

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

**LICENSING AND SAFETY REQUIREMENTS OF
PARTICLE ACCELERATOR FACILITIES FOR THE
PRODUCTION OF RADIOISOTOPES**

CPR PART 21

I. GENERAL PROVISIONS

SECTION 1. Purpose and Scope.

- a) The regulations in this Part establish the requirements for licensing the construction and operation of a particle accelerator facility for the production of radioisotopes, and safety requirements in connection with the construction, installation, operation, and decommissioning of such facility pursuant to the provisions of Republic Act No. 5207, as amended.
- b) This Part provides for the protection of the health and safety of the public and workers and are in addition to, and not in substitution for, other Parts in the Code of PNRI Regulations (CPR).
- c) Relevant requirements of CPR Parts 2, 3, 4, 13 and 20 shall apply to certain practices incident to the operation of the particle accelerator, such as the processing, handling, dispensing, and transport of radioisotopes produced by the particle accelerator, and the therapeutic or diagnostic administration of the radioisotopes, unless specifically stated otherwise.

SECTION 2. Definitions.

As used in this Part;

- a) **“Accelerator” or “Particle Accelerator”** means any machine, device or equipment capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV;
- b) **“Act”** means Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended;
- c) **“CPR Part 2”** means the PNRI regulations, “Licensing of Radioactive Material”;
- d) **“CPR Part 3”** means the PNRI regulations, “Standards for Protection Against Radiation”;
- e) **“CPR Part 4”** means the “Rules and Regulations on the Safe Transport of Radioactive Materials in the Philippines”;
- f) **“CPR Part 13”** means the PNRI regulations, “Licenses for the Medical Use of Radiopharmaceuticals”;
- g) **“CPR Part 20”** means the PNRI regulations, “Licenses to Manufacture and Dispense Radiopharmaceuticals”;
- h) **“Commissioning”** means all the radiation and non-radiation tests that are performed on the facility to ensure that it is ready for routine operation;
- i) **“Operator”** means the individual who is qualified and trained to operate the accelerator facility;

- j) **“Particle Accelerator Facility”** means the facility containing a particle accelerator determined by PNRI as an atomic energy facility;
- k) **“RHSO”** means the individual designated in the license to be the Radiological Health and Safety Officer for the accelerator facility.

SECTION 3. Interpretation.

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

SECTION 4. Communication.

All communication and reports concerning the license and the regulations in this Part should be addressed to the PNRI Director and may be mailed to the Philippine Nuclear Research Institute, Commonwealth Avenue, Diliman, Quezon City 1101.

II. REQUIREMENTS FOR LICENSE

SECTION 10. Activities Requiring License.

- a) No person shall acquire, receive, possess, own, transfer, import or export, construct or operate a particle accelerator facility, for the purpose of producing radioisotopes for medical use, except as authorized in a license issued by PNRI pursuant to this Part and specific provisions of the Act.
- b) No license issued pursuant to this Part shall be granted to an alien, or any corporation or other entity that is owned or controlled by an alien, a foreign corporation, or a foreign government, unless otherwise exempted by law.
- c) An applicant will be issued a license for activities authorized under this Part if:
 - 1) The proposed activities are consistent with the policies declared under the Act;
 - 2) The applicant is technically and financially qualified to engage in the proposed activities in accordance with the requirements of this Part and applicable Parts of the Code;
 - 3) The proposed activities will not pose undue risk to the health and safety of the workers and the general public; and
 - 4) The applicant has financial security to fulfill the obligations for decommissioning and liability for damage to life or property arising from the operation of the facility.

SECTION 11. Specific Exemptions.

Upon request by the applicant or licensee or upon its own initiative, the PNRI may grant such exemptions from the requirements of the regulations in this Part provided that such exemptions are authorized by the Act, will not pose undue risk to the health and safety of the public, and are otherwise consistent with the national interest.

SECTION 12. General Requirements for the Issuance of a License.

- a) An application for a license to possess, own, construct and operate a particle accelerator facility pursuant to this Part shall be filed in writing and duly affirmed, with the Director, Philippine Nuclear Research Institute, Diliman, Quezon City.
- b) The application shall state the name and citizenship of applicant, address and all means of communication available with the applicant; description of business and names of principal officers; and sufficient information to demonstrate the financial and technical qualifications of the applicant to engage in the operation of an accelerator facility.

- c) The application must include a description of the facility, identifying the location, the immediate surroundings of the building and all features and components of the building that will be relevant to safety.
- d) The application must include a **Safety Analysis Report (SAR)** of the Accelerator Facility that is in accordance with the regulations of this Part. The form and content of the Safety Analysis Report, which specifies the conditions under which the facility will be constructed and operated, are described in the "Guide for the Preparation of an Application for Licensing a Particle Accelerator Facility for the Production of Radioisotopes".
- e) On the basis of the technical information and data made available by the applicant in accordance with (a), (b), (c) and (d) of this Section, a **Provisional License to Construct** that permits the commencement of construction activities shall be issued if:
 - 1) The applicant has submitted the organizational set-up and list of contractors, the site suitability and facility design information, civil works drawings and specifications, construction plans and the schedule of activities for construction, and initial technical information relevant to the facility;
 - 2) The schedule of construction activities are adequately defined according to specified phases of construction;
 - 3) Based on the information and data available and submitted, PNRI is assured that the proposed construction activities will not pose any undue risk to the safety of the public; and
 - 4) The proposed activities do not include those that will involve any operation of facility that will result in the production of radioisotopes.
- f) Upon satisfactory completion of activities under the provisional license to construct, the provisional license to construct will be converted to a **License to Construct** that will authorize succeeding phases of construction to be undertaken if:
 - 1) All information required in the Safety Analysis Report (SAR) for a construction approval have been submitted and are acceptable to PNRI;
 - 2) Construction activities under each phase are adequately described according to the approved schedule; and
 - 3) Construction activities are in accordance with the licensee's quality assurance program.
- g) The License to Construct will be converted to a **License to Operate for Commissioning** if:
 - 1) The licensee has submitted a **Final Construction Report** which shows that all phases of construction activities have been performed and completed as planned;
 - 2) The licensee has submitted a **Commissioning Plan** that stipulates the plans for pre-operational testing and initial operations of the facility; and the technical specifications and operating procedures of the facility;
 - 3) PNRI is assured that the commissioning plans are in accordance with the regulations and will not endanger the safety of the operators performing the tests and commissioning activities.
- h) The License to Operate for commissioning will be converted to a **License to Operate for Routine Operation** if:
 - 1) The licensee has submitted a **Commissioning Report** which gives assurance that the commissioning plans were performed as planned and that the safety features of the facility are operable;
 - 2) The proposed operators of the facility are qualified by training and experience to use the accelerator in accordance with this Part and other applicable regulations of the Code in a manner as to minimize danger to public health and safety or damage to property;
 - 3) The proposed accelerator facility, auxiliary equipment, Quality Assurance program for the

operation phase, Security Plan for the radioactive sources in the facility and Fire Protection Program are adequate to protect health and minimize danger to public health and safety or property;

- 4) The technical specifications and operating procedures of the facility are adequately established for the safe operation of the facility;
- 5) The licensee has submitted an adequate plan for the conduct of operations, including repair, maintenance, surveillance and periodic testing of equipment;
- 6) The licensee has submitted an emergency plan that will provide reasonable assurance that adequate protection and protective measures can and will be taken in the event of any emergency that could have radiological consequences;
- 7) The licensee has submitted a Physical Protection Program. The program shall identify the vital equipment, vital areas, and isolation zone and shall address tests, inspections, and other means to provide and ensure protection against potential sabotage and associated radiological consequences.
- 8) A qualified Radiological Health and Safety Officer (RHSO) and Assistant RHSO have been appointed, and have accepted their functions and responsibilities in writing ;
- 9) An adequate training program for the operators and technical staff of the particle accelerator has been developed and approved;
- 10) A Safety Committee has been established to review and evaluate the safe operation and maintenance of the accelerator facility;
- 11) PNRI has determined in the Safety Evaluation Report (SER) that the Safety Analysis Report is acceptable; and
- 12) The issuance of the license will not be inimical to the health and safety of the public and the national interest.

SECTION 13. *Regulatory Fees.*

- a) Each applicant for a license pursuant to this Part shall be charged the corresponding fee for each licensing procedure undertaken by PNRI in accordance with the Act.
- b) An application fee shall be charged and collected when PNRI formally accepts the application after finding that the application is sufficient in substance and form. The application fee shall not be refundable.
- c) The license fee for the grant of a license to operate shall be based on the full cost of the review and assessment of the application including the cost of all routine inspections conducted within the validity period of the license.
- d) Fees for applications for renewal of license, license amendment, other required approvals and requests for dismantling, decommissioning and termination of license shall be charged for the corresponding cost of review of the application and are payable upon notification by PNRI.
- e) Fees for non-routine inspections will be assessed on a per inspection basis and will be billed based on the full recovery cost.

SECTION 14. *Standards for the Issuance of Licenses.*

- a) In determining the grant of a license with authority to construct, PNRI will be guided by the suitability of the proposed site and structural stability in accordance with standards imposed by relevant government agencies; the adequacy of the systems and equipment proposed to be installed based on approved design and certified model; and the radiation protection criteria applied to the design and installation of shielding and for the protection of the public against the hazards of radiation.
- b) In determining the grant of a license to operate, PNRI will be guided by the following considerations:

- 1) The safety processes to be performed, the adequacy of operating procedures, the safety of the facility and auxiliary equipment, and the adequacy of the technical specifications for the operation of the facility;
- 2) The establishment of an approved fire protection program and emergency plan for the facility;
- 3) The establishment of an approved security plan for the prevention of unauthorized access to the facility or theft of radioactive sources for possible unauthorized use.
- 4) The qualifications of the designated individuals authorized to operate and use the facility;
- 5) The compliance with specific industry codes and standards addressed by the applicant; and
- 6) The commitment to submit a decommissioning plan twenty-four (24) months before the scheduled activity.

III. SPECIFIC LIMITATIONS AND CONDITIONS OF THE LICENSE

SECTION 21. *Issuance of License.*

Any license issued pursuant to this Part shall be subject to all the provisions of the Act, now or hereafter in effect, the requirements of this Part and all applicable PNRI rules, orders, and regulations of the CPR.

SECTION 22. *Period of the License to Operate and Renewal of License.*

- a) The initial license to operate issued pursuant to this Part for the operation of an accelerator facility shall be valid for a maximum period of **five (5) years** and for five (5) years thereafter upon renewal of the license.
- b) An application for the renewal of the license to operate must be filed not less than sixty (60) calendar days before the expiration date indicated in the license.
- c) In determining the grant of the renewal of a license, PNRI shall be guided by the technical information submitted by the licensee in support of the application for renewal. The regulatory guide discussed in this Part shall be addressed.

SECTION 23. *Regulatory Review and Assessment.*

As an integral part for the determination on whether or not the application for a license or amendment thereto shall be granted or denied, the Safety Analysis Report and all other information pertinent to the application shall be subjected to a technical review by the PNRI regulatory staff, utilizing applicable standards and guidelines, including other standards adopted by the applicant.

SECTION 24. *Amendment of License.*

- a) An application for an amendment of the license to operate shall specify the particulars in which the applicant desires his license to be amended and the grounds for such amendment. The application for amendment of the license shall follow, as far as applicable, the form prescribed for an original application.
- b) In determining whether or not an application for an amendment of a license will be granted, PNRI will be guided by the rules that govern the issuance of the initial license, as may be appropriate.

IV. TECHNICAL REQUIREMENTS

SECTION 31. *General Safety Considerations.*

- a) Each licensee shall have established workload of the facility which shall correspond adequately to the shielding design.
- b) Each licensee shall establish a radiation protection program in accordance with the requirements of CPR Part 3.
- c) Each licensee shall provide each authorized personnel suitable personnel monitoring devices and radiation detection and measurement instruments that shall be periodically calibrated for the appropriate radiations and energies of radiation produced by the particle accelerator facility.
- d) The particle accelerator facility shall be provided with such primary and/or secondary barriers as necessary to assure compliance with dose limitations prescribed in CPR Part 3.
- e) The particle accelerator facility shall be provided with safety interlocks which shall be designed so that any defect or component failure in the safety interlock system will prevent the operation of the accelerator.

SECTION 32. *Particle Accelerator Controls and Interlock Systems.*

- a) All safety interlocks installed in the facility must be fail-safe and in accordance with appropriate standards.
- b) Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernable.
- c) Each entrance into a target room or other high radiation area shall be provided with an interlock system that shuts down the machine under conditions of barrier penetration.
- d) Each safety interlock shall be on a circuit that shall allow it to operate independent of all other safety interlocks.
- e) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.
- f) When safety interlock has been tripped, it shall only be possible to resume operation of the accelerator by first, manually resetting controls at the position where the safety interlock has been tripped, lastly, at the main control console.
- g) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

SECTION 33. *Warning Signages and Devices.*

- a) Each location designated as high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.
- b) Each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of prompt radiation. Such warning device shall be clearly discernible in all high radiation areas.
- c) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted

in accordance with CPR Part 3.

SECTION 34. Operation of the Facility.

- a) The particle accelerator, when not in operation, shall be secured to prevent its unauthorized use.
- b) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency, or to undertake any test the interlocks.
- c) The interlocks may be prevented from operation only to test, adjust, maintain, and/or rearrange equipment provided that a clear indication of such condition is made at the control panel.
- d) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:
 - 1) Authorized in writing by the RHSO;
 - 2) Recorded in a permanent log and a notice posted at the accelerator control console; and
 - 3) Terminated as soon as possible.
- e) All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed 3 months. Results of such tests shall be maintained at the accelerator facility for regulatory inspection.
- f) Electrical circuit diagrams of the accelerator and the associated safety interlocks shall be kept current and maintained for regulatory inspection.
- g) No individual shall be permitted to enter an area, the access of which is controlled by interlocks while such interlocks are prevented from operation, to test, adjust, maintain, and/or rearrange equipment and/or parts of the particle accelerator unless such individual is utilizing appropriate personnel monitoring equipment which will give an audible indication when a dose-rate of **0.25 milligray per hour** is exceeded. The personnel monitoring equipment referred to in this paragraph is in addition to those required elsewhere in this Part.
- h) A copy of the current operating and emergency procedures shall be maintained and kept in an appropriate location, such as the accelerator control panel.

SECTION 35. Operating and Emergency Procedures.

The operating and emergency procedures shall include instructions in at least the following:

- a) Minimizing exposure of operators and staff to radiation doses in excess of the limits established in CPR Part 3;
- b) Methods and frequency for conducting radiation surveys;
- c) Methods for controlling access to high radiation areas;
- d) Methods for locking the control panel of the particle accelerator;
- e) Personnel monitoring and use of personnel monitoring equipment;
- f) Minimizing exposure of persons in the event of an accident;
- g) Notification of the proper persons in the event of an accident; and
- h) Maintenance of records.

SECTION 36. *Radiation Survey Requirements.*

- a) There shall always be available at the particle accelerator facility appropriate monitoring equipment that is operable and has been appropriately calibrated for the radiation being produced at the facility. Such equipment shall be calibrated for proper operation before first use, after each repair, every 6 months, or in such frequency as may be recommended by PNRI.
- b) A radiation protection survey shall be performed and documented by the RHSO when changes have been made in the shielding, operation, equipment, or occupancy of adjacent areas.
- c) Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing readout at the control panel.
- d) All fixed area monitors shall be calibrated at intervals not to exceed 1 year and after each servicing or repair.
- e) Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.
- f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.
- g) All surveys shall be made in accordance with approved written procedures.
- h) Records of all radiation survey, calibrations, and tests shall be maintained in an auditable form at the accelerator facility and shall be available for regulatory inspection.

SECTION 37. *Personnel Training.*

The licensee shall ensure that all operators and operators' assistants of the particle accelerator:

- a) Receive instructions on the fundamentals of radiation protection and safety;
- b) Receive instructions on the methods used to limit radiation doses at the accelerator facility, including, shielding, interlock system, safety rules, and radiation monitoring equipment;
- c) Receive instructions on the use and care of individual monitoring devices used at the facility;
- d) Are knowledgeable of the location and use of all operating controls, the operating and emergency procedures and the pertinent requirements of this Part;
- e) Receive at least 3 months of on-the-job training in an operating accelerator facility of similar design before assuming operational responsibility; and
- f) Undertake periodic refreshers training appropriate to their particular assignments.

SECTION 38. *Production and Use of Radioactive Materials.*

- a) The production of multiple quantities or types of radioactive materials resulting from the operation of the particle accelerator and management of radioactive wastes shall be subject to the licensing requirements of **CPR Part 20**.
- b) The medical application of radioisotopes produced from the accelerator facility shall be subject to the licensing requirements of **CPR Part 13**.

SECTION 39. Security of Licensed Radioactive Materials.

The licensee shall ensure that the security measures are appropriate for the category of radioactive materials in use at the facility and are consistent with the administrative and technical requirements prescribed by the PNRI.

V. INSPECTIONS, RECORDS AND REPORTS

SECTION 41. Inspection and Tests.

- a) The licensee shall afford PNRI the opportunity to inspect, at all reasonable times, the licensed facility and operations and to make available to PNRI inspectors, upon reasonable notification, records kept and maintained at the facility.
- b) The licensee may conduct such tests or make changes in the facility and procedures, as are appropriate or necessary, to assure compliance with PNRI rules and regulations.

SECTION 42. Records and Reports.

- a) The licensee shall maintain such records and make such reports in connection with the licensed activity, as may be required by the conditions of the license and this Part, or by other regulations and orders of PNRI.
- b) Records that are required by this Part, by license condition, or by technical specification, shall be maintained for the respective specified period. If a retention period is not otherwise specified, such records shall be maintained until PNRI authorizes their disposition.

SECTION 43. Notification.

The licensee shall notify PNRI as soon as possible and in all cases within twenty-four (24) hours of the occurrence of any event that:

- a) Requires the initiation of the emergency plan or any section of the plan;
- b) Exceeds the technical specification safety limit that may result in the facility to go out of control while operating;
- c) Threatens the safety and security of the facility and the workers, including civil disturbances, labor strikes or instances of sabotage or attempted sabotage;
- d) Results in any fatality or serious injury occurring onsite and requiring transport to an offsite medical facility or treatment;
- e) Results in serious personnel radioactive contamination requiring extensive onsite decontamination or outside assistance; or
- f) Meets the criteria for notification of incidents pursuant to CPR Part 3 of the Code.

VI. ENFORCEMENT AND EFFECTIVITY

SECTION 51. Violations.

- a) A notice of violation shall be issued if the licensee is found to have violated the requirements of this Part, or any applicable rule, regulation, or order issued by PNRI; or any term, condition, or limitation of the license issued thereunder.
- b) Any person who willfully violates, attempts to violate, or conspires to violate any rule, order or

regulation issued by PNRI, or the provisions of the Act, 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, as amended.

SECTION 52. *Modification and Revocation of License.*

- 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 rule, regulation or order of the PNRI.
- b) Any license may be modified, suspended, or revoked, after due process, for any willful violation that PNRI determines could adversely affect the health, interest or safety of the workers and the public.

SECTION 53. *Termination of License.*

- a) The licensee may request for the termination of his license to operate a particle accelerator when he decides to permanently cease licensed activities and shall inform PNRI within sixty (60) after arriving at such decision.
- b) The licensee may request PNRI for authority to dismantle the facility and dispose of its component parts. The PNRI may require information including particulars on proposed procedures for the disposal of radioactive material, decontamination of the site and other procedures, to provide reasonable assurance that the dismantling of the facility and disposal of the component parts will be performed in accordance with the approved Decommissioning Plan and will not pose undue risk to the health and safety of the public.
- c) PNRI will formally terminate the license to operate when the procedures and activities described in an approved decommissioning plan are satisfactorily accomplished.

SECTION 54. *Effective Date.*

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

Approved:



ALUMANDA M. DELA ROSA, Ph.D.
Director, PNRI

October 20, 2005