conduct a safety assessment and keep it up to date in accordance with Section 16.

(i) The licensee shall, for the sources for which they are authorized and for which the PNRI requires a prospective assessment to be made for radiological environmental impacts, conduct an assessment and keep it up to date.

(j) The licensee shall assess the likelihood and magnitude of potential exposures, their likely consequences and the number of individuals who may be affected by them.

(k) The licensee shall have in place operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system in accordance with Section 15.

(l) The licensee shall permit access by authorized inspectors of the PNRI to carry out inspections of their facilities and activities and of their protection and safety records, and shall cooperate in the conduct of inspections.

(m) The licensee shall establish procedures for reporting on and learning from accidents and other incidents.

(n) The licensee shall establish arrangements for the periodic review of the overall effectiveness of the measures for protection and safety.

(o) The licensee shall ensure that adequate maintenance, testing and servicing are carried out as necessary so that sources and associated equipment remain capable of fulfilling their design requirements for protection and safety throughout their lifetime.

(p) The licensee shall ensure safe management of and control over all radioactive waste that is generated, and shall dispose of such waste in accordance with applicable national laws and the requirements of the Code of PNRI Regulations, and in accordance with the license conditions.

(q) During the entire life cycle of radiation sources, from the moment of their manufacturing up to their final disposal, the respective licensee shall ensure that the appropriate safety measures are taken.

(r) 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.

III. REQUIREMENTS FOR RADIATION PROTECTION AND SAFETY

Section 13. Application of Radiation Protection Principles.

13.1. Justification of Practices.

(a) An applicant or licensee seeking to undertake authorized activities referred to in Section 2 shall establish that the practice is justified.

(b) No practice shall be authorized by PNRI 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.

(c) The following practices are deemed to be not justified:

(1) 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, in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being;

(2) Practices involving the frivolous use of radiation or radioactive substances in commodities or in products such as toys and personal jewelry or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation; and

(3) Human imaging using radiation that is performed as a form of art or for publicity purposes.

(d) With respect to human imaging for purposes other than medical diagnosis, medical treatment or biomedical research, the justification process shall include the consideration of:

(1) The benefits and detriments of implementing the type of human imaging procedure;

(2) The benefits and detriments of not implementing the type of human imaging procedure;

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

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

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

13.2. Optimization of Protection and Safety.

(a) The licensee shall ensure that protection and safety is optimized in all activities that give rise to radiation risks so that the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures are kept as low as reasonably achievable (ALARA), social and economic factors taken into account.

(b) The licensee shall 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.

(c) For occupational exposure and public exposure, the licensee shall ensure, as appropriate, that relevant constraints are used in the optimization of protection and safety for any particular source within a practice.

13.3. Dose Limits.

(a) The licensee shall be restricted to exposures of individuals due to the authorized practices so that neither the effective dose nor the equivalent dose to tissues or organs exceeds any relevant dose limit specified in the applicable sections of this Part.

(b) The dose limits do not apply to medical exposures from authorized practices.

Section 14. Radiation Protection and Safety Program.

14.1. Establishment of Radiation Protection and Safety Program.

(a) The licensee shall use and observe, to the extent practicable, the radiation protection principles referred to in Section 13 and the safety requirements in this Part in the establishment of its Radiation Protection and Safety Program.

(b) In particular, the Radiation Protection and Safety Program shall include the following actions:

(1) 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;

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

(3) To facilitate consultation and cooperation among all relevant parties with respect to radiation safety;

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

(c) The licensee shall develop and implement an ALARA program as part of the RPSP that shall include the following:

(1) Management formal commitment to the ALARA philosophy;

(2) Periodic review of the program and provision of continuing education and training for all personnel who work with or in the vicinity of the licensed facility;

(3) Notice to workers of the program's existence and workers' duties and responsibilities to help keep doses ALARA;

(4) Establishment of Investigation Levels (IL) and description of actions to be taken if radiation exposure exceeds the IL; and

(5) Review of the doses received by workers.

(d) The licensee shall ensure that, in the implementation of the Radiation Protection and Safety Program:

(1) The measures and resources that are necessary for achieving the objectives for protection and safety have been determined and are duly provided;

(2) The program is reviewed, at least annually, to assess its effectiveness and its continued fitness for purpose;

(3) Any failures or shortcomings in protection and safety are identified and corrected, and steps are taken to prevent their recurrence;

(4) Arrangements are made to consult with interested parties;

(5) Appropriate records are maintained.

14.2. Radiation Protection Officer (RPO) and Qualified Expert.

A. Radiation Protection Officer (RPO).

(a) The licensee shall designate an independent and qualified RPO, who agrees in writing, to be responsible for implementing the Radiation Protection and Safety Program. An Assistant RPO shall act for and in behalf of the RPO in his/her absence.

(b) The licensee shall ensure that the designated RPO is technically competent in radiation protection matters relevant to a given type of practice. The qualification and training requirements for the RPO shall be commensurate with the levels of risks associated with the authorized practices or sources within a practice as specified in the specific CPR.

(c) The licensee shall establish and state in writing the authority, duties and responsibilities of the RPO.

(d) The licensee shall provide the RPO sufficient authority, organizational freedom, time, resources, and management prerogative to –

(1) Identify radiation protection and safety problems and conduct briefings to management as appropriate;

(2) Initiate, recommend, or provide corrective actions;

(3) Monitor dose of staff and environment;

(4) Develop procedures to improve safety culture in the organization and maintain safe work practices;

(5) Stop unsafe operations as deemed necessary;

(6) Verify implementation of corrective actions;

(7) Coordinate the establishment, maintenance, conduct of drills/exercise of Emergency Plan and procedures;

(8) Train new personnel and other personnel who work in or frequent supervised areas; and

(9) Interface with regulatory inspectors and provide access to required records of inspection.

B. Qualified Expert.

(a) The licensee shall ensure that qualified experts are identified and made available for providing advice on the observance of this Part when so required by the PNRI.

(b) 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.

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

(d) The licensees shall keep the PNRI informed of the arrangements made with respect to paragraphs a and b above.

14.3. Content of Radiation Protection and Safety Program.

The Radiation Protection and Safety Program shall include the following information, as far as practicable:

(1) A description of the organization, including its functions, responsibilities of individual assignments, and qualification and training of these individuals;

(2) The ALARA Program in accordance with para. (c) of Subsection (14.1) duly signed by the senior management;

(3) A description of the authority, duties and responsibilities of the RPO and the Assistant RPO;

(4) A description of the radiation facility including the areas where radioactive sources are used and stored;

(5) The number and type of equipment and devices incorporating radioactive material instruments and monitoring devices used and their proper maintenance;

(6) Arrangement made for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and the maintenance of exposure records;

(7) Methods for the implementation of the program that includes radiation exposure control, control of the workplace, monitoring of the workplace and assessment of the consequences of radioactive releases;

(8) Methods for evaluating the performance of radiation protection and safety program that will include program reviews, audits, corrective actions and follow-up;

(9) A radioactive waste management program;

(10) An emergency plan for responding to any accident that results in the release of radioactive material to the environment which includes protection of workers, intervention/protective action and emergency procedures; and

(11) Other applicable safety requirements as specified in other Parts of the Code of PNRI Regulations.

Section 15. Management for Protection and Safety.

15.1. Protection and Safety Elements of the Management System.

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

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

(c) The licensee shall establish a management system, commensurate with the size and nature of the authorized activity, which ensures that:

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

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

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

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

(5) 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.

(d) The licensee shall ensure that the management system is designed and applied to enhance protection and safety by:

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

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

(3) Ensuring that protection and safety are not compromised by other requirements;

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

(5) Promoting safety culture.

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

(f) The licensee shall be able to demonstrate the effective fulfilment of the requirements for protection and safety in the management system.

15.2. Safety Culture

The licensee shall promote and maintain safety culture by:

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

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

(3) 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;

(4) 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;

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

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

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

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

15.3. Human Factors

(a) The licensee shall take into account human factors and shall support good performance and good practices to prevent human and organizational failures, by ensuring among other things that:

(1) 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 could lead to

accidents, and to reduce the possibility that indications of normal conditions and abnormal conditions could be misinterpreted.

(2) Appropriate equipment, safety systems and procedural requirements are provided, and other necessary provision is made:

(i) To reduce, as far as practicable, the possibility that human errors or inadvertent actions could give rise to accidents or to 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.

(b) The licensee shall inform all employees at least annually of the importance of effective measures for protection and safety and be trained in their implementation as appropriate.

(c) The licensee shall routinely evaluate and update training programs commensurate with the practice.

Section 16. Safety Assessment.

(a) Prior to the granting of a license, the applicant/licensee shall, as deemed necessary and appropriate by the PNRI, conduct a safety assessment, which shall be reviewed and assessed by PNRI.

(b) The licensee shall conduct safety assessment at different stages, including the stages of siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof, as appropriate, so as:

(1) 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;

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

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

(c) The safety assessment shall include, as appropriate, a systematic critical review of:

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

(2) 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;

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

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

(5) The implications for protection and safety of any modifications;

(6) The implications for protection and safety of security measures or of any modifications to security measures;

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

(d) The licensee shall take into account in the safety assessment:

(1) 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;

(2) 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;

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

(4) 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 exposures.

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

(f) The licensee 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:

(1) Significant modifications to the facility or to its operating procedures or maintenance procedures are envisaged;

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

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

(4) Any significant changes in activities are envisaged;

(5) Any relevant changes in guidelines or standards have been made or are envisaged.

(g) 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 favorable assessment of all the implications for protection and safety. The implementation of all improvements shall be prioritized so as to optimize protection and safety.

Section 17. Monitoring, Testing and Verification of Compliance.

(a) The licensee shall conduct monitoring and testing to verify compliance with the requirements for protection and safety.

(b) The licensee shall ensure that:

(1) Monitoring and measurements of parameters are performed at appropriate established intervals for verification of compliance with the requirements of regulations and license conditions as prescribed in the specific Parts.

(2) Suitable equipment is provided and procedures for verification are implemented;

(3) Equipment is properly maintained, tested and calibrated at appropriate intervals with reference to standards traceable to national or international standards as provided in the specific Parts;

(4) Records of the results of monitoring and verification of compliance are maintained, as required by PNRI, including records of the tests and calibrations carried out in accordance with regulations and license conditions;

(5) The results of monitoring and verification of compliance are shared with the PNRI as required.

Section 18. Prevention and Mitigation of Accidents.

18.1. Good Engineering Practice.

The licensee shall ensure that the siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof are based on good engineering practice which shall, as appropriate:

(1) Take account of international and national standards;

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

(3) 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;

(4) 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.

18.2. Defense in Depth.

(a) The licensee shall ensure that a multilevel (defense in depth) system of sequential, independent provisions for protection and safety that is commensurate with the likelihood and magnitude of potential exposures is applied to sources for which the licensees are authorized.

(b) The licensee shall ensure that if one level of protection were to fail, the subsequent independent level of protection would be available. Such defense in depth shall be applied for the purposes of:

(1) Preventing accidents;

(2) Mitigating the consequences of any accidents that do occur; and

(3) Restoring the sources to safe conditions after any such accidents.

18.3. Accident Prevention

(a) The licensee 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.

(b) The licensee for any facility or activity shall make suitable arrangements:

(1) To prevent reasonably foreseeable accidents in the facility or the activity;

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

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

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

(5) 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;

(6) 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;

(7) 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;

(8) 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;

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

Section 19. Investigations and Feedback of Operating Experience.

(a) The licensee shall ensure that information on normal operation performance as well as abnormal conditions and events significant to radiation safety is disseminated or made available, as appropriate, to the PNRI and other relevant parties.

(b) In addition, and where applicable, the licensee 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.

(c) The licensee shall conduct an investigation in the event that:

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

(2) 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.

(d) The licensee shall conduct an investigation 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, including corrective actions for preventing the recurrence of the event and the occurrence of similar events.

(e) The licensee shall communicate to the PNRI and to any other relevant parties, as appropriate, a written report in accordance to Section 66 of this Part of any formal investigation relating to events prescribed by the PNRI, including exposures giving rise to doses exceeding a dose limit. The licensee also shall immediately report to the PNRI any event in which a dose limit is exceeded.

Section 20. Safety Measures and Control of Radioactive Sources.

(a) Licensees who are importers or suppliers of devices containing radioactive sources shall ensure that the following responsibilities are discharged, as applicable:

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

(i) Provides for protection and safety in accordance with the requirements of this Part;

(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 the appropriate language understandable to users;

(2) Ensuring that devices containing radioactive sources are tested to demonstrate compliance with the relevant specifications;

(3) Making information available, in the appropriate language understandable to users, on the proper installation and use of the radioactive source or devices containing radioactive material and on its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety;

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

(b) Where applicable, the licensee shall make suitable arrangements with suppliers of devices containing radioactive sources, the PNRI and relevant parties for the purposes of:

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

(2) 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 radioactive sources.

(c) When choosing a location to use or to store a device containing radioactive source, the licensee shall take into account:

(1) Factors that could affect the safe management of and control over the radioactive source;

(2) Factors that could affect occupational exposure and public exposure due to the radioactive source;

(3) The feasibility of taking the foregoing factors into account in engineering design.

(d) In selecting a site for a facility that will contain a large amount of radioactive material and that will have the potential for the release of significant amounts of radioactive material, the licensee shall take into account features that might affect protection and safety, features that might affect the integrity or functioning of the facility, and the feasibility of carrying out off-site protective actions if they become necessary.

(e) The licensee shall maintain an inventory that includes records of:

(1) The location and description of each radioactive source for which they are responsible; and

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

(f) The licensee shall provide the PNRI with appropriate information from their inventory records of radioactive sources in accordance with Section 21 of this Part.

(g) The licensee shall keep radioactive sources under control so as to prevent loss or damage and to prevent any unauthorized person from carrying out any of the authorized activities, by ensuring that:

(1) Control over a radioactive source is relinquished only in compliance with all relevant requirements specified in the license;

(2) The PNRI is notified within twenty-four (24) hours of information regarding a radioactive source that is lost, missing or not under control;

(3) A radioactive source is transferred only if the recipient possesses the necessary license; and

(4) An inventory, as required in paragraph (e) of this section, of radioactive sources is checked periodically to confirm that they are in their assigned locations and are under control.

(h) The licensee shall ensure that sealed sources are categorized in accordance with the categorization scheme set out in Appendix B.

(i) The licensee, in cooperation with manufacturers, shall ensure that, where practicable, sealed radioactive sources are identifiable and traceable.

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

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

(l) The importer of a radioactive source or a device containing a Category 1, 2 or 3 radioactive source shall ensure that, where practicable, the source itself and its container are marked with the ionizing radiation supplementary symbol recommended by the International Organization for Standardization (ISO) (Fig. 1).

Fig. 1: ISO 21482:2007 Ionizing-radiation warning -- Supplementary symbol

Section 21. Inventory and Records.

(a) The licensee shall establish, maintain and be able to retrieve records relating to:

(1) Inventory of radioactive sources;

(2) Records of doses from occupational exposures;

(3) Records relating to facilities and activities;

(4) Inventory of radioactive waste;

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

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

(7) The transfer of radioactive sources; and

(8) The testing of instruments and safety systems, and calibrations carried out in accordance with the regulations.

(b) Individual sealed source records shall include the:

(1) Location of the source;

(2) Radionuclide;

(3) Radioactivity on a specified date;

(4) Serial number or unique identifier;

(5) Chemical and physical form;

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

(7) Receipt, transfer or disposal of the source; and

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

(c) The licensee shall provide the PNRI as required with appropriate information from their inventory records of radioactive sources. The licensee shall check inventory periodically to confirm that radioactive sources are in their assigned locations and are under control.

IV. ADDITIONAL REQUIREMENTS FOR OCCUPATIONAL EXPOSURE

Section 22. Responsibilities of Licensees.

(a) For workers who are engaged in activities in which they are or could be subject to occupational exposure, the licensee shall be responsible for:

(1) Protection of workers against occupational exposure;

(2) Compliance with relevant requirements of regulations and license conditions.

(b) The licensee shall ensure, for all workers engaged in activities in which they are or could be subject to occupational exposure, that:

(1) Occupational exposure is controlled so that the relevant dose limits for occupational exposure specified in Section 23 of this Part are not exceeded;

(2) Protection and safety is optimized in accordance with Sub-section 13.2 of this Part;

(3) Decisions with regard to measures for protection and safety are recorded and made available to workers, through their representatives;

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

(5) 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;

(6) Necessary workers' health surveillance and health services for workers are provided;

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

(8) 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;

(9) Adequate records are maintained in accordance with the requirements of regulations and license conditions;

(10) 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; and

(11) Necessary conditions for promoting a safety culture are provided.

(c) The licensee shall:

(1) Involve workers, through their representatives where appropriate, in optimization of protection and safety;

(2) Establish and use, as appropriate, constraints as part of optimization of protection and safety.

(d) The licensee shall ensure that employees 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.

(e) The licensee 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 program 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.

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

(g) The licensee shall facilitate compliance by workers with the requirements of this Part.

Section 23. Occupational Dose Limits.

23.1. Dose Limits for Adult Workers.

(a) The licensee shall control the occupational dose to any worker over the age of 18 years to the following dose limits:

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

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

(3) An equivalent dose to the extremities (hands and feet) or to the skin of 500 mSv in a year.

(b) The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 1 mSv. Additional restrictions apply to occupational exposure for a female worker who has notified pregnancy or is breast-feeding.

23.2. Dose Limits and Conditions for Young Apprentices, Trainees and Students.

(a) For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are:

(1) An effective dose of 6 mSv in a year;

(2) An equivalent dose to the lens of the eye of 20 mSv in a year;

(3) An equivalent dose to the extremities (hands and feet) or to the skin of 150 mSv in a year.

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

(c) The licensee shall ensure that no person under the age of 16 years is or could be subject to occupational exposure.

23.3. Verification of Compliance with Occupational Dose Limits.

(a) The licensee shall demonstrate compliance with the dose limits by summing the relevant doses from external exposure in the specified period and the relevant

committed doses from intakes in the same period; the period for calculating the committed dose shall normally be 50 years for intakes by adults and shall be up to age 70 years for intakes by children.

(b) In compliance with the dose limits established above, the personal dose equivalent $H_p(10)$ may be used as an approximation of the effective dose from external exposure to penetrating radiation, $H_p(0.07)$ for the equivalent dose to the extremities (hands and feet) or to the skin and the $H_p(3)$ for the equivalent dose to the lens of the eye.

(c) For internal exposure, the licensee shall apply the doses per unit intake (dose coefficients) for the estimation of the committed effective dose for ingestion and inhalation of radionuclides set out in the IAEA GSR Part 3 (Tables III.2A–III.2D) Dose Coefficients for Intakes of Radionuclides by Workers, until the IAEA updates these with new internal dose conversion coefficients.

(d) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by another person.

Section 24. Special Arrangements for Female Workers.

(a) The licensee shall provide female workers who are liable to enter controlled areas or supervised areas or who may undertake emergency duties with appropriate information on:

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

(2) 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;

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

(b) 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.

Section 25. Dose Constraints.

The licensee shall establish relevant dose constraints to be used in the optimization of protection and safety for any particular source within a practice subject to the review and approval by the PNRI.

Section 26. Classification of Areas.

26.1. Controlled Areas

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

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

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

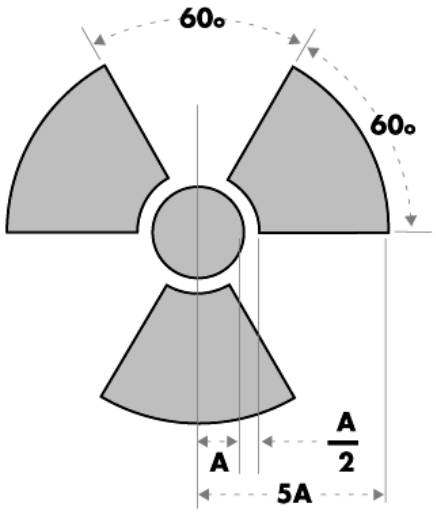
(b) In defining the boundaries of any controlled area, the licensee shall take account of the magnitude of the exposures expected in normal operation, the likelihood and magnitude of exposures in anticipated operational occurrences and in accident conditions, and the type and extent of the procedures required for protection and safety.

(c) The licensee shall:

(1) Delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means approved by the PNRI.

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

(3) Display a radiation warning symbol, the words "**CAUTION, RADIATION AREA**" and display instructions at access points to and at appropriate locations within controlled areas. The radiation warning symbol prescribed by this section is the conventional three-bladed design:



Cross-hatched area is to be magenta or purple. Background is to be yellow.

(4) 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.

(5) 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.

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

(i) Personal protective equipment;

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

(iii) Suitable storage for personal clothing.

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

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

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

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

(iv) Suitable storage for contaminated personal protective equipment.

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

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

26.2. Supervised Areas

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

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

(1) Delineate the supervised areas by appropriate means;

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

(3) 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.

Section 27. Contamination Level Limits in Controlled and Supervised Areas.

(a) The licensee shall contain or confine radioactive material in his/her possession, or otherwise make every reasonable effort to avoid contamination of surfaces accessible to persons or other property in excess of the following limits over an average area of 300 square centimeters (300 cm^2):

(1) For long-lived alpha emitters: 3 Bq/cm^2

(2) For long lived beta or gamma emitters: 30 Bq/cm^2

(3) For short-lived beta or gamma emitters: 300 Bq/cm^2

(b) Under conditions where contamination is suspected or may have occurred, the licensee shall make or cause to be made periodic surveys to determine the levels of contamination.

(c) Contamination levels on all surfaces shall be kept as low as reasonably achievable.

Section 28. Local Rules and Procedures and Personal Protective Equipment.

(a) The licensee 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:

(1) Engineered controls;

(2) Administrative controls; and

(3) Personal protective equipment.

(b) The licensee shall, in consultation with workers, through their representatives, in a language appropriate to the audience addressed:

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

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

(3) 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; and

(4) 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.

(c) The licensee shall ensure that:

(1) 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;

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

(3) 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;

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

(5) 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.

Section 29. Individual Monitoring.

29.1. External Exposure.

(a) The licensee shall monitor the external exposure of individuals working in a controlled area and those individuals entering a high radiation area.

(b) The licensee shall supply and require the use of a suitable and adequate external monitoring device such as, but not limited to, thermoluminescent dosimeter (TLD), optically stimulated luminescence dosimeter (OSL) or pocket dosimeter to individuals required under para. (a) of this Section. The licensee shall ensure that each monitoring device is assigned to, and worn only by one individual for each monitoring period.

(c) All personnel monitoring devices (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with Section 23 shall be processed and evaluated by PNRI-recognized dosimetry service providers that operate under a quality management system.

(d) The licensee shall maintain a record of total exposures of all individuals who are required to wear external monitoring devices in accordance with Section 32 of this Part.

29.2. Internal Exposure.

(a) The licensee shall monitor the occupational intake of radioactive material by and assess the committed effective dose equivalent to individuals working in a controlled area where radioactive aerosols, volatile radiopharmaceuticals or radioactive gases may be produced, used or handled.

(b) For purposes of assessing dose used to determine compliance with occupational dose limits, the licensee shall, when required under para. (a) of this Sub-section, take suitable and timely measurements of

(1) Concentrations of radioactive materials in air in work areas; or

(2) Quantities of radionuclides in the body; or

(3) Quantities of radionuclides excreted from the body; or

(4) Combinations of these measurements.

(c) Unless respiratory protective equipment is used, as provided in Section 28 (c) (1) (ii), or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

Section 30. Monitoring of the Workplace.

(a) The licensee shall establish, maintain and keep under review a program for the monitoring of the workplace under the supervision of a Radiation Protection Officer or Qualified Expert.

(b) The type and frequency of monitoring of workplaces shall:

(1) 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;

(2) 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.

(c) The programs for monitoring of the workplace shall specify:

(1) The quantities to be measured;

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

(3) The most appropriate measurement methods and procedures;

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

(d) The licensee shall maintain records of the findings of the workplace monitoring program. The findings of the workplace monitoring program shall be made available to workers, where appropriate through their representatives.

(e) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated annually for the radiation measured.

Section 31. Occupational Exposure Assessment.

(a) The licensee shall be responsible for making arrangements for the assessment of the occupational exposure of workers, on the basis of individual monitoring as required in Section 29, and shall ensure that arrangements are made with PNRI-approved dosimetry service providers that operate under a quality management system.

(b) In cases where individual monitoring of the worker is inappropriate, inadequate or not feasible, the licensee shall assess occupational exposure on the basis of the results of workplace monitoring and information on the locations and duration of exposure of the worker.

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

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

Section 32. Records of Occupational Exposure.

(a) The licensee shall maintain records of occupational exposure for each worker for whom assessment of occupational exposure is required under Section 31.

(b) 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.

(c) Records of occupational exposure shall include:

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

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

(3) 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;

(4) 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.

(d) The licensee shall:

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

(2) Provide the supervisor of the program for workers' health surveillance, the PNRI and the relevant employer with access to workers' records of occupational exposure;

(3) Provide copies of workers' exposure records to new employers when workers change employment;

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

(5) In complying with (1)–(4) above, give due care and attention to maintaining the confidentiality of records.

(e) If the licensee ceases to conduct activities in which workers are subject to occupational exposure, the licensee shall make arrangements for the retention of workers' records of occupational exposure by the PNRI or by the relevant employer or licensee.

Section 33. Compliance by Workers and Worker's Health Surveillance.

(a) The licensee shall ensure that each worker:

(1) Have the knowledge and understanding of all applicable regulations, local rules and the licensee's Radiation Protection and Safety Program;

(2) Use properly the monitoring equipment and personal protective equipment provided;

(3) Cooperate with the employer or licensee with regard to protection and safety, and programs for workers' health surveillance and programs for dose assessment;

(4) Provide to the employer or licensee such information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others;

(5) Abstain from any willful action that could put themselves or others in situations that would not be in accordance with the requirements of this Part;

(6) Report circumstances that could adversely affect protection and safety to the licensee as soon as possible; and

(7) Accept such information, instruction and training in protection and safety as will enable them to conduct their work in accordance with the requirements of this Part.

(b) The licensee 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.

(c) 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 PNRI or other relevant authority.

Section 34. Information, Instructions and Training.

(a) The licensee 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) The licensee 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) The licensee shall maintain records of the training provided to individual workers.

V. ADDITIONAL REQUIREMENTS FOR MEDICAL EXPOSURE

Section 35. Responsibilities of Licensees.

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

(1) 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 program;

(2) 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 program;

(3) A radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in para. d (1) of this Section;

(4) 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.

(b) The licensee shall ensure that no individual incurs a medical exposure as part of a program of biomedical research unless the exposure has been approved as required in Section 36 (f) and a radiological medical practitioner has assumed responsibility as specified in para. d (1) of this Section. The licensee shall ensure that the requirements are met for the optimization of protection and safety for individuals subject to exposure as part of a program of biomedical research.

(c) The licensee 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. The licensee shall ensure that dose constraints are established for the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

(d) The licensee shall ensure that:

(1) 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 Section 36 and the optimization of protection and safety, in cooperation with the medical physicist and the medical radiation technologist;

(2) 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;

(3) Sufficient medical personnel and paramedical personnel are available as specified by the Department of Health;

(4) Medical personnel and paramedical personnel are specialized in the appropriate area and meet the respective requirements for education, training and competence in radiation protection;

(5) The names of all medical and paramedical personnel are named in a list maintained up-to-date;

(6) For therapeutic radiological procedures, the requirements in this Part for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in applicable subsections in Sections 37 and 38 are conducted by or under the supervision of a medical physicist.

(7) For diagnostic radiological procedures, the requirements of this Part for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in applicable subsections in Sections 37 and 38 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;

(8) Any delegation of responsibilities to an authorized personnel as indicated in the license is documented and approved by the PNRI.

Section 36. Justification of Medical Exposure.

(a) 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 exposure to radiation.

(b) 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 are pediatric, of:

(1) The appropriateness of the request;

(2) The urgency of the radiological procedure;

(3) The characteristics of the medical exposure;

(4) The characteristics of the individual patient;

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

(c) 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.

(d) 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 program, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

(e) The exposure of volunteers as part of a program of biomedical research is deemed to be not justified unless it has been approved by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee), subject to any dose constraints that may be specified and subject to applicable regulations.

Section 37. Optimization of Protection for Medical Exposures.

37.1. Design Considerations.

In addition to ensuring that the responsibilities stated in Section 35 are discharged, as applicable, the licensee, 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 conform to the applicable standards of the International Electrotechnical Commission (IEC), the International Organization for Standardization (ISO) or to the applicable standards adopted by PNRI that is specified in a regulation or order.

37.2. Operational Considerations.

(a) For diagnostic radiological 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:

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

(2) 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 Subsection 37.5.

(b) 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.

(c) 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.

(d) The licensee shall ensure that the particular aspects of medical exposures are considered in the optimization process for:

(1) Pediatric patients subject to medical exposure;

(2) Individuals subject to medical exposure as part of a health screening program;

(3) Volunteers subject to medical exposure as part of a program of biomedical research;

(4) Relatively high doses to the patient;

(5) 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;

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

37.3. Calibration.

In accordance with Section 35 (d) para. (6) and (7), the medical physicist shall ensure that:

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

(2) Calibration is 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 PNRI;

(3) Calibration of radiotherapy units is subject to independent verification prior to clinical use; and

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

37.4. Dosimetry of Patients

The licensee 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:

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

(2) 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;

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

37.5. Diagnostic Reference Levels

The licensee shall ensure that:

(1) Local assessments, on the basis of the measurements required in Subsection 37.4, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established.

(2) 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.

37.6. Dose Constraints

(a) The licensee 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.

(b) The licensee shall ensure that dose constraints are used the optimization of protection and safety for individuals subject to exposure as part of a program of biomedical research.

Section 38. Quality Assurance for Medical Exposure.

(a) The licensee shall establish a comprehensive program 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.

(b) The licensee shall ensure that programs of quality assurance for medical exposures include, as appropriate to the medical radiation facility:

(1) 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;

(2) Implementation of corrective actions if measured values of the physical parameters mentioned in (1) are outside established tolerance limits;

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

(4) Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment;

(5) Maintaining records of relevant procedures and results; and

(6) All corresponding reports prepared and duly signed by the medical physicist.

(c) The licensee shall ensure that regular and independent audits are made of the program 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.

Section 39. Pregnant or Breast-feeding Female Patients.

(a) The licensee 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.

(b) The licensee shall ensure that signs in appropriate languages or local dialects 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:

(1) She is or might be pregnant;

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

(c) The licensee 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 and in the optimization of protection and safety.

(d) The licensee 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 and in the optimization of protection and safety.

Section 40. Release of Patients after Radionuclide Therapy.

(a) The licensee 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.

(b) The licensee shall ensure that no patient who has undergone a therapeutic radiological procedure with a sealed source or an unsealed source is discharged from a medical radiation facility until it has been established by either the medical physicist or the facility's Radiation Protection Officer that the dose that could be received by members of the public and family members is not likely to exceed 3 mSv.

(c) The licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv.

Section 41. Unintended and Accidental Medical Exposures.

(a) The licensee 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.

(b) The licensee shall promptly investigate any of the following unintended or accidental medical exposure:

(1) 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;

(2) Any diagnostic radiological procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;

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

(4) Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;

(5) 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.

(c) The licensee shall, with regard to any unintended or accidental medical exposures investigated as required above:

(1) Calculate or estimate the doses received and the dose distribution within the patient;

(2) Indicate the corrective actions required to prevent recurrence of such an unintended or accidental exposure;

(3) Implement all the corrective actions that are under their own responsibility;

(4) Produce and keep, as soon as possible after the investigation or as otherwise required by the PNRI, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (1) to (3) above, as relevant, and any other information as required by the PNRI; and for significant unintended or accidental medical exposures or as otherwise required by the PNRI, submit this written record, as soon as possible, to the PNRI, and to the relevant health authority if appropriate;

(5) 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.

Section 42. Radiological Reviews.

(a) The licensee shall ensure that radiological reviews are performed periodically by the medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists.

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

VI. ADDITIONAL REQUIREMENTS FOR PUBLIC EXPOSURE

Section 43. Responsibilities of Licensees.

(a) The licensee shall apply the requirements of this Part and shall verify and demonstrate compliance with them in relation to any public exposure delivered by a source for which they have responsibility.

(b) The licensee, 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:

(1) 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;

(2) Good practice in the operation of similar sources or the conduct of similar practices;

(3) Possible build up and accumulation in the environment of radioactive substances from discharges during the lifetime of the source;

(4) 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.

(c) The licensee, for sources under their responsibility, shall establish, implement and maintain:

(1) Policies, procedures and organizational arrangements for protection and safety in relation to public exposure, in accordance with the requirements of this Part;

(2) 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 Section 44;

(3) Measures for ensuring the safety of such sources;

(4) 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;

(5) Programs 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;

(6) Provision for appropriate monitoring equipment, monitoring programs and methods for assessing public exposure;

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

(8) Adequate records of monitoring programs.

Section 44. Dose Limits for Individual Members of the Public.

(a) For public exposure, the dose limits are:

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

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

(3) An equivalent dose to the lens of the eye of 15 mSv in a year;

(4) An equivalent dose to the skin of 50 mSv in a year.

(b) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(c) Notwithstanding para. (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released under Section 40 to receive a radiation dose greater than 1 mSv if -

(1) The radiation dose received does not exceed 3 mSv; and

(2) The authorized user determined before the visit that it is appropriate.

Section 45. Dose Constraints.

In case of release of radioactive material to the environment, the dose constraints shall be established by PNRI so that the prospective annual doses to members of the public, including people distant from the source and people of future generations, summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits specified in Section 44 of this Part.

Section 46. Control of Visitors.

The licensee shall:

(1) Apply the relevant requirements of this Part in respect of public exposure for visitors to a controlled area or a supervised area;

(2) Ensure that visitors are accompanied in any controlled area by a person who knows the measures for protection and safety for the controlled area;

(3) 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;

(4) 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.

Section 47. Sources of External Exposure.

The licensee shall ensure that if a source can give rise to external exposure of members of the public:

(1) 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 PNRI prior to commissioning;

(2) 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.

Section 48. Contamination in Areas Accessible to Members of the Public.

(a) The licensee shall ensure that 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) The licensee shall implement measures for protection and safety for restricting public exposure due to contamination in areas within a facility that are accessible to members of the public in excess of the following limits over an average area of 300 square centimeters(300 cm^2):

(1) For long-lived alpha emitters: 0.3 Bq/cm2

(2) For long lived beta or gamma emitters: 3 Bq/cm2

(3) For short-lived beta or gamma emitters: 30 Bq/cm2

Section 49. Monitoring and Reporting of Public Exposure.

(a) The licensee shall establish and implement monitoring programs 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 programs shall include monitoring of the following, as appropriate:

(1) External exposure from such sources;

(2) Discharges;

(3) Radioactivity in the environment; and

(4) Other parameters for the assessment of public exposure.

(b) The licensee shall maintain appropriate records of the results of the monitoring programs and estimated doses to members of the public.

(c) The licensee shall report or make available the results of the monitoring program to the PNRI 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) The licensee shall report within twenty-four (24) hours to the PNRI any levels exceeding the operational limits and conditions relating to public exposure, including authorized limits on discharges, in accordance with the reporting criteria established by the PNRI.

(e) The licensee shall report promptly to the PNRI any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the authorized practice, in accordance with the reporting criteria established by the PNRI.

(f) The licensee shall 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) The licensee shall verify the adequacy of the assumptions made for the assessment of public exposure and radiological environmental impacts.

(h) The licensee shall publish or make available on request, as appropriate, results from source monitoring and environmental monitoring programs and assessments made of doses from public exposure.

Section 50. Consumer Products

(a) 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 PNRI, and either their use has been exempted on the basis of the criteria specified in Section 9 or their provision to the public has been authorized.

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

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

(1) 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 PNRI;

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

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

(d) Providers of consumer products shall provide clear and appropriate information and instructions with each such consumer product on:

(1) Correct installation, use and maintenance of the product;

(2) Servicing and repair;

(3) The radionuclides and their activities;

(4) Dose rates in normal operation and during servicing and repair;

(5) Required or recommended options for recycling or disposal.

(e) Providers of consumer products shall provide the product retailers with appropriate information on safety and instructions on transport and storage.

VII. REQUIREMENTS FOR RADIOACTIVE WASTE MANAGEMENT AND DISPOSAL OF LICENSED RADIOACTIVE MATERIAL

Section 51. General Responsibilities of Licensees.

(a) The licensee shall be responsible for the safe management of the radioactive waste generated by the practices or sources for which they are authorized and shall take all necessary measures to ensure that:

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

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

(3) Disposal of radioactive waste is not unnecessarily delayed;

(4) Reporting is made to the PNRI of required information at intervals as may be specified in the license, including those related to the changes of ownership of waste.

(b) The licensee shall establish, implement or cause to be implemented a radioactive waste management program to ensure an effective control and disposal of radioactive wastes generated under the license for the protection of the public and the environment. Such radioactive waste management program shall ensure that, as appropriate:

(1) The activity and volume of radioactive waste generated are kept to the minimum practicable;

(2) The radioactive waste is collected, handled, treated, conditioned, transported, stored and disposed of, in accordance with the requirements of this Part and any other applicable Part of the Code;

(3) Different types of radioactive waste are segregated and treated separately to warrant differences in factors such as radionuclide content, half-life, concentration, volume and physical and chemical properties, taking into account the available options for waste disposal.

(4) Transport of radioactive waste is in accordance with CPR Part 4, “Regulations for the Safe Transport of Radioactive Material in the Philippines”, and including any applicable national regulations;

(5) Disposal of waste complies with the general radiation protection principles, including ALARA.

(6) Administrative controls and surveillance procedures are maintained in accordance with quality assurance requirements.

(7) Records that show the receipt, transfer and disposal of radioactive waste are maintained.

(c) The licensee shall dispose licensed radioactive material only:

(1) By transfer to an authorized recipient as provided in the applicable requirements in the Code of PNRI Regulations;

(2) By decay in storage;

(3) By discharge to the environment within the limits specified in Appendix C of this Part

(4) As authorized to dispose of as ordinary waste; or

(5) By disposal as radioactive waste in accordance with an approved radioactive waste management program.

Section 52. Transfer of Licensed Radioactive Material.

(a) Any licensed radioactive material or sealed source that is “disused” or no longer suitable as originally intended in the license may be transferred to another person licensedby PNRI to receive such material in accordance with the requirements provided in this Part.

(b) If the transfer of disused sealed source to another licensee is not possible, the disused sealed source shall be returned to the supplier or manufacturer or disposed as radioactive waste to a person licensed by PNRI.

(c) In the transport of disused sealed source to the supplier or manufacturer, the disused sealed source shall be packaged and shipped in the original shipping container, or provisions should be made to acquire another acceptable container if the original container is not available. The regulations of CPR Part 4, “Regulations for the Safe Transport of Radioactive Material in the Philippines”, shall apply.

Section 53. Storage of Radioactive Waste.

(a) All radioactive wastes that are for disposal shall be appropriately stored in on-site facilities under controlled conditions. Interim storage of unconditioned waste shall be as short as possible and not to exceed five (5) years.

(b) Containers used for decay-in-storage shall be properly labeled including the date when the source may be disposed of as non-radioactive waste.

(c) Storage facilities for radioactive wastes shall be constructed and secured to prevent unauthorized access to the wastes and such that subsequent handling, transport and disposal will not be endangered.

Section 54. Required Conditions During Normal Operation Involving Radioactive Discharges.

(a) All radioactive discharges shall be kept as far below the authorized clearance levels in Appendix C as is reasonably achievable.

(b) Radioactive discharges shall be monitored with sufficient detail and accuracy to demonstrate compliance with authorized clearance levels and to permit proper assessment of the exposure of critical groups.

(c) Results of monitoring and exposures must be recorded and reported to the PNRI annually.

(d) Radioactive discharges that exceed the authorized clearance levels must be reported to PNRI in accordance with the applicable requirements in this Part.

Section 55. Disposal by Release to the Atmosphere.

(a) The licensee shall work with radioactive gases or aerosols in a fume cupboard or in the immediate vicinity of an extraction hood. Fume cupboard exhaust trunking from active laboratories shall be isolated from normal ventilation systems and exhausted to the atmosphere through stacks so as not to re-enter the building or adjacent buildings.

(b) If filtration of exhaust has been deemed necessary in particular circumstances, then the appropriate type of filter shall be employed for trapping the emission; the installation shall have been approved; the assembly tested and the performance continuously monitored.

Section 56. Required Conditions Prior to Discharge to Environment.

(a) The characteristics and the activity of any solid, liquid or gaseous radioactive waste to be discharged, and the potential points and methods of discharge shall be determined.

(b) All possible exposure pathways by which discharged radioactive waste can cause public exposure shall be determined.

(c) The doses to the critical groups due to planned discharges must be assessed.

(d) Discharge of radioactive substances, including wastes, to the environment is prohibited unless:

(1) The discharges are within the clearance levels as defined by PNRI:

(i) Airborne effluents discharged into the atmosphere either directly or through filtration systems shall not exceed the clearance levels given in Appendix C – 1;

(ii) Aqueous effluents discharged directly to sewer systems, or to septic tanks, or collection ponds, or to freshwater bodies shall not exceed the clearance levels given in Appendix C – 2;

(iii) Solid waste shall not exceed the clearance levels given in Appendix C – 3;

(2) The discharges are controlled and that such control is optimized; and

(3) The public exposures committed by the discharges shall not exceed the dose limits prescribed in this Part.

Section 57. Radioactive Waste that are Exempt from Regulatory Control.

The PNRI may exempt from regulatory control the discharge of radioactive waste if:

(1) The effective dose expected to be received by any member of the public due to the waste is of the order of 10 μSv or less in a year; and

(2) The activity of the waste does not exceed the clearance levels given in Appendix C of this Part.

Section 58. Compliance with Environmental and Health Protection Regulations.

Nothing in this Part relieves the licensee from complying with other government regulations that cover any other toxic or hazardous properties of materials that may be disposed of under this Part.

VIII. REQUIREMENTS FOR EMERGENCY PREPAREDNESS AND RESPONSE

Section 59. Emergency Plan.

(a) The licensee shall prepare an emergency plan for the protection of people and the environment 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.

(b) 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:

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

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

(c) The licensee 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:

(1) 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;

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

(3) Train and periodically retrain personnel in the procedures to be followed and conduct emergency drills to exercise the procedures.

(d) The 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:

(1) 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;

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

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

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

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

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

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

(8) Provide for training personnel involved in implementing emergency plans and be rehearsed at suitable intervals based on requirements defined in item (c)(3) of this Section in conjunction with designated authorities; and

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

Section 60. Implementation of Intervention.

(a) 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.

(b) 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.

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

(1) The current situation and its expected evolution;

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

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

IX. DOCUMENTATION OF RECORDS, REPORTS AND NOTIFICATIONS

Section 61. Documentation of Records.

(a) Each record required under this Part shall be legibly written or printed on a specified form throughout the retention period. Each record shall be authenticated by authorized personnel and shall have adequate safeguards against tampering or loss.

(b) The licensee shall use the International System of Units (SI): Becquerel, Gray, Sievert, including multiples and subdivisions and shall clearly indicate the units of all quantities on records required by this Part.

(c) The licensee may record quantities in traditional units in parentheses following each of the units specified in para. (b) of this section. However, all quantities shall be recorded as stated in para. (b) of this section.

(d) The licensee shall make a clear distinction among the quantities entered on the records required by this Part (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

Section 62. Records Related to Medical Exposures

(a) Licensees shall maintain for a period as specified by the PNRI and shall make available, as required, the following personnel records:

(1) Records of any delegation of responsibilities by licensees as required in Section 36(d)(8);

(2) Records of training of personnel in radiation protection.

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

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

(2) Records of dosimetry of patients, as required in Section 37.4;

(3) Records of local assessments and reviews made with regard to diagnostic reference levels, as required in Section 37.5;

(4) Records associated with the quality assurance programme, as required in Section 38.

(c) Licensees shall maintain for a period specified in the license and shall make available, as required, the following records for medical exposure:

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

(2) 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;

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

(4) 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;

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

(6) Reports on investigations of unintended and accidental medical exposures, as required in Section 41(c)(4).

Section 63. Reports of Theft or Loss of Radioactive Material.

(a) The licensee shall notify the PNRI by telephone or by any other fast means of communication, of any lost, stolen, or missing radioactive material immediately after its occurrence becomes known to the licensee.

(b) In addition to the notification required above, the licensee shall, within 30 days after the occurrence, make a report in writing to PNRI that shall include the following information:

(1) A description of the radioactive material involved including kind, quantity, chemical, and physical form;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition or probable disposition of the radioactive material involved;

(4) Estimated radiation exposures to individuals, circumstances under which the exposures occurred, and the extent of possible hazards;

(5) Actions which have been taken, or will be taken, to recover the material; and

(6) Procedures or measures which have been or will be adopted to prevent a recurrence of the circumstances which led to the loss or theft of the licensed material.

(c) Notwithstanding the requirement to file a written report, the licensee shall also report immediately any substantive additional information on the loss or theft which becomes available to the licensee.

(d) Any report filed with PNRI pursuant to this section shall identify the individuals who may be exposed to radiation or may be involved in the incident.

Section 64. Notification of Incidents.

(a) The licensee shall notify the PNRI within 24 hours by telephone, or by any other fast means of communication, of any incident involving a licensed activity, licensed facility, source material, special fissionable material or any other radioactive material possessed by the licensee that may have caused, or threatens to cause:

(1) Exposure of the whole body of any individual in excess of 50 mSv; or

(2) The release of radioactive material inside or outside of a controlled area, so that, if an individual is present in the area for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake.

(b) Any report filed with PNRI pursuant to this Section shall specify the names of individuals who have received exposure to radiation and other persons involved in the incident, including telephone numbers and addresses as may be practicable.

Section 65. Reports of Overexposures and Excessive Levels and Concentrations.

(a) In addition to any report or notification required by this Part, the licensee shall make a report in writing to PNRI concerning any one of the following incidents within 30 days of its occurrence:

(1) Exposure to individuals in excess of the limits of this Part allowed for occupational, or public exposures or as may be indicated in the license conditions;

(2) Levels of radiation or concentration of radioactive material in a controlled area in excess of any applicable limit in this Part or in the license; or

(3) Levels of radiation or concentrations of radioactive material, whether or not involving exposures of any individual, in a supervised area in excess of 10 times of any applicable limit set forth in this Part or in the license issued by PNRI.

(b) Each report required under this Section must describe the extent of exposure of individuals to radiation or to radioactive material, including estimates of each individual's total exposure; levels of radiation and concentrations of radioactive material involved; the cause of the exposure; and corrective steps taken or planned to prevent a recurrence.

(c) In any case where a licensee is required to report to PNRI any exposure of an individual to radiation or to radioactive material, the licensee shall also notify such individual of the nature and extent of exposure. Such notice shall be in writing and a copy shall be furnished to PNRI.

(d) Unless otherwise specified, all reports required by this Article shall be made in writing within 30 days.

X. ENFORCEMENT

Section 66. Violations.

(a) Any person found to have violated any rule, regulation, or order issued by PNRI, or any term, condition, or limitation of any license issued there under shall be notified of such violation and required to take corrective steps to prevent recurrence.

(b) Any license may be modified, suspended, or revoked, after due process, for any violation which PNRI determines to adversely affect the health and safety of the workers and the public.

(c) Any person who willfully violates, attempts to violate, or conspires to violate any rule or regulation or order by PNRI issued hereunder may be guilty of a crime, and upon conviction, may be punished by a fine or imprisonment or both as provided by Sections 64 and 65 of Republic Act No. 5207.

XI. EFFECTIVITY

Section 67. Effective Date.

The regulations in this Part shall take effect fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation.

APPROVED:

(original signed)

CARLO A. ARCILLA, Ph. D.
Director

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APPENDICES

APPENDIX A. EXEMPTION AND CLEARANCE

CRITERIA FOR EXEMPTION

A.1. The general criteria for exemption of a practice or a source within a practice from some or all of the requirements of these Standards are that:

(a) Radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption; or

(b) Regulatory control of the practice or the source would yield no net benefit, in that no reasonable measures for regulatory control would achieve a worthwhile return in terms of reduction of individual doses or of health risks.

A.2. A practice or a source within a practice may be exempted without further consideration from some or all of the requirements of these Standards under the terms of para. A.1(a) provided that under all reasonably foreseeable circumstances the effective dose expected to be incurred by any individual (normally evaluated on the basis of a safety assessment) owing to the exempt practice or the exempt source within the practice is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion could be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

A.3. Under the criteria set out in paras. A.1 and A.2, the following sources within justified practices are automatically exempted without further consideration from the requirements of these Standards, including requirements for notification, registration or licensing:

(a) Material in a moderate amount for which either the total activity of an individual radionuclide present on the premises at any one time or the activity concentration as used in the practice does not exceed the applicable exemption level given in Table I-1.

(b) Material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Table I-2.

A.4. For radionuclides of natural origin, exemption of bulk amounts of material is necessarily considered on a case by case basis by using a dose criterion of the order of 1 mSv in a year, commensurate with typical doses due to natural background levels of radiation.

A.5. The IAEA Regulations for the Safe Transport of Radioactive Material do not apply to exempt material or exempt consignments; that is, they do not apply to material in transport for which the activity concentration of the material (for exempt material) or the total activity of radionuclides in the consignment (for an exempt consignment) does not exceed the relevant ‘basic radionuclide value’ given in the IAEA Transport Regulations for exemption from the requirements of the IAEA Transport Regulations. Usually, such basic

radionuclide values are numerically equal to the corresponding exempt activity concentrations or exempt activities given in Table I-1.

A.6. Exemptions may be granted subject to conditions specified by the PNRI, such as conditions relating to the physical or chemical form of the radioactive material, and to its use or the means of its disposal. In particular, such an exemption may be granted for equipment containing radioactive material that is not otherwise automatically exempted without further consideration from some or all of the requirements of these Standards under para. A.3(a) provided that:

(a) The equipment containing radioactive material is of a type approved by the PNRI.

(b) The radioactive material:

(i) Is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage; or

(ii) Is in the form of an unsealed source in a small amount such as sources used for radioimmunoassay.

(c) 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 equipment.

(d) Necessary conditions for disposal of the equipment have been specified by the PNRI.

A.7. For exemption of radioactive material containing more than one radionuclide, on the basis of the levels given in Tables I-1 and I-2, the condition for exemption from some or all of the requirements of these Standards is that the sum of the individual radionuclide activities or activity concentrations, as appropriate, is less than the derived exemption level for the mixture (Xm), determined as follows:

$$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}}$$

where

f(i) is the fraction of activity or activity concentration, as appropriate, of radionuclide i in the mixture;

X(i) is the applicable level for radionuclide i as given in Table I-1 or Table I-2; and n is the number of radionuclides present.

A.8. Radioactive material arising from authorized discharges is exempt from any requirements for notification, registration or licensing unless otherwise specified by the PNRI.

A.9. The values provided in Tables I-1 and I-2 are not intended to be applied to the control of discharges or to the control of residual radioactive material in the environment.

CRITERIA FOR CLEARANCE

A.10. The general criteria for clearance are that:

(a) Radiation risks arising from the cleared material are sufficiently low as not to warrant regulatory control, and there is no appreciable likelihood of occurrence for scenarios that could lead to a failure to meet the general criterion for clearance; or

(b) Continued regulatory control of the material would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or reduction of health risks.

A.11. Material may be cleared without further consideration under the terms of para. A.10(a) provided that in reasonably foreseeable circumstances the effective dose expected to be incurred by any individual owing to the cleared material is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion can be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

A.12. Radioactive material within a notified practice or an authorized practice may be cleared without further consideration provided that:

(a) The activity concentration of an individual radionuclide of artificial origin in solid form does not exceed the relevant level given in Table I-2; or

(b) The activity concentrations of radionuclides of natural origin do not exceed the relevant level given in Table I-3; or

(c) For radionuclides of natural origin in residues that might be recycled into construction materials, or the disposal of which is liable to cause the contamination of drinking water supplies, the activity concentration in the residues does not exceed specific values derived so as to meet a dose criterion of the order of 1 mSv in a year, which is commensurate with typical doses due to natural background levels of radiation.

A.13. Clearance may be granted by the PNRI for specific situations, on the basis of the criteria of paras A.10 and A.11, with account taken of the physical or chemical form of the radioactive material, and its use or the means of its disposal65. Such clearance levels may be specified in terms of activity concentration per unit mass or activity concentration per unit surface area.

A.14. For clearance of radioactive material containing more than one radionuclide of artificial origin, on the basis of the levels given in Table I-2, the condition for clearance is that the sum of the activity concentrations for individual radionuclides is less than the derived clearance level for the mixture (Xm), determined as follows:

$$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}}$$

where

$f(i)$ is the fraction of activity concentration of radionuclide i in the mixture;

$X(i)$ is the applicable level for radionuclide i as given in Table I-2; and

n is the number of radionuclides present.

A.15. For clearance of bulk quantities of material containing a mixture of radionuclides of natural origin and radionuclides of artificial origin, the conditions given in paras A.12(b) and A.14 both have to be satisfied.

TABLE I-1. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
H-3	1×10^{6}	1×10^{9}	Ni-63	1×10^{5}	1×10^{8}
Be-7	1×10^{3}	1×10^{7}	Ni-65	1×10^{1}	1×10^{6}
C-14	1×10^{4}	1×10^{7}	Cu-64	1×10^{2}	1×10^{6}
O-15	1×10^{2}	1×10^{9}	Zn-65	1×10^{1}	1×10^{6}
F-18	1×10^{1}	1×10^{6}	Zn-69	1×10^{4}	1×10^{6}
Na-22	1×10^{1}	1×10^{6}	Zn-69m	1×10^{2}	1×10^{6}
Na-24	1×10^{1}	1×10^{5}	Ga-72	1×10^{1}	1×10^{5}
Si-31	1×10^{3}	1×10^{6}	Ge-71	1×10^{4}	1×10^{8}
P-32	1×10^{3}	1×10^{5}	As-73	1×10^{3}	1×10^{7}
P-33	1×10^{5}	1×10^{8}	As-74	1×10^{1}	1×10^{6}
S-35	1×10^{5}	1×10^{8}	As-76	1×10^{2}	1×10^{5}
Cl-36	1×10^{4}	1×10^{6}	As-77	1×10^{3}	1×10^{6}
Cl-38	1×10^{1}	1×10^{5}	Se-75	1×10^{2}	1×10^{6}
Ar-37	1×10^{6}	1×10^{8}	Br-82	1×10^{1}	1×10^{6}
Ar-41	1×10^{2}	1×10^{9}	Kr-74	1×10^{2}	1×10^{9}
K-40	1×10^{2}	1×10^{6}	Kr-76	1×10^{2}	1×10^{9}
K-42	1×10^{2}	1×10^{6}	Kr-77	1×10^{2}	1×10^{9}
K-43	1×10^{1}	1×10^{6}	Kr-79	1×10^{3}	1×10^{5}
Ca-45	1×10^{4}	1×10^{7}	Kr-81	1×10^{4}	1×10^{7}
Ca-47	1×10^{1}	1×10^{6}	Kr-83m	1×10^{5}	1×10^{12}
Sc-46	1×10^{1}	1×10^{6}	Kr-85	1×10^{5}	1×10^{4}
Sc-47	1×10^{2}	1×10^{6}	Kr-85m	1×10^{3}	1×10^{10}
Sc-48	1×10^{1}	1×10^{5}	Kr-87	1×10^{2}	1×10^{9}
V-48	1×10^{1}	1×10^{5}	Kr-88	1×10^{2}	1×10^{9}
Cr-51	1×10^{3}	1×10^{7}	Rb-86	1×10^{2}	1×10^{5}
Mn-51	1×10^{1}	1×10^{5}	Sr-85	1×10^{2}	1×10^{6}
Mn-52	1×10^{1}	1×10^{5}	Sr-85m	1×10^{2}	1×10^{7}
Mn-52m	1×10^{1}	1×10^{5}	Sr-87m	1×10^{2}	1×10^{6}
Mn-53	1×10^{4}	1×10^{9}	Sr-89	1×10^{3}	1×10^{6}
Mn-54	1×10^{1}	1×10^{6}	Sr-90*	1×10^{2}	1×10^{4}
Mn-56	1×10^{1}	1×10^{5}	Sr-91	1×10^{1}	1×10^{5}
Fe-52	1×10^{1}	1×10^{6}	Sr-92	1×10^{1}	1×10^{6}
Fe-55	1×10^{4}	1×10^{6}	Y-90	1×10^{3}	1×10^{5}
Fe-59	1×10^{1}	1×10^{6}	Y-91	1×10^{3}	1×10^{6}
Co-55	1×10^{1}	1×10^{6}	Y-91m	1×10^{2}	1×10^{6}
Co-56	1×10^{1}	1×10^{5}	Y-92	1×10^{2}	1×10^{5}
Co-57	1×10^{2}	1×10^{6}	Y-93	1×10^{2}	1×10^{5}
Co-58	1×10^{1}	1×10^{6}	Zr-93*	1×10^{3}	1×10^{7}
Co-58m	1×10^{4}	1×10^{7}	Zr-95	1×10^{1}	1×10^{6}
Co-60	1×10^{1}	1×10^{5}	Zr-97*	1×10^{1}	1×10^{5}
Co-60m	1×10^{3}	1×10^{6}	Nb-93m	1×10^{4}	1×10^{7}
Co-61	1×10^{2}	1×10^{6}	Nb-94	1×10^{1}	1×10^{6}
Co-62m	1×10^{1}	1×10^{5}	Nb-95	1×10^{1}	1×10^{6}
Ni-59	1×10^{4}	1×10^{8}	Nb-97	1×10^{1}	1×10^{6}

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Nb-98	1×10^{1}	1×10^{5}	I-123	1×10^{2}	1×10^{7}
Mo-90	1×10^{1}	1×10^{6}	I-125	1×10^{3}	1×10^{6}
Mo-93	1×10^{3}	1×10^{8}	I-126	1×10^{2}	1×10^{6}
Mo-99	1×10^{2}	1×10^{6}	I-129	1×10^{2}	1×10^{5}
Mo-101	1×10^{1}	1×10^{6}	I-130	1×10^{1}	1×10^{6}
Tc-96	1×10^{1}	1×10^{6}	I-131	1×10^{2}	1×10^{6}
Tc-96m	1×10^{3}	1×10^{7}	I-132	1×10^{1}	1×10^{5}
Tc-97	1×10^{3}	1×10^{8}	I-133	1×10^{1}	1×10^{6}
Tc-97m	1×10^{3}	1×10^{7}	I-134	1×10^{1}	1×10^{5}
Tc-99	1×10^{4}	1×10^{7}	I-135	1×10^{1}	1×10^{6}
Tc-99m	1×10^{2}	1×10^{7}	Xe131m	1×10^{4}	1×10^{4}
Ru-97	1×10^{2}	1×10^{7}	Xe-133	1×10^{3}	1×10^{4}
Ru-103	1×10^{2}	1×10^{6}	Xe-135	1×10^{3}	1×10^{10}
Ru-105	1×10^{1}	1×10^{6}	Cs-129	1×10^{2}	1×10^{5}
Ru-106*	1×10^{2}	1×10^{5}	Cs-131	1×10^{3}	1×10^{6}
Rh-103m	1×10^{4}	1×10^{8}	Cs-132	1×10^{1}	1×10^{5}
Rh-105	1×10^{2}	1×10^{7}	Cs-134m	1×10^{3}	1×10^{5}
Pd-103	1×10^{3}	1×10^{8}	Cs-134	1×10^{1}	1×10^{4}
Pd-109	1×10^{3}	1×10^{6}	Cs-135	1×10^{4}	1×10^{7}
Ag-105	1×10^{2}	1×10^{6}	Cs-136	1×10^{1}	1×10^{5}
Ag-110m	1×10^{1}	1×10^{6}	Cs-137*	1×10^{1}	1×10^{4}
Ag-111	1×10^{3}	1×10^{6}	Cs-138	1×10^{1}	1×10^{4}
Cd-109	1×10^{4}	1×10^{6}	Ba-131	1×10^{2}	1×10^{6}
Cd-115	1×10^{2}	1×10^{6}	Ba-140*	1×10^{1}	1×10^{5}
Cd-115m	1×10^{3}	1×10^{6}	La-140	1×10^{1}	1×10^{5}
In-111	1×10^{2}	1×10^{6}	Ce-139	1×10^{2}	1×10^{6}
In-113m	1×10^{2}	1×10^{6}	Ce-141	1×10^{2}	1×10^{7}
In-114m	1×10^{2}	1×10^{6}	Ce-143	1×10^{2}	1×10^{6}
In-115m	1×10^{2}	1×10^{6}	Ce-144*	1×10^{2}	1×10^{5}
Sn-113	1×10^{3}	1×10^{7}	Pr-142	1×10^{2}	1×10^{5}
Sn-125	1×10^{2}	1×10^{5}	Pr-143	1×10^{4}	1×10^{6}
Sb-122	1×10^{2}	1×10^{4}	Nd-147	1×10^{2}	1×10^{6}
Sb-124	1×10^{1}	1×10^{6}	Nd-149	1×10^{2}	1×10^{6}
Sb-125	1×10^{2}	1×10^{6}	Pm-147	1×10^{4}	1×10^{7}
Te-123m	1×10^{2}	1×10^{7}	Pm-149	1×10^{3}	1×10^{6}
Te-125m	1×10^{3}	1×10^{7}	Sm-151	1×10^{4}	1×10^{8}
Te-127	1×10^{3}	1×10^{6}	Sm-153	1×10^{2}	1×10^{6}
Te-127m	1×10^{3}	1×10^{7}	Eu-152	1×10^{1}	1×10^{6}
Te-129	1×10^{2}	1×10^{6}	Eu-152m	1×10^{2}	1×10^{6}
Te-129m	1×10^{3}	1×10^{6}	Eu-154	1×10^{1}	1×10^{6}
Te-131	1×10^{2}	1×10^{5}	Eu-155	1×10^{2}	1×10^{7}
Te-131m	1×10^{1}	1×10^{6}	Gd-153	1×10^{2}	1×10^{7}
Te-132	1×10^{2}	1×10^{7}	Gd-159	1×10^{3}	1×10^{6}
Te-133	1×10^{1}	1×10^{5}	Tb-160	1×10^{1}	1×10^{6}
Te-133m	1×10^{1}	1×10^{5}	Dy-165	1×10^{3}	1×10^{6}
Te-134	1×10^{1}	1×10^{6}	Dy-166	1×10^{3}	1×10^{6}

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Ho-166	1×10^3	1×10^5
Er-169	1×10^4	1×10^7
Er-171	1×10^2	1×10^6
Tm-170	1×10^3	1×10^6
Tm-171	1×10^4	1×10^8
Yb-175	1×10^3	1×10^7
Lu-177	1×10^3	1×10^7
Hf-181	1×10^1	1×10^6
Ta-182	1×10^1	1×10^4
W-181	1×10^3	1×10^7
W-185	1×10^4	1×10^7
W-187	1×10^2	1×10^6
Re-186	1×10^3	1×10^6
Re-188	1×10^2	1×10^5
Os-185	1×10^1	1×10^6
Os-191	1×10^2	1×10^7
Os-191m	1×10^3	1×10^7
Os-193	1×10^2	1×10^6
Ir-190	1×10^1	1×10^6
Ir-192	1×10^1	1×10^4
Ir-194	1×10^2	1×10^5
Pt-191	1×10^2	1×10^6
Pt-193m	1×10^3	1×10^7
Pt-197	1×10^3	1×10^6
Pt-197m	1×10^2	1×10^6
Au-198	1×10^2	1×10^6
Au-199	1×10^2	1×10^6
Hg-197	1×10^2	1×10^7
Hg197m	1×10^2	1×10^6
Hg-203	1×10^2	1×10^5
Tl-200	1×10^1	1×10^6
Tl-201	1×10^2	1×10^6
Tl-202	1×10^2	1×10^6
Tl-204	1×10^4	1×10^4
Pb-203	1×10^2	1×10^6
Pb-210*	1×10^1	1×10^4
Pb-212*	1×10^1	1×10^5
Bi-206	1×10^1	1×10^5
Bi-207	1×10^1	1×10^6
Bi-210	1×10^3	1×10^6
Bi-212*	1×10^1	1×10^5
Po-203	1×10^1	1×10^6
Po-205	1×10^1	1×10^6
Po-207	1×10^1	1×10^6
Po-210	1×10^1	1×10^4
At-211	1×10^3	1×10^7
Rn-220*	1×10^4	1×10^7
Rn-222*	1×10^1	1×10^8
Ra-223*	1×10^2	1×10^5
Ra-224*	1×10^1	1×10^5
Ra-225	1×10^2	1×10^5
Ra-226*	1×10^1	1×10^4
Ra-227	1×10^2	1×10^6
Ra-228*	1×10^1	1×10^5
Ac-228	1×10^1	1×10^6
Th-226*	1×10^3	1×10^7
Th-227	1×10^1	1×10^4
Th-228*	1×10^0	1×10^4
Th-229*	1×10^0	1×10^3
Th-230	1×10^0	1×10^4
Th-231	1×10^3	1×10^7
Th-nat (incl.Th-232)	1×10^0	1×10^3
Th-234*	1×10^3	1×10^5
Pa-230	1×10^1	1×10^6
Pa-231	1×10^0	1×10^3
Pa-233	1×10^2	1×10^7
U-230*	1×10^1	1×10^5
U-231	1×10^2	1×10^7
U-232*	1×10^0	1×10^3
U-233	1×10^1	1×10^4
U-234	1×10^1	1×10^4
U-235*	1×10^1	1×10^4
U-236	1×10^1	1×10^4
U-237	1×10^2	1×10^6
U-238*	1×10^1	1×10^4
U-nat	1×10^0	1×10^3
U-239	1×10^2	1×10^6
U-240	1×10^3	1×10^7
U-240*	1×10^1	1×10^6
Np-237*	1×10^0	1×10^3
Np-239	1×10^2	1×10^7
Np-240	1×10^1	1×10^6
Pu-234	1×10^2	1×10^7
Pu-235	1×10^2	1×10^7
Pu-236	1×10^1	1×10^4
Pu-237	1×10^3	1×10^7
Pu-238	1×10^0	1×10^4
Pu-239	1×10^0	1×10^4
Pu-240	1×10^0	1×10^3
Pu-241	1×10^2	1×10^5
Pu-242	1×10^0	1×10^4

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Pu-243	1×10^3	1×10^7	Cf-246	1×10^3	1×10^6
Pu-244	1×10^0	1×10^4	Cf-248	1×10^1	1×10^4
Am-241	1×10^0	1×10^4	Cf-249	1×10^0	1×10^3
Am-242	1×10^3	1×10^6	Cf-250	1×10^1	1×10^4
Am-242m*	1×10^0	1×10^4	Cf-251	1×10^0	1×10^3
Am-243*	1×10^0	1×10^3	Cf-252	1×10^1	1×10^4
Cm-242	1×10^2	1×10^5	Cf-253	1×10^2	1×10^5
Cm-243	1×10^0	1×10^4	Cf-254	1×10^0	1×10^3
Cm-244	1×10^1	1×10^4	Es-253	1×10^2	1×10^5
Cm-245	1×10^0	1×10^3	Es-254	1×10^1	1×10^4
Cm-246	1×10^0	1×10^3	Es-254m	1×10^2	1×10^6
Cm-247	1×10^0	1×10^4	Fm-254	1×10^4	1×10^7
Cm-248	1×10^0	1×10^3	Fm-255	1×10^3	1×10^6
Bk-249	1×10^3	1×10^6			

* Parent nuclides and their progeny included in secular equilibrium are listed in the following:
Sr-90 Y-90
Zr-93 Nb-93m
Zr-97 Nb-97
Ru-106 Rh-106
Cs-137 Ba-137m
Ba-140 La-140
Ce-134 La-134
Ce-144 Pr-144
Pb-210 Bi-210, Po-210
Pb-212 Bi-212, Tl-208 (0.36), Po-212 (0.64)
Bi-212 Tl-208 (0.36), Po-212 (0.64)
Rn-220 Po-216
Rn-222 Po-218, Pb-214, Bi-214, Po-214
Ra-223 Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224 Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212(0.64)
Ra-226 Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228 Ac-228

Th-226 Ra-222, Rn-218, Po-214
Th-228 Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229 Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212,
Tl-208 (0.36), Po-212 (0.64)
Th-234 Pa-234m
U-230 Th-226, Ra-222, Rn-218, Po-214
U-232 Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36),
Po-212 (0.64)
U-235 Th-231
U-238 Th-234, Pa-234m
U-nat Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214,
Po-214, Pb-210, Bi-210, Po-210
U-240 Np-240m
Np-237 Pa-233
Am-242m Am-242
Am-243 Np-239

TABLE I-2. LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION AND FOR CLEARANCE OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN

Radionuclide	Activity concentration (Bq/g)	Radionuclide[a]	Activity concentration (Bq/g)
H-3	100	Co-58	1
Be-7	10	Co-58m	10 000
C-14	1	Co-60	0.1
F-18	10	Co-60m	1 000
Na-22	0.1	Co-61	100
Na-24	1	Co-62m	10
Si-31	1 000	Ni-59	100
P-32	1 000	Ni-63	100
P-33	1 000	Ni-65	10
S-35	100	Cu-64	100
Cl-36	1	Zn-65	0.1
Cl-38	10	Zn-69	1 000
K-42	100	Zn-69m[a]	10
K-43	10	Ga-72	10
Ca-45	100	Ge-71	10 000
Ca-47	10	As-73	1 000
Sc-46	0.1	As-74	10
Sc-47	100	As-76	10
Sc-48	1	As-77	1 000
V-48	1	Se-75	1
Cr-51	100	Br-82	1
Mn-51	10	Rb-86	100
Mn-52	1	Sr-85	1
Mn-52m	10	Sr-85m	100
Mn-53	100	Sr-87m	100
Mn-54	0.1	Sr-89	1 000
Mn-56	10	Sr-90a	1
Fe-52a	10	Sr-91a	10
Fe-55	1 000	Sr-92	10
Fe-59	1	Y-90	1 000
Co-55	10	Y-91	100
Co-56	0.1	Y-91m	100
Co-57	1	Y-92	100

Radionuclide	Activity concentration (Bq/g)
Y-93	100
Zr-93	10
Zr-95a	1
Zr-97a	10
Nb-93m	10
Nb-94	0.1
Nb-95	1
Nb-97a	10
Nb-98	10
Mo-90	10
Mo-93	10
Mo-99a	10
Mo-101a	10
Tc-96	1
Tc-96m	1 000
Tc-97	10
Tc-97m	100
Tc-99	1
Tc-99m	100
Ru-97	10
Ru-103a	1
Ru-105a	10
Ru-106a	0.1
Rh-103m	10 000
Rh-105	100
Pd-103a	1 000
Pd-109a	100
Ag-105	1
Ag-110ma	0.1
Ag-111	100
Cd-109a	1
Cd-115a	10
Cd-115ma	100

Radionuclide[a]	Activity concentration (Bq/g)
In-111	10
In-113m	100
In-114ma	10
In-115m	100
Sn-113a	1
Sn-125	10
Sb-122	10
Sb-124	1
Sb-125a	0.1
Te-123m	1
Te-125m	1 000
Te-127	1 000
Te-127m[a]	10
Te-129	100
Te-129ma	10
Te-131	100
Te-131ma	10
Te-132a	1
Te-133	10
Te-133m	10
Te-134	10
I-123	100
I-125	100
I-126	10
I-129	0.01
I-130	10
I-131	10
I-132	10
I-133	10
I-134	10
I-135	10
Cs-129	10
Cs-131	1 000

Radionuclide	Activity concentration (Bq/g)	Radionuclide[a]	Activity concentration (Bq/g)
Cs-132	10	Er-171	100
Cs-134	0.1	Tm-170	100
Cs-134m	1 000	Tm-171	1 000
Cs-135	100	Yb-175	100
Cs-136	1	Lu-177	100
Cs-137a	0.1	Hf-181	1
Cs-138	10	Ta-182	0.1
Ba-131	10	W-181	10
Ba-140	1	W-185	1 000
La-140	1	W-187	10
Ce-139	1	Re-186	1 000
Ce-141	100	Re-188	100
Ce-143	10	Os-185	1
Ce-144a	10	Os-191	100
Pr-142	100	Os-191m	1 000
Pr-143	1 000	Os-193	100
Nd-147	100	Ir-190	1
Nd-149	100	Ir-192	1
Pm-147	1 000	Ir-194	100
Pm-149	1 000	Pt-191	10
Sm-151	1 000	Pt-193m	1 000
Sm-153	100	Pt-197	1 000
Eu-152	0.1	Pt-197m	100
Eu-152m	100	Au-198	10
Eu-154	0.1	Au-199	100
Eu-155	1	Hg-197	100
Gd-153	10	Hg-197m	100
Gd-159	100	Hg-203	10
Tb-160	1	Tl-200	10
Dy-165	1 000	Tl-201	100
Dy-166	100	Tl-202	10
Ho-166	100	Tl-204	1
Er-169	1 000	Pb-203	10

Radionuclide	Activity concentration (Bq/g)
Bi-206	1
Bi-207	0.1
Po-203	10
Po-205	10
Po-207	10
At-211	1 000
Ra-225	10
Ra-227	100
Th-226	1 000
Th-229	0.1
Pa-230	10
Pa-233	10
U-230	10
U-231	100
U-232[a]	0.1
U-233	1
U-236	10
U-237	100
U-239	100
U-240a	100
Np-237[a]	1
Np-239	100
Np-240	10
Pu-234	100
Pu-235	100
Pu-236	1
Pu-237	100
Pu-238	0.1
Pu-239	0.1
Pu-240	0.1
Pu-241	10
Pu-242	0.1
Pu-243	1 000
Pu-244[a]	0.1
Am-241	0.1
Am-242	1 000
Am-242m[a]	0.1
Am-243[a]	0.1
Cm-242	10
Cm-243	1
Cm-244	1
Cm-245	0.1
Cm-246	0.1
Cm-247[a]	0.1
Cm-248	0.1
Bk-249	100
Cf-246	1 000
Cf-248	1
Cf-249	0.1
Cf-250	1
Cf-251	0.1
Cf-252	1
Cf-253	100
Cf-254	1
Es-253	100
Es-254a	0.1
Es-254m[a]	10
Fm-254	10 000
Fm-255	100

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

Fe-52	Mn-52m	Sn-113	In-113m
Zn-69m	Zn-69	Sb-125	Te-125m
Sr-90	Y-90	Te-127m	Te-127
Sr-91	Y-91m	Te-129m	Te-129
Zr-95	Nb-95	Te-131m	Te-131
Zr-97	Nb-97m, Nb-97	Te-132	I-132
Nb-97	Nb-97m	Cs-137	Ba-137m
Mo-99	Tc-99m	Ce-144	Pr-144, Pr-144m
Mo-101	Tc-101	U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
Ru-103	Rh-103m		
Ru-105	Rh-105m		
Ru-106	Rh-106	U-240	Np-240m, Np-240
Pd-103	Rh-103m	Np-237	Pa-233
Pd-109	Ag-109m	Pu-244	U-240, Np-240m, Np-240
Ag-110m	Ag-110		
Cd-109	Ag-109m		
Cd-115	In-115m	Am-242m	Np-238
Cd-115m	In-115m	Am-243	Np-239
In-114m	In-114	Cm-247	Pu-243
		Es-254	Bk-250
		Es-254m	Fm-254

Note: The exemption levels set out in Table I-1 and the exemption and clearance levels set out in this table are subject to the following considerations: (a) they were derived using a conservative model based on (i) the criteria of paras A.2 and A.11, respectively, and (ii) a series of limiting (bounding) scenarios for use and disposal; (b) if there is more than one radionuclide, the derived exemption level or derived clearance level for the mixture is determined as specified in paras A.7 and A.14.

TABLE I-3. LEVELS FOR CLEARANCE OF MATERIAL: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF NATURAL ORIGIN

Radionuclide	Activity concentration (Bq/g)
K-40	10
Each radionuclide in the uranium decay chain or the thorium decay chain	1

APPENDIX B. CATEGORIES FOR SEALED SOURCES USED IN COMMON PRACTICES

TABLE B-1. CATEGORIES FOR SEALED SOURCES USED IN COMMON PRACTICES

Source Category	Ratio of activity in the source to activity that is considered dangerous[a] (A/D)	Example of Sources[b] and Practices
1	A/D ≥ 1000	Radioisotope thermoelectric generators (RTGs) Irradiators Teletherapy Fixed multi-beam teletherapy (gamma knife)
2	1000 > A/D ≥ 10	Industrial radiography High/medium dose rate brachytherapy
3	10 > A/D ≥ 1	Fixed industrial gauges (e.g. level, dredger, conveyor) Well logging gauges
4	1 > A/D ≥ 0.01	Low dose rate brachytherapy (except eye plaques and permanent implants) Industrial gauges that do not incorporate high activity sources (typically portable) Bone densitometers Static eliminators

[a] A is the activity of the radionuclide in a source and D is the activity of that radionuclide that is regarded as dangerous. A dangerous source is defined as one that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. Values of D for selected radionuclides are given in Table B-2 on the basis of the quantity of radioactive material that could give rise to severe deterministic effects for given exposure scenarios and for given dose criteria. This column of the table can, thus, be used to determine the category of a source, purely on the basis of the value of A/D. This may be appropriate if, for example: the practice is not known or is not listed; if sources have a short half-life and/or are unsealed; or if sources are aggregated.

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

5	0.01 > A/D and A > Exempt	Low dose rate brachytherapy eye plaques and permanent implant sources X ray fluorescence devices Electron capture devices Mossbauer Spectrometry sources Positron Emission Tomography (PET) check sources

TABLE B-2. ACTIVITY[a] CORRESPONDING TO A DANGEROUS SOURCE (D VALUE) FOR SELECTED RADIONUCLIDES

Radionuclide	D Value (TBq)	Radionuclide[a]	D Value (TBq)
Am-241	6 × 10–2	Mo-99	3 × 10–1
Am-241/Be	6 × 10–2	Ni-63	6 × 101
Au-198	2 × 10–1	P-32	1 × 101
Cd-109	2 × 101	Pd-103	9 × 101
Cf-252	2 × 10–2	Pm-147	4 × 101
Cm-244	5 × 10–2	Po-210	6 × 10–2
Co-57	7 × 10–1	Pu-238	6 × 10–2
Co-60	3 × 10–2	Pu-239/Be	6 × 10–2
Cs-137	1 × 10–1	Ra-226	4 × 10–2
Fe-55	8 × 102	Ru-106 (Rh-106)	3 × 10–1
Gd-153	1 × 100	Se-75	2 × 10–1
Ge-68	7 × 10–2	Sr-90 (Y-90)	1 × 100
H-3	2 × 103	Tc-99m	7 × 10–1
I-125	2 × 10–1	Tl-204	2 × 101
I-131	2 × 10–1	Tm-170	2 × 101
Ir-192	8 × 10–2	Yb-169	3 × 10–1
Kr-85	3 × 101		

[a] Since this table does not state which dose criteria were used, these D values cannot be used ‘in reverse’ to derive possible doses from exposure due to sources of known activity.

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APPENDIX C. CLEARANCE LEVELS

C - 1 DERIVED GENERIC CLEARANCE LEVELS FOR AIRBORNE RELEASES

Radionuclide	Annual Release Rate (Bq per annum)	Main Exposure Pathways and Limiting Age Group
H-3	1×10^{11}	Ingestion
C-14	1×10^{10}	Ingestion
Na-22	1×10^{6}	External from deposit (Adults and Infants)
Na-24	1×10^{9}	External from deposit (Adults and Infants)
P-32	1×10^{8}	Ingestion (Infants)
S-35	1×10^{8}	Ingestion (Infants)
Cl-36	1×10^{7}	Ingestion (Infants)
K-42	1×10^{10}	External from deposit (Adults and Infants)
Ca-45	1×10^{8}	Ingestion (Infants)
Ca-47	1×10^{9}	External from deposit and ingestion (Adults and Infants)
Cr-51	1×10^{9}	External from deposit (Infants)
Fe-59	1×10^{8}	External from deposit (Adults and Infants)
Co-57	1×10^{9}	Ingestion (infants)
Co-58	1×10^{9}	Ingestion (infants)
Ga-67	1×10^{10}	External from deposit (Adults and Infants)
Se-75	1×10^{8}	External from deposit (Adults and Infants)
Sr-85	1×10^{8}	External from deposit (Adults and Infants)
Sr-89	1×10^{8}	Ingestion (infants)
Y-90	1×10^{10}	Inhalation and Ingestion (Infants)
Mo-99	1×10^{9}	External from deposit (Adults and Infants)
Tc-99	1×10^{7}	Ingestion (infants)
Tc-99m	1×10^{11}	External from deposit (Adults and Infants)
In-111	1×10^{9}	External from deposit (Adults and Infants)
I-123	1×10^{10}	External from deposit (Adults and Infants)
I-125	1×10^{8}	Ingestion (infants)
I-131	1×10^{8}	Ingestion (infants)
Xe-127	1×10^{11}	External from cloud (Adults and Infants)
Xe-133	1×10^{12}	External from cloud (Adults and Infants)
Pm-147	1×10^{10}	Inhalation (Adults and Infants)

Radionuclide	Annual Release Rate (Bq per annum)	Main Exposure Pathways and Limiting Age Group
Er-169	1×10^{10}	Inhalation and ingestion (Infants)
Au-198	1×10^{9}	External from deposit (Adults and Infants)
Hg-197	1×10^{10}	External from deposit (Adults and Infants)
Hg-203	1×10^{8}	External from deposit and ingestion (Infants)
Tl-201	1×10^{10}	External from deposit (Adults and Infants)
Ra-226	1×10^{6}	Inhalation and Ingestion (Adults and infants)
Th-232	1×10^{5}	Inhalation (Adults)

Reference: IAEA TECDOC 1000

Notes:

(a) The calculations on which these values are based assume releases from a building vent or window. The closest individual is located 20 m from the release point and gets his food, 100 and 800 m from the release point. Doses are evaluated via inhalation, ingestion and external exposure routes.

(b) Significant differences in these values are possible for different source to receptor distances.

C - 2 DERIVED GENERIC CLEARANCE LEVELS FOR LIQUID RELEASES

Radionuclide	Annual Release Rate (Bq per annum)	Main Exposure Pathways
H-3	1×10^{12}	River - Ingestion
C-14	1×10^{10}	River - Ingestion
Na-22	1×10^{5}	Sewage – External
Na-24	1×10^{8}	Sewage – External
P-32	1×10^{6}	River – Ingestion fish
S-35	1×10^{9}	River – Ingestion fish
Cl-36	1×10^{10}	River – Ingestion fish and water
K-42	1×10^{9}	Sewage – External
Ca-45	1×10^{10}	River – Ingestion fish and water
Ca-47	1×10^{8}	Sewage – External
Cr-51	1×10^{8}	Sewage – External
Fe-59	1×10^{6}	Sewage – External
Co-57	1×10^{9}	Sewage – External
Co-58	1×10^{8}	Sewage – External
Ga-67	1×10^{8}	Sewage – External
Se-75	1×10^{6}	Sewage – External
Sr-85	1×10^{6}	Sewage – External
Sr-89	1×10^{9}	River – Ingestion fish and water
Y-90	1×10^{10}	River – Ingestion fish and water
Mo-99	1×10^{8}	Sewage – External
Tc-99	1×10^{10}	River – Ingestion fish and water
Tc-99m	1×10^{9}	Sewage – External
In-111	1×10^{8}	Sewage – External
I-123	1×10^{9}	Sewage – External
I-125	1×10^{8}	Sewage – External
I-131	1×10^{7}	Sewage – External
Xe-127	Not applicable	
Xe-133	Not applicable	
Pm-147	1×10^{10}	Sewage – External and River - Ingestion fish and water
Er-169	1×10^{10}	River - Ingestion fish and water
Au-198	1×10^{8}	Sewage – External
Hg-197	1×10^{9}	Sewage – External
Hg-203	1×10^{7}	Sewage – External
Tl-201	1×10^{8}	Sewage – External
Ra-226	1×10^{6}	Sewage – External
Th-232	1×10^{6}	Sewage – External

(Reference: IAEA TECDOC 1000)

Note:

The values are the most restrictive of those calculated following discharge to a river or discharge to a sewer.

C - 3 GENERIC CLEARANCE LEVELS FOR SOLID WASTE (Bq/g)

Radionuclide	Clearance Level for Moderate Quantities (a)	Radionuclide	Clearance Level for Moderate Quantities (a)
H-3	1×10^{6}	Sr-89	1×10^{3}
C-14	1×10^{4}	Y-90	1×10^{3}
Na-22	1×10^{1}	Mo-99	1×10^{2}
Na-24	1×10^{1}	Tc-99	1×10^{4}
P-32	1×10^{3}	Tc-99m	1×10^{2}
S-35	1×10^{5}	In-111	1×10^{2}
Cl-36	1×10^{4}	I-123	1×10^{2}
K-42	1×10^{2}	I-125	1×10^{3}
Ca-45	1×10^{4}	I-131	1×10^{2}
Ca-47	1×10^{1}	Pm-147	1×10^{4}
Cr-51	1×10^{3}	Er-169	1×10^{4}
Fe-59	$1x\ 10^{1}$	Au-198	1×10^{2}
Co-57	1×10^{2}	Hg-197	1×10^{2}
C0-58	1×10^{1}	Hg-203	1×10^{2}
Ga-67	$1\ x10^{2}$	Tl-201	1×10^{2}
Se-75	1×10^{2}	Ra-226	$1\ x10^{1}$
Sr-85	1×10^{2}	Th-232	$1\ x10^{0}$

(Reference: IAEA TECDOC 1000)

(a) Moderate quantity means less than 3 tonnes per year and per facility. For larger quantities the clearance level is one tenth of the levels in Appendix C - 3.