



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

**CPR PART 2**

**LICENSING OF RADIOACTIVE MATERIALS AND RADIATION FACILITIES, Rev. 01**

**TABLE OF CONTENTS**

<b>I.</b>	<b>GENERAL PROVISIONS.....</b>	<b>1</b>
	Section 1. Purpose and Scope. ....	1
	Section 2. Definitions.....	1
	Section 3. Interpretation. ....	3
	Section 4. Communication.....	3
	Section 5. Applicability of other Regulations, and Resolution of Conflicts. ....	3
	Section 6. Activities Subject to License. ....	4
	Section 7. Exemptions.....	4
	7.1. Exempt Quantities.....	4
	7.2. Radioactive Material Used in a PNRI-Owned Laboratory or Under a PNRI Contract. ....	4
	7.3. Carriers. ....	4
	7.4. Source Material and Ores Containing Source Material. ....	5
	7.5. Consumer Products Containing Radioactive Material.....	5
	Section 8. Additional Regulatory Requirements.....	5
<b>II.</b>	<b>REQUIREMENTS FOR RADIOACTIVE MATERIAL LICENSE .....</b>	<b>5</b>
	Section 9. Practices Requiring a Radioactive Material License.....	5
	Section 10. Application for New License.....	6
	Section 11. Review, Evaluation and Verification of License Application.....	7
	Section 12. Issuance of Radioactive Material License. ....	7
	Section 13. Terms and Conditions of Radioactive Material License.....	7
	Section 14. Amendment of Radioactive Material License. ....	8
	Section 15. Renewal of Radioactive Material License. ....	8
	Section 16. Expiration of Radioactive Material License.....	9
	Section 17. Termination of Radioactive Material License.....	9

<b>III.</b>	<b>REQUIREMENTS FOR LICENSE TO OPERATE A RADIATION FACILITY .....</b>	<b>10</b>
	Section 18. Radiation Facilities Requiring a License to Operate .....	10
	Section 19. Application for License to Operate. ....	10
	Section 20. Review, Evaluation and Verification of License Application.....	12
	Section 21. Issuance of a Provisional License.....	12
	Section 22. Issuance of License to Operate. ....	12
	Section 23. Terms and Conditions of License to Operate. ....	13
	Section 24. Amendment of License to Operate. ....	13
	Section 25. Renewal of License to Operate.....	14
	Section 26. Expiration of License to Operate.....	15
	Section 27. Termination of License to Operate.....	15
<b>IV.</b>	<b>INSPECTION AND ENFORCEMENT .....</b>	<b>17</b>
	Section 28. Inspection. ....	17
	Section 29. Violations and Issuance of Notice of Violation.....	17
	Section 30. Issuance of Orders and Related Administrative Sanctions.....	18
	Section 31. Administrative Sanctions.....	19
	Section 32. Protective Measures in Cases of Suspension, Revocation or Expiration of License.....	19
	Section 33. Right to Withhold or Recall Radioactive Material.....	19
<b>V.</b>	<b>EFFECTIVITY .....</b>	<b>19</b>
	Section 34. Effectivity Date.....	19



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

**CPR PART 2**

**LICENSING OF RADIOACTIVE MATERIALS AND RADIATION FACILITIES, Rev. 01**

**I. GENERAL PROVISIONS**

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

- (a) This Part is promulgated pursuant to Republic Act No. 5207, otherwise known as the "Atomic Energy Regulatory and Liability Act of 1968", as amended, to establish the licensing and regulation of atomic energy facilities and materials in the Republic of the Philippines.
- (b) This Part provides for the general requirements with respect to applications for a Radioactive Material License, and to applications for a License to Operate a radiation facility.
- (c) The requirements in this Part also provide for license renewal, amendment, exemption, modification, and termination. This Part also provides for the conduct of regulatory inspection and enforcement.

Section 2. ***Definitions***

As used in this Part:

- (a) **“Act”** means Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended by Presidential Decree No. 1484;
- (b) **“Code or CPR”** means the Code of PNRI Regulations;
- (c) **“Commissioning”** means the process by means of which systems and components of facilities and activities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria;
- (d) **“Construction”** means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this Part that are related to the radiological safety or security;
- (e) **“Decommissioning”** means removing a facility or site safely from service and reducing residual radioactivity to a level that permits:
  - (1) Release of the property for unrestricted use and termination of the license; or
  - (2) Release of the property under restricted conditions and termination of the license.

- (f) **“Enforcement”** means the application by a regulatory body of sanctions against a licensee, intended to correct and, as appropriate, penalize non-compliance with conditions of an authorization;
- (g) **“Interested parties”** means a person or company with a concern or interest in the activities and performance of an organization, business, system, etc.;
- (h) **“License to Operate”** means legal document issued by the PNRI to the applicant granting authorization to operate a radiation facility and to perform specified activities relating to a facility or activity;
- (i) **“Licensee”** means a holder of a valid license issued by the PNRI pursuant to this Part, and having overall responsibility for the conduct of authorized activities involving a licensed radioactive material or the operation of a radiation facility;
- (j) **“Order”** means a written PNRI directive to modify, suspend, or revoke a license, to cease and desist all authorized activities, to lift an order or to take such other action as may be proper;
- (k) **“Person”** means:
- (1) Any individual, firm, partnership, association, trust, estate, private or public body, whether corporate or not, or any government agency other than the PNRI, any province, city, municipality, or any political entity within the Philippines; and
  - (2) Any legal successor, representative, agent or agency of the foregoing;
- (l) **“Philippine Nuclear Research Institute or PNRI”** means an authority designated by the government as having legal authority to conduct the regulatory process, including issuing a license, inspection, and enforcement;
- (m) **“Provisional License”** means an authorization issued by the PNRI to the applicant of a License to Operate, on the basis of the technical information and data so far made available, to allow the conduct of activities prior to the issuance of a License to Operate;
- (n) **“Radiation facility”** means a facility, other than nuclear installations:
- (1) With one or several sources of radiation, intended for irradiation and for which it is likely to cause overexposure of individuals;
  - (2) With one or several sources of radiation in teletherapy machine, intended for therapeutic use and for which it is likely to cause overexposure of individuals;
  - (3) For the production of one or more unsealed radioactive sources, which are likely to cause an overexposure of individuals; or
  - (4) For radioactive waste management where radioactive waste is treated, conditioned, stored or disposed of;
- (o) **“Radioactive material”** means a material designated by PNRI as being subject to regulatory control because of its radioactivity;
- (p) **“Radioactive source or source”** means any radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control;
- (q) **“Radiation Protection Officer (RPO)”** means a person technically competent in radiation protection matters relevant for a given type of practice who is designated by the licensee or employer to oversee the implementation of the radiation protection and safety program;
- (r) **“Radiation Protection and Safety Program”** means systematic arrangements that are aimed at providing adequate consideration of radiation protection measures in accordance with CPR Part 3;

- (s) **“Regulatory inspection”** means an activity undertaken by the regulatory body to determine by investigation, examination and evaluation of objective evidence the adequacy of, and adherence to, the Act, regulations, standards, administrative or operational programs and other applicable documents, and the effectiveness of their implementation;
- (t) **“Safety”** means measures intended to minimize the likelihood of accidents with radioactive sources and, should such an accident occur, to mitigate its consequences;
- (u) **“Safety assessment”** means the systematic process that is carried out throughout the design process (and throughout the lifetime of the facility or the activity) to ensure that all the relevant safety requirements are met by the proposed (or actual) design. Safety assessment includes, but is not limited to, the formal safety analysis; that is, it includes the evaluation of the potential hazards associated with the operation of a facility or the conduct of an activity;
- (v) **“Safety Culture”** means the assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues received the attention warranted by their significance; and
- (w) **“Security”** means measures to prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources.

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

### Section 4. **Communication.**

All communications and reports concerning this Code shall be addressed to:

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

### Section 5. **Applicability of other Regulations, and Resolution of Conflicts.**

- (a) The requirements in this Part shall be applied in conjunction with CPR Part 3 – “Standards for Protection against Radiation”, CPR Part 4 – “Regulations on the Safe Transport of Radioactive Material in the Philippines”, CPR Part 26 – “Security of Radioactive Sources”, CPR Part 27 – “Security Requirements in the Transport of Radioactive Materials” and with applicable CPRs providing for the administrative and technical requirements of specific practices and facilities.
- (b) This Part does not relieve the applicant or licensee from complying with the applicable laws of the Republic of the Philippines and regulations of other responsible government agencies.
- (c) Nothing in this Part shall be construed as restricting any actions that may otherwise be necessary to ensure protection and safety of the workers, the general public and the environment.
- (d) If a conflict exists between the requirements contained herein and other laws or regulations, the PNRI shall be notified to initiate steps towards resolution.

## Section 6. **Activities Subject to License.**

- (a) No person shall manufacture, produce, receive, possess, own, use, transfer, import or export any radioactive material, except under a license issued by the PNRI pursuant to this Part.
- (b) No person shall construct and operate a radiation facility except under a license issued by the PNRI pursuant to this Part.

## Section 7. **Exemptions.**

### **7.1. Exempt Quantities.**

- (a) The following radioactive materials within justified practices are automatically exempted without further consideration from the requirements for licensing set forth in this Part:
  - (1) Radioactive materials with total activity or activity concentration not exceeding the exemption levels given in **Table I.1 of Appendix A**;
  - (2) Radioactive material of artificial origin with activity concentration not exceeding the exemption levels given in **Table I.2 of Appendix A**;
  - (3) Radiation sources, including substances, materials, radioactive waste and objects within licensed activities that fall under the criteria for clearance or clearance levels given in **Appendix B**;
- (b) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in **Appendix A**.
- (c) For radioactive materials of natural origin, exemption of bulk amounts of material is necessarily considered on a case-by-case basis by using a dose criterion of the order of **1 mSv** in a year, commensurate with typical doses due to natural background levels of radiation. that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

### **7.2. Radioactive Material Used in a PNRI-Owned Laboratory or Under a PNRI Contract.**

- (a) Any person is exempt from the requirements for a license set forth in this Part to the extent that such person operates a PNRI-owned laboratory, or conducts activities on behalf of the PNRI.
- (b) 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 PNRI. 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.

### **7.3. Carriers.**

Common and contract carriers, freight forwarders, are exempted from the requirements for a license, to the extent that they transport radioactive material in the regular course of carriage for another or storage incident thereto.

#### **7.4. Source Material and Ores Containing Source Material.**

- (a) 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 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.
- (b) 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 PNRI pursuant to the regulations in this Part.

#### **7.5. Consumer Products Containing Radioactive Material.**

- (a) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following consumer products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:
  - (1) Smoke detectors containing americium-241;
  - (2) Luminous clocks and watches containing a small quantity of hydrogen-3 (tritium) or promethium-147 or older watches and clocks (made before 1970) which may contain radium-226;
  - (3) Older camera lenses incorporated with thorium;
  - (4) Gas lantern mantles that generate light by heating thorium-232;
  - (5) Ceramics materials such as tiles and pottery that contain elevated levels of naturally occurring uranium, thorium, and/or potassium;
  - (6) Glassware containing uranium, potassium-40 or thorium-232;
  - (7) Commercial fertilizers containing varying levels of radioactive potassium, phosphorous, and nitrogen; and
  - (8) EXIT signs containing the radioactive gas tritium.

#### **Section 8. *Additional Regulatory Requirements.***

The PNRI may impose upon the applicant or licensee, by appropriate rule, regulation, or order after due process or consultation, such requirements in addition to those established in this Part as it deems appropriate or necessary to protect the health and safety of the workers, public and the environment, or minimize danger to life or property and ensure the security of radioactive sources.

## **II. REQUIREMENTS FOR RADIOACTIVE MATERIAL LICENSE**

#### **Section 9. *Practices Requiring a Radioactive Material License.***

The following practices require a radioactive material license:

- (1) Medical use of unsealed radioactive materials in nuclear medicine, including radioimmunoassay and Positron Emission Tomography (PET);
- (2) Medical use of sealed sources in brachytherapy;
- (3) Use of sealed sources in industrial radiography;
- (4) Use of sealed sources contained in industrial devices;
- (5) Use of sealed sources in blood irradiators;
- (6) Use of radioactive materials for education and training;
- (7) Commercial sale and distribution of radioactive materials and its associated devices;
- (8) Manufacture and dispense of radiopharmaceuticals;
- (9) Use of radioactive materials by commercial providers of nuclear technical services; and
- (10) Any other practice as will be determined by the PNRI.

**Section 10. Application for New License.**

- (a) An application for a radioactive material license shall include the following:
  - (1) Duly accomplished, signed by the head of the company, and notarized *PNRI/NRD Form – 01, "Application for Radioactive Material License"*;
  - (2) Copy of current business permit issued by the responsible government agency and a proof of authenticity of business name; and
  - (3) Payment of license fees and other charges in accordance with **CPR Part 22**, "Fees and Charges for Radioactive Material Licenses and Other Related Regulatory Services".
- (b) The application shall adequately describe the following information required in the application form:
  - (1) Name and address of the applicant, including the name and address of the principal officer, and the location where the radioactive material will be used;
  - (2) Name, title and training of the individual/s who will use and/or directly supervise the use of radioactive material with documentation of qualification, training, and experience requirements;
  - (3) Name of the Radiation Protection Officer (RPO) and Assistant RPO with documentation of qualification, training, and experience requirements;
  - (4) Description of the radioactive material (element and mass number); the chemical and/or physical form and maximum number of becquerels of each radioactive material; and purpose for which the radioactive material is to be used; and
  - (5) Description of the radiation detection instruments; type, use, and sensitivity range; and the method, frequency and standards used in calibrating radiation detection instruments.
- (c) The following documents shall be submitted along with the application form:
  - (1) Radiation Safety Management Plan;
  - (2) Radiation Protection and Safety Program;
  - (3) Emergency Preparedness and Response Plan;
  - (4) Security Plan, as applicable; and
  - (5) Radioactive Waste Management Program.



Section 11. ***Review, Evaluation and Verification of License Application.***

- (a) The application will be accepted and processed only when it is deemed by PNRI to be complete in substance and form and accompanied by proof of payment of the corresponding application fee.
- (b) The PNRI may, at any time after the filing of the application, require further information to enable PNRI to determine whether the license shall be granted or denied.
- (c) The PNRI may verify information contained in applications and secure additional information deemed necessary by conducting a pre-licensing inspection on the facility or location.

Section 12. ***Issuance of Radioactive Material License.***

The PNRI shall issue a Radioactive Material License in such form and containing such conditions and limitations, as it deems appropriate and necessary, upon determining that:

- (1) The application is for a purpose authorized by the Act;
- (2) The application is complete in substance and form and the proposed equipment, facilities and procedures are adequate to protect health and minimize danger to life or property as well as to ensure the security of the radioactive sources;
- (3) The applicant is qualified by reason of training and experience to use the radioactive material/s for the purpose requested;
- (4) The issuance of the license will not pose undue risk to the health and safety of the workers, the public and the environment;
- (5) The applicant satisfies all the applicable administrative and technical requirements of other practice-specific Code of PNRI Regulations;
- (6) The applicant has paid the required license fee and other charges, if any, in accordance with the **CPR Part 22**.

Section 13. ***Terms and Conditions of Radioactive Material License.***

- (a) Each license shall be subjected to the provisions of the Act, the specific conditions of the license, and to applicable rules, regulations, and orders of PNRI.
- (b) The Radioactive Material License shall be valid for a period of **three (3) or five (5) years**: provided, however, that the PNRI in its discretion may limit the period of validity to less than three (3) or five (5) years if the licensee was found to have recurring non-compliance(s) with safety and security implication(s). The validity period for different practices and activities requiring a Radioactive Material License is found in **Annex 1**.
- (c) The Radioactive Material License 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 the PNRI in accordance with the terms of the Act.
- (d) The Radioactive Material License, including any right thereunder, shall not be transferred nor assigned in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless that person has been granted a new license in accordance with the requirements in **Section 10** of this Part.
- (e) The use, possession and storage of the radioactive materials shall be confined to the locations authorized in the license.

- (f) The licensee shall maintain a current and valid license at all times. A copy of the license shall be conspicuously posted in the premises where authorized activities are conducted and applicable CPRs shall be kept and be made available at each authorized location.
- (g) The licensee shall notify PNRI immediately in writing following the filing of a voluntary or involuntary petition for bankruptcy under existing Philippine laws.

**Section 14. *Amendment of Radioactive Material License.***

- (a) An application for amendment of license shall be made by submitting the following:
  - (1) Duly accomplished, signed by the head of the company, and notarized PNRI/NRD Form – 01, "Application for Radioactive Material License";
  - (2) The details of the proposed amendment and the assessment of its impact on safety and security, if applicable; and
  - (3) Payment of applicable amendment fee required in **CPR Part 22**.
- (b) A licensee shall apply for and shall receive the amended license before:
  - (1) It permits anyone to work as Authorized Users, Radiation Protection Officer (RPO), Assistant Radiation Protection Officer (ARPO), and other personnel other than those previously authorized in the license;
  - (2) It possesses at any one-time radioactive material in excess of the activity authorized in the license;
  - (3) It leases, receives and uses radioactive material other than what is authorized in the license;
  - (4) It uses the radioactive material for purposes other than those specified in the license;
  - (5) It uses or stores radioactive material in locations other than those specified in the license; or
  - (6) It implements any major change in the equipment and facilities, or in the approved programs and plans.
- (c) In determining whether an application for an amendment of a license will be granted, the PNRI will be guided by the considerations that govern the issuance of the initial license, to the extent applicable and appropriate.

**Section 15. *Renewal of Radioactive Material License.***

- (a) An application for license renewal shall be made by submitting the following not less than **sixty (60) days** before the expiration date of the license:
  - (1) Duly accomplished, signed by the head of the company, and notarized PNRI/NRD Form – 01, "Application for Radioactive Material License";
  - (2) A complete and up-to-date information and documentation as required in this Part, if many outdated documents are referenced or there had been changes in the regulatory requirements, the licensee's organization, or the required programs and plans; and
  - (3) Payment of license renewal fee and other outstanding regulatory fees in accordance with **CPR Part 22**.

- (b) An application for license renewal that is filed less than sixty (60) days before the expiration date of the license shall be subjected to a surcharge equivalent to **twenty-five percent (25%)** of the required license renewal fee.
- (c) An application for license renewal that is filed after the expiration date of the license shall be assessed a surcharge equivalent to **fifty percent (50%)** of the prescribed license renewal fee. In addition to the written application, the licensee is required to:
  - (1) Discontinue the conduct of licensed activities until the PNRI issued the renewed license.
  - (2) Ensure that all radioactive sources are safe in their authorized storage locations; and
  - (3) Submit a written explanation about the delay in the filing of application and a justification on why PNRI should not impose the appropriate administrative action against the licensee.

**Section 16. *Expiration of Radioactive Material License.***

- (a) A Radioactive Material License shall expire at the end of the day, in the month and year stated therein.
- (b) Upon expiration of the license, the licensee is required to discontinue the conduct of licensed activities and ensure that all radioactive sources are safe in their authorized storage locations.
- (c) The PNRI may, if necessary to protect the public health and safety or the national interest, take temporary custody of any radioactive material held by the licensee pending its appropriate and lawful disposition by or for the licensee.
- (d) If a license has expired and the licensee has not requested a renewal of the license within **thirty (30) days** after the expiry date, the PNRI shall issue a Notice of Violation and require the licensee to submit a written explanation why an Order to place the radioactive material under temporary regulatory custody should not be issued.
- (e) If a licensee decides not to renew its license, the licensee shall request, in writing, the termination of the license in accordance with **Section 17** of this Part.

**Section 17. *Termination of Radioactive Material License.***

- (a) When a licensee decides to permanently discontinue activities involving a radioactive material authorized under the license, the licensee shall immediately notify the PNRI, in writing, of its intent to terminate. During this time, the licensee shall:
  - (1) Cease to engage in any licensed activity involving the radioactive material except to keep the radioactive material under safe and secure storage;
  - (2) Transfer or dispose all radioactive material to an entity licensed to receive and possess the same specified radioactive material, such as the original manufacturer or supplier, another specific licensee, or a licensed radioactive waste management facility. Obtain proof of transfer or disposal from the final recipient of the radioactive material; and
  - (3) Perform a contamination survey of the premises where licensed activities were carried out. If contamination is found, the licensee shall decontaminate the areas until no removable contamination is present. The licensee shall document all wipe assays and decontamination activities.
- (b) To be relieved of the responsibility for the material and the other conditions in his license, the licensee shall submit a written request for termination of the license to PNRI. The letter shall be accompanied by the following:

- (1) An inventory of radioactive material transferred or disposed and the method of disposal for each item;
  - (2) Proof of transfer or disposal of radioactive material;
  - (3) A final contamination survey report of the premises; and
  - (4) An agreement that records and facilities will be available for inspection by PNRI at a mutually agreed date within the next **six (6) months**.
- (c) The PNRI may verify information contained in the request for termination and secure additional information deemed necessary by conducting a termination inspection on the facility or location.
- (d) The PNRI will officially terminate the license by issuing a formal notice when the following conditions are satisfactorily met:
- (1) If the licensee is no longer in possession of any radioactive material that requires a license; and
  - (2) If the premises are not contaminated and are suitable for release.
- (e) The licensee shall cause the proper termination of his license in accordance with this Section within **one (1) year** after the expiration of the license.
- (f) Failure to legally terminate a Radioactive Material License shall be subject to the penal provisions provided in Section 64 of the Act, as amended.

### **III. REQUIREMENTS FOR LICENSE TO OPERATE A RADIATION FACILITY**

#### **Section 18. *Radiation Facilities Requiring a License to Operate.***

- (a) The following radiation facilities require a License to Operate:
- (1) Gamma irradiation facility;
  - (2) Teletherapy facility utilizing radioactive sources;
  - (3) Radioactive waste management facility;
  - (4) Particle accelerator facility for the production of radionuclides; and
  - (5) Any other radiation facility, other than nuclear installations, as may be determined by the PNRI.
- (b) No person may begin the commissioning or operation of a radiation facility until that person has been issued a License to Operate in accordance with this Part.

#### **Section 19. *Application for License to Operate.***

- (a) An application for a License to Operate shall include the following:
- (1) Duly accomplished, signed by the head of the company, and notarized *PNRI/NRD Form – 02, "Application for License to Operate"*;
  - (2) Copy of current business permit issued by the responsible government agency and a proof of authenticity of business name; and
  - (3) Payment of license fees and other charges in accordance with **CPR Part 22**.

- (b) The application shall adequately describe the following information required in the application form:
- (1) Name of the applicant, business address, citizenship (if the applicant is an individual), and the names, addresses and citizenship of its principal officers;
  - (2) Brief description of the nature of the proposed radiation facility, its technical characteristics and specifications, the operating principles, the operations to be performed in it;
  - (3) Name, title and training of the individual/s who will use and/or directly supervise the operation of the radiation facility with documentation of qualification, training, and experience requirements;
  - (4) Name of the Radiation Protection Officer (RPO) and Assistant RPO with documentation of qualification, training, and experience requirements;
  - (5) Description of the radioactive source (element and mass number); the maximum activity; the chemical and/or physical form; and purpose for which the radioactive material is to be used;
  - (6) A map of the location and a site plan indicating the areas, structures, systems and perimeter of the proposed facility, including the buildings, if any, with their current uses;
  - (7) Description of the radiation detection instruments; type, use, and sensitivity range; and the method, frequency and standards used in calibrating radiation detection instruments;
  - (8) Information sufficient to demonstrate the technical qualification of the applicant to carry out the proposed activities;
  - (9) Information describing its human resource requirements;
  - (10) Information on the contractors and a description of responsibilities between the applicant and any contractors responsible for the siting, design, construction and operation of the proposed radiation facility;
  - (11) Information describing the applicant's projected financial resource requirements necessary to, as applicable:
    - (i) Cover estimated construction costs and radioactive source costs;
    - (ii) Cover estimated operation costs for the period of the license; and
    - (iii) Cover estimated decommissioning costs of the facility, including the management of the resulting radioactive waste and disused sources.
- (c) The following documents shall be submitted along with the application form:
- (1) Radiation Safety Management Plan;
  - (2) Environmental Compliance Certificate, and a copy of the Environmental Impact Assessment Report;
  - (3) Radiation Protection and Safety Program;
  - (4) Safety Analysis Report;
  - (5) Emergency Preparedness and Response Plan;
  - (6) Security Plan;
  - (7) Environmental Monitoring Program;
  - (8) Radioactive Waste Management Program; and
  - (9) Decommissioning Plan.

Section 20. ***Review, Evaluation and Verification of License Application.***

- (a) The application will be accepted and processed only when it is deemed by PNRI to be complete in substance and form and accompanied by proof of payment of the corresponding application fee.
- (b) The PNRI may, at any time after the filing of the application, require further information to enable PNRI to determine whether the license shall be granted or denied.
- (c) The PNRI may verify information contained in applications and secure additional information deemed necessary by conducting a pre-licensing inspection on the facility or location.

Section 21. ***Issuance of a Provisional License.***

- (a) Upon the request of the applicant and subject to the conditions set forth of this Part, the PNRI may issue a **Provisional License** to the applicant prior to the issuance of a License to Operate if the application is otherwise acceptable, to authorize commencement of construction.
- (b) The PNRI shall issue a Provisional License in such form and containing such conditions and limitations, as it deems appropriate and necessary, upon determining that:
  - (1) The application is for the purpose authorized by the Act; and
  - (2) There is reasonable assurance that the proposed radiation facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.
- (c) Such a provisional license may be granted even if the health and safety information then available is less than would be needed for a License to Operate provided that the PNRI is satisfied that there is reasonable assurance that questions of health and safety will be so resolved as to warrant the issuance of a License to Operate.
- (d) Any activities undertaken prior to the issuance of the License to Operate are entirely at the risk of the applicant and have no bearing on the issuance of a License to Operate with respect to the requirements of the Act, as amended, and rules, regulations, and orders issued under the Act.

Section 22. ***Issuance of License to Operate.***

The PNRI shall issue a License to Operate in such form and containing such conditions and limitations, as it deems appropriate and necessary, upon determining that:

- (1) The application is for the purpose authorized by the Act;
- (2) The application is complete in substance and form and the proposed equipment, facilities and procedures are adequate to protect health and minimize danger to life or property as well as to ensure the security of the radioactive sources;
- (3) All information required in the Safety Assessment Report have been submitted and are acceptable to PNRI;
- (4) The applicant has adequate human resources to safely operate and maintain the radiation facility;
- (5) The proposed radiation facility is designed in accordance with the relevant site parameters identified by the applicant and agreed with the PNRI, and in an adequate manner;

- (6) Radiological monitoring equipment and devices are clearly defined, and will be installed and operational before the radioactive source is brought onto the facility;
- (7) Provisions are made in the design to account for security aspects to minimize potential conflicts between safety and security considerations;
- (8) There are no unresolved safety issues relating to the activities to be conducted under the License to Operate that would constitute good cause for withholding the license;
- (9) The applicant has satisfied all the applicable administrative and technical requirements of other practice-specific Code of PNRI Regulations applicable to the activities to be conducted under the License, and that notifications, if any, to other agencies or bodies have been duly made; and
- (10) The applicant has paid the required license fee and other charges, if any, in accordance with the **CPR Part 22**.

**Section 23. Terms and Conditions of License to Operate.**

- (a) The License to Operate shall be subject to the provisions of the Act now or hereafter in effect, the general and specific conditions of the license, and to all applicable rules, regulations, and orders of the PNRI.
- (b) The License to Operate shall be valid for a period of not more than **five (5) years**: provided, however, that the PNRI in its discretion may limit the period of validity to less than five (5) years if the licensee was found to have recurring non-compliance(s) with safety and security implication(s). The validity period for radiation facilities requiring a Radioactive Material License is found in **Annex 1**.
- (c) The License to Operate 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 the PNRI in accordance with the terms of the Act.
- (d) The License to Operate, including any right thereunder, shall not be transferred nor assigned in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless that person has been granted a new License to Operate in accordance with the requirements in **Section 19** of this Part.
- (e) The use, possession and storage of the radioactive sources shall be confined to the location authorized in the license.
- (f) The licensee shall maintain a current and valid license at all times. A copy of the license shall be displayed in a conspicuous area within the radiation facility and all applicable regulations of the Code shall be kept and made available.
- (g) The licensee shall notify the PNRI immediately in writing following the filing of a voluntary or involuntary petition for bankruptcy under existing Philippine laws.

**Section 24. Amendment of License to Operate.**

- (a) An application for amendment of license shall be made by submitting the following:
  - (1) Duly accomplished, signed by the head of the company, and notarized *PNRI/NRD Form – 02, "Application for License to Operate"*;
  - (2) The details of the proposed amendment, the assessment of its impact on safety and security, if applicable, and the justification for such amendment; and
  - (3) Payment of the applicable amendment fee required in **CPR Part 22**.

- (b) The licensee shall apply for and must receive the amended license before:
- (1) It permits anyone to work as Authorized Operators, Radiation Protection Officer (RPO), Assistant Radiation Protection Officer (ARPO), and other personnel other than those previously authorized in the license;
  - (2) It possesses at any one-time radioactive material in excess of the activity authorized in the license;
  - (3) It leases, receives and uses radioactive material other than what is authorized in the license;
  - (4) It uses the radioactive material for purposes other than those specified in the license;
  - (5) It uses or stores radioactive material in locations other than those specified in the license;
  - (6) It incorporates any modification in the approved design or licensing basis of the radiation facility;
  - (7) It implements any major change in the equipment related to safety, or in the approved programs and plans; or
  - (8) It implements any substantial change in any condition of the license that takes effect, in consultation with PNRI.
- (c) In determining whether an application for an amendment of a license will be granted, the PNRI will be guided by the considerations that govern the issuance of the initial license, to the extent applicable and appropriate.
- (d) The PNRI may make a final determination that a proposed amendment to a License to Operate involves no significant hazards consideration in the operation of the radiation facility in accordance with the proposed amendment.

**Section 25. Renewal of License to Operate.**

- (a) An application for license renewal shall be made by submitting the following not less than **sixty (60) days** before the expiration date of the license:
- (1) Duly accomplished, signed by the head of the company, and notarized *PNRI/NRD Form – 02, "Application for License to Operate"*;
  - (2) A complete and up-to-date information and documentation as required in this Part, if many outdated documents are referenced or there had been changes in the regulatory requirements, the licensee's organization, or the required programs and plans; and
  - (3) Payment of license renewal fee and other outstanding regulatory fees in accordance with **CPR Part 22**.
- (b) An application for license renewal that is filed less than sixty (60) days before the expiration date of the license shall be subjected to a surcharge equivalent to **twenty-five percent (25%)** of the required license renewal fee.
- (c) An application for license renewal that is filed after the expiration date of the license shall be assessed a surcharge equivalent to **fifty percent (50%)** of the prescribed license renewal fee. In addition to the written application, the licensee is required to:
- (1) Discontinue the operation of the radiation facility until the PNRI issued the renewed license;
  - (2) Ensure that all radioactive sources are safe in their authorized storage locations; and



- (3) Submit a written explanation about the delay in the filing of application and the reason why PNRI should not impose the appropriate administrative action against the licensee.

**Section 26. *Expiration of License to Operate.***

- (a) A License to Operate shall expire at the end of the day, in the month and year stated therein.
- (b) Upon expiration of the license, the licensee shall discontinue the operation of the radiation facility and shall ensure that all radioactive sources are safe and secure in their authorized storage locations.
- (c) The PNRI may, if necessary to protect the public health and safety or the national interest, take temporary custody of any radioactive material or facilities held by the licensee pending their appropriate and lawful disposition by or for the licensee.
- (d) If the license has expired and the licensee has not requested a renewal of the license within **thirty (30) days** after the expiry date, the PNRI shall issue a Notice of Violation and require the licensee to submit a written explanation why an Order to place the radiation facility under temporary regulatory custody should not be issued.
- (e) If the licensee does not submit an application for license renewal and has decided to permanently cease operations, the License to Operate continues in effect beyond the expiration date to authorize ownership and possession of the radioactive source/s, notify the PNRI for the termination of license
- (f) If a licensee decides not to renew its expired license, the licensee shall request, in writing, the termination of the license in accordance with **Section 27** of this Part.

**Section 27. *Termination of License to Operate.***

- (a) When a licensee has decided to permanently cease operations, the licensee shall, within **30 days**, notify the PNRI, in writing, of its intent to terminate and request to modify the license to authorize ownership and possession of the radioactive source/s. During this time, the licensee shall:
  - (1) Submit an updated Decommissioning Plan, and notify all interested parties of the plan;
  - (2) Cease to engage in any licensed activity involving the radioactive material except to keep the radioactive material under safe and secure storage;
  - (3) Continue to control entry to restricted areas; and
  - (4) Transfer or dispose all radioactive material to an entity licensed to receive and possess the same specified radioactive material, such as the original manufacturer or supplier, another specific licensee, or a licensed radioactive waste management facility. The licensee shall obtain proof of transfer or disposal from the final recipient of the radioactive material.
- (b) The Decommissioning Plan shall include:
  - (1) A description of the controls and limits on procedures and equipment to protect occupational and public health and safety;
  - (2) A description of the planned final radiation survey;
  - (3) An updated cost estimate for the decommissioning activities, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning; and

- (4) A description of technical specifications, quality assurance provisions and physical security plan provisions in place during decommissioning.
- (c) If the Decommissioning Plan demonstrates that the decommissioning will be performed in accordance with the radiation protection and safety requirements, and after notice to interested parties, the PNRI will approve, by amendment, the plan subject to such conditions and limitations as it deems appropriate and necessary.
- (d) Within **sixty (60) days** after the approval of the Decommissioning Plan, the licensee shall begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, including management of radioactive waste, in compliance with applicable regulations.
- (e) On the completion of decommissioning activities, the licensee shall submit a written request for termination of the license to PNRI. The letter shall be accompanied by the following:
- (1) A final decommissioning report to demonstrate that the end state of the facility as specified in the approved Decommissioning Plan has been reached;
  - (2) An inventory of radioactive material transferred or disposed, and proof of transfer or disposal of radioactive material; and
  - (3) An agreement that records and facilities will be available for inspection by PNRI at a mutually agreed date within the next **twelve (12) months**.
- (f) The PNRI may verify information contained in the request for termination and secure additional information deemed necessary by conducting a termination inspection on the facility or site.
- (g) The PNRI will officially terminate the license by issuing a formal notice if it determines that—
- (1) The licensee is no longer in possession of any radioactive material that requires a license;
  - (2) The decommissioning has been performed in accordance with the approved decommissioning plan; and
  - (3) The terminal radiation survey and associated documentation demonstrate that the facility and site are suitable for release.
- (h) The licensee shall cause the proper termination of his license in accordance with this Section within **two (2) years** following permanent cessation of operations, and in no case later than **one (1) year** after the expiration of the License to Operate.
- (i) Failure to legally terminate a license to operate a radiation facility shall be subject to the penal provisions provided in **Section 64** of the Act.

#### IV. INSPECTION AND ENFORCEMENT

##### Section 28. *Inspection.*

- (a) The licensee shall afford to authorized PNRI Inspectors the opportunity to enter its premises, at all reasonable times, and to perform inspections as may be necessary, announced or unannounced, of the radioactive materials in possession and the premises, equipment and activities related to the licensed facility as may be necessary to effectuate the purposes of the Act, as amended.
- (b) The licensee shall cooperate in the conduct of inspections and shall provide to the PNRI Inspectors, on demand, all kinds of data, information, and full access to all relevant records kept pursuant to these rules and regulations without any obstruction or delay.
- (c) In case of any resistance during entry and inspection, or in case of locked premises, the PNRI Inspectors shall make reasonable efforts of coordinating with the owner before entering the premises and may seek assistance of the local government unit or the local police upon the approval of the PNRI Director.

##### Section 29. *Violations and Issuance of Notice of Violation.*

- (a) The licensee shall be subject to enforcement actions upon any one of the following grounds:
  - (1) The licensee has violated any of the provisions of the Act, the rules and regulations made thereunder, any of the terms, conditions, limitations of the license, or any of the orders issued by the PNRI;
  - (2) Action or inaction of the licensee has resulted in the breach of any of the provisions of the Act or the rules and regulations in the Code of PNRI Regulations;
  - (3) If any of the allegation of possible violations to any of the provisions of the Act, or the rules and regulations in the Code of PNRI Regulations, is determined by the PNRI to be correct; or
  - (4) A default in payment of fee or any other dues imposed by the PNRI.
- (b) A Notice of Violation shall be issued if a licensee is found to have violated any of the provisions of the Act, the rules and regulations made thereunder, any of the terms, conditions, limitations of the license, or any of the orders issued by the PNRI.
- (c) A licensee who receives a Notice of Violation shall show cause why PNRI should not impose further enforcement action and shall submit a written reply within ten (10) days, containing:
  - (1) An explanation why or how the violation occurred or, if contested, the basis for disputing the violation;
  - (2) Corrective actions made and the results achieved;
  - (3) Corrective measures to be taken to prevent recurrence; and
  - (4) The date when full compliance will be achieved.
- (d) The licensee shall ensure that the corrective actions would restore safety, security and compliance with the license conditions, regulations, or other requirements.
- (e) The licensee shall develop and implement, in a timely manner, corrective measures that will not only prevent recurrence of the subject violation, but will be appropriately comprehensive, given the significance and complexity of the violation to prevent occurrence of violations with similar root causes.

- (f) The PNRI shall evaluate the corrective actions implemented by the licensee as part of the process of assessing further enforcement actions against the licensee.

**Section 30. Issuance of Orders and Related Administrative Sanctions.**

- (a) Any license may be modified, suspended, or revoked, 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 PNRI.
- (b) Any license may be suspended or revoked if the PNRI has identified deliberate misconduct that may cause a licensee to violate a regulatory requirement, or where incomplete or inaccurate information is deliberately submitted, or where the PNRI is not assured that the licensee, or any of its authorized personnel, will meet PNRI requirements.
- (c) A License Modification Order shall be issued:
- (1) When the licensee takes upon itself to implement changes in its equipment, program, procedures, or management control without prior approval from the PNRI; and
  - (2) When PNRI determines that the licensee can no longer comply with the safety requirements specified in the license, or, on any privilege granted in the license.
- (d) A Suspension Order shall be issued:
- (1) To remove a threat to public health and safety, security of radioactive sources, the environment or the national interest;
  - (2) To stop the construction of a facility when further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component;
  - (3) When the PNRI determines that the implementation of the licensee's quality assurance or Radiation Protection And Safety Program is not adequate to provide the needed confidence that safety measures can be properly carried out;
  - (4) When the licensee has not responded adequately to a previous enforcement action;
  - (5) When the licensee interferes with the conduct of an inspection or investigation; or
  - (6) For any reason not mentioned above for which license suspension is legally authorized under Section 27 of the Atomic Energy Regulatory and Liability Act of 1958, "R.A No. 5207", as amended.
- (e) A Cease-and-Desist Order shall be issued to any licensee to stop an unauthorized or unsafe activity that has continued after notification by the PNRI that the activity is unauthorized or unsafe, and/or a suspension order has not been followed.
- (f) A Revocation Order shall be issued:
- (1) When a licensee refuses to correct a violation;
  - (2) When a licensee does not respond to a Notice of Violation where a response was required;
  - (3) When a certain violation has been repeated at least three (3) times, as determined by the PNRI;
  - (4) When a licensee refuses to pay any prescribed fee under the PNRI regulations; or
  - (5) For any other reason for which revocation is authorized under Section 27 R.A No. 5207, as amended.

- (g) An Order to take temporary custody of any radioactive material or radiation facility held by the licensee may be issued to a licensee when the license has been suspended or revoked or when the PNRI has identified a deliberate misconduct or violation of requirements to remove a threat to public health, safety and security.
- (h) A Lifting Order shall be issued when the PNRI determines full compliance with regulatory requirements and the licensee's response and corrective actions are deemed acceptable.

Section 31. ***Administrative Sanctions.***

- (a) In addition to Notices of Violations and Orders, the PNRI may use administrative regulatory sanctions to supplement its enforcement program in the form of:
  - (1) **Confirmatory Action Letters** confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety or the environment;
  - (2) **Letters of Reprimand** addressed to the licensee identifying a significant deficiency in the performance of licensed activities; and
  - (3) **Demand Letters** to the licensee for information for the purpose of enabling the PNRI to determine whether an order or other enforcement action should be issued.
- (b) The licensee shall adhere to any obligations and commitments resulting from these sanctions and shall ensure that they are met.

Section 32. ***Protective Measures in Cases of Suspension, Revocation or Expiration of License.***

- (a) Upon the suspension or revocation of a license, pursuant to an Order, the PNRI shall take, or shall require the licensee to take, such measures as may be necessary to protect the health, safety and security of the public or the national interest.
- (b) The PNRI may, if necessary to protect the public health, safety and security or the national interest, take temporary custody of any radioactive material or radiation facilities held by the licensee pending full compliance with regulatory requirements at which time, the suspension or revocation may be lifted or a new license, upon due application, is issued.
- (c) Orders are made effective immediately whenever it is determined that the interest of public health, safety, or security so requires, or when the order is responding to a violation involving willfulness.

Section 33. ***Right to Withhold or Recall Radioactive Material.***

The PNRI 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 PNRI, 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 PNRI.

## V. EFFECTIVITY

Section 34. ***Effectivity Date.***

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

**CARLO A. ARCILLA, Ph. D.**  
Director, PNRI

Date of Approval:

\_\_\_\_\_

DRAFT

DRAFT