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CPR Part 13

LICENSES FOR MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL

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Department of Science and Technology
PHILIPPINE NUCLEAR RESEARCH INSTITUTE
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CPR Part 13. LICENSES FOR MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL

I. GENERAL PROVISIONS

Section 1. Purpose and Scope.

(a) This Part prescribes the requirements and provisions for the issuance of licenses authorizing the medical use of unsealed radioactive material in diagnosis, therapy, in-vitro clinical and laboratory studies, and in medical research.

(b) The requirements in this Part provide for the protection of the health and safety of the workers, patients undergoing medical diagnostic and therapeutic procedures, the general public and the environment.

(c) The licensing requirements of this Part shall only apply to nuclear medicine facilities that offer services mentioned in subsection (a) in hospitals, medical centers and medical clinics.

(d) The provisions and requirements in this Part shall be applied in conjunction with the radiation safety requirements of CPR Part 3 – "Standards for Protection against Radiation" and the safe transport requirements of CPR Part 4 – "Regulations on the Safe Transport of Radioactive Material in the Philippines".

(e) 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) "**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. 2067, otherwise known as the Science Act of 1958, as amended by Republic Act No. 3589, and Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended by Presidential Decree No. 1484;

(c) "**Airborne radioactive material**" means radioactive material released in air in the form of dusts, fumes, particulates, mists, vapors, or gases;

(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) **"Ambient radiation dose rate"** means the dose of ionizing radiation delivered per unit time attributable to all sources other than the one(s) specified;

(f) **"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;

(g) **"Authorized User"** means a physician who meets the requirements of Section 39 of this Part and is identified as an authorized user in the license issued by the PNRI pursuant to this Part;

(h) **"Code"** or **"CPR"** means Code of PNRI Regulations;

(i) **"Contamination"** means undesirable radioactive materials deposited on surfaces, or within solids, liquids and gases (including human body) in a concentration that makes the medium unfit for its next intended use;

(j) **"Decommissioning"** means removing a facility or site safely from service and 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;

(k) **"Dedicated check source"** means a radioactive source that is used to ensure the operability of a radiation detector or measurement device;

(l) "**Disused radioactive source**" means a radioactive source which is no longer used, and is not intended to be used for the practice authorized by the license;

(m) **"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;

(n) **"In-vitro study"** means a procedure used to determine the nature, activity or retention of radionuclides on materials excreted or otherwise removed from the body;

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

(p) **"Management"** refers to the individual or group of individuals who are responsible for the conduct and control of the radiation safety program and who are responsible for the license, including the necessary resources to achieve regulatory compliance;

(q) "**Medical Physicist**" means a health professional, with specialist education and training in the concepts and techniques of applying physics in nuclear medicine and who meets the requirements in Section 40;

(r) **"Medical use"** means the intentional internal administration of radioactive material to patients or research subjects under the supervision of an authorized user;

(s) **"Nuclear Medicine"** means a specialized practice of medicine comprising all applications of unsealed radioactive materials in medical diagnosis, therapy and research including in-vitro clinical and laboratory studies;

(t) **"Nuclear Medicine Technologist"** means a licensed health professional with specialist education and training in nuclear medicine, competent to carry out nuclear medicine procedures, on delegation from the authorized user, for diagnostic or therapeutic purposes, and who meets the requirements in Section 41;

(u) ***"Patient intervention"*** means an intentional or unintentional action by the patient prematurely terminating the administration;

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

(w) **"Physician"** means a medical doctor licensed or authorized by the Professional Regulations Commission to prescribe drugs in the practice of medicine in the Philippines;

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

(y) **"Radiation Safety Officer (RSO)"** means the individual designated in the license issued pursuant to this Part to be responsible for implementing the radiation safety program of the licensee;

(z) "**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;

(aa) **"Radioimmunoassay"** means a method of employing radioactive materials to quantify specific substances in biological samples;

(bb) **"Radiopharmaceutical"** means a chemical compound labeled with radionuclide and administered to patients in nuclear medicine for diagnosis and/or therapy;

(cc) "**Source**" means anything that may cause radiation exposure – such as by emitting ionizing radiation or by releasing radioactive material – and can be treated as a single entity for protection and safety purposes;

(dd) **"Trigger level"** means a level or condition, as determined by the licensee, to act as an initiator for setting off an event or action (especially a response);

(ee) **"Unsealed radioactive material"** means a radioactive material that is neither (a) permanently sealed in a capsule nor (b) closely bonded and in a solid form; and

(ff) **"Written directive"** means an authorized user's written order for the administration of radioactive material or radiopharmaceutical to a specific patient as specified in Section 17 of this Part.

NOTE*: Terms defined in the Act and in other Parts of the CPR shall have the same meaning when used in this Part unless such terms are specifically defined otherwise in this Part.*

Section 3. Interpretation.

Except as specifically authorized by the Director in writing, no interpretation of the meaning of the regulations in this Part by any officer or employee of the PNRI will be binding upon the 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 acquire, receive, possess, own, use, import, export, or transport unsealed radioactive material for medical use except in accordance with a license issued by the PNRI pursuant to this Part.

Section 6. Application for a License.

An application for license for the medical use of unsealed radioactive material described in Section 18 shall only be received by the PNRI if made by –

(1) Filing an original and one copy of **PNRI/NRD Form–013, "Application for a License for the Medical Use of Unsealed Radioactive Material"**, that includes the pre-approved facility diagram, equipment, and training and experience of the Radiation Safety Officer, Authorized User(s), Medical Physicist, and Nuclear Medicine Technologist(s). 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;

(2) Submitting the proposed Radiation Safety Program, in accordance with Section 8 of CPR Part 3, “Standards for Protection against Radiation”, addressing the following, where applicable:

(i) Organization, duties and responsibilities of the Radiation Safety Committee
(ii) Designation of a qualified Radiation Safety Officer (RSO) and Assistant RSO
(iii) Duties and responsibilities of the RSO
(iv) ALARA Program
(v) Personnel Monitoring Program
(vi) Training Program
(vii) Procedures for ordering, receiving and opening of packages
(viii) Procedures for keeping records of radiopharmaceutical use/dosages
(ix) Procedures for developing, maintaining and implementing written directives
(x) QA/QC of the proposed nuclear medicine equipment
(xi) Rules for safe use of radiopharmaceuticals
(xii) Procedures for leak testing
(xiii) Procedures for area monitoring
(xiv) Minimization of contamination/Spill procedures
(xv) Monitoring, calculating and controlling airborne radioactive materials
(xvi) Procedure for safety during radiopharmaceutical therapy
(xvii) Procedures for waste disposal and decay-in-storage
(xviii) Radiation safety precautions and instructions for patients
(xix) Hospital care and handling of radioactive patients including safety instructions to all personnel caring for confined patients
(xx) Procedures for handling radioactive cadavers
(xxi) Procedure for radiation surveys and calibration of survey instruments

(xxii) Operating and emergency procedures
(xxiii) Proposed decommissioning plan; and

(3) Paying 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. Issuance of License.

The PNRI shall issue a license for the medical use of unsealed radioactive material if the following conditions are satisfactorily met –

(1) The application is for the purpose authorized by the Act;
(2) The applicant has filed **PNRI/NRD Form–013** in accordance with the instructions in Section 6; and
(3) The PNRI finds that the application is complete in substance and form and the proposed equipment, facilities and procedures are adequate to ensure the health and safety of radiation workers, members of the public and the environment.

Section 8. Terms and Conditions of License.

(a) Each license shall be subject to the provisions of the Act, the 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 in order to protect the health and safety of the public.

(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) Consent 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 and applicable regulations of the Code shall be kept and made available at each authorized location of use indicated in the license.

(f) The license shall be valid for a period as determined by the PNRI.

Section 9. Amendment of License.

(a) An application for amendment of a license shall be filed in **PNRI/NRD Form-013**, and shall specify in what respect the licensee desires his license to be amended 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 must receive a license amendment before:

(1) It receives and uses radiopharmaceuticals for a clinical procedure other than what is permitted under his license;
(2) It permits anyone to work as an RSO or ARSO, authorized user, medical physicist and nuclear medicine technologists other than those previously authorized in the license;
(3) It procures radiopharmaceuticals in excess of the authorized amount, or in a form different from what is authorized by 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 changes or includes additional isolation room for therapeutic patients;
(6) It implements any major change in the accepted radiation safety program; or
(7) Any substantial change in any condition of the license takes effect, in consultation with the PNRI.

Section 10. 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 11 of this Part.

(b) If the license has expired and the licensee fails to renew its license, the licensee shall refrain from undertaking licensed activities involving radioactive material except to keep the radioactive materials under safe storage until the applicable provisions of Section 11 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 37 of this Part, if the license will be terminated.

Section 11. Renewal of License.

(a) A request for license renewal shall be made by submitting an original and one copy of **PNRI/NRD Form-013** not less than thirty (30) 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 Section 6 (a) and (b), 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 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.

(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 (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 taken action on the application;
(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 the 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 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.

(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.

Section 12. Termination of License.

(a) The termination of a license maybe initiated at any time at the request of the licensee.

(b) Before the license can be terminated, the licensee must:
(1) Discontinue all activities involving licensed radioactive materials;
(2) Transfer or dispose all licensed radioactive materials which were in his possession in accordance with the regulations;
(3) Determine by survey or other means that no contamination levels in excess of the limits shown in Table 1, Section 13.5 of CPR Part 3, over an average area of 300 square centimeters exist in his facilities; and
(4) Assure that the required records are complete and up-to-date.

(c) To be relieved of the responsibilities for the licensed radioactive material and other conditions in his license, the licensee shall submit to the PNRI:
(1) His request that the license be terminated;
(2) A certified statement that he no longer has in his possession any radioactive material requiring a license;
(3) A listing of the radioactive material transferred or disposed of and the person to whom the material was transferred or the method of disposal for each item;
(4) A radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual contamination; and
(5) An agreement that his records and facilities will be available for inspection by the PNRI at a mutually agreeable date within the next three months.

(d) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues to be in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the PNRI notifies the licensee in writing that the license is terminated. During this time the licensee shall:
(1) Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for the release of the affected area for unrestricted use; and
(2) Continue to control entry to restricted area until they are found suitable for release for unrestricted use and the PNRI notifies the licensee in writing that the license is terminated.

(e) When these procedures are satisfactorily completed, the PNRI will formally inform the licensee that the license has been terminated.

Section 13. 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.

II. ADMINISTRATIVE REQUIREMENTS

Section 14. Radiation Safety Program.

(a) The licensee shall develop, document and implement a written radiation safety program commensurate with the scope and extent of licensed activities and sufficient 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 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).

(c) 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 15. Radiation Safety Officer (RSO) and Assistant Radiation Safety Officer (ARSO).

(a) The licensee shall designate an independent and qualified RSO who shall 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;
   (2) Initiate, recommend, or provide corrective actions;
   (3) Stop unsafe operations; and
   (4) Verify implementation of corrective actions.

(c) The licensee shall establish and state in writing the authorities, duties and responsibilities of the RSO.

Section 16. Radiation Safety Committee (RSC).

(a) The licensee shall establish a Radiation Safety Committee (RSC) that oversees the implementation of the Radiation Safety Program. The Committee must undertake the following:
   (1) Review at least semi-annually, with the assistance of the RSO, a summary of the occupational radiation dose records of all personnel working with unsealed radioactive materials;
   (2) Review at least semi-annually the procurement and administration of radiopharmaceuticals; and
   (3) Provide the PNRI a report on their accomplished activities as a prerequisite to the renewal of license.

(b) The Committee must include an authorized user, the RSO and/or medical physicist, a representative of the nursing service, a nuclear medicine technologist, and an administrator representing the management who is neither an authorized user nor a RSO. Other members may be included as the licensee deems appropriate.

Section 17. Written Directives.

(a) A written directive must be dated and signed by an authorized user before the administration of diagnostic and therapeutic dose of radiopharmaceutical. It must contain the patient's name, the radioactive drug, dosage and route of administration.

(b) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, a verbal directive is acceptable but must be documented within forty-eight (48) hours after the verbal directive is given.

(c) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to ensure the following:
(1) The patient's identity is verified before each administration; and
(2) Each administration is in accordance with the written directive.

(d) The licensee shall retain a copy of each written directive for two (2) years, and make available for inspection by the PNRI.

III. TECHNICAL REQUIREMENTS

Section 18. Unsealed Radioactive Materials for Medical Use.

(a) The licensee shall receive, acquire, possess, use, own, import, export, or transport unsealed radioactive material –
(1) For diagnosis involving measurements of uptake, dilution, or excretion for medical use;
(2) From any generator or reagent kit for preparing radiopharmaceuticals used for imaging and localization studies;
(3) For palliative and/or curative therapeutic nuclear medicine procedures;
(4) For administration to human research subjects; and
(5) For in-vitro clinical and laboratory tests not involving internal or external administration to human beings or animals.

(b) The licensee shall receive, acquire, possess, use, or transport of the following radioactive materials in pre-packed units for in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings:
(1) Iodine-125, Iodine-131, Carbon-14, units not exceeding 370 kBq each;
(2) Hydrogen-3 (tritium), in units not exceeding 1.85 MBq each;
(3) Iron-59, in units not exceeding 740 kBq each;
(4) Selenium-75, in units not exceeding 370 kBq each;
(5) Cobalt-57 reference or calibration sources, in units not exceeding 370 kBq each;
(6) Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq of Iodine-129 and 185 Bq of Americium-241 each.

(c) The licensee shall only use unsealed radioactive materials on pre-labeled pharmaceuticals that are manufactured, labeled, packaged and distributed by manufacturers or distributors licensed by the PNRI under a commercial license or in accordance with a license issued

pursuant to CPR Part 20 and that are registered by the Food and Drug Administration (FDA) of the Department of Health or by internationally recognized competent authorities.

Section 19. Determination of Dosages of Unsealed Radioactive Material for Medical Use.

(a) The licensee shall determine and record the activity of each dosage of unsealed radioactive material before medical use.

(b) For a unit dosage, this determination must be made by direct measurement of radioactivity or a decay correction based on the activity or activity concentration as determined by the manufacturer or PET radioactive drug producer.

(c) For multi-dosages, this determination must be made by direct measurement of radioactivity, by mathematical calculations, or a combination of volumetric measurements and mathematical calculations based on the measurement made by the manufacturer or PET radioactive drug producer.

(d) The licensee shall ensure that the administered dosage is within the prescribed dosage range or within ±20 percent of the prescribed dosage, as applicable.

(e) The licensee shall keep a record of the measurements required by this section in accordance with Section 43 of this Part.

Section 20. Personnel Monitoring.

(a) The licensee shall not allow any worker to perform any licensed activity unless he/she wears a calibrated personnel monitoring device, such as but not necessarily limited to thermoluminescent dosimeter (TLD) or optically stimulated luminescence dosimeter (OSL), in compliance with the provisions of Sections 13.8 and 13.9 of CPR Part 3.

(b) Individuals engaged in the elution of Technetium-99m pertechnetate from generators and/or preparation of the labeled radiopharmaceuticals shall have the exposures to their fingers or hands monitored using appropriate dosimeters, whenever necessary.

(c) 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 processor.

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

(e) The licensee shall maintain a record of total exposures of all individuals who are required to wear personnel monitoring devices in accordance with Section 44 of this Part.

Section 21. Syringes, Vials, Radiation Shields and Labels.

(a) The licensee shall conspicuously label each syringe and vial that contains an unsealed radioactive material in order to identify its contents. Each syringe radiation shield and vial radiation shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(b) The licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe or vial radiation shield when preparing the kit and shall require each individual to use a

syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for the patient.

Section 22. Possession, Use, Calibration and Check of Dose Calibrators.

(a) For direct measurements performed in accordance with Section 19 of this Part, a licensee shall have in its possession a dose calibrator or an activity meter and use it to measure the amount of activity administered to each patient.

(b) The licensee shall calibrate the dose calibrator for constancy, accuracy, linearity and geometry dependence in accordance with internationally recognized standards.

(c) The licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator or relocation of the dose calibrator.

(d) The licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds ten (10) percent 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 (10) percent.

(e) The licensee shall retain a record of calibration required by paragraph (b) in accordance with Section 45 of this Part.

Section 23. Possession, Use and Calibration of Radiation Detection and Measuring Instruments.

(a) The licensee shall have in its possession calibrated and operable radiation detection and measuring 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.

(c) The licensee shall cease to use an instrument if the difference between the indicated exposure rate and the calculated value is more than twenty (20) percent.

(d) The licensee is required to keep records of calibration certificates issued by the service provider in accordance with Section 45 of this Part for inspection by the PNRI.

Section 24. Possession of Check, Calibration, Transmission and Reference Sources.

The licensee may receive, possess, and use, wherever applicable, the following radioactive material for check, calibration, transmission and reference use:

(1) Sealed sources that do not exceed 0.6 GBq each;
(2) Any radioactive material with a half-life not longer than 100 days and in individual amounts not to exceed 0.6 GBq each;
(3) Any radioactive material with a half-life longer than 100 days and in individual amounts not to exceed 8 MBq each;

(4) Technetium-99m in individual amounts not to exceed 3.7 GBq; and
(5) Any radioactive material that maybe authorized by the PNRI upon request by the licensee.

Section 25. Leak Test of Radioactive Sources.

(a) The licensee in possession of a radioactive source shall test the source for leakage before its first use and annually thereafter, or as recommended by the manufacturer. If the licensee has a certificate from the supplier indicating that the source was leak tested within twelve (12) months before it was delivered to the licensee, the leak test before first use is not required.

(b) If the licensee performs the entire leak test procedure himself/herself, the licensee shall describe and submit the procedure for taking the test sample and the instrumentation that will be used for measurement, including the instrument's recent calibration certificate, for approval by the PNRI.

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

(d) If the licensee intends to use a commercial leak-test kit, the kit model number and the name, address, and license number of the kit supplier shall be specified.

(e) The licensee shall retain a record of the results of leak tests on radioactive sources in accordance with Section 46 of this Part.

Section 26. Surveys for Contamination and Ambient Radiation Dose Rate.

(a) The licensee shall survey with a radiation detection survey instrument all areas where radiopharmaceuticals are routinely prepared for use or administered at the end of each day of use.

(b) The licensee shall survey with a radiation detection survey instrument all areas where radiopharmaceuticals, radioactive sources and radioactive wastes are stored at least once each week.

(c) The licensee shall establish radiation dose rate trigger levels for the surveys required by paragraphs (a) - (b) of this section. A licensee shall require that the individual performing the survey immediately notify the RSO if a dose rate exceeds the trigger level.

(d) The licensee shall survey for removable contamination with a contamination meter all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored once each week.

(e) The licensee shall survey for removable contamination the isolation room after discharge of therapeutic patients.

(f) The licensee shall conduct the surveys required by paragraphs (e) and (d) of this section so as to be able to detect contamination on each swipe sample and make every reasonable effort to avoid contamination of surfaces accessible to persons or other property in excess of the limits shown in Table 1, Section 13.5 of CPR Part 3, over an average area of 300 square centimeters.

(g) The licensee shall establish removable contamination trigger levels for the surveys required by paragraphs (e) and (d) of this section. A licensee shall require that the individual performing the survey immediately notify the RSO if contamination exceeds the trigger level.

(h) The licensee shall maintain a record showing the results of surveys in accordance with Section 47 of this Part.

Section 27. Release of Patients after Radionuclide Therapy.

(a) The licensee shall ensure that no patient who has undergone radionuclide therapy is discharged from a hospital or clinic until it has been established by either a medical physicist or the RSO that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 3 mSv.

(b) The authorized user shall provide the patient or legal guardian of the patient with:
(1) Written instructions for keeping doses to persons in contact or in the vicinity of the patient ALARA and for avoiding the spread of contamination;
(2) Information on the radiation risks; and
(3) Guidance on the interruption or discontinuation of breast-feeding, if applicable.

(c) The licensee shall maintain a record of the basis for authorizing the release of a patient after radionuclide therapy and the written instructions given to the patient or his legal guardian. These records shall be retained for two (2) years after the date of release of the individual.

Section 28. Safety Precautions in Handling Radioactive Patients.

(a) The licensee shall survey with a radiation detection instrument patients administered with low doses of radioactive material before discharge.

(b) For each patient who cannot be released under Section 27, the licensee shall
(1) Confine the patient in a designated isolation room that is properly shielded and has a private sanitary facility; and
(2) Visibly post the patient's room with a "CAUTION: RADIATION AREA" sign;

(c) The licensee shall control access to the isolation room and must be located as far away from the nursing station and from the hallways that may be used frequently by people.

(d) The licensee shall delineate the area where visitors can approach the patient by physical means, or where this is not reasonably practicable, by some other suitable means, and limit the visiting time to minimize the visitor's exposure to radiation from the patient.

(e) The licensee shall not allow the room vacated by radioactive patient to be occupied by non-radioactive patient until the RSO has certified it to be free from contamination or have conducted decontamination activities, if required, and issued a certification of unrestricted use.

Section 29. Safety Instructions.

(a) The licensee shall provide radiation safety instructions, initially and at least annually, to all personnel caring for in-patients receiving radionuclide therapy. The instructions must address the licensee's procedures for:
(1) Patient control;
(2) Visitor control;
(3) Contamination control;

(4) Waste control; and
(5) Notification of the RSO in case of the patient's death or medical emergency.

(b) The licensee shall keep for two (2) years a list of individuals receiving instructions required by subsection (a), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

Section 30. Safe Handling of Dead Persons that Contain Unsealed Radioactive Material.

The licensee shall implement procedures for safe handling of dead persons or human remains that are known to contain unsealed radioactive material in accordance with the procedure approved by the PNRI.

Section 31. Quality Assurance (QA) Program of Nuclear Medicine Equipment.

(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 nuclear medicine imaging and non-imaging equipment, including 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, as applicable;
(2) Implementation of corrective actions if measured values as required in paragraph (1) are outside established tolerance limits;
(3) Verification of the appropriate physical and clinical factors used in nuclear medicine procedures;
(4) Periodic checks of the calibration and conditions of operation; and
(5) Regular and independent external audit reviews.

(b) The licensee shall keep written records of relevant quality control procedures and performance test results of all nuclear medicine equipment in accordance with Section 48 of this Part.

Section 32. Control of Airborne Radioactive Materials.

(a) A licensee that operates a laboratory where radioactive aerosols or gases may be produced or handled shall install, maintain, and use a dedicated nuclear medicine fume hood to provide a mechanical means to cause all air from the laboratory to flow toward the hood with a face velocity sufficient both to prevent dispersal of radioactive substances from inside the hood and to exhaust the contaminated air to the outside through appropriate filters.

(b) The system must maintain sufficient room air changes to ensure that airborne concentrations are kept within clearance levels given in CPR Part 3, APPENDIX D-1 (Derived Generic Clearance Levels for Airborne Releases).

(c) The licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shielded container. The licensee shall store the multi-dose container in a fume hood after drawing the first dosage from it.

(d) The licensee shall conduct fume hood performance test at least annually, and the measurements of fume hood average face velocity and determination of room air changes per hour shall be done every six (6) months. Records of these tests shall be kept in accordance with Section 48 of this Part and shall be made available during inspection.

Section 33. Surveys of Packages Containing Radioactive Material on Receipt.

(a) As soon as possible after receipt of each package of radioactive material other than those exempted in subsection (b), the licensee shall monitor the package for radioactive contamination on the external surfaces and for radiation levels outside of the package. If removable contaminations in excess of 4 Bq/cm^2 or radiation levels exceeding 2 mSv/h at the surface of the package or 0.1 mSv/h at one (1) meter from the surface are found, the licensee shall immediately notify the final delivering carrier and the PNRI. A written report shall be submitted to the PNRI within thirty (30) days.

(b) The following packages of radioactive materials are exempted from being monitored on receipt as required in subsection (a):
   (1) Packages containing radioactive material exempted from licensing requirements;
   (2) Packages containing not more than 370 MBq of Tritium, Carbon-14, Sulfur-35 or Iodine-125;
   (3) Packages containing only radioactive material as gases or special form (e.g. sealed sources);
   (4) Packages containing radioactive material other than liquid form and not exceeding the Type A Package quantity limit specified in CPR Part 4; and
   (5) Packages containing radionuclides with half-lives less than thirty (30) days and a total quantity of no more than 3.7 MBq.

(c) The licensee shall maintain a record showing the results of surveys in accordance with Section 47 of this Part.

Section 34. Waste Management and Disposal of Radioactive Materials.

(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 a 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 survey meter set on its most sensitive scale and with no interposed shielding;
   (2) All radiation labels have been removed or obliterated; and/or
   (3) Each generator column have been separated and monitored individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(c) The licensee shall return Mo-99/Tc-99m generators to the supplier if not decayed in storage for 60 days, following the specifications in CPR Part 4.

(d) The licensee shall keep a record of disposal of radioactive wastes and disused sealed sources in accordance with Section 49 of this Part.

Section 35. Transport of Radioactive Materials.

The licensee shall transport radioactive materials in accordance with the requirements of CPR Part 4, “Regulations for the Safe Transport of Radioactive Materials in the Philippines”.

Section 36. Emergency Plan.

(a) The licensee shall establish an Emergency Plan in accordance with Section 17.1 of CPR Part 3.

(b) The licensee shall develop and implement written procedures and instructions on the following in the event of an accident:
(1) Minimizing exposure of persons;
(2) Use of emergency spill kits, survey instruments and other safety equipment;
(3) Preventing the spread of contamination; and
(4) Notifying proper individuals.

(c) The licensee shall post at convenient, visible location in the licensed facility copies of the emergency procedures and local rules that include the telephone numbers of the RSO/ARSO and other key personnel responsible for response in the event of an emergency.

Section 37. Decommissioning.

(a) The licensee shall submit to the PNRI for approval a proposed decommissioning plan six (6) 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, upon completion of decommissioning, a report of the results of the radiation survey performed.

IV. TRAINING AND EXPERIENCE REQUIREMENTS

Section 38. Radiation Safety Officer (RSO) and Assistant Radiation Safety Officer (ARSO).

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

(1) 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;

(2) Has completed 200 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of radioactive material, including radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, radiation biology, and nuclear regulations and licensing; and

(3) Has at least one (1) year of relevant, fulltime experience on radiation safety at a medical institution under the supervision of the individual identified as the RSO in a PNRI license that authorizes the medical use of unsealed radioactive material.

Section 39. Authorized User.

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

(1) Is a physician duly licensed by the Professional Regulations Commission;
(2) Is certified by a medical specialty board whose certification process has been recognized by the PNRI;
(3) Has completed 200 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of radioactive material, including radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, radiation biology, and nuclear regulations and licensing; and
(4) Has at least two (2) years of relevant, fulltime clinical training and work experience under the supervision of an Authorized User who meets the requirements pursuant to this Part.

Section 40. Medical Physicist.

The licensee shall designate a Medical Physicist, upon the endorsement and approval of the Radiation Safety Committee, who:

(1) Holds a Bachelor of Science degree in physics, applied physics, other physical sciences or engineering;
(2) Has earned graduate credit units in Radiation Physics, Physics of Nuclear Medicine, Radiation Protection, Radiation Dosimetry, Radiation Biology in a masteral degree program in Medical Physics or its equivalent;
(3) Has completed 200 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of radioactive material, including radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, radiation biology, and nuclear regulations and licensing; and
(4) Has at least one (1) year of relevant, fulltime training and work experience in radiation protection, radiation dosimetry, quality assurance and quality control, and equipment management, under the supervision of a clinically qualified medical physicist.

Section 41. Nuclear Medicine Technologist.

The licensee shall designate a nuclear medicine technologist, upon the endorsement and approval of the Radiation Safety Committee, who:

(1) Holds a Bachelor of Science degree in allied health courses such as, but not limited to medical technology, radiologic technology, pharmacy, or nursing; and/or fulltime certificate, diploma or degree courses in nuclear medicine; and is duly licensed by the Philippine Professional Regulations Commission, as applicable;
(2) Has completed 200 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of radioactive material, including radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, radiation biology, and nuclear regulations and licensing; and

(3) Has at least six (6) months of relevant, fulltime work experience in nuclear medicine activities at a medical institution under the supervision of the individual identified as a Nuclear Medicine Technologist in a PNRI license that authorizes the medical use of unsealed radioactive material.

Section 42. Refresher Course.

The licensee shall require workers occupationally exposed to radiation to undertake a refresher course on radiation safety, as appropriate and approved by the PNRI, every five (5) years.

V. RECORDKEEPING

Section 43. Records of Dosages of Radiopharmaceuticals for Medical Use.

(a) The licensee shall maintain a record of dosage determinations as required by Section 19 of this Part for two (2) years.

(b) To satisfy this requirement, the record must contain the:
(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;
(2) Patient's name and identification number, if one has been assigned;
(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 0.4 MBq;
(4) Date and time of the dosage determination; and
(5) Name and initial of the individual who made the record.

Section 44. Records of Personnel Exposure Monitoring.

(a) The licensee shall maintain a record of total exposures to radiation of all individuals, as required by Section 20 of this Part,

(b) 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 disposition.

(c) Upon the request of the employee, the licensee shall furnish a report referring to employee’s total radiation exposure during the period of employment or work assignment in the licensee’s facility whenever termination of employment is made. Such report shall be furnished within thirty (30) days after the exposure of the employee has been determined by the licensee or ninety (90) days after the date of termination of employment or work assignment.

Section 45. Records of Calibration of Instruments.

(a) The licensee shall retain a record of each instrument and reference sources calibration certificates for two (2) years as required by Sections 22 and 23 of this Part.

(b) The record must include:
(1) A description of the calibration procedure, if applicable;
(2) The 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.

Section 46. Records of Leak Test.

(a) The licensee shall retain a record of the results of leak tests on sealed sources as required by Section 25 for two (2) years or until the sealed sources are transferred or disposed.

(b) The records must contain:
(1) The model number, and serial number if assigned, of each source tested;
(2) The identity of each source radionuclide and its estimated activity;
(3) The measured activity of each test sample expressed in becquerels;
(4) A description of the method used to measure each test sample;
(5) A diagram to show the leak tested areas;
(6) The date of the test;
(7) The name and signature of the individual who conducted the test; and
(8) The signature of the RSO.

Section 47. Records of Surveys.

(a) The licensee shall maintain a record showing the results of surveys incident to the use, storage, and packages containing radioactive materials on receipt and in the isolation room until PNRI authorizes their disposition as required by Sections 26 and 33 of this Part.

(b) A licensee shall make available to the PNRI inspectors a record of each survey and retain for two (2) years. The record must include:
(1) The date and time of the survey;
(2) A floor plan/diagram of each area surveyed;
(3) The trigger level established for each area;
(4) The detected dose rate at several points in each area expressed in microsieverts per hour (μSv/h) or the removable contamination in each area expressed in Bq per 300 cm^2;
(5) The background levels in CPM, CPS, DPS, or DPM;
(6) The instrument used to make the survey or analyze the samples; and
(7) The name and initial of the individual who performed the survey.

Section 48. Records of Performance Test, Maintenance and Repair.

(a) The licensee shall maintain a record of the performance tests, maintenance and repair of medical imaging and non-imaging equipment or instruments at the Nuclear Medicine facility.

(b) The licensee shall retain the records of regular quality control tests, maintenance and repair for two (2) years and the annual performance evaluation of the nuclear medicine imaging equipment for five (5) years. The record must include:
(1) The names and signatures of the individuals who performed the performance test, maintenance or repair;
(2) The date; and
(3) A description of the results of test, maintenance or repair performed.

Section 49. Records of Disposal of Radioactive Wastes and Disused Radioactive Sources.

(a) The licensee shall maintain and retain records of disposal of radioactive wastes and disused sealed sources as required by Section 34 of this Part until the PNRI authorizes their disposal.

(b) The record must include, as applicable, the:
(1) Radionuclide disposed;
(2) Activity of disused sources at the time of disposal;
(3) Dose rate measured at the surface of each waste container;
(4) Date on which the radioactive material was placed on storage;
(5) Estimated date of disposal;
(6) Background dose rate;
(7) Survey instrument used;
(8) Date of the disposal; and
(9) Name and signature of the individual who performed the survey.

VI. REPORTS AND NOTIFICATIONS

Section 50. Notifications of Incidents.

(a) The licensee shall immediately notify the PNRI within twenty-four (24) hours by telephone, or by any similarly fast means of communication, of any lost, stolen or missing licensed radioactive material, or any incident involving a radioactive material possessed by the licensee which may have caused or threatened to cause a single exposure of the whole body of any individual in excess of 50 mSv.

(b) The licensee shall immediately report to the 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) 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 report.

Section 51. Reports and Notifications of Medical Events.

(a) The licensee shall report any event, except for an event that results from patient intervention, in which the administration of radiopharmaceuticals results in:
(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 50 mSv effective dose equivalent, 500 mSv to an organ or tissue, or 500 mSv shallow equivalent dose to the skin; and
(2) The total dosage delivered differs from the prescribed dose by 20 percent or more or falls outside the prescribed dosage range.
(3) A dose that exceeds 50 mSv effective equivalent dose, 500 mSv to an organ or tissue, or 500 mSv shallow dose equivalent to the skin from any of the following:
(i) An administration of a wrong radiopharmaceuticals;
(ii) An administration of a radiopharmaceuticals by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual; or
(iv) An administration of a dose or dosage delivered by the wrong mode of treatment.

(b) The licensee shall notify the PNRI by telephone, or by any similarly fast means of communication, no later than the next calendar day after the discovery of the medical event.

(c) The licensee shall submit a written report to the PNRI within fifteen (15) days after discovery of the medical event.

(d) The written report must include:
(1) The licensee's name;
(2) The name of the prescribing physician;
(3) A brief description of the event;
(4) Why the event occurred;
(5) The effect, if any, on the individual(s) who received the administration;
(6) What actions, if any, have been taken or are planned to prevent recurrence;
(7) Certification that the licensee notified the patient (or the patient's responsible relative or guardian), and if not, why not; and
(8) The date when of the medical event.

(e) The report may or may not contain the individual's name or any other information that could lead to the identification of the individual.

Section 52. Notifications on Specific Changes in the License.

(a) The licensee shall notify the PNRI immediately by telephone or by any similarly fast means of communications:
(1) When the Radiation Safety Officer permanently discontinues performance of duties under the license; or
(2) When the licensee's mailing address changes.

(b) The licensee shall submit a written report to the PNRI and request for license amendment in accordance with Section 9 within thirty (30) days.

VII. INSPECTION AND ENFORCEMENT

Section 53. Inspection.

(a) The licensee shall afford to the PNRI, at all reasonable times, the opportunity to inspect the radioactive material in his possession and the premises, equipment and facilities 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 54. Violations.

(a) A notice 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, after due process, 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 55. 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 the PNRI rules and regulations, or by reason of rules, regulations and orders issued by the 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.

Section 56. Right to Cause the Withholding or Recall of Radioactive Material.

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

VIII. EFFECTIVITY

Section 57. Transitory Provisions.

Previously licensed facilities shall be given two (2) years to comply with the provisions of this Code not covered in the Code of PNRI Regulations Part 13, “Licenses for the Medical Use of Radiopharmaceuticals”, Rev. 01 published in the Official Gazette on December 26, 2005; Vol. 101, No. 52.

Section 58. Effective Date.

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

Approved:

(Sgd) ALUMANDA M. DELA ROSA, Ph. D.
Director

Date: 23 December 2013