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Republic of the Philippines
Department of Science and Technology
PHILIPPINE NUCLEAR RESEARCH INSTITUTE
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LICENSING OF RADIOACTIVE MATERIAL

CPR PART 2

I. GENERAL PROVISIONS

***Section 1. Purpose and Scope*.**

This Part sets forth the rules and regulations applicable to all persons in the Philippines governing the licensing of radioactive material by the Philippine Nuclear Research Institute (PNRI or Institute) pursuant to Section 16 of Republic Act No. 2067 as amended by Republic Act No. 3589, and the exemption from licensing issued pursuant to Section 17 of Republic Act No. 5207, as amended, and Order No. 128.

***Section 2. Resolution of Conflict*.**

The requirements of this Part are in addition to, and not in substitution for, other requirements in the Code of PAEC Regulations* (CPR or Code). In any conflict between the requirements in this Part and a specific requirement in another Part in the Code, the specific requirement governs.

***Section 3. Activities Requiring License*.**

Except for persons exempt as provided in this Part, no person shall manufacture , produce, transfer , sell, receive , acquire , own, possess, use, import or export radioactive material except as authorized in a license issued pursuant to these rules and regulations; provided, however, that (a) these rules and regulations shall apply to naturally - occurring radioactive material only after removal of such radioactive material from its place of deposit in nature, when it is considered to be source material and (b) the acquisition, possession, use and transfer of special fissionable material shall be governed by special rules and regulations or specific requirements of the Code.

***Section 4. 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;

*The "Code of PAEC Regulations", established by PAEC Administrative Order No. 1, Series of 1981, consists of all rules and regulations promulgated by the Philippine Atomic Energy Commission implementing the licensing and regulatory provisions of Sections 16-a of R.A. 2067 as amended and R.A. 5207 as amended. The Commission was reorganized and renamed Philippine Nuclear Research Institute in accordance with Executive Order No. 128, series of 1987.

b) "**CPR or Code"** means the Code of PAEC Regulations, including those Parts established by the PNRI;

c) **"Institute"** means the Philippine Nuclear Research Institute and its duly authorized representative;

d) **"Medical Institution"** means an organization in which several medical disciplines are practiced;

e) **"Medical use"** means the internal or external administration of radioactive material, or the radiation therefrom, to human beings by physicians;

f) **"Nuclear medicine"** means a specialized practice of medicine whereby unsealed sources or radiopharmaceuticals are administered internally to human beings for purposes of diagnosis or treatment and also includes in-vitro applications of radioisotopes for diagnosis or research;

g) **"Person"** means (i) any individual, firm, partnership, association, trust, estate, private or public body, whether corporate or not, or government agency other than the Institute, any province, city, municipality, or any political entity within the Philippines and (ii) any legal successor, representative, agent or agency of the foregoing;

h) **"Physician"** means any individual licensed by the Professional Regulatory Commission of the Republic of the Philippines to prescribe drugs in the practice of medicine or any individual authorized by the Philippine Government to practice medicine in this country;

i) **"Quality Assurance"** means all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service, and that the standards of safety prescribed in the rules and regulations issued by the Institute are achieved in practice;

j) **"Radioactive material"** means any material which spontaneously gives off electromagnetic and/or ionizing radiation having a specific activity greater than 70 kBq/kg (0.002 uCi/g)*. This includes source material, special fissionable material, and atomic energy material as defined herein and any elsewhere in the act and code;

k) **"Radiopharmaceutical"** means a chemical compound labeled with radioisotope(s) and administered to patients in nuclear medicine for diagnosis and/or treatment;

l) **"Sealed source"** means any radioactive material that is encased in, and to be used in, a capsule designed to prevent leakage or escape of the radioactive material;

m) **"Source material"** means uranium containing the mixture of isotopes occurring in nature, uranium depleted in the isotope 235; thorium; any of the foregoing in the form of metal, alloy, chemical compound, or concentrate and other material containing one or more of the foregoing in such concentration as the Institute may from time to time determine;

*The **International System of Units (SI)** is used throughout the regulations as the primary legal unit. However, units previously used have been included in parenthesis to facilitate implementing the standards. In some cases, owing to rounding off of the numbers, the two values are not precisely comparable. In such cases, the **SI** value will control.

n) **"Special fissionable material"** means plutonium-239, plutonium-241, uranium-233, uranium-235, any material containing one or more of the foregoing and such other fissionable material as the Institute shall from time to time determine; but does not include source material;

Note: *Terms defined in the Act and in other Parts of the Code 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. Interpretations

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

II. EXEMPTIONS

Section 6. Persons Using Radioactive Material in an Institute - Owned Laboratory or Under an Institute Contract.

Any person is exempt from the requirements for a license set forth in this Part and other rules and regulations of the Institute to the extent that such person operates an Institute-owned laboratory on behalf of the Institute, or manufactures, produces, transfers, imports, exports, receives, acquires, owns, possesses, or uses radioactive material under and in accordance with a contract with and for the account of the Institute. In any such case, such person's obligations with respect to the radioactive material are covered by the applicable contract between such person and the Institute. Under the terms of the contract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

Section 7. Common and Contract Carriers, Freight Forwarders, and Warehousemen.

Common and contract carriers, freight forwarders, warehousemen and the Bureau of Posts, are hereby exempt from the regulations in this Part and the requirements for a license set forth in Section 16 of the Act to the extent that they transport or store radioactive material in the regular course of carriage for another or storage incident thereto.

***Section 8. Exempt Quantities*.**

a) Except as provided in paragraphs (b), (c), and (d) of this section, any person is exempt from the requirements for a license set forth in this Part and other Parts of the Code to the extent that such person imports, exports, receives, possesses, uses, transfers, owns or acquires radioactive materials in individual quantities each of which does not exceed the applicable quantity set forth in Appendix A.

b) Persons are not authorized to produce, package, repackage or transfer radioactive material under this exemption for purposes of commercial distribution or to incorporate radioactive material into any product for commercial distribution.

c) Persons are not authorized to administer the radioactive material under this exemption in any form to a human being or to transfer the material in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

d) Commercial distribution of radioactive material in these individual quantities to persons exempt from licensing is prohibited except under a license specifically authorizing the transfer of such quantities to persons exempt from licensing.

***Section 9. Source Material*.**

Any person is exempt from the requirements for a license set forth in this Part and other Parts of the Code to the extent that such person imports, exports, receives, possesses, uses, transfers, owns or acquires source material (U or Th) in any chemical mixture, compound, solution or alloy in which the source material is by weight less than one-twentieth of one percent (0.05 percent) of the mixture, compound, solution or alloy.

Section 10. Ores Containing Source Material.

Except as indicated, any person is exempt from the requirements for a license set forth in this Part to the extent that such person imports, exports, receives, possesses, uses, transfers, owns or acquires unrefined and unprocessed ore containing source material; provided, however, that no person shall refine or process such ore except as authorized to do so in a specific license issued by the Institute pursuant to the regulations in this Part.

Section 11. Specific Exemption for Items Containing Radioactive Material.

a) Except for persons who apply or incorporate radioactive material into any of the products exempted under this section and persons who import, or initially transfer, for sale or distribution any of the products exempted under this section, any person is exempt from the requirements set forth in this Part and from all other rules and regulations of the Institute to the extent that such person imports, acquires, receives, possesses, uses, transfers, or owns any of the products which the Institute has determined to be exempted under this section.

b) The products exempted under this section include only items which have been manufactured or produced under a license issued (i) by the Institute which exempts the use of these products from licensing requirements in the Philippines or (ii) by the licensing authority of the country of origin of the product and which exempts their use from licensing requirements in that country.

c) Among the products to be considered for exemption are the following:
   (1) Self-luminous timepieces, hands, dials (including bezels), exit markers, marine compasses, depth gages, marine navigational instruments, automobile lock illuminators, telephone dials, automobile shift quadrants, thermostat dials, and pointers, containing tritium, krypton-85 or promethium-147.
   (2) Gas and aerosol detectors, designed to protect life or property from fires (e.g. smoke detectors) and airborne hazards, containing americium- 241.
   (3) Precision balances containing tritium.
   (4) Electron tubes containing tritium, cobalt-60, nickel-63, krypton-85, cesium-137 or promethium- 47.
   (5) Spark gap irradiators containing cobalt-60.
   (6) Lightning arresters containing americium- 241.
   (7) Incandescent gas mantles, vacuum tubes, welding rods, electric lamps for illumination purposes (50 milligrams / lamp), germicidal lamps, sunlamps and lamps for outdoor or industrial lightning (2grams/lamp), personnel neutron dosimeters (50milligrams / dosimeter) or finished optical lenses, containing not more than 30% by weight thorium.
   (8) Glazed ceramic tableware, provided the glaze contains not more than 20% by weight source material, piezoelectric ceramic containing not more than 2% by

weight source material, glassware containing not more than 10% by weight source material but not including glass brick, pane glass, ceramic tile or other glass or ceramic used in construction; rare earth metals and compounds, mixtures and products containing not more than 0.25% by weight source material; or photographic film, negatives and prints containing source material.

(9) Any finished product or part fabricated of tungsten-, nickel-, or magnesium-thorium alloys not exceeding 4% by weight of thorium.

(10) Depleted uranium in aircraft counterweights which are imprinted **"Depleted Uranium"** and permanently marked **"Unauthorized Alterations Prohibited."**

(11) Natural or depleted uranium as shielding in shipping containers impressed with: **"Caution- Radioactive Shielding- Uranium."**

(12) Fire detector heads containing not more than 185 Bq (0.005 uCi) uranium in each head.

(13) Depleted uranium in teletherapy heads.

(14) Natural or depleted uranium and thorium compounds as analytical reagents.

***Section 12. Other Exemptions*.**

The Institute may, upon application of any interested person, or upon its own initiative, exempt certain classes or quantities of radioactive materials or kinds of uses or users from the requirements for a license set forth in this Part when it determines that such exemption is authorized by law and will not endanger life or property or the national defense and security and is otherwise in the public interest.

III. LICENSES

***Section 13. Types of Licenses*.**

The following types of radioactive material licenses will be issued by the Institute under the regulations in this Part:

a) For medical use of radiopharmaceuticals in medical institution;

b) For medical use of radiopharmaceuticals by individual Physicians;

c) For medical use of sealed sources;

d) For use of sealed sources in industrial radiography (see Part 11);

e) For use of sealed sources in installed industrial devices;

f) For research and development;

g) To manufacture and initially transfer items for sale or distribution to person exempt from licensing;

h) To manufacture and distribute radioactive material for medical use;

i) For commercial sale or distribution of radioactive materials in the form received to other licensees and/or for installation of such devices containing such material;

j) For use in an educational program;

k) For a contaminated laundry or waste processing facility;

l) For use not specified in this section;

m) For export only.

***Section 14. Applications for Licenses*.**

a) Applications for licenses should be filed in duplicate with the **Nuclear Regulations, Licensing and Safeguards Division of the Philippine Nuclear Research Institute, Don Mariano Marcos Avenue, Diliman, Quezon, City** or may be filed in person at the PNRI offices at the same address. Information contained in previous applications, statements, or reports filed with the Institute may be incorporated by reference provided that such references are clear and specific.

b) The Institute may, at any time after the filing of the original application, and before the expiration of the current license, require further statements in order to enable the Institute to determine whether the application should be granted or denied or whether a license should be modified, suspended or revoked.

c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for or on his behalf.

d) Each application for a license shall be accompanied by the fee prescribed in the PNRI Schedule of Fees, as published**.**

Section 15. General Requirements for Issuance of a License.

An application for a license will be approved if:

a) The application is for a purpose which the Institute considers to be justifiable and is authorized by the Act;

b) The locations at which the radioactive material will be used and stored are found acceptable by the Institute for the radioactive material requested in the application;

c) The radioactive material to be used as a sealed source is in a form which has been approved as a sealed source for the intended purpose by the Institute or by the licensing authority of the country of origin of the source;

d) The applicant's proposed equipment and facilities are adequate to use the radioactive material for the purpose requested and to protect health and minimize danger to life or property;

e) The applicant and/or proposed users are qualified by training and experience to use the material for the purpose requested in such a manner as to protect health and minimize danger to life and property;

f) The applicant has designated a qualified RHSO responsible for implementing the radiation safety program;

g) The applicant, through the RHSO, has ensured that radiation safety activities will be performed in accordance with approved procedures and regulatory requirements;

h) The applicant has established and stated in writing the authorities, duties, responsibilities and radiation safety activities of the RHSO;

i) The applicant's proposed program of radiation protection, type and number of instruments to be available for radiation protection are adequate for the activities requested;

j) The procedures for disposing of radioactive waste and/or release of effluents described in the application are acceptable to the Institute;

k) The proposed quality assurance is adequate for the activities requested;

l) The applicant proposed security measures to prevent loss or theft of radioactive material are adequate; and

m) The applicant satisfies the additional requirements specified in the following sections and any special requirements in other parts of the Code which are applicable to the type of license requested in the application.

ADDITIONAL REQUIREMENTS FOR EACH TYPE OF LICENSE

Section 16. License for Medical Use of Radiopharmaceuticals in an Institution.

An application by an institution for a license for medical use of radiopharmaceuticals will be approved if:

a) The applicant satisfies the general requirements specified in section 15;

b) The applicant has appointed a Medical Isotope Committee (MIC) to oversee the use of licensed material throughout the institution and to review the Institutions radiation protection program. Membership in the committee must include at least the following: an authorized user for each type of use permitted by the license, a representative of the nursing staff, a representative of the institutions management, and the RHSO;

c) The applicant possesses adequate facilities for clinical care and monitoring of patients;

d) Each physician designated on the application as an authorized user has substantial experience in the proposed use, handling and administration of radioisotopes and where applicable, the clinical management of the radioactive patients;

e) The applicant has a Q.A. program for ensuring proper operation of his nucleonic equipment; and

f) The applicant has a program of quality control of dosage for patients.

Section 17. License for Medical Use of Radiopharmaceuticals by Individual Physicians.

An application by an individual physician or group of physicians for a license for medical use of radioactive material will be approved if:

a) The applicant satisfies the general requirements in Section 15;

b) Each physician designated on the application as an individual user has extensive experience in the proposed use, handling, and administration of radioisotopes and

where applicable, the clinical management of radioactive patients. The physician shall furnish suitable evidence of such experience with his application. (A statement from a medical Isotopes Committee in the institution where he acquired his experience indicating the nature and extent, may be submitted as an evidence of such experience);

c) The applicant has clinical facilities adequate for the hospitalization of patients or has access to a hospital possessing adequate facilities to hospitalize the applicant's radioactive patients whenever it is advisable; or

d) For use in the premises of a medical institution which does not hold a PNRI license for medical use:
   (1) The use of radioactive material by the physician is limited to the administration of radiopharmaceuticals for therapeutic purposes only;
   (2) For each administration the physician brings the radioactive material with him and removes the radioactive material when he departs (the institution cannot receive, possess or store radioactive material other than that which remains in the patient); and
   (3) The physician has included in his application a copy of the institution's administrator's approval for the intended uses in a specific room of the hospital.

Section 18. License for Medical Use of Sealed Sources.

An application for a license for medical use of radioactive material in a sealed source will be approved if:

a) The applicant satisfies the general requirements in Section 15; and

b) The applicant or, if the application is made by the institution, the individual user: (1) is a physician; and (2) has specialized training in the therapeutic use of radioactive device considered (teletherapy unit, beta applicator, cobalt-60 or iridium-192 implants, etc.) or has experience equivalent to such training.

***Section 19. License for Use of Sealed Sources in Industrial Radiography*.**

a) This section sets forth the special requirements for a license to possess and use sealed sources in industrial radiography, i.e. the examination of materials by non-destructive methods utilizing sealed sources of radioactive material.

b) An application for a license to use radioactive material in radiography will be approved if:
   (1) The applicant satisfies the general requirements in Section 15;
   (2) The applicant will permit only radiographers and radiographer's assistants who have had adequate training and experience to perform radiography in compliance with the applicable regulatory requirements of the Institute;
   (3) The applicant will use, transport and/or store the sealed sources in source changers and radiographic camera devices, the designs of which have been approved with the sealed sources (Section 15 (c)), for radiography by the Institute or by the competent authority of the country by which the device was manufactured;
   (4) The applicant has submitted a description of its organization for the radiography program including delegations of authority and responsibility for all operations;
   (5) The applicant has established and submits to the Institute satisfactory written operating and emergency procedures;

(6) The applicant has an adequate program of radiation protection including written administrative procedures, training programs for all radiographers and radiographer's assistants and provision of radiation survey instrument and personnel monitoring devices. At least one calibrated and operable radiation survey instrument with a range such that 0.02 mSv/h (2mrem/h) through 10 mSv/h (1 rem/h) can be measured must be available at each site where radiographic operations are being performed. Each portable radiation survey instrument shall be calibrated at intervals not to exceed 3 months and after each servicing. Each radiographer and each radiographer's assistant must be provided with and required to wear a direct reading pocket dosimeter and either a film badge or a thermoluminescent dosimeter (TLD) at all times during radiographic operations;

(7) If the applicant plans to conduct his own leak tests of sealed sources, he has adequate procedures including method of testing, instrumentation, and personnel with experience to carry out the test.

Section 20. License for Use of Sealed Sources in Installed Industrial Devices.

a) This section sets forth the special requirements for a license to possess and use sealed sources contained in one or more device designed and manufactured for the purpose of detecting, measuring, gauging and controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. Licenses issued pursuant to this Part apply only to sealed sources contained in devices manufactured under a specific license issued by the Institute or by the licensing authority in the country of origin of the device.

b) An application for a license to use sealed sources in installed devices will be approved if:

(1) The applicant satisfies the general requirements of Section 15;

(2) The application shows that the devices will be installed by persons licensed by the Institute or foreign consultants accredited by the Institute to install such devices and that access to the devices is controlled;

(3) The applicant has indicated that he will observe the precautions and restrictions in his license and on the labels on the devices and will not dispose of the radioactive material in the device except by transfer to the Institute or to someone licensed to receive and possess such a device and the radioactive material it contains.

c) Licenses issued pursuant to this section cover only use of devices for the purposes listed in 20(a) after installation and do not authorize disassembly of the devices.

Section 21. License for Research and Development.

An application for a license for the use of radioactive material in research and development will be approved if:

a) The applicant satisfies the general requirements specified in Section 15; and

b) The program of research and development has been reviewed and approved by the appropriate body.

Section 22. License to Manufacture or Initially Transfer Items for Sale and Distribution to Persons Exempt from Licensing.

a) This section sets forth the requirements for the issuance of a license to manufacture, or produce, or initially transfer, items containing small quantities of radioactive material for sale or distribution to persons exempt from licensing pursuant to section 11 of this Part.

b) An application for specific license to apply radioactive material to, or to incorporate radioactive material into, any of the products listed in section 11, of the quantities listed in Appendix A, or to import or acquire for initially transferring such products for sale or distribution to persons for use under the exemption in section 11 or Appendix A, will be approved if:
   (1) The applicant satisfies the general requirements for a license specified in Section 15;
   (2) The applicant submits sufficient information relating to the design, manufacture, testing of prototypes and production items, quality control procedures, labeling and marking and anticipated conditions or handling, storage, use, and disposal of the product to demonstrate that the single exempt unit will meet the safety criteria applicable to that product established by the Institute, or by the regulatory authority of the country in which the design of the product originated, and can be distributed and used without undue hazard. The information should include, where applicable:
      (i) A description of the product and its intended use or uses and anticipated method of disposal;
      (ii) The type and quantity of radioactive material in each unit;
      (iii) Chemical and physical form of radioactive material in the product, and solubility in water and body fluids of those forms;
      (iv) Details of construction and design of the product as related to containment and shielding of the radioactive material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product;
      (v) Maximum external radiation levels from the product;
      (vi) Degree of access of human being to the product during normal handling and use;
      (vii) Total number of units expected to be distributed annually;
      (viii) The expected useful life of a unit;
      (ix) The proposed method of labeling or marking each unit with the name of the manufacturer or initial transferor of the product and the radioactive material in the product;
      (x) Procedures for testing the product to demonstrate the effectiveness of the device for the intended purpose and of the containment and shielding and other safety features under normal and severe conditions of handling, storage, use and disposal of the product;
      (xi) Results of the test;
      (xii) The estimated external radiation doses and dose commitments anticipated in normal use and disposal;
      (xiii) Quality control procedures and quality control standards the product will be required to meet;
      (xiv) Any additional information, including studies and experimental tests, the Institute may require.

c) Notwithstanding the provisions of paragraph (b), the Institute may deny an application for a specific license to manufacture, or initially transfer items under this section if the end uses of the product cannot be reasonably foreseen.

Section 23. License to Manufacture and Distribute Radioactive Material for Medical Use.

a) An application for a license to manufacture and distribute radioactive material in generators, or reagent kits for preparation of radiopharmaceuticals, and radiopharmaceuticals for medical use by persons licensed pursuant to section 16 or 17 of the part will be approved if:
   (1) The applicant satisfies the general requirements specified in Section 15;
   (2) The applicant meets requirements of the **Department of Health**; or submits evidence that the radioactive drug generators, or reagent kit or radiopharmaceutical, is not subject to **Bureau of Food and Drugs** Licensing;
   (3) A durable, clearly visible label will be affixed to each container, package, generator or reagent kit containing information on the radionuclide, quantity, and date of assay;
   (4) The label on each container, package, generator or reagent kit or a leaflet or brochure which accompanies each container, package, generator or reagent kit will contain:
      (i) A statement that the radiopharmaceutical, generator or reagent kit (as appropriate) is licensed by the **Philippine Nuclear Research Institute** for distribution to persons licensed pursuant to Sections 16 and 17 of this Part; and
      (ii) Adequate information, from a radiation protection stand-point, on the procedures to be followed and the equipment and shielding to be used in carrying out those procedures with the radiopharmaceutical, generator or reagent kit.

   NOTE: *The labels, leaflets or brochures required by this paragraph are in addition to the labeling required by the* ***Department of Health.*** *They may be separated from or with the approval from the* ***Department of Health,*** *may be combined with the labeling required by the* ***Bureau of Foods and Drugs.***

Section 24. License for Commercial Sale or Distribution of Radioactive Materials in the Form Received to other Licensees and/or for Installation of Devices Containing Such Material.

a) This section sets forth the special requirements for the issuance of a license to possess radioactive material for the commercial sale and distribution of that material in the form received to other persons licensed to receive the material in that form. The material may be imported or it may be acquired in the **Philippines.** Also, if the material is contained in a device the design of which has been approved by the Institute or by the licensing authority in the country of origin, installation of the device in the licensed user's plant may be authorized.

b) The application for a license for sale or distribution to licensees of radioactive material in the form in which it is received and/or installation of devices containing such radioactive material will be approved if:
   (1) The applicant satisfies the general requirements in Section 15;
   (2) The location at which the radioactive material will be stored and the facilities and equipment available thereat are appropriate for the types, forms and maximum quantities of radioactive material requested in the application;
   (3) The proposed program of accounting and control of the radioactive material is adequate;
   (4) For the installation of devices, the procedures, training program, and instructions to person who will install the devices are adequate to comply with

the regulatory requirements of the Institute and to ensure proper installation; and

(5) Only individuals who are specifically licensed by the Institute or by the licensing authority of the country of origin of the device shall be allowed to install the device.

Section 25. License for Use in Educational Program.

a) This section sets forth the special requirements for a license to use radioactive materials in an educational program.

b) An application for a license to use radioactive material in an educational program will be approved if:
   (1) The applicant satisfies the general requirements of Section 15;
   (2) The applicant has provided convincing evidence in the application that the educational program requires quantities of the radioactive materials which exceed the exempt quantities specified in Appendix A;
   (3) the applicant has adequate procedures for use of the radioactive material for training or education which are unlikely to result in radiation exposures of person under the age of **18 greater than one-tenth the dose limits for adults**; and
   (4) The applicant has an adequate program for accounting for all radioactive materials before and after each training session in which that material is used.

Section 26. License for a Contaminated Laundry or Waste Processing Facility.

a) This section sets forth the special requirements for issuance of a license to receive and possess radioactive material, in the form of contamination on items of clothing or equipment for the purpose of decontaminating such items or as radioactive waste for the purpose of processing or preparing that waste for disposal. For the present, the Institute will not license waste disposal operation, i.e., authorize anyone to dispose of someone else's waste by any means, including burial in the ground, or dumping into the sewer or release into the air or water.

b) An application for a license to decontaminate items or clothing or equipment or to process or prepare waste for disposal will be approved if:
   (1) The applicant satisfies the general requirements in Section 15;
   (2) The applicant demonstrate that he has adequate facilities, procedures, equipment and trained staff to monitor, handle, store, and decontaminate or process the items he will accept and control exposures of employees and the public, to preclude release of unacceptable levels of radioactivity to the sewer, air or water, and to monitor and control items to be returned only when decontaminated to an acceptable level or wastes prepared for disposal;

Section 27. License for Uses Not Specified in this Part.

a) This section covers the issuance of a license to use radioactive material for a purpose not specified in this part.

b) An application for a license to use radioactive material for a purpose not specified in this Part will be approved if the applicant:
   (1) Satisfies the general requirements in section 15;
   (2) Proposes procedures for storage, use, handling and disposal which are adequate for the type and quantity of radioactive material required for the purpose specified;

***Section 28. License for Export*.**

a) This section sets forth the special requirements for issuance of license to export radioactive material.

b) An application for a license to export radioactive material will be approved if:
   (1) The application is submitted by a person holding a valid license issued by the **Institute** for possession and use of the material for which the export license is requested; and
   (2) The applicant provides evidence that the person to whom the material is to be transferred has a license or permit to import that material issued by the competent authority of the country to which it is to be exported.

c) Packaging and transportation shall comply with **CPR Part 4, "Rules and Regulations in the Safe Transport of Radioactive Materials in the Philippines"** and other applicable national and international transport regulations.

Section 29. Issuance of a License.

a) Upon a determination that an application for a license meets the requirement of the Act and the relevant regulations of the Institute, and that the applicable license fees have been paid, the Institute will issue a license authorizing the possession and use of radioactive material of the type, form, and quantity for the purpose and at the location specified therein.

b) The Institute may incorporate in any license, at the time of issuance or thereafter by rules, regulations, or orders, such additional requirements and conditions with respect to the licensee's receipt, possession, use transfer and disposal of radioactive material as it deems appropriate or necessary in order to:
   (1) Protect the national defense and security;
   (2) Protect health and minimize danger to life and property;
   (3) Protect restricted data; or
   (4) Fulfill international obligations of the State.

Section 30. Terms and Conditions of Licenses.

a) Each license issued pursuant to the rules and regulations of this Part shall be subject to all the provisions of the Act, and amendments thereto, to the applicable provisions of the Code, and orders of the Institute and the conditions stated in the license, including appropriate portions of the application.

b) Neither the license nor any right under the license shall be transferred, assigned or in any manner disposed of through transfer to any person unless approved by the Institute in writing.

c) Each licensee shall confine his possession and use of radioactive material to the locations and purposes authorized in the license.

d) Each licensee shall assure that the equipment and facilities described in his application are available and functioning properly while operations are being carried out under his license, and maintain sufficient calibrated and operable radiation survey instruments and personnel monitoring devices to carry out the radiation surveys and measurements of exposure required by this and other Parts of the CPR and the conditions of his license.

e) Each licensee preparing technetium - 99m radiopharmaceuticals from molybdenum-99 / technetium-99m generators shall test the eluates for molybdenum-99 breakthrough in accordance with the instructions furnished by the manufacturer. The licensee shall not administer to patients technetium-99m if it contains more than 6 kBq Mo-99 per 37 Mbq Tc-99m (0.15 uCi Mo-99 per mCi of Tc-99m).

f) Each licensee shall cause each sealed sources or device containing more than 3.7 Mbq (100uCi) of β-, γ- emitters or 370 Kbq (10uCi) of α-emitters with half life greater than 30 days, except iridium-192 seeds encased in nylon ribbon, to be tested for contamination and / or leakage prior to its first use and at intervals not to exceed six months or at such other intervals as are specified on the label or in the leaflet or brochure which accompanies the source or device, or approved by the Institutę. If the test reveals the presence of 185 Bq (0.005 uCi) of removable contamination, the licensee shall immediately withdraw the source or device from use and cause it to be decontaminated and repaired or to be disposed of it in accordance with Institute regulations.

g) Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and devices received and possessed.

h) Except as otherwise provided in the license, the licensee shall carry with it the right to import, acquire, receive, own, and possess the radioactive material specified on the license.

i) A copy of the approved license shall be available at each location.

Section 31. Special Requirements for Teletherapy Licenses.

In addition to the applicable terms and conditions in Section 30, each licensee authorized to use a teletherapy unit under Section 18 shall:

a) Cause full calibration measurements to be performed in each teletherapy unit by a qualified expert* using a dosimetry system that has been calibrated within the previous two (2) years;

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*A qualified expert has the following minimum training and experience:

(1) A Master's or Doctor's degree in Physics, biophysics, radiological physics or health physics;

(2) **One year** of full time training in therapeutic radiological physics; and

(3) **One year** of full time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit:

- (1) Prior to first use of the unit for medical treatment;
- (2) Whenever spot-check indicate that output differs by more than 5 per cent from the last calibration value corrected for decay;
- (3) Following removal or replacement of the source, major repair of the source exposure assembly, or reinstallation of the unit in a new location; and
- (4) At intervals not exceeding one year.

b) Cause spot check measurement to be performed on each teletherapy unit at intervals not exceeding one month.

c) Install a permanent radiation monitor in each teletherapy room for continuous monitoring of beam status;

d) Cause each teletherapy unit to be fully inspected and serviced during

e) Maintain records of the measurements, tests, corrective actions, inspection and servicing of each teletherapy unit, for inspection by the Institute.

Full calibration measurements required by paragraph (a) shall include determination of:

(1) The exposure or dose rate to 3% for the range of field sizes and for distances used in teletherapy;
(2) The congruence between radiation field and the field indicated by the light beam localizing device;
(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
(4) Timer accuracy; and
(5) The accuracy of all distance measuring devices used for treating humans.

Spot - check measurements required by paragraph (b) shall include determination of:

(1) Timer accuracy;
(2) Congruence of radiation and light beam localizer fields;
(3) Accuracy of distance-measuring device;
(4) The reference output; and
(5) The percentage difference between the measured output and the anticipated output (i.e., the last calibration value corrected for decay).

***Section 32. Monitoring of Packages of Radioactive Material on Receipt*.**

a) As soon as possible after receipt of each package of radioactive material other than those exempted below, the licensee shall monitor the package for radioactive contamination on the external surfaces and for the radiation levels outside of the package. If removable contamination in excess of 4 Bq/cm^2 (0.01 µCi/100 cm^2) or radiation levels exceeding 2 mSv/h (200 mrem/h) at the surface of the package or 0.1 mSv/h (10mrem/h) at one meter from the surface are found, the licensee shall immediately notify the final delivering carrier and the Institute. A written report should be submitted to the Institute within 30 days.

b) Packages of radioactive material identified below are exempted from being monitored on receipt as required in (a) above:
   (1) Packages containing radioactive material exempted from licensing (see Section 8 thru 11).
   (2) Packages containing no more than 370 MBq (10 µCi) of tritium, Carbon-14, sulfur-35, or Iodine-125.
   (3) Packages containing only radioactive material as gases or special form (e.g. sealed sources).
   (4) Packages containing only radioactive material other than liquid form and not exceeding the Type A Package quantity limit specified in the transport regulations (Part 4, Code of PNRI Regulations).
   (5) Packages containing only radionuclides with half-lives less than 30 days and a total quantity of no more than 3.7 MBq (100 mCi).

Section 33. Transfer of Radioactive Material.

a) Except as otherwise provided in the license, no licensee may transfer radioactive material to anyone other than :
   (1) To the Institute, or
   (2) To any person exempt from the licensing requirements of the rules and regulations in this Part to the extent permitted under such exemption, or
   (3) To any person authorized to receive such radioactive material by a valid license issued by the Institute, or

(4) To any person abroad pursuant to an export license issued under Section 28 of this Part.

b) Before transferring radioactive material to a person licensed by the Institute**,** the licensee transferring the radioactive material shall verify that the transferee's license is valid and authorizes receipt of the type, form and quantity of the radioactive material to be transferred by having in his possession a copy of that license or a written certification by the transferee to that effect with the license number and expiration date.

c) Within ten days after each transfer of radioactive material the licensee who made the transfer shall submit a report to the Institute showing his name, address, and licensee number of the type, form, and quantity of radioactive material transferred, the date transferred and the name, address and license number of the person to whom the material was transferred.

Section 34. Expiration and Renewal of Licenses.

a) Each license shall expire at the end of the day in the month stated therein.

b) Application for renewal of license shall be filed in accordance with Section 14, not less than thirty (30) days prior to the expiration of the existing license; a licensee shall file an application in proper form for renewal. Such existing license shall remain valid until the application for renewal has been finally determined by the Institute, but in no case shall be more than 30 days after the expiration of the license.

Section 35. Application for Amendment of License

A licensee shall apply for and must receive a license amendment before he can:

a) Use the radioactive material covered in his license for purposes other than those specified in the license;

b) Use or store said radioactive material in locations other than those specified in the license;

c) Use radioactive materials other than those specified in the license;

d) Use the same radionuclides in quantities exceeding those specified in the license for the purposes and at the locations specified in the license;

e) Change personnel listed therein, e.g. the authorized individual user(s), the person designated as Radiation Safety Officer, etc.; and

f) Make major change in the equipment and facilities in which the license radioactive material is stored, used or handled.

An application for amendment of a license shall be filed with the Institute and shall specify in what respect the licensee desires his license to be amended and the grounds for such amendment.

Section 36. Institute Action on Application to Renew or Amend.

In considering an application by a licensee to renew or amend his license, the Institute will apply the applicable criteria set forth in Section 15 thru 29.

***Section 37. Termination of License*.**

a) The procedure for terminating a license may be initiated at anytime at the request of the licensee. It is assumed that if a license is allowed to expire and the licensee has not requested a renewal of the license within one month after the expiry date, the licensee wishes his license to be terminated and the Institute shall initiate the termination procedure.

b) Before the license can be terminated, the licensee must:
   (1) Discontinue all activities involving licensed radioactive materials;
   (2) Transfer or dispose of all licensed materials which were in his possession in accordance with the regulations;
   (3) Determine by the survey or other means that no contamination levels in excess of the limits for unrestricted areas exist in his facilities; and
   (4) Assure that the required records are complete and up-to-date.

c) To be relieved of the responsibility for the material and the other conditions in his license, the licensee shall submit a letter to the Institute containing:
   (1) His request (or agreement) 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 in the past year and the person to whom the material was transferred or the method of disposal for each item;
   (4) The statement of the qualified expert that his facilities are not contaminated; and
   (5) An agreement that his records and facilities will be available for inspection by PNRI at a mutually agreed date within the next three months.

(d) When these procedures have been completed to its satisfaction, the Institute will issue a termination of the license.

IV. RECORDS, REPORTS, INSPECTION AND TESTS

Section 38. Records and Reports.

a) Each person to whom a license has been issued pursuant to the rules and regulations in this Part shall keep records showing the receipt, location, use, transfer, export, loss and disposal of all radioactive material received pursuant to that license, and shall submit copies of such records to the Institute upon request.

b) Records which are required by the regulations in this Part and other regulations of the Code shall be maintained for the period specified by the appropriate regulations or the license conditions. If the retention period is not otherwise specified, such record shall be maintained until the Institut**e** authorizes their disposition.

c) Each licensee shall submit to the Institute reports of license activities, the subject and frequency of which shall be specified by the appropriate regulations or license conditions.

d) The Institute may require additional records and reports as it deems necessary.

***Section 39. Inspection*.**

a) Each licensee shall afford to the Institute at all reasonable times opportunity to inspect the radioactive material in his possession and the premises, equipment and facilities wherein that radioactive material is used or stored.

b) Each licensee shall make available to the Institute for inspection, upon reasonable notice, records kept by him pursuant to this rules and regulations at the address specified in the license.

***Section 40. Tests*.**

a) Each licensee shall perform such tests as appropriate or necessary for assuring compliance with these rules and regulations, including tests of:
   (1) Radioactive material;
   (2) Facilities wherein radioactive material is used or stored;
   (3) Radiation detection and measuring instruments; and
   (4) Other equipment and devices used in connection with the use, storage, or disposal of radioactive material.

c) The licensee shall permit the Institute to perform such other tests as the Institute deems necessary.

V. ENFORCEMENT

Section 41. Modification and Revocation of License.

a) The terms and conditions of each license shall be subject to the amendments, revision or modification by reason of amendments to these rules and regulations, or by reason of rules, regulations and orders issued by the Institute in accordance with 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 to observe by the licensee, any of the terms and conditions of the license or any of the requirements and provisions of these rules and regulations or of any 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 lawful requirements.

Section 42. Right to Withhold or Recall Radioactive Material.

The Institute may withhold, recall or order the withholding or recalling of radioactive material from any licensee who is not equipped to observe or fail to observe such safety standards to protect health as may be established by the Institute, or who uses such materials in violation of law or regulation of the Institute, or in a manner other than as disclosed in the application and approved by the Institute.

***Section 43. Violations*.**

Any person who shall willfully violate, 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 and Section 25 of Republic Act No. 2067, as amended.

***Section 44. Effectivity*.**

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. However, licenses in effect of that date shall remain valid until the expiration date given on that license. Application for amendments and renewals of existing licenses received after that date will be considered under this regulation.

Approved:

ORIGINAL SIGNED
QUIRINO O. NAVARRO
Director, PNRI

Approved:

ORIGINAL SIGNED
CEFERINO L. FOLLOSCO
Secretary, DOST

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APPENDIX A

EXEMPT QUANTITIES OF RADIOACTIVE MATERIALS

RADIONUCLIDE	EXEMPT QUANTITY	
	kBq	µCi
Antimony 122 (Sb-122)	3.7E3	100
124	3.7E2	10
125	3.7E2	10
Arsenic 73 (As-73)	3.7E3	100
74	3.7E2	10
76	3.7E2	10
77	3.7E3	100
Barium 131 (Ba-131)	3.7E2	10
133	3.7E2	10
140	3.7E2	10
Bismuth 210 (Bi-210)	37	1
Bromine 82 (Br-82)	3.7E2	10
Cadmium 109 (Cd-109)	3.7E2	10
115m	3.7E2	10
115	3.7E3	100
Calcium 45 (Ca-45)	3.7E2	10
47	3.7E2	10
Carbon 14 (C-14)	3.7E3	100
Cerium 141 (Ce-141)	3.7E3	100
143	3.7E3	100
144	37	1
Cesium 131 (Cs-131)	3.7E4	1000
134m	3.7E3	100
134	37	1
135	3.7E2	10
136	3.7E2	10
137	3.7E2	10
Chlorine 36 (Cl-36)	3.7E2	10
38	3.7E2	10
Chromium 51 (Cr-51)	3.7E4	1000
Cobalt 58 (Co-58m)	3.7E2	10
60	37	1
Copper 64 (Cu-64)	3.7E3	100
Dysprosium 165 (Dy-165)	3.7E2	10
166	3.7E3	100
Erbium 169 (Er-169)	3.7E3	100
171	3.7E3	100
Europium 152 (Eu-152),(9.2h)	3.7E3	100
152 , 13yrs.	37	1
154	37	1
155	3.7E2	10
Flourine 18	3.7E4	1000
Gadolinium 153 (Gd-153)	3.7E2	10
159	3.7E3	100
Gold 198 (Au-198)	3.7E3	100
199 (Au-199)	3.7E3	100
Hafnium 181 (Hf-181)	3.7E2	10

RADIONUCLIDE	EXEMPT QUANTITY	
	kBq	µCi
Homium 166 (Ho-166)	3.7E3	100
Hydrogen 3 (H-3)	3.7E4	1000
Indium 113m	3.7E3	100
114m	3.7E2	10
115m	3.7E3	100
115	3.7E2	10
Iodine 125 (I-125)	37	1
126	37	1
129	3.7	0.1
131	37	1
132	3.7E2	10
133	37	1
134	3.7E2	10
135	3.7E2	10
Iridium 192	3.7E2	10
194	3.7E3	100
Iron 55 (Fe-55)	3.7E3	100
59	3.7E2	10
Krypton 85 (Kr-85)	3.7E3	100
87	37	1
Lanthanum 140 (La-140)	3.7E2	10
Lutetium 177 (Lu-177)	3.7E3	100
Manganese 52 (Mn-52)	3.7E2	10
54	3.7E2	10
Manganese 56	3.7E2	10
Mercury 197m (Hg-197m)	3.7E3	100
197	3.7E3	100
203	3.7E2	10
Molybdenum 99 (Mo-99)	3.7E3	100
Neodymium 147 (Nd-147)	3.7E3	100
149	3.7E3	100
Nickel 59 (Ni-59)	3.7E3	100
63	3.7E2	10
65	3.7E3	100
Niobium 93m (Nb-93m)	3.7E2	10
95	3.7E2	10
97	3.7E2	10
Osmium 185 (Os-185)	3.7E2	10
191m	3.7E3	100
191	3.7E3	100
193	3.7E3	100
Palladium 103 (Pd-103)	3.7E3	100
109	3.7E3	100
Phosphorus 32 (P-32)	3.7E2	10
Platinum 191 (Pt-191)	3.7E3	100
193m	3.7E3	100
193	3.7E3	100
197m	3.7E3	100
197	3.7E3	100
Polonium 210 (Po-210)	3.7	0.1
Potassium 42 (K-42)	3.7E2	10
Praseodymium 142 (Pr-142)	3.7E3	100

RADIONUCLIDE	EXEMPT QUANTITY	
	kBq	µCi
143	3.7E3	100
Promethium 147 (Pm-147)	3.7E2	10
149	3.7E2	10
Rhenium 186 (Re-186)	3.7E3	100
188	3.7E3	100
Rhodium 103m (Rh-103m)	3.7E3	100
105	3.7E2	10
Rubidium 86 (Pb-86)	3.7E2	10
87	3.7E2	10
Ruthenium 97 (Ru-97)	3.7E3	100
103	3.7E2	10
105	3.7E2	10
106	37	1
Samarium 151 (Sm-151)	3.7E2	10
153	3.7E3	100
Scandium 46 (Sc-46)	3.7E2	10
47	3.7E3	100
48	3.7E2	10
Selenium 75 (se-75)	3.7E2	10
Silicon 31 (Si-31)	3.7E3	100
Silver 105 (Ag-105)	3.7E2	10
110m	37	1
111	3.7E3	100
Sodium 24 (Na-24)	3.7E2	10
Strontium 85 (Sr-85)	3.7E2	10
89	37	1
90	3.7	0.1
91	3.7E2	10
Strontium 92	3.7E2	10
Sulfur 35 (S-35)	3.7E3	100
Tantalum 182 (Ta-182)	3.7E2	10
Technetium 96 (Tc-96)	3.7E2	10
97m	3.7E3	100
97	3.7E3	100
99m	3.7E3	100
99	3.7E2	10
Tellurium 125m (Te-125m)	3.7E2	10
127m	3.7E2	10
127	3.7E3	100
129m	3.7E2	10
129	3.7E3	100
131m	3.7E2	10
132	3.7E2	10
Terbium 160 (Tb-160)	3.7E2	10
Thallium 200 (Tl-200)	3.7E3	100
201	3.7E3	100
202	3.7E3	10
204	3.7E2	10
Thulium 170 (Tm-170)	3.7E2	10
171	3.7E2	10
Tin 113 (Sn-113)	3.7E2	10
125	3.7E2	10

RADIONUCLIDE	EXEMPT QUANTITY	
	kBq	µCi
Tungsten 181 (W-181)	3.7E2	10
185	3.7E2	10
187	3.7E3	100
Vanadium 48 (V-48)	3.7E2	10
Xenon 131m (Xe-131m)	3.7E3	100
133	3.7E3	100
135	3.7E2	10
Ytterbium 175 (Yb-175)	3.7E3	100
Yttrium 90 (Yt-90)	3.7E2	10
91	3.7E2	10
92	3.7E3	100
93	3.7E3	100
Zinc 65 (Zn-65)	3.7E2	10
69m	3.7E3	100
69	3.7E4	1000
Zirconium 93 (Zr-93)	37	1
95	3.7E2	10
97	3.7E2	10
Any other radionuclide not listed above which is not an alpha emitter.	3.7	0.1

* **kBq** = kilobequerel or 1E3 Becquerel
* **µCi** = microcurie or 1E-6 Curie or 37 kBq or 3.7E4 Bq
* **Ci** = curie or 3.7E10 Bq