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

CPR PART 31

LICENSING REQUIREMENTS FOR BLOOD IRRADIATORS

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CPR Part 31. LICENSING REQUIREMENTS FOR BLOOD IRRADIATORS

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 prescribes the requirements for the issuance of licenses for the use of sealed radioactive sources in blood irradiators.

(c) This Part provides the requirements for the safety and security of radioactive sources in blood irradiators.

(d) 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 the requirements of other Code of PNRI Regulations (CPR).

Section 2. *Definitions.*

As used in this Part:

(a) **"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;

(b) **"Act"** means Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended;

(c) **"ALARA"** means as low as reasonably achievable; making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(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 other societal and socio-economic considerations;

(d) **"Assistant Radiation Protection Officer (ARPO)"** means the individual who is identified in the license issued pursuant to this Part to perform the duties and responsibilities in the absence of Radiation Protection Officer;

(e) **"Blood Irradiator Facility"** means the facility in which a blood irradiator is installed as determined by PNRI;

(f) **"Decommissioning"** means administrative and technical actions taken to allow the removal of some or all 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.

(g) **"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;

(h) **"Blood Irradiator"** means a medical device which uses high activity sealed radioactive source to irradiate blood and blood products;

(i) **"Licensee"** means a holder of a valid license issued by PNRI pursuant to this Part;

(j) **"PNRI"** means the Philippine Nuclear Research Institute and its duly authorized representative;

(k) **"Quality Assurance 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;

(l) **"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;

(m) **"Radionuclide"** means an unstable nuclide or isotope of an element that decays or disintegrates spontaneously.

(n) **"Radioactive Source"** means a source containing radioactive material that is used as a source of radiation;

(o) **"RPO"** means the individual designated in the license to be the Radiation Protection Officer for the blood irradiator facility;

(p) **"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;

(q) **"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 PNRI Director in writing, no interpretation of the meaning of the requirements in this Part shall be recognized to be binding upon PNRI.

Section 4. ***Communication.***

All communications 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. ***Applicability of other Regulations and Requirements, and Resolution of Conflicts.***

(a) The requirements in this Part shall be applied in conjunction with the radiation protection and safety requirements of CPR Part 3 – "Standards for Protection against Radiation", the safe transport requirements of CPR Part 4 – "Regulations on the Safe Transport of Radioactive Material in the Philippines", and the security requirements of CPR Part 26 – "Security of Radioactive Sources" and CPR Part 27 – "Security Requirements in the Transport of Radioactive Materials" and other applicable regulations.

(b) This Part are in addition to, and not in place of, other applicable national and local laws and regulations.

(c) 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.

(d) If a conflict exists between requirements contained herein and other laws or regulations, the PNRI shall be notified of such conflict in order to initiate steps towards resolution.

(e) Nothing in this Part shall be construed as restricting any actions that may otherwise be necessary for protection and safety.

Section 6. ***Activities Requiring License.***

No person shall acquire, receive, possess, own, use, transfer or import radioactive sources and blood irradiator except in accordance with a license issued by PNRI pursuant to this Part.

Section 7. ***Application for New License.***

(a) The applicant shall file an application for a new license pursuant to this Part on PNRI/NRD Form-31, "Application for Radioactive Material License for Blood Irradiators".

(b) Each application for a license pursuant to this Part shall be duly affirmed and notarized and shall be signed by the applicant or a person duly authorized to act for and on his behalf upon submission to PNRI.

(c) The applicant shall submit a copy of current business permit issued by the responsible government agency and a proof of authenticity of business name issued by the:

(1) Securities and Exchange Commission, for corporation; or

(2) Department of Trade and Industry, for single proprietorship.

(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”.

(e) The PNRI may, at any time after the filing of the application, require further statements to enable PNRI to determine whether the license shall be granted or denied.

Section 8. ***Issuance of License.***

The PNRI shall approve an application for a license pursuant to this Part if:

(a) The application is for a purpose authorized by the Act;

(b) The applicant has submitted to the PNRI a description of its over-all organization responsible for the use of blood irradiator, including specific delegation of authorities and responsibilities to workers involved;

(c) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property as well as to ensure the security of the radioactive sources;

(d) The locations and areas where the blood irradiator will be used and stored are in accordance with the safety and security requirements of the relevant CPRs;

(e) The applicant has designated a Radiation Protection Officer (RPO) and an Assistant Radiation Protection Officer (ARPO) in accordance with the requirements in II.Section 17 of this Part;

(f) The applicant has submitted technical specifications of the blood irradiator and radioactive source contained;

(g) The applicant has submitted written operating and emergency procedures in accordance to III.Section 21 of this Part;

(h) The applicant has a program for training and refresher course of the workers;

(i) The applicant possesses, or has access to a calibrated and operable radiation survey instrument required in III.Section 24 of this Part;

(j) The applicant has submitted a Radiation Protection and Safety Program that addresses CPR Part 3 and the technical requirements of this Part;

(k) The applicant has established procedures for the transport of radioactive sources in accordance with the requirements of CPR Part 4 “Regulations for the Safe Transport of Radioactive Material in the Philippines.”;

(l) The applicant has established and submitted to PNRI a Source Security Plan in accordance with the requirements of CPR Part 26 for Category 1 Radioactive Sources and CPR Part 27 “Security Requirements in the Transport of Radioactive Material;

(m) The applicant has provided PNRI documents from the manufacturer of the equipment, on the maintenance and service to the blood irradiator;

(n) The applicant has established decommissioning and disposal plans for the radioactive source in accordance with III.Section 28 of this Part;

(o) The applicant has ensured that disused sources shall be returned to the original supplier or manufacturer in the country of origin and adequate funds shall be allocated to process return to supplier; and

(p) The applicant has paid the required license fee and other charges, if any, in accordance with the CPR Part 22.

Section 9. ***Terms and Conditions of License.***

(a) The license shall be valid for a period as may be determined by PNRI;

(b) Each license shall be subjected to the provisions of the Act, the general and specific conditions of the license, and to applicable rules, regulations and orders of PNRI;

(c) 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.

(d) 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 to any other person.

(e) Each licensee shall confine the use, possession and storage of the radioactive sources to the locations authorized in the license;

(f) Each licensee shall strictly comply with the requirements in this Part regarding the renewal, amendment and expiration of license;

(g) Each licensee shall maintain and retain records as required in this Part;

(h) Each licensee shall notify PNRI immediately in writing following the filing of a voluntary or involuntary petition for bankruptcy under existing Philippine laws; and

(i) A copy of the existing license and applicable regulations of the Code shall be displayed at conspicuous area and made available at each authorized location of use indicated in the license.

Section 10. ***Amendment of License.***

(a) An application for amendment of a license shall be filed in PNRI/NRD Form-31, “Application for Radioactive Material License for Blood Irradiators” and shall specify in what respect the licensee desires his license to be amended in accordance with (b) and the grounds for such amendment. The corresponding license amendment fee required in CPR Part 22 shall be paid upon filing of the application.

(b) The licensee shall apply for and shall receive a license amendment before:

(1) It permits anyone to work as an RPO or ARPO, authorized technologist;

(2) It uses radioactive source(s) in excess of the authorized possession limit;

(3) 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;

(4) It implements any major change in the accepted Radiation Protection and Safety Program; or

(5) 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. ***Expiration of License.***

(a) Each license shall expire at the end of the day of the expiration date stated in the license. Pending any PNRI discretion on the disposition of the license, the licensee shall keep all radioactive sources under safe and secure storage in accordance with the security plan.

(b) If the licensee fails to file an application for the renewal of his license or fails to notify PNRI about the safe and secure disposition of the radioactive sources thirty (30) days after the expiration date, the PNRI shall require the licensee to show cause why an order to place the radioactive sources under temporary regulatory custody should not be issued.

(c) If the license is deemed to have expired and will not be renewed, the licensee shall notify PNRI accordingly and shall cease to engage in any licensed activity involving the radioactive sources except to keep the radioactive sources under safe and secure storage until determined by the PNRI.

(d) The discontinued use of radioactive sources as a result of the expiration of the license shall not relieve the licensee of the responsibility to cause the decommissioning of the facility and termination of the license.

Section 12. ***Renewal of License.***

(a) A request for license renewal shall be filed in PNRI/NRD Form-31, “Application for Radioactive Material License (Blood Irradiator)”, not less than thirty (30) days before the expiration date of the license.

(b) An application for license renewal that is filed less than thirty (30) days before the expiration date of the license shall be subjected to a surcharge equivalent to twenty-five (25) percent of the required license renewal fee. In addition to the written application, the licensee shall submit the following:

(1) A written explanation about the delay in the filing of application;

(2) An assurance that the licensee shall not undertake any principal licensed activity involving the radioactive source after the expiration date of the license; and

(3) An explanation why PNRI should not impose an administrative sanction against the licensee.

(c) If PNRI determines that the licensee’s reasons in (b) of this Section are acceptable and safety has not been compromised, the application will be accepted and processed on

the condition that the licensee shall not undertake any principal activity involving the licensed radioactive source after the expiration date of the license.

(d) An application for license renewal that is filed in less than thirty (30) days after the expiration date of the license shall be assessed a surcharge equivalent to fifty (50) percent 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 has issued a new license;

(2) Ensure that all radioactive materials are safe and secure in their authorized storage locations; and

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

(e) If an application for license renewal is filed in more than thirty (30) days after the expiration date stated in the license, the PNRI shall cause the temporary cessation of the activity until the PNRI has determined whether or not the application shall be accepted and processed. Upon such order, the licensee shall not undertake any principal licensed activity. If the PNRI approved the renewal, a surcharge equivalent to fifty (50) percent of the prescribed license renewal fee shall be collected in addition to the renewal fee.

(f) If the license is deemed to have expired and will not be renewed, the licensee shall cease to engage in any licensed activity involving the radioactive source, except to keep the radioactive source under safe and secure storage until the disposition of the radioactive source is determined by PNRI.

(g) The discontinued use of radioactive source(s) as a result of the expiration of the license shall not relieve the licensee of the responsibility to cause the decommissioning of the blood irradiator and termination of the license.

(h) Each application for license renewal shall be accompanied by the corresponding license renewal fee and other applicable 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) Before the license can be terminated, the licensee shall implement its decommissioning plan and shall:

(1) Discontinue performing all activities involving radioactive sources;

(2) Transfer or dispose of all licensed material which are in the licensee’s possession in accordance with the regulations;

(3) Assure that no contamination levels in excess of the limits for supervised areas exist in the facilities; and

(4) Assure that the required records are complete and up-to-date.

(c) To be relieved of the responsibility for the material and the other conditions of the license, the licensee shall submit to PNRI a written document as proof that:

(1) The licensee has no longer in possession of any radioactive source that requires a license;

(2) All radioactive sources have been transferred or disposed of, with the name of the licensee to whom the material was transferred and the method of disposal for each item; and

(3) The facilities are not contaminated.

(d) When these procedures have been satisfactorily completed, the PNRI will cause the termination of the license.

Section 14. ***Additional Regulatory Requirements.***

The PNRI may impose upon the 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 public or minimize danger to life or property and ensure the security of radioactive sources.

Section 15. ***Application for 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.

II. ADMINISTRATIVE REQUIREMENTS

Section 16. ***Radiation Protection and Safety Program.***

(a) The licensee shall develop and implement a written Radiation Protection and Safety Program that includes provisions for keeping doses ALARA in accordance with this Part and CPR Part 3.

(b) The Radiation Protection and Safety Program shall include the following, as applicable:

(1) Organization, duties and responsibilities of the Radiation Safety Committee

(2) Designation of a qualified Radiation Protection Officer (RPO) and Assistant RPO

(3) Duties and responsibilities of the RPO and ARPO

(4) ALARA Program

(5) Personnel Monitoring Program

(6) Training and Refresher Course Program

(7) Calibration of Survey Instruments and Other Devices

(8) Repair and Maintenance Program

(9) Quality Assurance Program

(10) Leak Testing Procedures

(11) Operating Procedures

(12) Emergency Plan

(13) Transport of Radioactive Materials; and

(14) Radioactive Waste Management Program.

(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 Protection and Safety Program and its implementation at least annually to comply with new regulations and conditions of the license. The licensee shall incorporate changes in radiation safety procedures and measures and submit the revised Radiation Protection and Safety Program to PNRI, as applicable.

Section 17. ***Radiation Protection Officer (RPO) and Assistant Radiation Protection Officer (ARPO).***

(a) The licensee shall designate a Radiation Protection Officer (RPO) and an assistant Radiation Protection Officer (ARPO), who shall both consent and agree, in writing, to be responsible for implementing the Radiation Protection and Safety Program.

(b) The Assistant RPO shall take over the duties and responsibilities of the RPO, in the absence of the latter.

(c) The licensee shall provide the RPO sufficient authority, organizational freedom, and management prerogative to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Verify implementation of corrective actions;

(4) Monitor dose of workers;

(5) Perform dose mapping of the facility;

(6) Stop unsafe operations as deemed necessary;

(7) Coordinate the establishment, maintenance, drills or exercise of Emergency Procedures;

(8) Train new personnel and other personnel who work in supervised areas; and

(9) Interface with regulatory inspectors and provide access to required records of inspection.

(d) The licensee shall establish and state in writing the authorities, duties and responsibilities of the RPO and ARPO.

Section 18. ***Radiation Safety Committee.***

(a) The licensee shall establish a Radiation Safety Committee (RSC) that oversees the implementation of the Radiation Protection and Safety Program. The Committee must undertake the following:

(1) Review at least annually, with the assistance of the RPO, a summary of the occupational radiation dose records of all personnel using the blood irradiator;

(2) Provide the PNRI an Annual Report on the Use of Radioactive Materials as a prerequisite to the renewal of license.

(b) The RPO of the blood irradiator facility shall at least be a member of the RSC including authorized technologists.

Section 19. ***Management Responsibility.***

To ensure adequate management involvement, a management representative shall sign the submitted application acknowledging management's commitment and responsibility for the following:

(a) Radiation safety, security and control of radioactive materials, and compliance with the regulations;

(b) Completeness and accuracy of the radiation safety records and all information provided to the PNRI;

(c) Knowledge about the contents of the license and application;

(d) Provision of adequate resources to the Radiation Protection and Safety Program to ensure that public and workers are protected from radiation hazards and compliance with the regulations is maintained;

(e) Conduct of annual review of the Radiation Protection and Safety Program; and

(f) Compliance with the current PNRI regulations and the specific license conditions.

III. TECHNICAL REQUIREMENTS

Section 20. ***General Safety Considerations.***

(a) The licensee shall have records of the technical specifications that include, but are not limited to:

(1) Manufacturer, model and serial number of the blood irradiator;

(2) Source certificate of the radionuclide contained in the blood irradiator, that shows the manufacturer, model, serial number, initial activity and date of measurement of activity;

(3) Initial leak test certificate; and

(4) Quality control certificate of the blood irradiator.

(b) Each blood irradiator shall have a clearly visible label that includes the:

(1) Details specified in Paragraphs a.1 and a.2 of this Section; and

(2) Sign that states “CAUTION: THIS UNIT SHOULD NOT BE SCRAPPED/ DISPOSED OFF/ DISMANTLED WITHOUT PRIOR APPROVAL OF SUPPLIER AND PNRI.”

(c) The licensee shall provide personnel monitoring devices for each suitable worker and radiation survey and monitoring instruments that shall be calibrated in accordance with Section 24 of this Part.

(d) The licensee shall establish adequate design of the blood irradiator facility with security interlocks and key arrangements restricting access for unauthorized entry.

(e) The licensee shall secure the source from unauthorized removal from its storage and shall be under constant surveillance and immediate control.

(f) The licensee shall confirm that the location of the blood irradiator is equipped with an automatic fire-detection system that ensures the integrity of the equipment and radioactive source in fire.

Section 21. ***Operating and Emergency Procedures.***

(a) The licensee shall establish operating and emergency procedures for the use of blood irradiator in accordance with CPR Part 3.

(b) The operating procedures shall be kept at the blood irradiator facility. It shall include, but is not limited to the:

(1) Step-by-step procedures for the operation of the blood irradiator.

(2) Determination and recording of radiation doses of authorized technologists operating the blood irradiator.

(3) Methods to ensure that only authorized technologists will use the blood irradiator.

(4) Methods and procedures for conducting radiation surveys, and use of radiation survey and monitoring instruments;

(5) Proper use of personnel monitoring devices;

(6) Maintenance of records;

(7) Inspections, test procedures, and maintenance to ensure that all safety interlocks, devices, and components associated with the blood irradiator are functioning properly. Prohibited modifications, such as changing the safety control system or removing the source, should be stated.

(8) Minimizing exposure of persons in the event of an accident;

(9) Procedure for notifying proper persons and authorities in the event of an accident;

(10) Measures to prevent unauthorized access or damage to, loss, theft or sabotage of radioactive source and/or the blood irradiator;

(11) Identifying and reporting of noncompliance to the requirements of this Part; and

(12) Procedures for leak testing of radioactive sources in accordance with Section 26 of this Part.

(c) The emergency procedures shall be kept at the blood irradiator facility. It shall include, but is not limited to:

(1) Step-by-step emergency procedures in the blood irradiator; and

(2) Measures to comply with the incident reporting requirements in accordance with VII.Section 39 of this Part;

(d) The telephone numbers of the RPO/ARPO, equipment's manufacturer or supplier's representative, PNRI and other key personnel responsible for response in the event of an emergency shall be conspicuously posted in the facility.

Section 22. ***Quality Assurance 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 blood irradiator, which includes, among others, the procedures for:

(1) Measurements and verification of physical parameters at the time of the installation or acceptance testing, 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) Internal audit reviews.

(b) The licensee shall have the blood irradiator to be fully inspected, serviced and maintained in accordance with the manufacturer's recommendation by qualified personnel in accordance with the approved Quality Assurance Program.

Section 23. ***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 limited to thermoluminescent dosimeter (TLD) or optically stimulated luminescence dosimeter (OSL).

(b) The licensee shall ensure that each personnel monitoring device is assigned to, and worn only by one individual for each monitoring period.

(c) The licensee shall ensure that personnel monitoring devices, when not in use, are stored in a radiation-free, dry and cool place, so it will not be affected by adverse environmental conditions.

(d) All personnel dosimeters that require processing to determine the radiation dose shall be processed and evaluated immediately after each monitoring period by a PNRI-licensed or PNRI-recognized dosimetry service provider.

Section 24. ***Radiation Survey and Monitoring Instruments.***

(a) The licensee shall possess or has access to calibrated and operable radiation survey and monitoring 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 develop, implement, and maintain procedures to ensure calibration of instruments in compliance with this Part.

(c) Each radiation survey instruments shall be calibrated before its first use, annually and following any repair, by a PNRI-licensed or PNRI-recognized calibration service provider. 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%).

Section 25. ***Radiation Monitoring.***

(a) A survey with a calibrated and operable radiation survey and monitoring instruments shall be made before, during and after use of blood irradiator.

(b) The radiation monitoring report shall include, but is not limited to the:

(1) Date of the surveys;

(2) Plan of area that was surveyed;

(3) Background dose rate level;

(4) Measured dose rate in mSv/hr at several points in each area;

(5) Survey instruments used including its last calibration period; and

(6) Name and signature of authorized technologists who made the survey.

(c) A radiation monitoring shall be performed and documented by the RPO when changes have been made in the shielding, operation, equipment, or occupancy of adjacent areas.

Section 26. ***Leak Testing.***

(a) The licensee shall perform leak testing to detect any leakage from the sealed sources in the blood irradiator before its first use and annually thereafter, or as recommended by the manufacturer. If the licensee performs the entire leak test procedure, he/she shall submit the procedure for taking the test sample and the instrument to be used for measurement, for approval by the PNRI.

(b) If the licensee avails itself of or engages the services of a service provider licensed by PNRI for leak testing of sealed sources, the name, address and PNRI license number of the service provider shall be specified and submitted to PNRI.

(c) The leak test report shall contain, but is not limited to:

(1) The identity of each radioactive source and its estimated activity, manufacturer, model number and serial number;

(2) The measured activity of each test sample, date of test and a description of the method used to measure each test sample; and

(3) The PNRI license number of the service provider or name and signature of the individual who conducted the test, as appropriate.

Section 27. ***Replacement of Radioactive Source Contained in Blood Irradiator.***

The licensee shall establish and submit to PNRI for approval, the procedures on the replacement of radioactive source contained in a blood irradiator.

Section 28. ***Decommissioning.***

(a) Each licensee shall be responsible for the decommissioning of their blood irradiator units or facilities.

(b) A licensee shall submit to PNRI for approval a proposed decommissioning plan that includes:

(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 planned final radiation survey;

(4) Assurance on the availability of adequate funds for completion of decommissioning; and

(5) Program for the disposition of the radioactive source after decommissioning.

(c) A licensee shall submit to PNRI, upon completion of decommissioning, a report of the results of the radiation survey performed.

(d) A licensee shall demonstrate that the premises are suitable for unrestricted use and occupancy after decommissioning.

IV. SECURITY OF RADIOACTIVE SOURCES

Section 29. ***Security Requirements.***

The licensee shall establish, document and implement a security plan for the sealed source contained in blood irradiator in accordance with the requirements of CPR Part 26, “Security of Radioactive Sources”, to prevent unauthorized access or damage to, loss, theft or sabotage of radioactive source for possible malevolent use.

Section 30. ***Training on Security of Radioactive Sources.***

The licensee shall require each worker who are authorized to access or handle radioactive sources contained in blood irradiator to have completed a training on security of radioactive sources, as approved by PNRI.

V. QUALIFICATION, TRAINING AND EXPERIENCE REQUIREMENTS

Section 31. ***Qualification and Training of RPO and ARPO.***

The minimum qualification, training, and experience for RPOs and ARPOs for the blood irradiator are as follows:

(a) Holds a Bachelor of Science degree in Natural Science, Physical Science, or Engineering and is duly licensed by the Philippine Professional Regulations Commission, as applicable;

(b) Has completed at least 40 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;

(c) Has obtained written certificate of completion of training on the operation of the blood irradiator; and

(d) Has at least one (1) year of relevant, full-time experience in the administrative and operational control of radiation within a facility.

Section 32. ***Authorized Technologist.***

The minimum qualification, training, and experience for the authorized technologist for the use of blood irradiator are as follows:

(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 supervised training in the technical aspects and safe operation of the blood irradiator.

Section 33. ***Refresher Course.***

The licensee shall require the RPO, ARPO, and authorized technologists to undertake a refresher course on radiation safety, as appropriate and approved by PNRI, every five (5) years.

VI. MANAGEMENT OF DISUSED SEALED RADIOACTIVE SOURCES

Section 34. ***General Requirements.***

Each licensee shall dispose of its disused radioactive sources only:

(a) By return of disused source to the original supplier or manufacturer;

(b) By transfer to a recipient authorized by PNRI; or

(c) By disposal as radioactive waste in accordance with an approved radioactive waste management program.

Section 35. ***Return of Disused Radioactive Sources to the Original Supplier or Manufacturer.***

(a) Each licensee shall keep its special agreement with the supplier of the source for the return of disused sources to the original supplier or manufacturer of the source in the country of origin. A copy of such agreement including any updates or amendments shall be submitted to PNRI.

(b) The disused radioactive sources shall be shipped in accordance with the packaging and shipping requirements specified in CPR Part 4 entitled “Regulations for the Safe Transport of Radioactive Materials in the Philippines”.

Section 36. ***Transfer of Licensed Radioactive Source.***

(a) A licensee may transfer disused sources to another licensee authorized by PNRI to receive the source for the same and/or another purpose.

(b) No licensee shall transfer disused sources to another licensee unless:

(1) He has notified and has received authorization from PNRI about the transfer;

(2) He has submitted to PNRI appropriate information that includes;

(i) transferee or licensee’s name, address and license number; and

(ii) type, form and quantity of radioactive material to be transferred.

(c) The records of transfer shall include, but is not limited to:

(1) the identity of each radioactive source and its estimated activity, date of measurement of activity, manufacturer, model, and serial number; and

(2) name and signature of the individual making the record, as appropriate.

VII. RECORDS, REPORTS AND NOTIFICATIONS

Section 37. ***Recordkeeping Requirements.***

(a) The licensee shall maintain and retain records specified in this Part or as may be required by PNRI.

(b) Each licensee shall maintain a copy of its license and other documents relevant to its practice approved by PNRI, or until PNRI terminates the license.

(c) The licensee shall maintain a copy of current operating and emergency procedures and shall make them available to PNRI when requested.

(d) Each records of personnel monitoring shall be made available to the PNRI for inspection or upon request and shall be kept and preserved until the PNRI authorizes their disposal.

(e) The licensee shall maintain records of radiation survey instruments calibration and retain each record for three (3) years. The records shall contain:

(1) A description of the calibration procedure, if applicable;

(2) The manufacturer, model and serial number of the instrument;

(3) The date of the calibration;

(4) The results of calibration; and

(5) The name and signature of the individual who performed the calibration.

(f) The licensee shall maintain records of radiation monitoring and retain each record for three (3) years. The records of radiation monitoring shall be in accordance with the III.Section 25 of this Part.

(g) Each licensee shall maintain records of leak test results for radioactive sources for three (3) years or until the sources are transferred or disposed of in accordance with the III.Section 26 of this Part.

(h) The licensee shall maintain records of quality assurance program and test results of the blood irradiator. The licensee shall retain the records of regular quality control tests for three (3) years and the annual performance evaluation for five (5) years.

(i) The licensee shall maintain records of annual inventory of radioactive sources contained in blood irradiator and shall retain each record for three (3) years. The record shall include the date of the inventory, radionuclide, activity, location of radioactive source and/or device, manufacturer, model, and serial number of each radioactive source and/or device, and name and signature of the individual conducting the inventory, as appropriate.

(j) The licensee shall maintain records and proof of training and refresher course attended of all workers for three (3) years.

(k) The licensee shall maintain and retain records showing the receipts and transfers of radioactive sources for five (5) years in accordance with VI.Section 36 of this Part.

Section 38. ***Reports of Personnel Exposure.***

(a) The licensee shall furnish a report referring to worker's total radiation exposure during the period of employment in the licensee's facility whenever termination of employment has made. Such report shall be furnished within thirty (30) days after the exposure of the worker has been determined by the licensee or ninety (90) days after the date of termination of employment.

(b) At the request of the worker, each licensee shall furnish a report of that worker's total exposure to radiation, as shown in records maintained by the licensee.

Section 39. ***Incident Reports.***

(a) The licensee shall provide a report within twenty-four (24) hours followed by a detailed written report within thirty (30) days to the PNRI of the occurrence of any of the following incidents:

(1) Failure of any component that are critical to safe operation of the device to properly perform its intended function;

(2) Overexposure of personnel;

(3) Occurrence of fire in the facility; or

(4) Occurrence of flood, earthquake and other natural calamities that may compromise the safety and security of the radioactive source in the facility.

(b) The licensee shall include the following information for each report submitted under Paragraph (a) of this Section:

(1) A description of the incident; include the readings from the survey instruments or pocket dosimeters.

(2) Cause of incident, if known;

(3) Manufacturer and model number of blood irradiator involved in the incident;

(4) Place, time and date of incident;

(5) Actions taken to establish normal operations;

(6) Corrective actions taken or planned to prevent recurrence;

(7) Qualifications of workers involved in the incident; and

(8) Reports of overexposure.

Section 40. ***Report of Theft or Loss of Radioactive Sources.***

(a) Each licensee shall notify PNRI by telephone or by any other fast means of communication within twenty-four (24) hours, of any lost, stolen, or missing radioactive sources.

(b) In addition to the report required in this Section, each licensee shall, within thirty (30) days after the occurrence of the theft or loss of the radioactive source, report in writing to PNRI. The written report shall include the following information:

(1) Description of the radioactive sources involved (i.e., isotope, quantity, chemical, and physical forms);

(2) Description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition or probable disposition of the radioactive sources involved;

(4) Actions which have been, taken or will be taken, to recover the radioactive source; and

(5) Procedures/Measures to be adopted to prevent recurrence of the circumstances which led to the loss or theft of the radioactive source.

(c) Subsequent to filing the written report, the licensee shall also report to PNRI any additional information which becomes available to the licensee.

VIII. INSPECTION AND ENFORCEMENT

Section 41. ***Inspections.***

(a) Each licensee shall allow authorized PNRI inspectors to enter its premises at all reasonable times and perform such inspections as may be necessary, announced or unannounced, of the radioactive sources in possession and the premises, equipment and facilities where radioactive sources are used or stored.

(b) During such inspections, the licensee shall make available to PNRI inspectors all relevant records kept pursuant to these rules and regulations at the location specified in the license.

Section 42. ***Violations.***

A notice of violation shall be issued if the licensee is found to have violated any rules, regulations, or orders issued by PNRI; or any terms, conditions, or limitations of any license issued thereunder.

Section 43. ***Modification and Revocation of License.***

(a) The terms and conditions of each license issued pursuant to the regulations in this Part shall be subject to amendment, revision or modification by reason of amendments to these regulations and the Act, or by reason of rules, regulations and orders issued by the PNRI in accordance with the terms of the Act.

(b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application, or for violation of, or failure by the licensee to observe, any of the terms and conditions of the license or any of the provisions of the Act, or any of the rule, regulation or order of the PNRI.

(c) Except in cases of willful violation or where immediate action is required in order to protect public health and safety or the security of the source, no order for the suspension, modification or revocation of license shall become effective until the licensee shall have been afforded the opportunity be heard.

(d) A license maybe modified by PNRI, or upon the request of the licensee, when:

(1) The licensee decides to discontinue any specific licensed activity authorized in the license or requests for another authorization to undertake another licensed activity prescribed in this Part;

(2) PNRI determines that the licensee can no longer perform the specific licensed activity authorized in the license; or

(3) The licensee has ceased to perform a principal licensed activity during a two (2) year period.

(e) 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.

IX. EFFECTIVITY

Section 44. ***Effective Date.***

The regulations in this Part shall take effect fifteen (15) days after the publication in the Official Gazette.

APPROVED:

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

Date: 13 December 2021