

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

**CPR PART 21. LICENSING AND SAFETY REQUIREMENTS OF PARTICLE
ACCELERATOR FACILITIES FOR THE PRODUCTION OF RADIONUCLIDE**

TABLE OF CONTENTS

PAGE

I. GENERAL PROVISIONS

| | | |
|-------------|---|---|
| Section 1. | Purpose and Scope | 1 |
| Section 2. | Definitions | 1 |
| Section 3. | Interpretation | 3 |
| Section 4. | Communication | 4 |
| Section 5. | Activities Requiring License | 4 |
| Section 6. | Application for New License | 4 |
| Section 7. | Types of Licenses and General Requirements | 4 |
| Section 8. | Issuance of License | 5 |
| Section 9. | Terms and Conditions of License | 6 |
| Section 10. | Amendment of License | 6 |
| Section 11. | Specific Conditions for Expiration of License | 7 |
| Section 12. | Renewal of License | 7 |
| Section 13. | Termination of License | 8 |
| Section 14. | Regulatory Safety Review and Assessment | 8 |
| Section 15. | Specific Exemptions | 9 |
| Section 16. | Additional Requirements | 9 |

II. ADMINISTRATIVE REQUIREMENTS

| | | |
|-------------|---|----|
| Section 17. | Radiation Safety Program | 9 |
| Section 18. | Radiation Safety Committee | 10 |
| Section 19. | Radiation Safety Officer (RSO) and Assistant RSO (ARSO) | 10 |
| Section 20. | Safety Analysis Report | 10 |

III. TECHNICAL REQUIREMENTS

| | | |
|-------------|--|----|
| Section 21. | General Safety Considerations | 11 |
| Section 22. | Particle Accelerator Controls and Interlock Systems | 11 |
| Section 23. | Warning Signages and Devices | 12 |
| Section 24. | Operating Procedure | 12 |
| Section 25. | Emergency Plan | 13 |
| Section 26. | Personnel Monitoring | 13 |
| Section 27. | Radiation Survey Requirements | 13 |
| Section 28. | Possession, Use, Calibration and Check of Dose Calibrators | 14 |
| Section 29. | Vials, Radiation Shields and Labels | 14 |

| | | |
|-------------|---|----|
| Section 30. | Production and Use of Radioactive Materials | 15 |
| Section 31. | Security of Particle Accelerator Facility | 15 |
| Section 32. | Quality Assurance (QA) Program | 15 |
| Section 33. | Laboratory Facilities for Radionuclide Production | 15 |
| Section 34. | Radioactive Waste Management | 16 |
| Section 35. | Decommissioning | 16 |

IV. QUALIFICATION, TRAINING AND EXPERIENCE REQUIREMENTS

| | | |
|-------------|---|----|
| Section 36. | Radiation Safety Officer (RSO) and Assistant RSO (ARSO) | 17 |
| Section 37. | Authorized Operator | 17 |
| Section 38. | Authorized Technical Staff | 17 |
| Section 39. | Refresher Course | 18 |

V. RECORDS, REPORTS AND NOTIFICATION

| | | |
|-------------|----------------------------|----|
| Section 40. | Records and Reports | 18 |
| Section 41. | Notifications of Incidents | 18 |

VI. INSPECTION AND ENFORCEMENTS

| | | |
|-------------|--|----|
| Section 42. | Inspection | 19 |
| Section 43. | Violations | 19 |
| Section 44. | Modification, Suspension and Revocation of License | 19 |

VII. EFFECTIVITY

| | | |
|-------------|----------------|----|
| Section 45. | Effective Date | 20 |
|-------------|----------------|----|

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CPR Part 21. LICENSING AND SAFETY REQUIREMENTS OF PARTICLE ACCELERATOR FACILITIES FOR THE PRODUCTION OF RADIONUCLIDE

I. GENERAL PROVISIONS

Section 1. Purpose and Scope.

- (a) This Part prescribes the requirements and provisions for the issuance of licenses to construct and operate a particle accelerator facility for the production of radionuclide for medical use, pursuant to the provisions of Republic Act No. 5207, as amended.
- (b) The requirements in this Part provide for the protection of the health and safety of the workers, the general public and the environment from the effects of ionizing radiation; and are in addition to, and not in substitution for, other Parts in the Code of PNRI Regulations (CPR).
- (c) Relevant requirements of applicable CPRs shall apply to certain practices incident to the operation of the particle accelerator, such as the production, processing, dispensing, and transport of radionuclides produced by the particle accelerator, unless specifically stated otherwise.
- (d) This Part does not relieve the applicant or licensee from complying with the applicable requirements of other responsible agencies of government.

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) **“Accident”** means any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety;
- (c) **“Act”** means Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended;
- (d) **“ALARA”** (As Low As Reasonably Achievable) means making every reasonable effort to maintain exposures to radiation as low as reasonably achievable:

- (1) Consistent with the purpose for which the licensed activity is undertaken; and
 - (2) Taking into account the state of the technology, the economics of improvement in relation to benefits, to the health and safety of the public and the radiation workers and to other societal and socio - economic considerations;
- (e) **“Assistant Radiation Safety Officer (ARSO)”** means the individual who is identified in the license issued pursuant to this Part to perform the duties and responsibilities of the RSO in his/her absence;
- (f) **“CPR Part 3”** means the Code of PNRI Regulations, "Standards for Protection Against Radiation";
- (g) **“CPR Part 4”** means the Code of PNRI Regulations, “Regulations for the Safe Transport of Radioactive Material in the Philippines”;
- (h) **“CPR Part 13”** means the Code of PNRI Regulations, "Licenses for the Medical Use of Unsealed Radioactive Material";
- (i) **“CPR Part 20”** means the Code of PNRI Regulations, "Licenses to Manufacture and Dispense Radiopharmaceuticals";
- (j) **“Commissioning”** means the process by 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;
- (k) **“Decommissioning”** means administrative and technical actions taken to allow the removal of some or all of the regulatory control from a facility and to reduce 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;
- (l) **“Emergency plan”** means a description of the objectives, policy and concept of operations for the response to an emergency and of the structure, authorities and responsibilities for a systematic, coordinated and effective response. The emergency plan serves as the basis for the development of other plans, procedures and checklists;
- (m) **“Licensee”** means a holder of a valid license issued by PNRI pursuant to this Part;
- (n) **“Operator”** means the individual who is qualified and trained to operate and/or to conduct repair and maintenance work to the particle accelerator;
- (o) **“Particle Accelerator Facility”** means the facility containing a particle accelerator determined by PNRI as an atomic energy facility;
- (p) **“PNRI”** means the Philippine Nuclear Research Institute and its duly authorized representative;

- (q) **“Quality Assurance (QA) Program”** means planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality specified in the license;
- (r) **“Radioactive material”** means any material containing radionuclide where both the activity concentration and the total activity exceed the values specified in Appendix A of CPR Part 3;
- (s) **“Radionuclide”** means an unstable nuclide or isotope of an element that decays or disintegrates spontaneously.
- (t) **“Radiopharmaceutical”** means a chemical compound labeled with radionuclide and administered to patients for diagnosis and/or therapy;
- (u) **“Radioactive Source”** means anything that may cause radiation exposure – such as emitting ionizing radiation or by releasing radioactive material – and can be treated as a single entity for protection and safety purposes;
- (v) **“RSO”** means the individual designated in the license to be the Radiation Safety Officer for the particle accelerator facility;
- (w) **“Security Plan”** means sets of actions for response to unauthorized acts indicative of attempted unauthorized removal or sabotage, including threats thereof, designed to effectively counter such acts;
- (x) **“Technical Staff”** means any health professional, with specialist education and training in manufacturing and dispensing of radioisotope according to the prescribed standard operating procedures and assessing radioisotope quality parameters prior to release for patients use;
- (y) **“Radiochemist”** means the technical staff who dispenses radionuclides according to the prescribed standard operating procedures.
- (z) **“Radiopharmacist”** means the technical staff who prepares radiopharmaceuticals to ensure safety and efficacy of radionuclides.
- (aa) **“Worker”** means any individual who works, whether full time, part time or temporarily, for a licensee and who has recognized rights and duties in the license in relation to occupational radiation protection;

Section 3. Interpretation.

Except as specifically authorized by the Director in writing, no interpretation of the meaning of the requirements in this Part will be binding upon PNRI.

Section 4. Communication.

All communication and reports concerning the license and the regulations in this Part shall be addressed to

**The Director
Philippine Nuclear Research Institute
Commonwealth Avenue, Diliman, Quezon City**

Section 5. Activities Requiring License.

No person shall produce, possess, use, transport and transfer radionuclides; and shall construct or operate a particle accelerator facility for the purpose of producing radionuclides for medical use except in accordance with a license issued by PNRI pursuant to this Part.

Section 6. Application for New License.

- (a) An application for a license shall be made by filing an original and one copy of PNRI/NRD Form-021, "Application for a License for Particle Accelerator Facilities for the Production of Radionuclides". The application must be duly affirmed, notarized and signed by the applicant or an individual duly authorized to act for and on his behalf upon submission to the PNRI.
- (b) The applicant shall submit a certified true copy of the registration from the Securities and Exchange Commission (SEC) and the current business permit issued by the responsible local government agency.
- (c) The applicant shall submit all necessary documents as outlined in Sections 7 and 17 for the license applied for.
- (d) The applicant shall pay the required license fees and other charges in connection with his license application in accordance with CPR Part 22, "Fees and Charges for Radioactive Material Licenses and Other Related Regulatory Services".

Section 7. Types of Licenses and General Requirements.

(a) Provisional Permit

- (1) A provisional permit shall be issued to the applicant to authorize commencement of construction of a facility. As used in this Part, the term "commencement of construction" means any clearing of land, excavation or other substantial action that would adversely affect the environment of the site. Such substantial action may include:
 - (i) Preparation of the site for construction of the facility (such as clearing, grading, construction of temporary access roads and borrow areas;
 - (ii) Installation of temporary construction support facilities (such as warehouse and shop facilities, utilities, concrete mixing plants, unloading facilities and construction support buildings);
 - (iii) Excavation for facility structures;

- (iv) Construction of service facilities such as paving, fencing, exterior utility and lighting systems; and
 - (v) Construction of structures, systems, and components which do not prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.
- (2) On the basis of the technical information and data made available by the applicant in accordance with (a) of this Section, a Provisional Permit that authorizes the commencement of construction activities shall be issued if:
- (i) The applicant has submitted the Preliminary Safety Analysis Report (PSAR) which includes 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;
 - (ii) The schedule of construction activities are adequately defined according to specified phases of construction;

(b) License to Construct

Upon satisfactory completion of activities under the provisional permit, the provisional permit 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 as stipulated in Section 32 of this Part.

(c) License to Operate

The License to Operate shall be issued if:

- (1) The licensee has submitted the 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 technical specifications, operating procedures of the facility and pre-operational testing that demonstrates the readiness of the operating organization before commencing the commercial operation;
- (3) The licensee has submitted the Final Safety Analysis Report (FSAR) which includes all requirements stipulated in Section 20 of this Part and the PNRI has determined in the Safety Evaluation Report (SER) that the FSAR is acceptable; and
- (4) The licensee has submitted a Radiation Safety Program designed to minimize radiation hazards and exposures to workers, general public and the environment during operation in accordance with the ALARA principle.

Section 8. Issuance of License.

The PNRI shall issue a license, depending on the type applied for, if the following conditions are satisfactorily met:

- (a) The application is for the purpose authorized by the Act;
- (b) The applicant has filed PNRI/NRD Form-021 in accordance with the instructions in Section 6; and
- (c) The PNRI finds that the application is complete in substance and form and the proposed equipment, facilities and procedures are adequate to protect the health and safety of the workers, the general public and the environment from the effects of ionizing radiation.

Section 9. Terms and Conditions of License.

- (a) Each license shall be subject to the provisions of the Act, the general and specific conditions of the license, and to applicable rules, regulations and orders of the PNRI.
- (b) The PNRI may incorporate in any license issued pursuant to this Part, at the time of issuance or thereafter, by appropriate notification, rule or order, such additional requirements and conditions with respect to the license as it deems appropriate or necessary to protect the health and safety of the workers, the general public and the environment from the effects of ionizing radiation.
- (c) Neither the license nor any right granted under the license shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license or licensed material to any other person, unless the PNRI, after securing full information:
 - (1) Finds that the proposed transfer, assignment or disposal is in accordance with the regulations of the Code and the provisions of the Act; and
 - (2) Consents in writing to the proposed transfer, assignment or disposal.
- (d) Upon the approval of the PNRI of the proposed transfer in accordance with subsection (c), the transferor shall ensure that the transferee is provided with all information required by the PNRI.
- (e) A copy of each of the existing license shall be displayed at conspicuous area and applicable regulations of the Code shall be kept and made available at each authorized location of use indicated in the license.
- (f) 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 every five (5) years thereafter upon renewal of the license.

Section 10. 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 initial or new license application.
- (b) The licensee shall apply for and must receive a license amendment before:

- (1) It produces radionuclide other than what is authorized under his license;
 - (2) It permits anyone to work as an RSO or ARSO, authorized operator, technical staff other than those previously authorized in the license;
 - (3) It produces radionuclide in excess of the authorized possession limit, or in a form different from what is authorized in the license;
 - (4) It changes the areas of use and/or location of use and storage of licensed radioactive material within the premises of the facility identified in the license;
 - (5) It implements any major change in the accepted radiation safety program; or
 - (6) Any substantial change in any condition of the license takes effect, in consultation with PNRI.
- (c) In determining whether or not an application for an amendment of a license will be granted, the PNRI will be guided by the rules that govern the issuance of the initial license, as may be appropriate.

Section 11. Specific Conditions for Expiration of License.

- (a) Each license shall expire at the end of the day of the expiration date specified in the license unless the licensee has filed an application for renewal of the license in accordance with Section 12 of this Part.
- (b) If the license has expired and the licensee fails to renew its license, the licensee shall not undertake any principal activities involving the use of the particle accelerator except to keep the radioactive materials, if any, under safe storage until the applicable provisions of Section 12 of this Part are satisfactorily met.
- (c) The expiration of the license shall not relieve the licensee of its responsibility to cause the decommissioning of its facility in accordance with Section 35 of this Part, if the license will be terminated.

Section 12. Renewal of License.

- (a) A request for license renewal shall be made by submitting an original and one copy of PNRI/NRD Form-021 not less than sixty (60) days before the expiration date of the license.
- (b) The licensee shall provide a complete and up-to-date information and documentation as required in Sections 7 and 17, if many outdated documents are referenced or there had been changes in the regulatory requirements, the licensee's organization, or radiation safety program.
- (c) If an application for license renewal is filed in the proper form, existing license shall be deemed to remain valid until the PNRI has taken final action on whether to renew or deny the license, but in no case shall it be more than thirty (30) days after the expiration of the existing license.
- (d) 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.
- (e) An application for license renewal that is filed less than thirty (30) days 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 any licensed activity until the PNRI issued the renewed license.
 - (2) Ensure that all radioactive materials 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.
- (f) If an application for license renewal is filed more than thirty (30) days after the expiration date stated in the license, the PNRI shall cause the temporary cessation of the activity until it has determined whether or not the application shall be accepted and processed. Upon such order, the licensee shall not undertake any principal licensed activity.
- (g) Each application for license renewal must be accompanied by the corresponding license renewal fee and other outstanding regulatory fees in accordance with CPR Part 22, "Fees and Charges for Radioactive Material Licenses and Other Related Regulatory Services".

Section 13. Termination of License.

- (a) The termination of a license may be initiated at any time at the request of the licensee.
- (b) The licensee may request PNRI for authority to dismantle the facility and to dispose its components with induced radioactivity as radioactive waste. The PNRI may require information including particulars on proposed procedures for the disposal of radioactive material, decontamination of the parts/component, equipment, site and other areas, to provide reasonable assurance that the dismantling of the facility and disposal of the components will be performed in accordance with the approved Decommissioning Plan and will not pose undue risk to the health and safety of the workers, the public and the environment.
- (c) The licensee shall submit a report on the completion of decommissioning activities, safe disposal of radioactive sources and personnel exposure doses received during the decommissioning operations.
- (d) The PNRI will formally terminate the license to operate when the procedures and activities described in the approved Decommissioning Plan were satisfactorily met.

Section 14. Regulatory Safety 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, utilizing applicable standards and guidelines, including other standards that may be adopted by the applicant, as appropriate.

Section 15. Specific Exemptions.

The PNRI may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this Part as it deems authorized by the Act and will not endanger life, property, and the environment.

Section 16. Additional Requirements.

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

II. ADMINISTRATIVE REQUIREMENTS

Section 17. Radiation Safety Program.

- (a) The licensee shall develop, document and implement a written radiation safety program to show compliance with the technical requirements of this Part and the provisions of Chapter II of CPR Part 3, "Standards for Protection against Radiation".
- (b) The proposed Radiation Safety Program shall include the following, where applicable:
 - (1) Organization, duties and responsibilities of the Radiation Safety Committee
 - (2) Designation of a qualified Radiation Safety Officer (RSO) and Assistant RSO
 - (3) Duties and responsibilities of the RSO/ARSO
 - (4) ALARA Program
 - (5) Personnel Monitoring Program
 - (6) Training/Refresher Program
 - (7) Procedures for Keeping Records of Radionuclide Produced
 - (8) Repair and Maintenance Program
 - (9) Quality Assurance/Quality Control Program
 - (10) Procedure for Radiation Surveys (dose rate and contamination monitoring)
 - (11) Monitoring, Calculating and Controlling Airborne Concentrations
 - (12) Calibration of Survey Instruments and Other Devices
 - (13) Radioactive Waste Management
 - (14) Procedure for Radiation Surveys
 - (15) Operating and Emergency Procedures including conduct of drill
 - (16) Transport of Radioactive Materials; and
 - (17) Proposed Decommissioning Plan
- (c) The licensee shall use, to the extent practical, procedures and technical controls based upon sound radiation safety principles to achieve occupational doses and doses to the members of the public that are as low as reasonably achievable (ALARA).
- (d) The licensee shall review the Radiation Safety Program and its implementation at least annually to comply with new regulations and conditions of the license and to incorporate changes in radiation safety procedures and measures, as applicable.

Section 18. Radiation Safety Committee.

- (a) The licensee shall establish a Radiation Safety Committee (RSC) that oversees the Radiation Safety Program. The Committee should include the RSO and/or ARSO, authorized operator, an administrator representing the management, and technical staff. Other members may be included as the licensee deems appropriate.
- (b) The Committee shall undertake the duties and responsibilities stated in the Radiation Safety Program; and provide the PNRI a report on their accomplished activities as a prerequisite to the renewal of license.
- (c) The Committee shall have the authority to terminate all operations in a particle accelerator facility if such action is deemed necessary to minimize danger to the workers, public health and safety or property.

Section 19. Radiation Safety Officer (RSO) and Assistant RSO (ARSO).

- (a) The licensee shall designate a qualified RSO and Assistant RSO who shall both consent and agree, in writing, to be responsible for implementing the radiation safety program. The ARSO shall act for and in behalf of the RSO in his absence.
- (b) The licensee shall provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to:
 - (1) Identify radiation safety problems and conduct briefings to management as appropriate;
 - (2) Initiate, recommend, or provide corrective actions;
 - (3) Monitor dose of staff and environment;
 - (4) Develop procedures to improve safety culture in the organization and maintain safe work practices;
 - (5) Stop unsafe operations as deemed necessary;
 - (6) Verify implementation of corrective actions;
 - (7) Coordinate the establishment, maintenance, drills/exercise of Emergency Plan and procedures;
 - (8) Train new personnel and other personnel who work in or frequent supervised areas; and
 - (9) Interface with regulatory inspectors and provide access to required records of inspection.
- (c) The licensee shall establish and state in writing the authorities, duties and responsibilities of the RSO and Assistant RSO.

Section 20. Safety Analysis Report.

- (a) The licensee shall submit a Safety Analysis Report (SAR) which specifies the conditions under which the facility will be constructed and operated, as required in Section 7 of this Part for appropriate types of licenses. The form and content of the Safety Analysis Report are described in the "Guide for the Preparation of an

Application for Licensing a Particle Accelerator Facility for the Production of Radioisotope".

- (b) The licensee shall update the SAR originally submitted as part of the application for each license to reflect the amendments made as a result of the regulatory safety review and assessment and assure that the information included in the report describes accurately the current status and conditions of the facility.

III. TECHNICAL REQUIREMENTS

Section 21. General Safety Considerations.

- (a) Each licensee shall have established workload of the facility which shall correspond adequately to the shielding design.
- (b) The licensee shall provide each authorized personnel suitable personnel monitoring devices and radiation detection and measuring instruments that shall be periodically calibrated for the appropriate types and energies of radiation produced by the particle accelerator facility in accordance with Sections 26 and 27 of this Part.
- (c) 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.
- (d) 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.
- (e) The licensee shall ensure that radioactive materials e.g. dust, airborne radioactivity, etc. are not drawn from the areas with high levels of contamination to the areas of low contamination.

Section 22. Particle Accelerator Controls and Interlock Systems.

- (a) All safety interlocks installed in the facility shall 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 understood.
- (c) Each entrance into a 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, the licensee shall establish an administrative

control that shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, 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 23. Warning Signages and Devices.

- (a) Each radiation area shall be posted with a conspicuous sign bearing the radiation symbol and the words, "CAUTION RADIATION AREA", or for high radiation area "CAUTION HIGH RADIATION AREA" or "DANGER HIGH RADIATION AREA".
- (b) 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.
- (c) 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.
- (d) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted with radiation warning signages in accordance with CPR Part 3.

Section 24. Operating Procedure.

- (a) The particle accelerator, when not in operation, shall be secured to prevent unauthorized access in accordance with CPR Part 26, "Security of Radioactive Sources".
- (b) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.
- (c) The interlocks may be prevented from operation only to test, adjust, 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 Radiation Safety Committee or RSO;
 - (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 three (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, 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 millisievert per hour is exceeded. The personnel monitoring equipment referred to in this paragraph is in addition to those required in Section 26 of this Part.
- (h) Key control measures to enable or disable any interlocks and the arrangements for the proper use and storage of such keys shall be commensurate with the safety of the facility and security level of the radioactive source.
- (i) A copy of the current operating procedures shall be maintained and kept in an appropriate location, such as the accelerator control panel.

Section 25. Emergency Plan.

- (a) The licensee shall establish an Emergency Plan in accordance with Section 17 of CPR Part 3.
- (b) A copy of the emergency procedures shall be posted at a convenient, visible location in the facility. It shall include telephone numbers of the RSO/ARSO and other key personnel responsible for response in the event of an emergency.

Section 26. Personnel Monitoring.

- (a) The licensee shall not allow workers to perform any licensed activity unless he/she wears a calibrated personnel monitoring device, such as but not necessarily limited to thermoluminescent dosimeter (TLD), optically stimulated luminescence dosimeter (OSL), finger monitor in compliance with the provisions of CPR Part 3.
- (b) The licensee shall ensure that each monitoring device is assigned to, and worn only by one individual for each monitoring period.
- (c) The licensee shall maintain and keep records of total exposures of all individuals who are required to wear personnel monitoring devices. Such records are retained until the duration of his/her employment. The licensee shall furnish an individual who terminates employment in the facility, a report of the exposure dose during the period of employment.
- (d) All personnel dosimeters that require processing to determine the radiation dose shall be processed and evaluated by the PNRI, or a PNRI-licensed or PNRI-recognized dosimetry service provider.

Section 27. Radiation Survey Requirements.

- (a) The licensee shall have in its possession calibrated and operable radiation survey instruments to evaluate:
 - (1) The magnitude and extent of radiation levels;

- (2) Concentrations or quantities of residual radioactivity; and
 - (3) The potential radiological hazards of the radiation levels and residual radioactivity detected.
- (b) The licensee shall calibrate or cause the calibration of the instruments to show compliance with this Part and CPR Part 3 before its first use, annually, and following any repair, unless otherwise recommended by the calibration laboratory. The date of calibration shall be conspicuously noted on the instrument. The licensee shall cease to use an instrument if the difference between the indicated exposure rate and the calculated value is more than twenty percent (20%).
 - (c) A radiation protection survey shall be performed and documented by the RSO when changes have been made in the shielding, operation, equipment, or occupancy of adjacent areas.
 - (d) Radiation levels in all radiation areas (i.e. airborne radioactivity and removable contamination) shall be continuously monitored.
 - (e) Records of all radiation survey, calibrations, and tests shall be maintained at the accelerator facility and shall be available for PNRI inspection.

Section 28. Possession, Use, Calibration and Check of Dose Calibrators.

- (a) The licensee shall have in its possession a dose calibrator and use it to measure the amount of activity of every product vial of radionuclide produced.
- (b) The licensee shall calibrate the dose calibrator for constancy, accuracy, linearity and geometry dependence in accordance with internationally recognized standards or the manufacturer's instructions.
- (c) The licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.
- (d) The licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds ten percent (10%) if the dosage is greater than 0.4 MBq and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ten percent (10%).
- (e) The licensee shall retain records of calibration required by subsection (b) for three (3) years.

Section 29. Vials, Radiation Shields and Labels.

- (a) The licensee shall conspicuously label each vial that contains radionuclides produced in the particle accelerator in order to identify its contents. Each vial radiation shield shall also be labeled unless the label on the vial is visible when shielded.
- (b) The licensee shall require each individual who prepares a radiopharmaceutical kit in the laboratory to use a vial radiation shield when preparing the kit.

Section 30. 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, Licenses to Manufacture and Dispense Radiopharmaceuticals.
- (b) The medical application of radionuclides produced from the accelerator facility shall be subject to the licensing requirements of CPR Part 13, Licenses for Medical Use of Unsealed Radioactive Material.
- (c) The transport of radioactive materials produced in the particle accelerator shall be subject to the requirements of CPR Part 4, Regulations for the Safe Transport of Radioactive Material in the Philippines.

Section 31. Security of Particle Accelerator Facility.

The licensee shall establish physical security measures for the particle accelerator facility and shall require each person who is authorized to operate and use the particle accelerator to have completed a security awareness training course.

Section 32. Quality Assurance (QA) Program.

- (a) The licensee shall establish a quality assurance program that sets out the principal tasks involved in supervising the operating condition and performance characteristics of particle accelerator, which includes, among others, the procedures for:
 - (1) Measurements and verification of physical parameters at the time of the commissioning (acceptance testing), periodically thereafter (performance testing), after any major repair, and after modification or installation of new software;
 - (2) Implementation of corrective actions if measured values as required in paragraph (1) are outside established tolerance limits;
 - (3) Periodic checks of the calibration and conditions of operation; and
 - (4) Regular and independent external audit reviews.
- (b) The licensee shall cause the particle accelerator to be fully inspected, serviced and maintained according to the manufacturer's recommendation by a qualified personnel in accordance with the approved Quality Assurance Program.
- (c) The licensee shall keep written records of relevant quality control procedures and test results of the particle accelerator. The licensee shall retain the records of regular quality control tests for two (2) years and the annual performance evaluation for five (5) years.

Section 33. Laboratory Facilities for Radionuclide Production.

- (a) The licensee shall make available an appropriate radiochemistry laboratory that shall take into account the flow of work as the radionuclides are prepared, irradiated, recovered, purified, quality checked, and packaged for transport.

- (b) The particle accelerator shall have a target processing area, which shall be contained in a shielded enclosure.
- (c) The purification of the radionuclides or the conversion of the radionuclide into radiopharmaceuticals shall be carried out in appropriately and adequately designed hot cells.
- (d) The licensee shall provide a quality control (QC) area, where the purity of the radionuclides or radiopharmaceuticals is checked.
- (e) Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in CPR Part 3, APPENDIX D-1 (Derived Generic Clearance Levels for Airborne Releases).

Section 34. Radioactive Waste Management.

- (a) A licensee who generates radioactive waste shall establish, implement or cause to be implemented a radioactive waste management program that will ensure effective control and disposal of radioactive wastes for the protection of the public and the environment in accordance with Chapter VI of CPR Part 3.
- (b) The licensee may hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal as ordinary trash without regard to its radioactivity if:
 - (1) It is determined that its radioactivity cannot be distinguished from the background radiation level using a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;
 - (2) All radiation labels have been removed or obliterated; and/or
- (c) The licensee shall keep and maintain records of disposal of radioactive wastes for three (3) years.

Section 35. Decommissioning.

- (a) The licensee shall submit to the PNRI for approval a proposed decommissioning plan twenty-four (24) months before the start of decommissioning activities, which must include:
 - (1) Description of planned decommissioning activities;
 - (2) Description of methods to assure protection of workers and the environment against radiation hazards during decommissioning;
 - (3) Description of the radiation survey to be undertaken before, during, and after the decommissioning activities; and
 - (4) A program for the disposition of the radioactive waste and other decommissioning waste.
- (b) The licensee shall submit to the PNRI a report of the results of the radiation survey performed upon completion of decommissioning activities

IV. QUALIFICATION, TRAINING AND EXPERIENCE REQUIREMENTS

Section 36. Radiation Safety Officer (RSO) and Assistant RSO (ARSO).

The licensee shall designate an RSO and ARSO, upon the endorsement and approval of the Radiation Safety Committee, who:

- (a) Holds a Bachelor of Science degree in Natural Science, Physical Science, or Engineering and is duly licensed by the Philippine Professional Regulations Commission, if applicable;
- (b) Has completed 200 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques of radioactive material, including radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material, radiation biology, and nuclear regulations and licensing; and
- (c) Has at least one (1) year of relevant, fulltime experience in the administrative and operational control of radiation within the facility.

Section 37. Authorized Operator.

The licensee shall designate an Authorized Operator, upon the endorsement and approval of the Radiation Safety Committee, who:

- (a) Holds a Bachelor of Science degree in applied science or engineering; and is duly licensed by the Philippine Professional Regulations Commission, as applicable
- (b) Has completed 40 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques of radioactive material, including radiation physics and radiation detection instrumentation, radiation protection, radiation biology, and nuclear regulations and licensing; and
- (c) Has at least six (6) months of supervised training in the technical aspects and safe operation of the particle accelerator.
- (d) Before being permitted to conduct repair and maintenance work with the particle accelerator and associated sources, the operator shall have received appropriate qualifications and training with respect to the type of facility authorized in the license.

Section 38. Authorized Technical Staff.

The licensee shall designate an Authorized Technical Staff (i.e., radiochemists, radiopharmacists), upon the endorsement and approval of the Radiation Safety Committee, who:

- (a) Holds a Bachelor of Science degree in chemistry, pharmacy, medical technology, biological sciences or engineering; and is duly licensed by the Philippine Professional Regulations Commission, as applicable;

- (b) Has completed 40 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques of radioactive material, including radiation physics and radiation detection instrumentation, radiation protection, radiation biology, and nuclear regulations and licensing; and
- (c) Has at least six (6) months of relevant, fulltime work experience in laboratory operations in a particle accelerator facility.

Section 39. Refresher Course.

The licensee shall require the RSO, ARSO, Authorized Technical Staff and Authorized Operators to undertake a refresher course on radiation safety, as appropriate and approved by PNRI, every five (5) years.

V. RECORDS, REPORTS AND NOTIFICATION

Section 40. 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 41. Notifications of Incidents.

- (a) The licensee shall immediately notify PNRI within twenty-four (24) hours by telephone, or by any similarly fast means of communication any incident involving the particle accelerator or the radionuclides it produced which may have caused or threatened to cause a single exposure of the whole body of any individual in excess of 50 mSv, or in the occurrence of any event that:
 - (1) Requires the initiation of the emergency plan or any section of the plan;
 - (2) Exceeds the technical specification safety limit that may result in the facility to go out of control while operating;
 - (3) Threatens the safety and security of the facility and the workers, including civil disturbances, labor strikes or instances of sabotage or attempted sabotage;
 - (4) Results in any fatality or serious injury occurring onsite and requiring transport to an offsite medical facility or treatment;
 - (5) Results in serious personnel radioactive contamination requiring extensive onsite decontamination or outside assistance; or
 - (6) Meets the criteria for notification of incidents pursuant to CPR Part 3 of the Code.

- (b) The licensee shall immediately report to PNRI within twenty-four (24) hours the occurrence of an equipment failure and malfunction, or a failure of, or damage to, the encapsulation of a sealed source, or upon the detection of 185 Bq or more of removable contamination. A written report which shall be submitted not more than thirty (30) days from the occurrence of the incident shall contain a brief description of the event and the remedial actions taken.
- (c) In addition to the notification required above, a written report shall be submitted not more than thirty (30) days from the occurrence of the incident and shall contain a description of the event, and the remedial actions taken, including measures to prevent recurrence of the incident.
- (d) The notification filed with the PNRI pursuant to this section shall specify the names of individuals who have received exposure to radiation and other persons involved in the incident in a separate part of the written report.

VI. INSPECTION AND ENFORCEMENT

Section 42. Inspection.

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

Section 43. Violations.

- (a) An appropriate enforcement action based on severity of violation shall be issued to any person found to have violated any rule, regulation, or order issued by the PNRI; or any term, condition, or limitation of any license issued hereunder.
- (b) Any license may be modified, suspended, or revoked, for any violation that the PNRI determines to adversely affect the health and safety of the workers, patients and the general public.
- (c) Any person who willfully violates, attempts to violate or conspires to violate any rule or regulation or order issued hereunder, may be guilty of a crime, and upon conviction, may be punished by a fine or imprisonment or both as provided by Sections 64 and 65 of Republic Act No. 5207, as amended.

Section 44. Modification, Suspension and Revocation of License.

- (a) The license shall be subject to revision or modification, and the terms and conditions of each license shall be subject to amendments, by reason of amendments to PNRI rules and regulations, or by reason of rules, regulations and orders issued by PNRI in accordance with 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 any of the terms and conditions of the license or any of the requirements and provisions of the regulations of this Part or of any rule, regulation or order of the PNRI.
- (c) Except in cases of willful violation or those in which the public health and 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.

VII. EFFECTIVITY

Section 45. 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

Date: 11 MARCH 2016

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