

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

STANDARDS FOR PROTECTION AGAINST RADIATION

CPR PART 3

I. GENERAL PROVISIONS

Section 1. Purpose.

- (a) The regulations in this Part establish the standards for protection against ionizing radiation arising from the use of radioactive materials and related activities conducted under licenses issued by the **Philippine Nuclear Research Institute, hereinafter referred to as PNRI**. This Part is promulgated pursuant to **Section 16-a of Republic Act 2067, as amended by R.A. 3589** and **Section 4(a) of Republic Act 5207, as amended by P.D. 1484**.
- (b) The regulations in this Part also establish the basic requirements for the safety of radiation sources.
- (c) It is the purpose of the Regulations in this Part to control all activities by any licensee involving radioactive material in such a manner that the total dose to an individual, except exposures to radiation from natural background sources or medical diagnosis and therapy, does not exceed the Standards prescribed in this Part.
- (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 all holders of PNRI licenses issued pursuant to the regulations of the Code of PNRI Regulations (CPR). However, the implementation of Section 13 (Medical Exposure) shall be the exclusive responsibility of licensees authorized pursuant to the licensing requirements of CPR Part 12 - "Licenses for Medical Use of Sealed Sources in Teletherapy", CPR Part 13 - "Licenses for Medical Use of Radiopharmaceuticals", or CPR Part 14 - "Licenses for Medical Use of Sealed Sources in Brachytherapy".
- b) The requirements in this Part are in addition to, and not in substitution for, other requirements of the CPR.
- c) Specific provisions of the IAEA Safety Series No. 115, "International Basic Safety Standards (IBSS) for Protection Against Ionizing Radiation and for the Safety of Radiation Sources" which are applicable in this Part, may be addressed pursuant to PNRI Administrative Order No. 1, Series of 2001.

Section 3. Exemptions.

- (a) The requirements in this Part do not apply to:

- (1) practices and sources involving radioactive materials that meet the exemption levels given in **Appendix A**; and
 - (2) any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of this Part.
- (b) The dose limits prescribed in this Part do not apply to:
- (1) radiation exposures due to background radiation;
 - (2) radiation exposure from individuals who have been administered with radioactive material and subsequently released in accordance with CPR Part 13; and
 - (3) medical exposures which include:
 - (i) radiation exposure incurred by patients as part of their own medical or dental diagnosis or treatment; and
 - (ii) radiation exposure of comforters and visitors of patients undergoing medical diagnosis or treatment.

Section 4. Definitions.

As used in this Part:

- (a) "**Accident**" means any unintended event, including an operating error, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety;
- (b) "**Act**" means **Republic Act No. 2067, as amended** and **Republic Act 5207, as amended**;
- (c) "**Action Level**" means the level of dose rate or activity concentration above which remedial actions or protective actions should be carried out in chronic exposure or emergency exposure situations;
- (d) "**Activity**" or "**Radioactivity**" means the number of spontaneous nuclear transformations per unit time of a radioactive material. The unit of activity is becquerel (**1 Bq = 1 disintegration per second**);
- (e) "**ALARA**" (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practicable:
 - (1) consistent with the purpose for which the licensed activity is undertaken; and
 - (2) taking into account the state of technology, the economics of improvement to benefit the health and safety of the public and the workers and other societal and socio-economic considerations.
- (f) "**Authorized Worker**" means the person authorized to conduct licensed activities according to his/her specific duties and responsibilities in the license issued pursuant to the Code of PNRI Regulations (CPR). (e.g. "Radiological Health and Safety Officer" for the safety officer in any PNRI license; "Authorized User", "Technologist", and "Medical Physicist" for users of radioactive materials in medicine; "Authorized Personnel" and "Authorized Operator" for users of radioactive material in research and industry.);
- (g) "**Bioassay**" (**radiobioassay**) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body (in vitro);
- (h) "**Chronic exposure**" means exposure persisting in time;

- (i) **“Controlled Area”** means any area in which specific protection measures and safety provisions are or could be required for:
 - (1) controlling normal exposures or preventing the spread of contamination during normal working conditions; and
 - (2) preventing or limiting the extent of potential exposures.
- (j) **“CPR”** means Code of PNRI Regulations, or the **“Code”** which is a listing of regulations promulgated by PNRI and published in the Official Gazette;
- (k) **“Critical group”** means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances;
- (l) **“Dose”** or **“Radiation dose”** means a measure of the radiation received or absorbed by a target. Modifying terms associated with this quantity include absorbed dose, organ dose, equivalent dose, effective dose, committed equivalent dose, or committed effective dose, depending on the context. These radiation dose quantities are described in **Appendix B**;
- (m) **“Dose constraint”** means a prospective and source related restriction on the individual dose delivered by the source which serves as a bound in the optimization of protection and safety of the source. For occupational exposure, dose constraint is a source related value of individual dose used to limit the range of options considered in the process of optimization. For public exposure, the dose constraint is an upper bound on the annual dose to any critical group, summed over all exposure pathways, arising from the planned operation of any controlled source. For medical exposure, the dose constraint levels should be interpreted as guidance levels, except when used in optimizing the protection of persons exposed for medical research purposes or of persons, other than workers, who assist in the care, support or comfort of exposed patients;
- (n) **“Exposure”** means the act or condition of being subject to ionizing radiation or to radioactive material. Exposure can be either external exposure (irradiation by sources outside the body) or internal exposure (irradiation by sources inside the body). Exposure can be classified as either normal exposure or potential exposure; either occupational, medical or public exposure; and, in intervention situations, either emergency exposure or chronic exposure;
- (o) **“Guidance level”** means the level of a specified quantity above which or substantially below which appropriate actions should be considered;
- (p) **“High Radiation Area”** means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an equivalent dose in excess of 1 mSv in an hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates;
- (q) **“IBSS”** means the International Basic Safety Standards published as IAEA Safety Series No. 115;
- (r) **“Intervention”** means any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident;
- (s) **“Intervention level”** means the level of avertable dose at which a specific protective action or remedial action is taken in an emergency exposure situation or a chronic exposure situation;

- (t) **"License"** means an authorization granted by **PNRI** for a specific practice or application described in the CPR. **"Licensee"** means the holder of such PNRI license;
- (u) **"Medical exposure"** means exposure incurred by patients as part of their own medical or diagnosis or treatment; by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a program of biomedical research involving their exposure;
- (v) **"Person"** means:
 - (1) any individual, firm, partnership, association, trust, estate, private or public body, whether corporate or not, or any government agency other than **PNRI**, any province, city, municipality, or any political subdivision within the **Republic of the Philippines**; and
 - (2) any legal successor, representative, agent, or agency of the foregoing;
- (w) **"Personnel monitoring device"** means a device designed to be worn or carried by an individual for the purpose of measuring the dose received by that individual;
- (x) **"PNRI"** means the Philippine Nuclear Research Institute and/or its duly authorized representatives;
- (y) **"Practice"** means the production of radioactive sources and the use of radioactive substances for medical, industrial, or agricultural purposes, or for education, training or research, including any activities related to that use which involve or could involve exposure to radiation or radioactive substances;
- (z) **"Protection and safety"** means the protection of people against exposure to ionizing radiation from radioactive substances and the safety of radioactive sources;
- (aa) **"Protective action"** means an intervention intended to avoid or reduce doses to members of the public in chronic or emergency exposure situations;
- (bb) **"Quality Assurance"** means planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality specified in the license;
- (cc) **"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;
- (dd) **"Radiation Area"** means an area, accessible to individuals, in which radiation levels could result in an individual receiving an equivalent dose in excess of 0.05 mSv in an hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;
- (ee) **"Radioactive material"** means any material which spontaneously gives off radiation;
- (ff) **"Radiological Health and Safety Officer"** means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee;

- (gg) “**Remedial action**” means an action taken when a specified action level is exceeded, to reduce radiation doses that might otherwise be received, in an intervention situation involving chronic exposure;
- (hh) “**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;
- (ii) “**Source**” means:
 - (1) radioactive substances and devices that contain radioactive substances;
 - (2) installations and facilities which contain radioactive substances.
- (jj) “**Special form radioactive material**” means radioactive material which satisfies the following conditions:
 - (1) it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
 - (2) the piece or capsule has at least one dimension not less than 5 millimeters; and
 - (3) it satisfies the test requirements for qualification of special form radioactive material specified in **CPR Part 4, “Rules and Regulations on the Safe Transport of Radioactive Materials in the Philippines”**;
- (kk) “**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;
- (ll) “**Survey**” means any evaluation of the radioactive hazards incident to the production, use, release, transport, disposal or presence of radioactive materials or other sources of radiation under a specific set of conditions; and
- (mm) “**Worker**” means any person who works, whether full time, part time or temporarily, for a licensee and who has recognized rights and duties in the license in relation to occupational radiation protection.

NOTE: *Terms defined in the Act and in other Parts of the CPR shall have the same meaning when used in this Part to the extent that such terms are not specifically defined in this Part.*

Section 5. Interpretation.

Except as specifically authorized by the **Director** in writing, no interpretation of the meaning of the regulations in this Part by any officer or employee of the **PNRI** other than a written interpretation by the **Director** will be recognized to be binding upon **PNRI**.

Section 6. Communication.

All communication and reports concerning the regulations in this Part should be addressed to the **Director, Philippine Nuclear Research Institute**, Commonwealth Avenue, Diliman, Quezon City.

II. RADIATION PROTECTION AND SAFETY REQUIREMENTS

Section 7. Radiation Protection and Safety Program.

- (a) Each licensee shall use and observe, to the extent practicable the regulations in this Part and the radiation protection and safety principles subscribed by **PNRI**.

- (b) Each licensee shall establish, document, and implement a radiation protection and safety program that is commensurate with the scope and extent of authorized activities and sufficient to ensure compliance with the requirements of this Part and the conditions of the license.
- (c) Each licensee shall review at least annually the content and implementation of its radiation protection and safety program.

Section 8. *Format and Content of the Radiation Protection and Safety Program.*

The Radiation Protection and Safety Program shall include the following information, as may be applicable:

- (a) A description of the radiation protection and safety organization, including its functions, responsibilities of individual assignments, and qualification and training of these individuals;
- (b) A description of the duties and responsibilities of the Radiological Health and Safety Officer (RHSO). The licensee shall appoint a RHSO, who agrees, in writing, to be responsible for implementing the radiation protection and safety program. The licensee, through the RHSO, shall ensure that radiation safety activities are being performed in accordance with the regulatory requirements and licensee-approved procedures.
- (c) A description of the radiation facility including the areas where radioactive materials are used and stored;
- (d) The number and type of equipment and devices incorporating radioactive substances, instruments and monitoring devices used and their proper maintenance;
- (e) 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;
- (f) 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;
- (g) Methods for evaluating the performance of radiation protection and safety program that will include program reviews, audits, corrective actions and follow-up; and
- (h) An emergency plan for responding to any accident that results in the release of radioactive material to the environment which includes:
 - (1) protection of workers;
 - (2) intervention/protective action; and
 - (3) emergency procedures

Section 9. *Justification of Practices.*

- (a) No practice or source within a practice shall be adopted, introduced or conducted except under a license issued by PNRI.
- (b) The licensee shall not authorize any practice or source within a practice unless such practice or source produces sufficient benefit to compensate for the potential radiation harm it might cause, taking into account social, economic and other relevant factors.

- (c) The following practices are not deemed to be justified whenever they would result in an increase, by deliberate addition of radioactive substances or by activation, in the activity of the associated commodities or products:
 - (1) practices involving food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being; and
 - (2) practices involving the frivolous use of radiation or radioactive substances in commodities or products such as toys and personal jewelry or adornments.

Section 10. Optimization of Protection and Safety.

- (a) In relation to exposures from any particular source within a practice, except for therapeutic medical exposures, protection and safety shall be optimized in order 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) Each licensee shall exert every reasonable effort to avoid any unnecessary radiation exposure or contamination of individuals and property, and any releases of radioactive material to the environment.
- (c) In the design, plan and subsequent conduct of practices and activities, each licensee shall take every reasonable protective measure to reduce exposures to the point that further reductions become less important than the additional effort required.

Section 11. Dose Constraints.

Except for medical exposure, the optimization of the protection and safety measures associated with any particular source within a practice shall be subject to dose constraints which:

- (a) Do not exceed either the appropriate values established or agreed to by PNRI for such a source or values which can cause the dose limits to be exceeded; and
- (b) Ensure, for any source (including radioactive waste management facilities) that can release radioactive substances to the environment, that the cumulative effects of each annual release from the source be restricted so that the effective dose in any year to any member of the public, including people distant from the source and people of future generations, is unlikely to exceed any relevant dose limit, taking into account cumulative releases and the exposures expected to be delivered by all other relevant sources and practices under control.

Section 12. Dose Limitation.

Normal exposure of individuals shall be restricted so that the total effective dose or the total equivalent dose to relevant organs or tissues, caused by the possible combination of exposures from authorized practices, does not exceed any relevant dose limit specified in Section 13 of this Part. Dose limits shall not apply to medical exposures from authorized practices.

III. ADDITIONAL REQUIREMENTS FOR EACH TYPE OF EXPOSURE

Section 13. Occupational Exposure.

13.1. Responsibilities.

- (a) Each licensee shall be responsible for the protection of workers from occupational exposure.
- (b) Each licensee shall ensure that policies, procedures and organizational arrangements for protection and safety are established for implementing the licensee's radiation protection and safety program, with priority given to the design and technical measures to control radiation hazards.
- (c) Each licensee shall ensure that workers are provided with the following:
 - (1) suitable and adequate facilities, equipment and services for protection and safety, the nature and extent of which are commensurate with the expected magnitude and likelihood of the occupational exposure;
 - (2) necessary health surveillance and health services;
 - (3) appropriate protective devices and monitoring equipment;
 - (4) suitable and adequate human resources and appropriate training in protection and safety, as well as periodic retraining and updating as required in order to ensure the necessary level of competence; and
 - (5) all necessary conditions to promote a safety culture.
- (d) Each licensee shall take such administrative actions as are necessary to ensure that workers are informed of their obligations and responsibilities for their own protection and the protection of others against radiation and for the safety of sources.

13.2. Occupational Dose Limits.

Each licensee shall ensure that the occupational exposure of any worker under his/her license shall be so controlled that the following limits will not be exceeded:

- (a) An effective dose of **20 mSv per year averaged over five consecutive years**;
- (b) An effective dose of **50 mSv in any single year**;
- (c) An equivalent dose to the lens of the eye of **150 mSv** in a year; and
- (d) An equivalent dose to the extremities (hands and feet) or the skin of **500 mSv** in a year.

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

- (a) No person under the age of 16 years shall be subjected to occupational exposure.
- (b) No person under the age of 18 years shall be allowed to work in a controlled area unless supervised and only for training purposes.
- (c) For apprentices that are 16 to 18 years of age who are training for employment involving exposure to radiation and for students of age 16 to 18 who are required to use radioactive sources in the course of their studies, the occupational exposure shall be controlled so that the following limits are not exceeded:
 - (1) an effective dose of **6 mSv** in a year;
 - (2) an equivalent dose to the lens of the eye of **50 mSv** in a year; and

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

13.4. Conditions for Pregnant Workers.

- (a) A female worker shall notify the licensee about her pregnancy in order that her working conditions maybe modified, if necessary.
- (b) Each licensee shall modify and make suitable the working conditions of his/her worker who has notified pregnancy with respect to occupational exposure, in order to ensure that the embryo or fetus be afforded the same broad level of protection as required for members of the public.
- (c) Each licensee shall make every reasonable effort to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant worker so as not to exceed **1 mSv** in a year.

13.5. Contamination Level Limits.

- (a) Each 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 limits shown in **Table 1**, over an average area of 300 square centimeters.

Table 1. Allowable Non-Fixed Contamination in Controlled and Public Areas

	Allowable Removable Contamination	
	Controlled Area (Bq/cm ²)	Public Area (Bq/cm ²)
Long lived alpha emitters	3	0.3
Long lived beta or gamma emitters	30	3
*Short lived beta or gamma emitters	300	30

* Include most of the commonly used radionuclides, e.g., H-3, C-14, P-32, P-33, I-125

- (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 is reasonably achievable.

13.6. Classification of Work Areas.

13.6.1. Controlled Areas.

- (a) Each licensee shall, in determining the boundaries of any controlled area, take account of the magnitudes of the expected normal exposures, the likelihood and magnitude of potential exposures, and the nature and extent of the required protection and safety procedures.
- (b) Each licensee shall:
 - (1) delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;

- (2) where a source is brought into operation or energized only intermittently 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 warning symbol, such as that recommended by the International Organization for Standardization (ISO), and appropriate instructions at access points and other appropriate locations within controlled areas;
- (4) establish occupational protection and safety measures, including local rules and procedures that are appropriate 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 magnitude and likelihood of the expected exposures;
- (6) provide, as appropriate, at entrances to controlled areas:
 - (i) protective clothing and equipment;
 - (ii) monitoring equipment; 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 object or substance being removed from the area;
 - (iii) washing or showering facilities; and
 - (iv) suitable storage for contaminated protective clothing and equipment
- (8) periodically review conditions to determine the possible need to revise the protection measures or safety provisions, or the boundaries of controlled areas.

13.6.2. Supervised Areas.

Each licensee shall, taking into account the nature and extent of radiation hazards in the supervised areas:

- (a) Delineate the supervised areas by appropriate means;
- (b) Display approved signs at appropriate access points to supervised areas; and
- (c) periodically review the conditions to determine any need for protective measures and safety provisions or changes to the boundaries of supervised areas.

13.7. Rules and Supervision.

Each licensee shall, in consultation with the RHSO:

- (a) Establish in writing such local rules and procedures as are necessary to ensure adequate levels of protection and safety for workers and other persons;
- (b) Include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded;
- (c) Make the local rules and procedures and the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them; and
- (d) Ensure that any work involving occupational exposure be adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions be observed.

13.8. Personnel Monitoring Devices and Protective Equipment.

- (a) Each licensee shall ensure that his/her personnel and workers are provided with suitable and adequate personnel monitoring and personal protective equipment, including, as appropriate:
 - (1) personnel monitoring devices such as film badge, pocket dosimeter, TLD, or alarm rate meter;
 - (2) protective clothing;
 - (3) protective respiratory equipment; and
 - (4) protective aprons and gloves and organ shields.
- (b) Each licensee shall provide workers adequate instructions in the proper use of protective equipment, including testing for good fit.
- (c) Each licensee shall ensure that all personal protective equipment be maintained in proper condition and if appropriate be tested at regular intervals.
- (d) Each licensee shall ensure that appropriate personal protective equipment be maintained for use in the event of intervention.
- (e) Each licensee shall minimize reliance on administrative controls and personal protective equipment for protection and safety during normal operations by providing appropriate protective measures and safety provisions, that include well-engineered controls and satisfactory working conditions.

13.9. Individual Monitoring.

- (a) The licensee shall be responsible for arranging for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate.
- (b) The licensee shall ensure that individuals working in a controlled area undertake individual monitoring where appropriate, adequate and feasible, otherwise the occupational exposure of the worker shall be assessed on the basis of the results of monitoring of the workplace and on information on the locations and durations of exposure of the worker.
- (c) The licensee shall not require individual monitoring for any worker who is regularly employed in a supervised area or who enters a controlled area only occasionally. However, the occupational exposure of the worker shall be assessed based on the results of monitoring of the workplace or individual monitoring.
- (d) The nature, frequency and precision of individual monitoring shall be determined with consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures.

13.10. Monitoring of the Workplace.

- (a) Each licensee, through the RHSO, shall establish, maintain and keep under review a program for the monitoring of the workplace.
- (b) The nature and frequency of monitoring the workplaces shall:
 - (1) be sufficient to enable:
 - (i) evaluation of the radiological conditions in all workplaces;
 - (ii) exposure assessment in controlled areas and supervised areas; and
 - (iii) review of the classification of controlled and supervised areas; and

- (2) depend on the levels of ambient dose equivalent and activity concentration, including their expected fluctuations and the likelihood and magnitude of potential exposures.
- (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; and
 - (4) reference levels and the actions to be taken if they are exceeded.
- (d) Each licensee shall keep appropriate records of the findings of the workplace monitoring program which shall be made available to workers.

13.11. Health Surveillance.

- (a) The licensee shall be responsible for the appropriate health surveillance arrangements for each worker.
- (b) Health surveillance programs shall be:
 - (1) based on the general principles of occupational health; and
 - (2) designed to assess the initial and continuing fitness of workers for their intended tasks.

13.12. Records of Occupational Exposure.

- (a) The licensee shall maintain the exposure records for each worker for whom assessment of occupational exposure is required by this Part.
- (b) The licensee shall:
 - (1) provide the workers access to information contained in their own exposure records;
 - (2) provide the representatives of **PNRI** access to the exposure records;
 - (3) provide copies of worker's exposure records to new employers when the worker changes employment, upon request;
 - (4) make arrangements with **PNRI** for the retention of the workers' exposure records when:
 - (i) a worker is terminated by the licensee ; and
 - (ii) the licensee ceases activities that involve occupational exposure of workers; and
 - (5) ensure the maintenance of confidentiality of records of exposures.
- (c) The licensee shall provide the worker with the relevant exposure records in case the worker is engaged in a work that involves or could involve exposure from a source that is not under the control of the licensee.
- (d) The exposure record shall include:
 - (1) information on the general nature of the work involving occupational exposure;
 - (2) doses, exposure and intakes that exceed the relevant recording level, and the data upon which the dose assessments have been based, including the doses, exposures, and intakes received if any, if the worker is occupationally exposed while in the employ of another; and
 - (3) records of any doses, exposures or intakes received as a result of emergency interventions or accidents, which shall include references to reports of any relevant investigations.

13.13. Records of Surveys and Measurements.

- (a) Each licensee shall maintain records showing the results of surveys and measurements required in this Part and shall retain these records in accordance with the license conditions.
- (b) Each licensee shall retain each of the following records until **PNRI** terminates the licensed activity:
 - (1) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment;
 - (2) records of results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;
 - (3) records of the results of surveys to determine the dose from external sources and used in the assessment of individual dose equivalents in the absence of or in combination with individual monitoring; and
 - (4) records showing the results of air sampling and bioassays, if required.

Section 14. Medical Exposure.

14.1. Responsibilities.

- (a) Each licensee shall ensure that no patient will be administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner designated in the license as the authorized user.
- (b) Each licensee shall optimize the protection and safety of the patient so that medical exposure is as low as reasonably achievable and consistent with the desired results.
- (c) Each licensee shall immediately investigate any accidental medical exposure involving any erroneous administration of therapeutic or diagnostic exposure and any equipment failure or unusual occurrence with the potential for causing patient exposure that is significantly different from what is intended.
- (d) Authorized users shall promptly inform the licensee of any deficiencies or needs regarding compliance with this Part with respect to protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.
- (e) For therapeutic and diagnostic uses of radioactive materials, each licensee shall ensure that calibration, dosimetry and quality assurance procedures be conducted by or under the supervision of qualified staff authorized in the license.

14.2. Justification of Medical Exposures.

Each licensee shall ensure that medical exposures be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

14.3. Optimization of Protection for Medical Exposures.

14.3.1. Design Considerations.

- (a) Each licensee shall:

- (1) based on the design of equipment, identify possible equipment failures and human errors that could result in unplanned medical exposures;
 - (2) take all reasonable measures to prevent failures and errors, including:
 - (i) the selection of suitably qualified personnel;
 - (ii) the establishment of adequate procedures for the calibration, quality assurance and operation of diagnostic and therapeutic equipment; and
 - (iii) the provision to personnel of appropriate training and periodic retraining in the procedures, including protection and safety aspects;
 - (3) take all reasonable measures to minimize the consequences of failures and errors that may occur; and
 - (4) develop appropriate emergency plans for responding to events that may occur and periodically conduct practice drills.
- (b) In specific cooperation with suppliers, each licensee shall ensure that, with regard to equipment containing sealed sources used for medical exposures:
- (1) whether imported into or manufactured in the country where it is used, the equipment conform to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards;
 - (2) performance specifications and operating and maintenance instructions, including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to “accompanying documents”, and that this information be translated into local languages when appropriate;
 - (3) where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user;
 - (4) radiation beam control mechanisms be provided, that indicate clearly and in a fail-safe manner whether the beam is “on” or “off”;
 - (5) as nearly as practicable, the exposure be limited to the area being examined or treated; and
 - (6) exposure rates outside the examination or treatment area due to radiation leakage or scattering be kept as low as reasonably achievable.

14.3.2. Operational Considerations.

14.3.2.1. Diagnostic Exposure.

Each licensee shall ensure that:

- (a) The authorized users who prescribe or conduct diagnostic applications of radionuclides:
 - (1) ensure that the exposure of patients be the minimum required to achieve the intended diagnostic objective;
 - (2) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations; and
 - (3) take into account the relevant guidance levels for medical exposure;
- (b) The authorized users, the technologist or other imaging staff, as appropriate, endeavour to achieve the minimum patient exposure consistent with acceptable image quality by:
 - (1) appropriate selection of the best available radiopharmaceutical and its activity, noting the special requirements for children and for patients with impairment of organ function;
 - (2) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable;
 - (3) appropriate image acquisition and processing;

- (c) The administration of radionuclides to pregnant women or likely to be pregnant be avoided unless there are strong clinical indications;
- (d) For mothers in lactation, discontinuation of nursing be recommended until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the infant; and
- (e) Administration of radionuclides to children for diagnostic procedures be carried out only if there is a strong clinical indication, and the amount of activity administered be reduced according to the body weight, body surface area or other appropriate criteria.

14.3.2.2. Therapeutic Exposure.

Each licensee shall ensure that:

- (a) Exposure of normal tissue during radiotherapy be kept ALARA consistent with delivering the required dose to the planning target volume, and organ shielding be used when feasible and appropriate;
- (b) Radiotherapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant be avoided unless there are strong clinical indications;
- (c) Administration of radionuclides for therapeutic procedures to women who are pregnant or likely to be pregnant or who are nursing be avoided unless there are strong clinical indications;
- (d) Any therapeutic procedure for pregnant women be planned to deliver the minimum dose to any embryo or fetus; and
- (e) The patient be informed of possible risks.

14.3.3. Calibration.

Each licensee shall ensure that:

- (a) The calibration of sources used for medical exposure be traceable to a Standards dosimetry laboratory;
- (b) Radiotherapy equipment be calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions and in accordance with the conditions of the license;
- (c) Sealed sources used for brachytherapy be calibrated in terms of activity, reference air kerma rate in air or absorbed dose rate in a specified medium, at a specified distance, for a specified reference date;
- (d) Unsealed sources for nuclear medicine procedures be calibrated in terms of activity of the radiopharmaceutical to be administered in accordance with the conditions of the license; and
- (e) The calibrations be carried out before its first use, following repair, or after any maintenance procedure that may have an effect on the dosimetry and at intervals approved by PNRI.

14.3.4. Clinical Dosimetry.

- (a) Each licensee shall ensure that the following items be determined and documented:
 - (1) for each patient treated with external beam radiotherapy equipment, the maximum and minimum absorbed doses to the planning target volume together with the absorbed dose to a relevant point such as the center of the planning target volume, plus the dose to other relevant points selected by the medical practitioner prescribing the treatment;
 - (2) in brachytherapeutic treatments performed with sealed sources , the absorbed doses at selected relevant points in each patient;
 - (3) in diagnosis or treatment with unsealed sources, representative absorbed doses to patients; and
 - (4) in all therapeutic treatments, the absorbed doses to relevant organs.
- (b) In radiotherapeutic treatments, licensees shall ensure, within the ranges achievable by good clinical practice and optimized functioning of equipment, that:
 - (1) the prescribed absorbed dose at the prescribed beam quality be delivered to the planning target volume; and
 - (2) doses to other tissues and organs be minimized.

14.3.5. Quality Assurance for Medical Exposures.

- (a) Each licensee shall establish a comprehensive quality assurance program for medical exposures.
- (b) Quality assurance program for medical exposures shall include:
 - (1) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;
 - (2) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;
 - (3) written records of relevant procedures and results;
 - (4) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and
 - (5) regular and independent quality audit reviews of the quality assurance program for radiotherapy procedures.

14.4. Guidance Levels.

Each licensee shall ensure that guidance levels for medical exposure, as determined in this Part, are revised as technology improves, and used as guidance by authorized users, in order that:

- (a) Corrective actions be taken as necessary if doses or activities fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;
- (b) Reviews will be considered if doses or activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice; and
- (c) For nuclear medicine examinations, the guidance levels be derived from the data from wide scale quality surveys from the activities of radiopharmaceuticals administered to patients for the most frequent examinations in nuclear medicine.

14.5. Dose Constraints.

Each licensee shall constrain any dose to individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment, and to visitors to patients who have received therapeutic amounts of radionuclides or who are being treated with brachytherapy sources, to a level not exceeding that specified in Section 15 of this Part.

14.6. Investigation of Accidental Medical Exposures.

- (a) Each licensee shall promptly investigate any of the following incidents:
 - (1) any application of diagnostic or therapeutic procedure to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the authorized users or which may lead to undue acute secondary effects; and
 - (2) any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

- (b) Each licensee shall, with respect to any of the above investigation:
 - (1) calculate or estimate the doses received and their distribution within the patient;
 - (2) indicate the corrective measures required to prevent recurrence of such an incident;
 - (3) implement all the corrective measures that are under their own responsibility;
 - (4) submit promptly to PNRI a written report of the results of the investigation; and
 - (5) inform the patient and his or her doctor about the incident.

14.7. Records of Medical Exposures.

- (a) Each licensee shall keep for a period specified in the license and make available, as required, the following records:
 - (1) in nuclear medicine, types of radiopharmaceuticals administered and their activities;

 - (2) in radiation therapy, a description of the planning target volume, the dose to the center of the planning target volume and the maximum and minimum doses delivered to the planning target volume, the doses to other relevant organs, the dose fractionation, and the overall treatment time; and
 - (3) the exposure of volunteers in medical research.

- (b) Each licensee shall keep and make available, as required in the license, the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatments.

Section 15. Public Exposure.

15.1. Responsibilities.

- (a) Each licensee shall ensure that protection and safety policies and procedures are established and implemented for any public exposure delivered by a practice or source for which he/she is responsible.

- (b) Each licensee shall be responsible for the establishment, implementation and maintenance of measures for ensuring the safety of sources under their responsibility in order that the likelihood of public exposures can be controlled in accordance with this Part.

15.2. Control of Visitors.

Each licensee shall:

- (a) Ensure that visitors be accompanied in any controlled area by a person knowledgeable about the protection and safety measures for that area;
- (b) Provide adequate information and instruction to visitors before they enter a controlled area so as to ensure appropriate protection of the visitors and of other individuals who could be affected by their actions; and
- (c) Ensure that adequate control over entry of visitors to a supervised area be maintained and that appropriate signs be posted in such areas.

15.3. Dose Limits for Members of the Public.

Each licensee shall ensure that the estimated average dose to any member of the public does not exceed the following dose limits:

- (a) An effective dose of **1 mSv in a year**;
- (b) In special circumstances, an effective dose of up to **5 mSv in a single year** provided that the average dose over five consecutive years does not exceed **1 mSv** per year;
- (c) An equivalent dose to the lens of the eye of **15 mSv in a year**; and
- (d) Equivalent dose to the skin of **50 mSv in a year**.

15.4. Dose Limits for Comforters and Visitors of Patients.

- (a) Each licensee shall ensure that doses of comforters and visitors of patients be constrained so that it is unlikely that his or her absorbed dose will exceed **5 mSv** during the period of a patient's diagnostic examination or treatment.
- (b) Each licensee shall ensure that the dose to children visiting patients who have ingested radioactive materials be similarly constrained to less than **1 mSv**.

Section 16. Potential Exposure: Safety and Security of Sources.

Each licensee shall:

- (a) Ensure the safety and security of the sources in his/her possession;
- (b) Establish clear lines of responsibility and accountability for protection and safety of the sources;
- (c) Maintain an accountability system that includes records of:
 - (1) the location and description of each source for which they are responsible; and

- (2) the activity and form of each radioactive substance for which they are responsible.
- (d) Ensure that adequate maintenance, testing, inspection and servicing be carried out as needed so that sources remain capable of meeting the requirements for protection and safety throughout their lifetime.

Section 17. Emergency Exposure Situations.

17.1. Emergency Plan.

- (a) Each licensee shall establish an emergency plan in case of an accident that could involve their radiation sources.
- (b) The emergency plan shall include the following information, where applicable:
 - (1) a description of the licensed facility and areas in the vicinity of the facility;
 - (2) an identification of each type of accident involving radioactive materials for which protective actions may be needed;
 - (3) a system for classifying accidents as alerts or site area emergencies;
 - (4) means and methods for detecting each type of accident in a timely manner;
 - (5) a description of the means and equipment for mitigating the consequences of each type of accident, including the means to protect workers on site and a description of the maintenance program for such equipment;
 - (6) a description of the methods and equipment to assess releases of radioactive materials;
 - (7) a description of the responsibilities of emergency response personnel including those responsible for notification of PNRI and off-site organizations, and for developing, maintaining and updating the plan;
 - (8) provisions for training of emergency response groups and for conducting emergency drills and exercise;
 - (9) a description of measures to restore the facility to safe normal condition after an accident; and
 - (10) provision for a periodic review, or update of the plan.
- (c) Each licensee shall provide training to personnel involved in emergency response.

17.2. Intervention.

- (a) Each licensee shall prepare an emergency plan for his/her licensed facility that will correspond to the authorized practices or sources which could give rise to a need for emergency intervention.
- (b) Each licensee shall ensure that adequate information dissemination and prompt notification measure are provided in the emergency plan to members of the public who could be affected by an accident and to the relevant authorities responsible for intervention.
- (c) Intervention in emergency exposure situations shall be carried out on the basis of intervention levels and action levels.
- (d) Intervention levels and action levels shall be optimized for the relevant protective actions but they should not allow that certain levels of doses, for which intervention will almost always be justified, be exceeded.

17.3. Protection of Workers Undertaking Intervention.

- (a) Each licensee shall ensure that his/her workers undertaking an intervention shall not be exposed in excess of the specified maximum single year dose limit for occupational exposures except:
 - (1) for the purpose of saving life or preventing injury;
 - (2) if undertaking actions intended to avert a large collective dose; or
 - (3) if undertaking actions to prevent the development of catastrophic conditions.
- (b) Each licensee shall ensure that all reasonable steps be taken to provide appropriate protection to workers and the public during and after emergency intervention and to assess and record the doses received by workers involved.
- (c) Each licensee shall ensure that an individual who has been assessed to have received in an emergency exposure situation an occupational dose or intake of radioactive material that exceeds ten times the maximum single year dose limit be afforded with appropriate medical assistance.
- (d) Records of accidental and emergency exposures and doses shall be maintained and clearly distinguished from normal exposure records.

IV. SAFETY MEASURES AND CONTROL OF RADIOACTIVE MATERIAL

Section 18. Surveys and Safety of Equipment.

- (a) Each licensee shall make or cause to be made, surveys that:
 - (1) may be necessary to comply with the regulations in this Part and the conditions of the license; and
 - (2) are reasonable under the circumstances to evaluate:
 - (i) the magnitude and extent of radiation levels;
 - (ii) concentrations or quantities of radioactive material; and
 - (iii) the potential radiological hazards that could be present.
- (b) Each licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically as required by regulations.

Section 19. Transport of Radioactive Material.

The licensee shall not transport or cause to be transported any radioactive material outside of the confines of his/her plant or other authorized location, or deliver or cause to be delivered any radioactive material to a carrier for transport, unless the licensee is authorized by PNRI and complies with the requirements of **CPR Part 4, "Rules and Regulations on the Safe Transport of Radioactive Materials in the Philippines"** and the rules and regulations of other government agencies that govern the means of transport employed.

Section 20. Storage and Control of Radioactive Material.

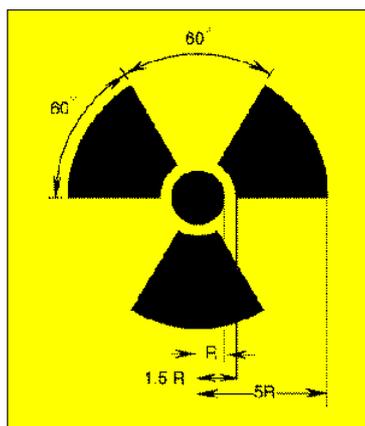
- (a) Each licensee shall secure from unauthorized removal of or access to licensed radioactive materials that are stored in controlled areas.
- (b) Each licensee shall control and maintain constant surveillance of licensed radioactive material that is not in storage in a controlled area.

V. PRECAUTIONARY REQUIREMENTS

Section 21. *Caution Signs, Labels, and Posting Requirements.*

(a) **Caution Signs and Labels.**

- (1) Signs and labels prescribed by this section shall use contrasting colors. The radiation caution symbol prescribed by this section is the conventional three-bladed design:



RADIATION SYMBOL

- (i) cross-hatched area is black, and
 - (ii) background is to be yellow.
 - (2) In addition to the contents of signs and labels prescribed in this section, the licensee may provide on or near such signs or labels any additional information which may be appropriate in aiding individuals minimize their exposure to radiation or to radioactive material.
- (b) **Posting.**
- (1) **Posting of Radiation Areas.** The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words **"CAUTION, RADIATION AREA"**.
 - (2) **Posting of High Radiation Areas.** The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words **"CAUTION, HIGH RADIATION AREA"** or **"DANGER, HIGH RADIATION AREA"**.
- (c) **Labelling of Containers.**
- (1) Each licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words, **"CAUTION, RADIOACTIVE MATERIAL"** or **"DANGER, RADIOACTIVE MATERIAL"**. The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.
 - (2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

Section 22. Posting of Notices and Important Documents.

- (a) Each licensee shall post at conveniently visible locations in the licensed facility current copies of the following documents:
- (1) the regulations, the license, and license conditions;
 - (2) the operating procedures applicable to licensed activities;
 - (3) the emergency procedures and local rules; and
 - (4) the "**Notice to Employees**" form issued by PNRI. Refer to **Appendix C**.

If posting of a document specified is not practicable, the licensee may post a notice which describes the document and states where each document may be examined.

- (b) Each licensee shall make available current copies of **CPR Part 3, "Standards For Protection Against Radiation", the specific Parts of the Code addressed in the license, and other Parts of the Code as may be determined by PNRI.**
- (c) Each licensee shall ensure that documents, notices, or forms posted pursuant to this Section appear in sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies, be conspicuous, and be replaced if defaced or altered.
- (d) Each licensee shall ensure that enforcement action documents provided by **PNRI** be posted within two (2) working days after receipt of the documents from **PNRI**. The licensee's response, if any, shall be posted within two (2) working days after dispatch by the licensee. Such documents shall remain posted for a minimum of five (5) working days or until the corrective action on the violation has been completed, whichever is later.

Section 23. Instructions to Workers.

Each licensee shall ensure that all individuals working in or frequenting any portion of a controlled or supervised area are:

- (a) Kept informed of the storage, transfer, or use of radioactive materials or of the presence of radiation in such portions of the area;
- (b) Instructed on the health protection problems associated with exposure to such radioactive materials or radiation, in the precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
- (c) Instructed to observe, to the extent within the worker's control, the applicable provisions of the regulations of the Code and the specific conditions of the license for the protection of personnel from exposures to radiation or radioactive material;
- (d) Instructed of their responsibility to report promptly to the RHSO or the licensee any condition which may lead to or cause a violation of the regulation of the Code or license conditions, or to cause unnecessary exposure to radiation or to radioactive material;
- (e) Instructed on the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
- (f) Advised as to the radiation exposure records which workers may request.

VI. WASTE MANAGEMENT AND DISPOSAL OF LICENSED RADIOACTIVE MATERIAL

Section 24. General Requirements.

- (a) Each licensee shall dispose of licensed radioactive material only:
 - (1) by transfer to an authorized recipient as provided in the regulations in Parts 2, 11, 12, 13, 14, 16 and 20;
 - (2) by decay in storage;
 - (3) by discharge to the environment within the limits specified in Appendix D 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.

- (b) A person must be specifically authorized by PNRI to receive radioactive waste from PNRI licensees for:
 - (1) treatment prior to disposal; or
 - (2) interim storage; or
 - (3) disposal at its facility specifically authorized by PNRI; or
 - (4) disposal in accordance with a procedure not otherwise approved under this Part.

- (c) The facility design, capacity and radiological safety considerations of the facility for the disposal or interim storage of radioactive waste must be reviewed and approved by PNRI.

Section 25. 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 authorized by PNRI to receive such material in accordance with the requirement provided correspondingly in Parts 2, 11, 12, 13, 14, 16 and 20 of the CPR.

- (b) If the transfer of disused sealed source to another person authorized by PNRI is not possible, the disused sealed source shall be returned to the supplier or manufacturer or disposed as radioactive waste to a person authorized by PNRI in Section 24 (a).

- (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, "Rules and Regulations for the Safe Transport of Radioactive Materials in the Philippines", shall apply.

Section 26. 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 27. Required Conditions During Normal Operation Involving Radioactive Discharges.

- (a) All radioactive discharges shall be kept as far below the authorized clearance levels 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 **Section 38** of this Part.

Section 28. Disposal by Release to the Atmosphere.

- (a) Work with radioactive gases or aerosols shall be done 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 must be employed for trapping the emission; the installation must have been approved; the assembly tested and the performance continuously monitored.

Section 29. 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 must be determined.
- (b) All possible exposure pathways by which discharged radioactive waste can cause public exposure must 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 authorized by PNRI:
 - (i) airborne effluents discharged into the atmosphere either directly or through filtration systems shall not exceed the clearance levels given in Appendix D – 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 D – 2;
 - (iii) solid waste shall not exceed the clearance levels given in Appendix D – 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 30. Waste Management Program.

- (a) Each 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.
- (b) The activity and volume of radioactive waste generated shall be kept to the minimum practicable.
- (c) Radioactive waste must be 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.
- (d) Different types of radioactive waste must be 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.
- (e) Transport of radioactive waste shall be in accordance with **CPR Part 4, "Rules and Regulations on the Safe Transport of Radioactive Materials in the Philippines"**, and including any applicable national regulations.
- (f) Disposal of waste shall comply with the general radiation protection principles, including ALARA.
- (g) Each licensee shall maintain records that show the receipt, transfer and disposal of radioactive waste as provided in the regulations in Parts 11, 12, 13, 14, 16 and 20 of the CPR, as may be applicable.
- (h) Administrative controls and surveillance procedures shall be maintained in accordance with quality assurance requirements.

Section 31. Characterization, Segregation and Collection of Radioactive Waste.

- (a) Radioactive waste shall be segregated as soon as possible after generation at the source according to their radiological content and characteristics, and chemical composition.
- (b) Radioactive waste shall be collected in adequately shielded and marked containers, tanks or drums depending upon their nature, chemical and radiochemical composition, quantities and concentration.
- (c) All radioactive waste shall be labeled and marked to properly identify their origin, radionuclide content and activity level.

Section 32. Treatment and Conditioning of Radioactive Waste.

- (a) The treatment method shall be consistent with the objective of the treatment, the subsequent conditioning and disposal methods.
- (b) Methods for conditioning of the waste shall be compatible with subsequent transport, storage and disposal methods.

Section 33. Radioactive Waste that are Exempt from Regulatory Control.

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

- (a) The effective dose expected to be received by any member of the public due to the waste is of the order of **10 μ Sv** or less in a year; and
- (b) The activity of the waste does not exceed the clearance levels given in **Appendix D** of this Part.

Section 34. Land Disposal of Radioactive Wastes.

Exposure to members of the general public from off-site releases of radioactive material emanating from a land disposal facility shall not exceed the limits set forth in Section 15 of this Part.

Section 35. 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.

VII. RECORDS, REPORTS AND NOTIFICATIONS

Section 36. Records of Radiation Protection and Safety Program.

- (a) Each licensee shall maintain records of the radiation protection and safety program and shall include:
 - (1) the provisions of the program; and
 - (2) results of audits and other reviews of program content and implementation.
- (b) The records required by this Section shall be retained for 3 years or until **PNRI** orders otherwise.

Section 37. Documentation of Records.

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

Section 38. Reports of Overexposures and Excessive Levels and Concentrations.

- (a) In addition to any report or notification required by this Part, each 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**.

Section 39. Reports of Theft or Loss of Radioactive Material.

- (a) Each licensee shall immediately notify **PNRI** by telephone or by any other fast means of communication, of any lost, stolen, or missing radioactive material.
- (b) In addition to the notification required above, each 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 40. Notification of Incidents.

- (a) Each licensee shall notify **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 **0.05 Sv**; 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.

VIII. EXEMPTIONS AND ADDITIONAL REQUIREMENTS

Section 41. Applications for Exemptions.

The PNRI may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this Part as it determines are authorized by law and will not result in undue hazard to life or property.

Section 42. Additional Requirements.

The PNRI may, by rule, regulation, or order impose upon any licensee such requirements, in addition to those established in these regulations, as it deems appropriate or necessary to protect health and safety of the public or to minimize danger to life or property.

IX. ENFORCEMENT

Section 43. 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 thereunder 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.**

Section 44. Effective Date.

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

Approved:



ALUMANDA M. DELA ROSA, Ph.D.

July 2, 2004
Date