

CPR PART 17

LICENSES FOR COMMERCIAL SALE AND DISTRIBUTION OF RADIOACTIVE MATERIALS AND ITS ASSOCIATED DEVICES

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CPR PART 17

**LICENSES FOR COMMERCIAL SALE AND DISTRIBUTION OF RADIOACTIVE
MATERIALS AND ITS ASSOCIATED DEVICES**

I. GENERAL PROVISIONS

Section 1. Purpose and Scope.

- (a) This Part prescribes licensing requirements for the acquisition and possession of radioactive materials that are subject to regulatory control and devices containing radioactive materials intended for commercial sale and distribution.
- (b) The regulations of this Part shall apply to persons who transfer, through commercial sale and distribution, radioactive materials and devices that contain radioactive materials to persons licensed by PNRI.
- (c) The provisions and requirements of this Part shall be applied in conjunction with the radiation safety requirements of CPR Part 3, radioactive source security requirements of CPR Part 26, and the safe transport requirements of CPR Part 4, as applicable.
- (d) Nothing in this Part relieves the applicant or licensee from complying with applicable regulations of other government agencies.

Section 2. Definitions.

As used in this Part:

- (a) "**Act**" means Republic Act No. 2067, otherwise known as the Science Act of 1958, as amended by Republic Act No. 3589, and Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended by Presidential Decree No. 1484;
- (b) "**ALARA (As Low As Reasonably Achievable)**" means making every reasonable effort to maintain exposure to radiation as far below the dose limits as is achievable:
 - (1) Consistent with the purpose for which the licensed activity is undertaken; and
 - (2) Taking into account the state of technology, the economics of improvements to benefit the health and safety of the public and the workers, and other societal and socio-economic considerations;
- (c) "**Assistant Radiation Safety Officer (ARSO)**" means an individual who will perform the duties and responsibilities of the RSO in his/her absence;
- (d) "**Authorized Personnel**" means those individuals who are authorized in the license to undertake the receipt, sale, distribution or transportation of radioactive material or devices containing radioactive material to persons licensed by PNRI;
- (e) "**CPR or Code**" means the Code of PNRI Regulations;

- (f) **"Distribute"** means to transfer, under a commercial sale arrangement, radioactive materials or devices that contain radioactive materials to persons who are authorized by PNRI to receive such transfer;
- (g) **"Export"** means the transport or shipment, from the Philippines to a foreign country, of radioactive materials and devices that contain radioactive materials covered by the regulations of this Part;
- (h) **"Import"** means the physical transfer, into the Philippines or to a recipient in the Philippines originating from an exporting State, of radioactive materials and devices that contain radioactive materials covered by the regulations of this Part;
- (i) **"Licensee"** means a holder of a valid license issued pursuant to this Part or other Parts of the Code as may be specified;
- (j) **"Person"** means (i) any individual, firm, partnership, association, trust, estate, private or public body, whether corporate or not, or government agency other than PNRI, any province, city, municipality, or any political subdivision of the Republic of the Philippines or any political entity in the Philippines and (ii) any legal successor, representative, agent or agency of the foregoing;
- (k) **"PNRI"** means the Philippine Nuclear Research Institute and its duly authorized representative;
- (l) **"Radiation Safety Officer (RSO)"** means the individual designated as the Radiation Safety Officer in the license issued pursuant to this Part; and
- (m) **"Sale"** means the transfer of ownership or rights of items containing radioactive material to licensed end-users or exempt persons under a commercial arrangement.

Note: Terms defined in the Act and in other Parts of the CPR shall have the same meaning when used in this Part unless such terms are specifically defined otherwise in this Part.

Section 3. Interpretation.

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

Section 4. Communication.

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

Section 5. Activities Requiring License.

No person shall acquire, possess, own, import, export, sell, distribute or transfer radioactive materials and devices containing radioactive materials, through commercial sale and distribution, except in accordance with a license issued by PNRI pursuant to this Part.

Section 6. Application for New License and Renewal of License.

- (a) An application for a new license or renewal of license pursuant to this Part shall be filed by completing **PNRI/NRLSD Form-017**, "Application for a License for Commercial Sale and Distribution of Radioactive Materials and Its Associated Devices", in duplicate copies.
- (b) Each application for a license must be affirmed and notarized upon submission to PNRI.
- (c) Each applicant shall submit a certified true copy of the Securities and Exchange Commission registration and current business permit issued by the responsible local government agency.
- (d) PNRI may, at any time after the filing of the application, require further information necessary to enable PNRI to determine whether the application should be granted or denied.
- (e) For license renewals, licensee shall provide a complete and up-to-date application if many outdated documents are referenced, or there have been significant changes in regulatory requirements, the licensee's organization, or radiation protection program.
- (f) The application shall include the technical requirements specified in this Part, as may be necessary, and will be accepted and processed only when PNRI has determined the completeness in substance and form of the submitted information, and payment of corresponding application fee or license renewal fee has been made.

Section 7. Issuance of License.

An application for a license pursuant to this Part shall be approved and license shall be granted if:

- (a) The applicant has satisfactorily complied with the requirements for the intended authorization(s) described in **Chapter III** of this Part;
- (b) The applicant has designated a qualified Radiation Safety Officer (RSO) and an Assistant RSO who shall both be responsible for implementing the radiation safety program;
- (c) The qualifications of personnel who are designated by the applicant as authorized personnel in the organization are acceptable;
- (d) The applicant possesses appropriate personnel monitoring devices, personal protective equipment and radiation survey instruments, as applicable;
- (e) The applicant has established procedures for transport of radioactive material in accordance with the requirements of CPR Part 4, "Regulations for the Safe Transport of Radioactive Material in the Philippines";
- (f) The location or storage area for the radioactive materials indicated in the license application is adequate to protect health and safety of workers and the public and minimize danger to life, property or the environment and ensure the security of radioactive material;
- (g) The applicant has established adequate security measures to prevent loss or theft of radioactive material while in storage and during transport;
- (h) The applicant has established emergency procedures during transport of radioactive material and equipment/devices containing radioactive material;

- (i) The applicant's operating and emergency procedures are acceptable to PNRI;
- (j) The applicant has submitted a written commitment to facilitate the return of disused sources from its licensed client/user to its original supplier or manufacturer; and
- (k) The applicant has paid all applicable fees in connection with his application.

Section 8. Terms and Conditions of License.

- (a) Each license shall be subject to the specific provisions of this Part, the specific conditions of the license, the requirements of CPR Part 3 and relevant regulations and orders of PNRI.
- (b) No license nor any right under the license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, to any person unless, after securing full information, PNRI finds that the transfer, assignment, or disposition is in accordance with the provisions of the Act and gives its consent in writing.
- (c) Each licensee shall confine his activities to the specified purposes authorized in the license.
- (d) Each shipment and transport of radioactive material shall be in accordance with the requirements of CPR Part 4, "Regulations for the Safe Transport of Radioactive Materials in the Philippines".
- (e) A copy of the license and applicable regulations of the Code shall be kept and made available at each location indicated in the license.
- (f) The license shall be valid for a period of **one (1) year** from the date of issuance or as may be determined by PNRI.

Section 9. Amendment of License.

- (a) An application for amendment of a license shall be filed by completing **PNRI/NRLSD Form-017A**, "Application for Amendment of License" in duplicate copies, duly affirmed and notarized, and accompanied by the corresponding license amendment fee. The application shall specify in what respect the licensee desires his license to be amended and the grounds for such amendment.
- (b) A licensee shall apply for and must receive a license amendment before:
 - (1) it acquires, procures, or transfers for commercial sale and distribution radioactive material other than those already specified in the license;
 - (2) it permits anyone to work as the Radiation Safety Officer (RSO) or authorized personnel designated in the license;
 - (3) it possesses at any one time radioactive material in excess of the activity authorized in the license;
 - (4) it implements any major change in the approved radiation safety program;
 - (5) it changes its official address and/or location of storage area of radioactive material indicated in the license; or
 - (6) any material change in the specific conditions of the license takes effect.

Section 10. Expiration of License.

- (a) Each license shall expire at the end of the day of the expiration date stated in the license. Pending any PNRI discretion on the disposition of the license, the licensee shall keep radioactive materials under safe and secure storage.
- (b) If the license has expired, the licensee shall not undertake licensed activities involving radioactive material until the applicable provision of **Section 12** is satisfactorily met.
- (c) If the license is deemed to have expired and will not be renewed, the licensee shall notify PNRI accordingly and shall cease or discontinue performing all authorized activities described in the license and initiate the procedure for termination of license.
- (d) The expiration of the license shall not relieve the licensee of his responsibility for decommissioning its facility and terminating the license.

Section 11. Specific Condition for Expired License.

If an application for license renewal is filed after the expiration date stated in the license but **not more than thirty (30) days** after that date, the licensee shall immediately cease from performing any licensed activity except to keep all radioactive sources under safe and secure storage in accordance with the security plan until PNRI has determined to renew or deny the license. This does not however preclude the imposition of any regulatory action arising from the late filing of the application. The licensee shall be assessed a surcharge equivalent to **fifty (50) percent** of the applicable fees if the application for license is accepted by PNRI.

Section 12. Renewal of License.

- (a) At least thirty (30) days before the expiration date specified in the license, the licensee shall either:
 - (1) Submit an application for renewal of the license, or
 - (2) If the licensee decides not to renew the license, notify the PNRI in writing and request that the license be terminated.
- (b) An application for renewal of license that is filed **less than thirty (30) calendar days** before the stated expiration date of the license shall be subjected to a surcharge equivalent to **25 percent** of the required license renewal fee.
- (c) If the licensee submits an application for renewal of license after the specified expiration date, but **not exceeding thirty (30) calendar days after that expiration date**, the application must include the following:
 - (1) An explanation for the delay in filing the application;
 - (2) An assurance that the licensee did not undertake any principal licensed activity involving the radioactive material after the expiration date of the license;
 - (3) An explanation why PNRI should not impose an administrative sanction against the licensee.
- (d) If PNRI determines that the licensee's reasons in (c) of this section are acceptable and that safety has not been undermined, the application will be accepted and processed, provided that the licensee shall not undertake any principal activity involving any commercial sale or distribution of licensed radioactive material until PNRI has granted license. A surcharge equivalent to **50 percent** of the license renewal fee shall be collected.

- (e) If an application for renewal of a license is filed **more than 30 calendar days after the expiration date** stated in the license, PNRI shall cause the temporary cessation of any principal licensed activity until PNRI has determined whether or not the application shall be accepted and processed.
- (f) In case a licensee submits an application for renewal of license within the allowed period, but decides to terminate all authorized activities under the existing license without transferring his right to possess or own the radioactive material, a new license authorizing for the storage of the radioactive material shall be issued, which will be subject to specific conditions ensuring the safety and security of stored radioactive materials.
- (g) Each application for renewal of license must include the corresponding license renewal fee and other outstanding regulatory fees.

Section 13. Termination of License.

- (a) The licensee shall notify PNRI, in writing, and request for the termination of the license when the licensee decides to permanently cease all activities involving radioactive material authorized under the license.
- (b) Before the license can be terminated, the licensee shall:
 - (1) Discontinue all activities involving licensed radioactive material;
 - (2) Transfer or dispose of all licensed radioactive material which are in his possession in accordance with the regulations;
 - (3) Conduct a radiation survey or other means to confirm that the premises are suitable for unrestricted use; and
 - (4) Assure that the required records are complete and up-to-date.
- (c) To be relieved of the responsibilities for the radioactive material and other conditions in his license, the licensee shall submit to the PNRI:
 - (1) His request that the license be terminated;
 - (2) A certified statement that he no longer has in his possession any radioactive material requiring a license;
 - (3) A listing of the radioactive material transferred or disposed of and to whom the material were transferred or the method of disposal;
 - (4) The statement of a qualified expert that his facilities are not contaminated; and
 - (5) An agreement that his records and facilities will be available for inspection by the PNRI at a mutually agreeable date.
- (d) PNRI will inform the licensee and formally terminate the license upon verification that the above requirements were satisfactorily complied with.

Section 14. Specific Exemptions.

PNRI may, upon application by the 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, property and the environment.

Section 15. Additional Requirements.

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

II. TECHNICAL REQUIREMENTS

Section 16. Radiation Safety Program.

- (a) Each licensee shall develop and implement written radiation safety program that includes provisions for keeping doses ALARA in accordance with the provisions of CPR Part 3.
- (b) Each licensee shall establish, document, and implement a radiation 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 safety program.

Section 17. Radiation Safety Officer (RSO).

- (a) The licensee shall designate a qualified RSO and an Assistant RSO, who shall both be responsible for implementing the radiation safety program. The assistant RSO shall act as the safety officer in the absence of the RSO. The licensee, through the RSO, shall ensure that radiation safety measures are being observed in accordance with approved procedures and regulatory requirements in the daily performance of the licensee's authorized activities. The RSO and ARSO must confirm, in writing, acceptance of their duties and responsibilities.
- (b) The Radiation Safety Officer shall:
 - (1) Ensure that licensed material possessed is limited to the types and quantities of licensed material listed on the license;
 - (2) Ensure security of radioactive materials while in their possession and during transport;
 - (3) Post documents, as required;
 - (4) Ensure that licensed material is transported in accordance with CPR Part 4;
 - (5) Ensure that radiation exposures are ALARA;
 - (6) Oversee all activities involving radioactive material, including monitoring and survey of all areas in which radioactive material is possessed, handled or stored;
 - (7) Act as liaison with PNRI on licensing and regulatory matters;
 - (8) Provide necessary information on all aspects of radiation protection to concerned personnel;
 - (9) Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive materials arriving at or leaving from the licensed facility;
 - (10) Distribute and maintain personnel radiation monitoring equipment, determine the need for and evaluate bioassays, and monitor personnel radiation exposure and bioassay records;
 - (11) Develop training courses and conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to possession, both at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.;
 - (12) Oversee the storage of radioactive material;
 - (13) Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments;
 - (14) Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized in the license;

- (15) Hold periodic meetings with, and provide reports to, licensee management;
 - (16) Perform periodic audits of the Radiation Safety Program to ensure that the licensee is complying with all applicable PNRI regulations, the terms and conditions of the license;
 - (17) Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review and ensure that prompt action is taken to correct deficiencies;

 - (18) Ensure that the audit results and corrective actions are communicated to all personnel who are involved in the licensed activities;
 - (19) Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA are investigated and reported to PNRI within the required time limit; and
 - (20) Maintain an understanding of, and up-to-date copies of, PNRI regulations, the license, and revised licensee procedures, and ensure that the license is amended whenever required in this Part.
- (c) The RSO shall be present during the performance of any licensed activity and during regulatory inspections conducted by PNRI.

Section 18. Statements of Authority and Responsibilities.

- (a) The licensee shall provide the RSO sufficient authority, organizational freedom, and management prerogative to:
- (1) Identify radiation safety problems;
 - (2) Initiate, recommend, or provide corrective actions; and
 - (3) Verify implementation of corrective actions.
- (b) The licensee shall establish and state in writing the actual authorities, duties and responsibilities of the RSO and submit a copy to PNRI.

Section 19. Training for RSO.

The designated RSO shall have completed:

- (a) The Radiation Safety Course for Commercial Sale and Services conducted by PNRI, or an equivalent course approved by PNRI; and
- (b) A Radiation Safety Officer's (RSO) Course conducted by PNRI, or an equivalent course approved by PNRI.

Section 20. Authorized Personnel.

Each licensee shall submit the names of qualified individuals who shall undertake the activities authorized under the license.

Section 21. Training for Authorized Personnel.

The authorized personnel shall have completed the training and instructions on radiation protection and safety principles and practices conducted by the RSO. Training syllabus and modules shall be submitted to PNRI for review and evaluation.

Section 22. Retraining.

The licensee shall require the RSO, ARSO, and authorized personnel to undertake refresher courses on safety and security, as appropriate and approved by PNRI, every **five (5) years**.

Section 23. Personnel Monitoring.

- (a) Each licensee shall make available the use of personnel monitoring devices such as film badge or thermoluminescent dosimeter (TLD) and direct reading dosimeters (pocket dosimeter or electronic personal dosimeter), as applicable.
- (b) Pocket dosimeters shall have a range from **0 to 2 mSv** and shall be charged to zero at the start of each shift.
- (c) Each personnel monitoring device shall be assigned to and worn by only one individual.
- (d) Direct reading dosimeters shall be read and exposures recorded for each use. Records of direct reading dosimeter readings shall be kept for two years.

Section 24. Possession and Calibration of Survey Instrument.

- (a) Each licensee shall have in his/her possession, as applicable, a portable radiation survey instrument capable of measuring dose rates over the range of **0 to 10 mSv** per hour.
- (b) Each licensee shall calibrate or cause the calibration of its survey instrument before first use, following repair and every twelve (12) months thereafter.
- (c) Each licensee shall retain a record of each survey instrument calibration for two years.
- (d) If the licensee shall engage the calibration services of another person or firm, the licensee shall submit that person's or firm's qualification and calibration procedures to PNRI for review.

Section 25. Import and Export of Radioactive Sources.

The licensee shall ensure that the import and export of radioactive sources are in accordance with **Appendix A, "Requirements on the Import and Export of Radioactive Sources"**, of this Part.

Section 26. Security Requirements.

The licensee shall ensure that the security of radioactive sources is in accordance with the requirements of **CPR Part 26**, "Security of Radioactive Sources".

Section 27. Security Awareness Training.

The licensee shall require each individual who is authorized to handle radioactive sources to have completed a training on security awareness.

Section 28. Return of Disused Sealed Sources to the Original Supplier or Manufacturer.

- (a) Each licensee shall ensure that its commercial sale agreement with a prospective client provides for the return of disused sealed sources to the supplier in the country of origin.
- (b) Each licensee shall ensure that disused sealed sources shall be returned to the supplier or manufacturer in accordance with **CPR Part 4**, "Regulations for the Safe Transport of Radioactive Material in the Philippines".
- (c) Each licensee shall return the disused radioactive sources to the original supplier or manufacturer in accordance with **Appendix A**, "Requirements on the Import and Export of Radioactive Sources", of this Part.

**III. ADDITIONAL REQUIREMENTS FOR EACH SPECIFIC
ACTIVITY APPLIED FOR LICENSE**

Section 29. Sell and Distribute Sealed Sources and Devices for Use in Industrial Gauges and Radiographic Operations.

- (a) The applicant shall submit sufficient information relating to the design (identification of the radiographic exposure devices and source changers by manufacturer, model number, serial number, etc), prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the sealed source and device;
- (b) The applicant shall assure that each device bears a durable, legible, clearly visible label which contains:
 - (1) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information); and
 - (2) The requirements for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, activity, and date of determination of the activity.
- (c) The applicant shall assure that a copy of the license or certificate of approval of the design of the sealed source/devices/source changers by the licensing authority of the country of origin shall be submitted to PNRI as evidence of approval of the design.

Section 30. Sell and/or Distribute Radiopharmaceuticals for Medical Use.

- (a) The applicant shall submit information on the radionuclide, chemical and physical form, packaging, including maximum activity per package, type, and shielding provided to ensure that it is appropriate for safe handling and storage; and
- (b) The applicant shall assure that:
 - (1) The radiopharmaceuticals meet the requirements imposed by PNRI in accordance with **CPR Part 13**; and
 - (2) The label affixed to each package of the radiopharmaceutical shall contain information of the radionuclide, activity and date of assay.

Section 31. Sell and/or Distribute Radioactive Materials for Certain In-Vitro Clinical or Laboratory Testing.

- (a) The applicant shall assure that the package containing the radioactive material shall bear a clearly visible label:
 - (1) Identifying the radioactive contents as to chemical form, activity and radionuclide; and
 - (2) Displaying the radiation caution symbol and the words "CAUTION, RADIOACTIVE MATERIAL" and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS", as appropriate.
- (b) The applicant shall assure that the label affixed to the package or the leaflet or brochure which accompanies the package shall contain adequate information as to the precautions to be observed in handling and storing such radioactive material and that the radioactive material will be used only for in-vitro clinical or laboratory tests not involving internal or external use of the material to human beings or animals.

Section 32. Sell and/or Distribute Generators.

- (a) The applicant shall submit information of the radionuclide, chemical and physical form and packaging, including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator.
- (b) The applicant shall assure that the label affixed to the generator contains information on the radionuclide, activity and date of assay.
- (c) The applicant shall assure that the leaflet or brochure which accompanies the generator contains adequate information on the procedures to be followed and on the equipment and shielding to be used with the generator.
- (d) The applicant shall assure that a copy of a license or certificate of approval of the generator by the licensing authority of the country of origin shall be submitted to PNRI as evidence of approval of the design.

Section 33. Sell and/or Distribute Sealed Sources and Devices for Medical Use in Teletherapy and Brachytherapy.

- (a) The applicant shall submit sufficient information regarding each type of source and device relevant to an evaluation of its radiation safety, including:

- (1) The radioactive material, its chemical and physical form, and activity;
 - (2) Details of design and construction of the source and device;
 - (3) Procedures for, and results of, prototype tests to demonstrate that the source and device will maintain its integrity under normal use and accident conditions;
 - (4) Details of quality control procedures to assure that production of sources and devices meet the standards of the design and prototype tests;
 - (5) Procedures and standards for calibrating sources and devices; and
 - (6) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the device or attached to a storage container for the source or device: Provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.
- (b) The applicant shall assure that the label affixed to the device containing the source, or to the storage container for the source or device, contains information on the radionuclide, activity and date of assay.

Section 34. Sell and Distribute Sealed Sources for Large Irradiators.

The applicant shall:

- (a) Identify each radionuclide (e.g., Co-60), the chemical or physical form, the number of sources, and the maximum activity;
- (b) Identify the manufacturer's name and model number of each sealed source that will be used in gamma irradiator;
- (c) Identify the manufacturer's name and model number of the gamma irradiator in which the sealed sources will be housed; and
- (d) Specify the purpose for which the licensed material will be used (e.g., food irradiation, etc.), the location where it will be used and the prospective users.

Section 35. Sell and/or Distribute Check, Reference and Calibration Sources.

Each applicant shall:

- (a) Specify as to what categories of licensees the check, calibration or reference sources will be used.
- (b) Ensure that the check, reference or calibration sources have been obtained from a manufacturer authorized to sell/distribute the sources.
- (c) Ensure that the manufacturer's labeling and packaging will not be altered and that the sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Section 36. Sell and/or Distribute Devices Containing Radioactive Material of Exempt Quantity to Persons Exempt from Licensing.

The applicant shall provide sufficient information on the devices containing radioactive material of exempt quantities to persons exempt from licensing relating to the design,

manufacture, prototype testing, quality control, labeling, marking and anticipated conditions or handling, storage, use, and disposal of the device to demonstrate that the single exempt unit will meet the safety criteria applicable to that device as established by PNRI, or by the regulatory authority of the country in which the design of the device originated, and can be distributed to persons exempt from licensing without undue hazard.

Section 37. Technical Services.

Any person who intends to provide commercial technical services such as, among others, the installation of the device, collection of the samples to be tested for leakage of radioactive material, repair/maintenance of the device, testing of the on-off mechanism and indicator, or removal of the device from its installation and other nuclear services, shall be subject to the licensing requirements of **CPR Part 25, "Licenses for Commercial Providers of Technical Services"**.

IV. RECORDS, REPORTS AND NOTIFICATIONS

Section 38. Records of Radiation Safety Program.

- (a) Each licensee shall maintain records of the radiation 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 three (3) years or until PNRI orders otherwise.

Section 39. Records of Personnel Monitoring.

- (a) Each licensee shall maintain records showing the total exposures of all personnel who are required to wear personnel monitoring devices. Such records shall be kept on clear and legible forms in accordance with the instructions and reporting requirements of PNRI.
- (b) Records of personnel monitoring shall be kept and maintained until PNRI authorizes their disposition.

Section 40. Records of Surveys.

- (a) Each licensee shall maintain records showing the results of surveys incident to the sale, distribution, or transfer of radioactive materials.
- (b) In support of records of personnel monitoring, records of result of surveys to determine external radiation doses shall be maintained until PNRI authorizes their disposition.

Section 41. Records of Disposition of Sealed Sources.

Records of disposition of sealed sources shall be maintained and retained until PNRI authorizes their disposition.

Section 42. Records and Reports of Sale, Distribution, and/or Transfer of Radioactive Material.

- (a) Each licensee shall submit to PNRI, on a **quarterly** basis, a summary report of the sale, distribution, and/or transfer of radioactive material.
- (b) Each licensee shall keep records of sale, distribution, and/or transfer of radioactive material, which include the following:
 - (1) Name, PNRI license number, and address of each person to whom radioactive material is delivered;
 - (2) Kinds and quantities/activities of each radioactive material sold/ transferred; and
 - (3) Date of each sale/transfer.
- (c) Each licensee shall maintain records of each sale/distribution/transfer for a period of **two years**, which shall be made available for inspection by PNRI.

Section 43. Reports of Theft or Loss of Radioactive Material.

- (a) The licensee shall immediately notify PNRI by telephone or by any other fast means of communication, of loss or theft of radioactive material within 24 hours and make a written report within thirty 30 calendar days after the notification which includes the following:
 - (1) Description of the sealed source involved i.e. isotope, quantity, chemical and physical forms;
 - (2) Description of the circumstances under which the loss or theft occurred;
 - (3) Estimated radiation exposure to individuals, if any;
 - (4) Actions to recover the source; and
 - (5) Measures to be adopted to prevent recurrence of the circumstances which led to the loss or theft of the sealed source.
- (b) Subsequent to filing the written report, the licensee shall also report immediately to PNRI any additional information which becomes available to the licensee.

Section 44. 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, 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) Release of radioactive material in the facility.
- (b) Any report filed with PNRI 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 45. Notification on Specific Changes in the License.

- (a) A licensee shall notify the PNRI immediately by telephone or by similarly fast means of communication and by letter within thirty (30) calendar days:

- (1) When the RSO, ARSO or the authorized personnel permanently discontinues performance of duties under the license or has a name change;
 - (2) When the licensee's mailing address changes; or
 - (3) When there is a change of the authorized storage location of radioactive materials.
- (b) The licensee shall send the report to:
- The Director**
Philippine Nuclear Research Institute
Commonwealth Avenue, Diliman
Quezon City 1101
- Attention: Chief: Nuclear Regulations, Licensing and Safeguards Division

V. ENFORCEMENT

Section 46. Inspections.

- (a) Each licensee shall afford to PNRI at all reasonable times the opportunity to inspect the radioactive material in his/her possession, the equipment, facilities or premises wherein that radioactive material is stored.
- (b) Each licensee shall make available to PNRI for inspection, records kept by him/her pursuant to these rules and regulations at the address specified in the license.

Section 47. Modification, Suspension and Revocation of License.

- (a) The terms and conditions of each license issued pursuant to the regulations in this Part shall be subject to amendment, revision, or modification by reason of amendments to these regulations and the Act, or by reason of rules, regulations and orders issued by PNRI in accordance with the terms of the Act.
- (b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application, or for violation of, or failure by the licensee to observe, any of the terms and conditions of the license or any of the provisions of the Act, or any of the rule, regulation or order of the Institute.
- (c) Except in cases of willful violation or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked until the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all regulatory requirements.
- (d) A license may be modified by PNRI, or upon the request of the licensee, when:
 - (1) The licensee decides to discontinue any specific licensed activity authorized in the license or to undertake another licensed activity prescribed in this Part;
 - (2) PNRI determines that the licensee can no longer perform the specific licensed activity authorized in the license; or
 - (3) The licensee has ceased to perform a licensed activity during a two (2) year period.

Section 48. Violations.

- (a) A notice of violation shall be issued to 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.
- (b) Any license may be modified, suspended, or revoked, after due process, for any violation that 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 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.

VI. EFFECTIVITY

Section 49. Effective Date.

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

APPENDIX A

REQUIREMENTS ON THE IMPORT AND EXPORT OF RADIOACTIVE SOURCES

These requirements on the import and export of **Categories 1 and 2** radioactive sources are in conformance with the import and export provisions in **Parts 4 and 26** of the Code of PNRI Regulations (CPR), the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and the IAEA Guidance Document on the Import and Export of Radioactive Sources. These requirements do not apply to radioactive sources within military or defense programs.

I. Import of Radioactive Sources.

- (a) Licensees intending to import radioactive sources in Categories 1 and 2 of **Table 1** shall apply to PNRI for an authorization and must receive such authorization prior to import.
- (b) The application shall include the following information:
 - (1) name of the exporter and photocopy of exporter's valid license issued by the competent authority of the exporting country;
 - (2) exporter location and legal address or principal place of business;
 - (3) radionuclide data, activity, and uses of the radioactive source(s);
 - (4) name of licensed local distributor and photocopy of distributor's valid license issued by PNRI; and
 - (5) the provisions for return or disposal of the radioactive source once it becomes disused, including copies of any contracts with distributor and exporter to re-export for return and proper management of the source.
- (c) Licensees shall ensure that the exporter of the radioactive sources is authorized by the Competent Authority of the exporting country to export such sources to the Philippines in accordance with laws and regulations of that country.
- (d) Licensees shall provide the Competent Authority of the exporting country with the following information in writing:
 - (1) name of the recipient;
 - (2) recipient location and legal address or principal place of business;
 - (3) radionuclide data, activity and reference date;
 - (4) intended purpose and proposed use(s) of the radioactive source; and
 - (5) a suggested timeframe for a decision on the request to import.
- (e) A licensee who is only authorized by PNRI to import, sell or distribute radioactive sources shall import these sources only if the recipient or consignee in the Philippines has a valid PNRI license to receive the source and is capable to manage the source consistent with **Section 11 of CPR Part 26 and other pertinent PNRI regulations.**
- (f) Licensees shall ensure that the Exporting Country allows the re-entry of spent or disused sources if, in the framework of that Country's national laws, it has approved that spent or disused sources be returned to a manufacturer authorized to manage the spent or disused sources.
- (g) Licensees shall secure from the PNRI:
 - (1) A **request for release** which is submitted to the Bureau of Customs Officer to allow the release of the radioactive source shipment from the customs cargo hold area; and

- (2) An **Authority to Transport** Certificate wherein PNRI gives approval to transport the radioactive source shipment to the recipient location.
- (h) Licensees shall ensure that the import of radioactive sources is in accordance with CPR Part 4, "Regulations for the Safe Transport of Radioactive Materials in the Philippines".

II. Export of Radioactive Sources.

- (a) Licensees intending to export radioactive sources in Categories 1 and 2, particularly **disused or spent sources**, shall apply to PNRI for an authorization and must receive such authorization prior to exportation.
- (b) The application for export shall include:
 - (1) copies of agreements or contracts to re-import the source once it becomes disused;
 - (2) confirmation letter from the Competent Authority of the importing country that the recipient is authorized to receive and possess the radioactive source or sources to be exported in accordance with its laws and regulations; and
 - (3) a copy of the recipient's valid authorization issued by the Competent Authority of the importing country.
- (c) Licensees involved in the export of radioactive sources in Categories 1 and 2 of **Table 1** shall ensure that the importing country has the appropriate technical and administrative capability, resources and regulatory infrastructure needed for the management of the radioactive sources.
- (d) Licensees shall take into consideration the risk of diversion or malicious acts involving radioactive sources by verification of the following information:
 - (1) whether the recipient has been engaged in illegal procurement of radioactive materials;
 - (2) whether an import or export authorization for radioactive sources has been denied to the recipient or importing country; or
 - (3) whether the recipient or importing country has diverted, for purposes inconsistent with the Code of PNRI Regulations, any import or export of radioactive sources previously authorized.
- (e) Licensees intending to export Category 1 and 2 sources shall notify the Competent Authority of the importing country, and should receive confirmation of such notification at least 7 days in advance of each shipment.
- (f) Licensees shall notify the Competent Authority of the importing country with the following information in advance, as applicable:
 - (1) estimated date of export,
 - (2) name and address of the exporting facility,
 - (3) name and address of the recipient,
 - (4) radionuclide, activity, and reference date,
 - (5) aggregate activity level, and
 - (6) number of radioactive sources and their unique identifiers (e.g., physical and chemical form).
- (g) Licensees shall provide PNRI with a copy of the above notification and secure from PNRI a written authorization to transport the radioactive source(s).
- (h) Licensees shall show proof to PNRI that the exported radioactive sources have been received by the authorized recipient.

III. Transfer of Radioactive Sources.

Licensees involved in the import and export of radioactive sources shall ensure that transfers are undertaken with a valid written authorization from PNRI.

IV. Transport of Radioactive Sources.

- (a) Licensees involved in the import or export of radioactive sources shall ensure that the transport of radioactive sources, either domestically or internationally, is in compliance with the requirements of **CPR Part 4**, "Regulations for the Safe Transport of Radioactive Materials in the Philippines ", and all applicable national and international governmental regulations.
- (b) Licensees shall ensure that the import or export of radioactive sources is conducted in a manner consistent with existing relevant international standards relating to the transport of radioactive materials.
- (c) Licensees shall ensure that the transport of radioactive sources through the territory of a transit or transshipment country is conducted in a manner consistent with existing relevant international standards relating to the transport of radioactive materials, in particular paying careful attention to maintaining continuity of control during international transport.
- (d) If the conditions in **II(c)** with respect to a particular export cannot be satisfied, that export may be authorized by PNRI in exceptional circumstances if an alternative arrangement has been made to ensure the source will be managed in a safe and secure manner.

TABLE 1. ACTIVITIES CORRESPONDING TO THRESHOLDS OF CATEGORIES***

Radionuclide	Category 1*		Category 2**	
	1000 x D		10 x D	
	(TBq)	(Ci)	(TBq)	(Ci)
Am-241	6.E+01	2.E+03	6.E-01	2.E+01
Am-241/Be	6.E+01	2.E+03	6.E-01	2.E+01
Cf-252	2.E+01	5.E+02	2.E-01	5.E-00
Cm-244	5.E+01	1.E+03	5.E-01	1.E+01
Co-60	3.E+01	8.E+02	3.E-01	8.E+00
Cs-137	1.E+02	3.E+03	1.E+00	3.E+01
Gd-153	1.E+03	3.E+04	1.E+01	3.E+02
Ir-192	8.E+01	2.E+03	8.E-01	2.E+01
Pm-147	4.E+04	1.E+06	4.E+02	1.E+04
Pu-238	6.E+01	2.E+03	6.E-01	2.E+01
Pu-239b/Be	6.E+01	2.E+03	6.E-01	2.E+01
Ra-226	4.E+01	1.E+03	4.E-01	1.E+01
Se-75	2.E+02	5.E+03	2.E+00	5.E+01
Sr-90 (Y-90)	1.E+03	3.E+04	1.E+01	3.E+02
Tm-170	2.E+04	5.E+05	2.E+02	5.E+03
Yb-169	3.E+02	8.E+03	3.E+00	8.E+01

* “**Category 1 sources**”, if not safely managed or securely protected, would be likely to cause permanent injury to a person who handled them, or were otherwise in contact with them, for more than a few minutes. It would probably be fatal to be close to this amount of unshielded radioactive material for a period of a few minutes to an hour. These sources are typically used in practices such as **Co-60 irradiators** and **teletherapy**.

** “**Category 2 sources**”, if not safely managed or securely protected, could cause permanent injury to a person who handled them, or were otherwise in contact with them, for a short time (minutes to hours). It could possibly be fatal to be close to this amount of unshielded radioactive material for a period of hours to days. These sources are typically used in practices such as **industrial gamma radiography**, **high dose rate brachytherapy** and **medium dose rate brachytherapy**.

*** **Categorization** is provided by activity levels for radionuclides that are commonly used. These are based on D-values which define a dangerous source i.e., a source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. A more complete listing of radionuclides and associated activity levels corresponding to each category, and a fuller explanation of the derivation of the D-values, may be found in **Appendix I of CPR Part 26**.

Approved:

(Sgd.) **ALUMANDA M. DELA ROSA, Ph.D.**
Director, PNRI

Date: December 4, 2009