Published in Volume 101, No. 52 of the Official Gazette dated December 26, 2005

Republic of the Philippines
Department of Science and Technology
PHILIPPINE NUCLEAR RESEARCH INSTITUTE
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CPR Part 13. LICENSES FOR MEDICAL USE OF RADIOPHARMACEUTICALS

I. GENERAL PROVISIONS

Section 1. Purpose and Scope

(a) This Part prescribes the requirements and provisions for the medical use of radiopharmaceuticals, and for the issuance of licenses authorizing the medical use of these materials in medical institutions.

(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 and the general public.

(c) Applicable requirements and provisions of Parts 2, 3, and 4 of the Code shall be in addition to, and not in substitution for this Part unless specifically stated otherwise.

(d) Nothing in this Part relieves the applicant or licensee from complying with applicable regulations of other government agencies.

(e) The licensing requirements of this Part shall apply only to medical facilities such as hospitals, medical centers, and similar institutions.

Section 2. Definitions

As used in this Part:

(a) **"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;

(b) **"ALARA"** (as low as reasonably achievable) means 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;

(c) **"Assistant Radiological Health and Safety Officer (ARHSO)"** means the individual who meets the requirements of Section 49 of this part and is designated by the licensee to perform the duties and responsibilities of the RHSO in his absence;

(d) **"Authorized Technologist"** means the individual who meets the requirements of Section 51 of this part and is authorized to assist the authorized user in the administration of radiopharmaceuticals to patient, for diagnostic or therapeutic purposes;

(e) **"Authorized User"** means a physician who meets the requirements of Section 50 of this Part and is identified as an authorized user in the license issued by PNRI pursuant to this Part;

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

(g) **"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.

(h) **"Dedicated check source"** means a radioactive source that is used to assure the constant operation of a radiation detector or measurement device;

(i) **"Emergency Plan"** means a set of procedures to be implemented in the event of a radiological accident that would affect the safety of the facility and the public in general;

(j) **"Management"** refers to the officers of the licensed institution who manage, direct, or control licensed activities;

(k) **"Medical Institution"** means an organization in which several medical practices are performed;

(l) **"Medical use"** means the intentional administration of radiopharmaceuticals to human beings under the supervision of an authorized user;

(m) **"Medical event"** means the administration of radiopharmaceuticals that differs from that prescribed by the authorized user;

(n) **"Nuclear Medicine"** means a specialized practice of medicine whereby unsealed sources are administered internally to human beings for purposes of diagnosis or treatment and includes also in-vitro applications of radioisotopes for diagnosis or research;

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

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

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

(r) **"Qualified Expert"** means an individual, by virtue of certification by appropriate boards or societies, professional licenses or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, radiation protection, occupational health and safety and quality assurance/quality control.

(s) **"Radiological Health and Safety Officer (RHSO)"** means the individual who meets the requirements of Section 49 of this part and designated by the licensee to be the Radiological Health and Safety Officer;

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

(u) **"Sealed Source"** means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material; and

(v) **"Written directive"** means an authorized user's written order for the administration of radiopharmaceutical to a specific patient:

(1) The dosage for any administration of quantities greater than 1.11 MBq of either sodium iodide 1-131; and

(2) The radiopharmaceutical, dosage, and route of administration for a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131.

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 official or employee of PNRI will be recognized to be binding upon PNRI.

Section 4. Communication

All communication and reports concerning the licenses and the regulations in this Part should be addressed to the Director, Philippine Nuclear Research Institute, Commonwealth Avenue, Diliman, Quezon City, Metro Manila.

Section 5. Activities Requiring License

Only medical institutions shall be granted a license. Such institutions may acquire, receive, possess, own, or use radiopharmaceuticals for medical use in accordance with a license issued by PNRI pursuant to this Part.

Section 6. Application for New License

(a) An application for a license for medical use of radiopharmaceuticals must be made by filing an original and one copy of NRLSD Form – 013, "Application for Radioactive Material License (Nuclear Medicine)".

(b) Each application for a license pursuant to this Part must be affirmed and notarized upon submission to PNRI.

(c) Each applicant shall show proof of authority to conduct business under its business name issued by the Securities and Exchange Commission or the responsible government agency.

(d) The application shall adequately describe the necessary information about the proposed facility, designated workers, equipment, and materials according to the technical and safety requirements specified in this Part and will be accepted and processed only when PNRI has determined the completeness of the submitted information, and payment of the application fee has been made.

(e) The application for a license shall be deemed complete in substance and form if the application, as submitted, contains the necessary facts and information to assure that the safety of the workers and the patients including the public is being addressed.

Section 7. Application for Amendment or Renewal of License

a) An application for amendment of license shall be filed in accordance with Section 10 of this part. An application for amendment of license shall specify in what respect the licensee

desires his license to be amended and the grounds for such amendment in accordance with Section 10 of this part.

b) An application for renewal of license shall be filed in accordance with Section 11 and Section 12 of this part.

Section 8. Issuance of License

PNRI shall issue a license for the medical use of radiopharmaceuticals if the following conditions are satisfactorily met:

(a) The applicant has filed NRLSD Form – 013, "Application for Radioactive Material License (Nuclear Medicine)" in accordance with the instructions in Section 6;

(b) The applicant's proposed equipment and facilities are designed to meet current radiation safety standards for the protection of the health and safety of the workers and patients including the public;

(c) The applicant meets the requirements of Part 3 of the Code;

(d) The applicant has designated a qualified RHSO and ARHSO who shall be responsible for implementing the radiation safety program. The ARHSO shall take over the duties and responsibilities of RHSO in his absence. The designated RHSO and ARHSO must consent to and accept the designation in writing;

(e) The applicant has designated authorized users and authorized technologists in accordance with Section 50 and 51 of this Part;

(f) The applicant has provided or installed adequate dispensing equipment and a ventilation/exhaust system appropriate for the type and activity of the radioactive material to be used;

(g) The applicant has submitted appropriate procedures for dispensing and storage of radioactive materials, and the use of fumehoods;

(h) The applicant has submitted an approved radiation safety program;

(i) The applicant possesses appropriate personnel monitoring devices, monitoring and measuring instruments or equipment required for the proposed authorization;

(j) The design, location, and shielding of the proposed facility is acceptable;

(k) The applicant has submitted a waste management program according to Section 38 of this part;

(l) The physical protection measures for the safety and security of radioactive materials during use or storage is acceptable;

(m) The applicant's operating and emergency procedures are acceptable;

(n) The applicant is committed to submit a decommissioning plan in accordance with Section 13 of this Part; and

(o) The applicant has paid all prescribed fees.

Section 9. 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 PNRI;

(b) Neither the license nor 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 PNRI, after securing full information:
   (1) Finds that the proposed transfer, assignment or disposal is in accordance with the regulations of the Code and the provisions of the Act; and
   (2) Consents in writing to the proposed transfer, assignment or disposal.

(c) Upon the approval of PNRI of a proposed transfer in accordance with b(2) of this section, the transferor shall ensure that the transferee is provided with all information required by PNRI.

(d) Each licensee shall confine the use and possession of the licensed radioactive material to the locations and for the purposes authorized in the license.

(e) Each licensee shall ship or transport radioactive materials in accordance with CPR Part 4.

(f) Each licensee shall strictly follow the regulatory requirements regarding the renewal, amendment and expiration of license.

(g) Each licensee shall apply for a license amendment not later than thirty (30) days after its Radiological Health and Safety Officer (RHSO) permanently ceases to discharge his/her duties and responsibilities under the license.

(h) In order to preclude any conflict of duties and responsibilities in the performance of licensed activities, the individual designated as RHSO and ARHSO shall not be designated as an authorized user in the license, and vice-versa.

(i) Each licensee shall ensure compliance with the requirements for decommissioning in order to secure a proper termination of the license in accordance with Section 13 of this Part as prescribed.

(j) 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; and

(k) Each licensee shall have its emergency plan approved by PNRI.

(l) Each licensee shall submit to PNRI within a specified period a physical security plan against theft or sabotage of its licensed radioactive material.

Section 10. Amendment of License

A licensee shall apply for and must receive a license amendment:

(i) **Before** it receives and uses radiopharmaceuticals for a clinical procedure other than what is permitted under his license;

(ii) **Before** it permits anyone to work as an RHSO or ARHSO, authorized user, and authorized technologists other than those permitted under the license;

(iii) **Before** it changes RHSO or ARHSO, authorized user, or authorized technologists;

(iv) **Before** it procures radiopharmaceuticals in excess of the authorized amount, or in a form different from what is authorized by the license;

(v) **Before** it changes the areas of use and/or location of storage of licensed material within the premises of the facility identified in the license,

(vi) **Before** it implements any major change in the approved radiation safety program; or

(vii) **Before** any substantial change in any condition of the license takes effect, in consultation with PNRI.

Section 11. Expiration of License

(a) Each license shall expire at the end of the day of the expiration date specified in the license. Upon the expiration of the license, the licensee shall cease to engage in any licensed activity specified in the license.

(b) The expiration of the license shall not relieve the licensee of the responsibility to cause the decommissioning of the licensed facility and termination of the license.

(c) If the licensee decides to discontinue all licensed activities and to terminate the license, decommissioning and termination procedures shall be in accordance with Section 13 and 14 of this Part.

Section 12. Renewal of License

(a) If the licensee decides to renew the license, the licensee must notify PNRI in proper form, at least thirty (30) days before the expiration date of the license, by submitting an application for renewal of the license. If an application for license renewal is filed in proper form, the existing license shall be deemed to remain valid until PNRI has taken final action on whether to renew or deny the license, but in no case shall be more than thirty (30) days after the expiration of the existing license. This does not however preclude the imposition of any regulatory action arising from the review of the application. The application for license renewal must be filed with the corresponding prescribed license renewal fee.

(b) An application for license renewal that is filed less than (30) days before the expiration date of the license shall be assessed a surcharge equivalent to 25 percent of the prescribed license renewal fee. The existing license shall be deemed to remain valid until PNRI has taken final action on whether to renew or deny the license, but in no case shall be more than thirty (30) days after the expiration of the existing license. This does not however preclude the imposition of any regulatory action arising from the review of the application.

(c) An application for license renewal that is filed less than thirty (30) days after the expiration date of the license shall be assessed a surcharge equivalent to fifty percent of the prescribed license renewal fee. In addition to the written application, the licensee is required to:
   (1) Discontinue any licensed activity until PNRI has taken action on the application;
   (2) Ensure that all radioactive materials are secured in their authorized storage locations;
   (3) Submit a written explanation about the delay in the filing of application and the reason why PNRI should not impose the appropriate administrative action against the licensee.

(d) A license is deemed to have expired if an application for license renewal is not filed within thirty (30) days after the date of expiration. The licensee is required to show cause why the appropriate administrative action shall not be taken against him.

Section 13. Decommissioning

(a) Licensee shall submit to the PNRI for approval a proposed decommissioning plan not earlier than six(6) months before the proposed activity, 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;
   (4) Assurance on the availability of adequate funds for completion of the decommissioning; and
   (5) Program for the disposition of the decommissioning waste and other radioactive waste, e.g., sources, etc.

(b) Licensee shall submit to the PNRI, upon completion of decommissioning, a report of the results of the radiation survey undertaken.

(c) Licensee shall demonstrate that the premises can be cleared for unrestricted use and occupancy after decommissioning.

Section 14. Termination of License.

(a) Each licensee shall immediately notify PNRI, in writing, and request for the termination of the license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. This notification and request shall include the following documents required to support that the licensee has:
   (1) Ceased and terminated any use of radioactive material;
   (2) Removed radioactive contamination to the level specified in CPR Part 3, to the extent practicable;
   (3) Properly transferred or disposed all radioactive materials; and
   (4) Submitted a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual contamination, the licensee demonstrates the absence of residual radioactive contamination in an appropriate manner. The radiation survey report shall specify the instrumentation used and certify that each instrument is properly calibrated and tested. As may be applicable, the licensee shall report levels of radioactivity in the following specified areas:
      (i) Beta and gamma radiation at 1cm from surfaces;
      (ii) Gamma radiation at 1m from surfaces;
      (iii) Removable radioactivity on surfaces in units of Becquerels per 100 sq. cm of the surface area;
      (iv) Fixed radioactivity on surfaces in units of Becquerels per 100 sq. cm of the surface area;
      (v) Radioactivity in contaminated liquids such as water, oil, or solvents in units of Becquerels per milliliter of volume; and
      (vi) Radioactivity in contaminated solids such as soil or concrete in units of Becquerel per gram of solid.

(b) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination is found. Upon verification, PNRI will notify the licensee in writing of the termination of license.

(c) If detectable levels of residual radioactive contamination attributable to activities conducted under the license is 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 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 PNRI notifies the licensee in writing that the license is terminated.

Section 15. Additional Regulatory Requirements.

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

Section 16. Applications 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 determines are authorized by law and will not result in undue hazard to life or property.

II. ADMINISTRATIVE REQUIREMENTS

Section 17. Radiation Safety Program.

(a) Each licensee shall develop and implement a written radiation safety program that includes provisions for keeping doses ALARA.

(b) The program must include a description of the organization, notice to workers of the program's existence, functions and responsibilities to help keep equivalent dose ALARA, a review of summaries of the types and amounts of radiopharmaceuticals used; occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for all personnel who work with, or in the vicinity of radiopharmaceuticals. The purpose of the review is to ensure that reasonable effort is made to maintain individual and collective occupational doses ALARA.

Section 18. Radiological Health and Safety Officer (RHSO).

(a) The licensee shall employ a qualified RHSO and an Assistant RHSO (ARHSO) who shall both consent and agree, in writing, to be responsible for implementing the radiation safety program. The ARHSO shall act in the absence of the RHSO. The licensee, through the RHSO, shall ensure that radiation safety measures are being implemented in accordance with approved procedures and regulatory requirements in the daily performance of the licensee's authorized activities.

(b) The Radiological Health and Safety Officer shall:

(1) Investigate, document and report to PNRI overexposures, accidents, spills, losses, thefts; unauthorized orders, receipts, uses, transfers, disposals; and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Establish, collect in one binder or file, and implement written policy and procedures for:

(i) Authorizing the purchase of radiopharmaceuticals;

(ii) Receiving and opening packages of radiopharmaceuticals;
(iii) Storing radiopharmaceuticals;
(iv) Keeping an inventory record of radioactive material;
(v) Using radiopharmaceuticals safely;
(vi) Taking emergency action if control of radioactive material is lost;
(vii) Performing periodic radiation surveys;
(viii) Performing operational checks of survey instruments and other safety equipment;
(ix) Disposing of radioactive waste;
(x) Transport of radioactive material or radioactive waste;
(xi) Training personnel who work in or frequent areas where radioactive material is used or stored; and
(xii) Keeping a copy of all records and reports required by the regulations in the Code, a copy of these regulations, a copy of each licensing request, license and license amendments, and the written policy and procedures required by the regulations.

(3) Be available when licensed activities are being performed.
(4) Interface with regulatory inspectors and provide access to required records for inspection;
(5) Conduct briefings to management once each year on the program of use of radiopharmaceuticals;
(6) Establish investigational levels for personnel exposure, that, when exceeded, will initiate an investigation by the RHSO of the cause of the exposure;
(7) Establish higher personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the RHSO of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence; and
(8) Assist the MIC in the performance of its duties described in Section 19.

Section 19. Medical Isotopes Committee (MIC).

The licensee shall ensure that a Medical Isotopes Committee (MIC) is established to oversee the medical uses of radiopharmaceuticals in the institution. If an MIC has been established to oversee other medical uses of radioactive material, the licensee must designate its representative/s to the MIC. The MIC shall review on the basis of safety and with regard to the training and experience standards in Sections 50 and 51 of this Part, and approve or disapprove any individual proposed to be an authorized user and an authorized technologist before submitting a license application or request for amendment or renewal of the license;

(a) The MIC must meet the following administrative requirements:
(1) Membership must consist of an authorized user and RHSO for each type of radioactive material license, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RHSO. Other members may be included as the licensee deems appropriate.
(2) The Committee must establish a program for the conduct of meetings, maintenance of records, and submission of reports to PNRI.

(b) To oversee the acquisition and use of licensed material, the Committee must undertake the following:
(1) Review recommendations on ways to maintain individual and collective doses ALARA;
(2) Review quarterly, with the assistance of the RHSO, a summary of the occupational radiation dose records of all personnel working with radiopharmaceuticals;
(3) Review quarterly, with the assistance of the RHSO, all incidents involving radiopharmaceuticals;
(4) Review quarterly the procurement and administration of radiopharmaceuticals.

(5) Review annually, with the assistance of the RHSO, the radiation safety program; and
(6) Provide PNRI a report on their accomplished activities as a prerequisite to the renewal of the license.

Section 20. Statements of Authority and Responsibilities.

(a) A licensee shall provide the RHSO and MIC, where applicable, sufficient authority, organizational freedom, and management prerogative, to:
(1) Identify radiation safety problems;
(2) Initiate, recommend, or provide corrective actions; and
(3) Verify implementation of corrective actions.

(b) The licensee shall establish and state in writing the authorities, duties and responsibilities of the RHSO/ARHSO.

(c) The RHSO/ARHSO shall indicate in writing his/her acceptance of the appointment.

Section 21. Written Directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabequerels (MBq), any therapeutic dose of radiopharmaceutical.

(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. The information contained in the verbal directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours after the verbal directive is given.

(c) The written directive must contain the patient's name and the following information:
(1) The dosage for any administration of quantities greater than 1.11 MBq of sodium iodide I-131; and
(2) The radioactive drug, dosage, and route of administration for an administration of a therapeutic dosage of unsealed radiopharmaceutical other than sodium iodide I-131.

(d) The written directive must identify the authorized individual(s) who will administer or carry out the directive.

(e) The licensee shall retain a copy of each written directive for 3 years, and make available for inspection by PNRI.

Section 22. Procedures for Administrations Requiring a Written Directive.

(a) 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.

(b) As a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of radiopharmaceuticals:
(1) Verifying the identity of the patient;
(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

(c) A licensee shall retain a copy of the procedures required under paragraph (a) for the duration of the license.

III. TECHNICAL REQUIREMENTS

Section 23. Radiopharmaceuticals for Medical Use.

A licensee shall only use radiopharmaceuticals for medical application and reagent kits for preparation of radiopharmaceuticals manufactured, labeled, packaged and distributed by a manufacturer or distributors licensed by PNRI under a commercial license or in accordance with a license issued pursuant to CPR Part 20 and that are registered by the Bureau of Food and Drugs (BFAD).

Section 24. Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radiopharmaceuticals.

(a) For direct measurements, a licensee shall possess and use adequately calibrated instrumentation to measure the activity of unsealed radiopharmaceuticals before it is administered to each patient.

(b) A licensee shall calibrate or cause the calibration of the instrumentation required in paragraph (a) of this section in accordance with the manufacturer's instructions or operating manual of the instruments.

(c) A licensee shall retain a record of each instrument calibration required by this section for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Section 25. Possession, Use, Calibration, and Check of Dose Calibrators.

(a) A licensee shall have in its possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(b) A licensee shall:
(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 2 MBq of any other photon - emitting radionuclide;
(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources with different principal photon energies whose activities the manufacturer has determined to be within 5 percent of its stated activity; at least one of the sealed sources must have a principal photon energy between 100 keV and 500 keV; other sources must be at least 2 MBq;
(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be dispensed and 0.4 MBq; and
(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of use of the dose calibrator.

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

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

(e) A licensee shall retain a record of each check and test required by this section for two years unless otherwise directed by PNRI. The records required in paragraphs (b)(1) through (b)(4) of this section must include:
- (1) For paragraph (b)(1) of this section, the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the name of the individual who performed the check;
- (2) For paragraph (b)(2) of this section, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the signature of the RHSO;
- (3) For paragraph (b)(3) of this section, the model and serial number of the dose calibrator, the calculated activities, the date of the test, and the signature of the RHSO; and
- (4) For paragraph (b)(4) of this section, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume, the date of the test, and the signature of the RHSO.

Section 26. Determination of Dosages of Unsealed Radiopharmaceuticals for Medical Use.

(a) A licensee shall determine and record the activity of each dosage of radiopharmaceutical before medical use.

(b) For a unit dosage, this determination must be made by:
- (1) Direct measurement of radioactivity; and
- (2) A decay correction based on the activity or activity concentration as determined by the manufacturer.

(c) For other than unit dosages, this determination must be made by:
- (1) Direct measurement of radioactivity; and
- (2) Combination of measurement of radioactivity and mathematical calculations; and
- (3) Combination of volumetric measurements and mathematical calculations based on the measurement made by the manufacturer.

(d) A licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the measurements required by this section for two years. 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) Initial of the individual who made the record.

Section 27. Syringe Shields and Labels.

(a) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

(b) A licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical in order to identify its contents. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, and the patient's name.

(c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for the patient.

Section 28. Vial Shields and Labels.

(a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(b) A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical to identify its contents. The label must show the radiopharmaceutical name or its abbreviation.

Section 29. Personnel Monitoring.

(a) No worker shall perform any licensed activity unless he/she wears either a film badge or a thermoluminescent dosimeter (TLD).

(b) Each film badge or TLD shall be assigned to and worn by only one individual.

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

Section 30. Quality Assurance for Medical Equipment Used for Therapy and Diagnosis.

a) A licensee shall establish a quality assurance program for the medical equipment used for therapy and diagnosis which includes procedures for:
   1) Measurements and verification of physical parameters at the time of the commissioning and periodically thereafter;
   2) Verification of the appropriate calibration and conditions of operation;
   3) Regular and independent audit reviews

b) A licensee shall cause each medical equipment used for therapy and diagnosis to be fully inspected and serviced by a qualified expert in accordance with the approved Quality Assurance program.

c) A licensee shall keep written records of relevant procedures and results for the established QA Program for the medical equipment.

Section 31. Possession of Survey Instruments.

Each licensee shall have in its possession a calibrated and operable radiation survey instrument indicated below at any time during the conduct of a licensed activity.

(a) A portable radiation survey meter capable of detecting and measuring dose rates over the range of 1 μSv per hour (0.1 milliroentgen per hour) to 10 mSv per hour (1 roentgen per hour).

(b) A contamination meter capable of measuring nanocurie or becquerel amounts of activity per unit area (Bq/cm^2).

Section 32. Calibration and Check of Survey Instruments.

(a) A licensee shall calibrate or cause the calibration of the survey instruments before first use, following repair, and annually thereafter. The licensee shall:
   (1) Calibrate all scales with readings up to 10 mSv/h with a standard radiation source;
   (2) Take at least two separate readings (at 20% and 80% of full range) on each scale that must be calibrated; and
   (3) Conspicuously attach on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(b) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a calibration sticker to the instrument. Correction chart and graph must be provided with the calibration certificate for the instrument. If the exposure rate exceeds 20% of calculated exposure rate, the survey instrument must be replaced or calibrated more frequently, or as the PNRI may require.

(c) A licensee shall check each survey instrument for proper operation with the dedicated check source at the start of each day of use. A licensee is not required to keep records of these checks.

Section 33. Leak Testing of Calibration and Reference Sources.

(a) The licensee authorized in this Part may receive, possess, and use, wherever applicable, the following radioactive material for check, calibration, 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; and
   (4) Technetium-99m in individual amounts not to exceed 2 GBq.

(b) Each licensee shall cause each sealed source or device containing more than 3.7 MBq (100uCi) of β-, γ- emitters or 370 KBq (10uCi) of α-emitters with half life greater than 30 days, except iridium-192 seeds encased in nylon ribbon, to be tested for contamination and / or leakage prior to its first use and at intervals not to exceed six months or at such other intervals as are specified on the label or in the leaflet or brochure which accompanies the source or device, or approved by the Institute. If the test reveals the presence of 185 Bq (0.005 uCi) of removable contamination, the licensee shall immediately withdraw the source or device from use and cause it to be decontaminated and repaired or to be disposed of in accordance with Institute regulations.

Section 34. Surveys for Contamination and Ambient Radiation Exposure Rate.

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

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

(c) A licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to detect dose rates as low as 1 uSv per hour.

(d) A licensee shall establish radiation dose rate action levels for the surveys required by paragraphs (a) and (b) of this section. A licensee shall require that the individual performing the survey immediately notify the RHSO if a dose rate exceeds the action level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe 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) A licensee shall establish removable contamination action levels for the surveys required by paragraph (e) of this section. A licensee shall require that the individual performing the survey immediately notify the RHSO if contamination exceeds the action level.

(h) A licensee shall make available to PNRI inspectors and retain a record of each survey for two years. The record must include:
(1) The date and time of the survey;
(2) A floor plan of each area surveyed;
(3) The action level established for each area;
(4) The detected dose rate at several points in each area expressed in millisieverts/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 of the individual who performed the survey.

Section 35. Installation, Maintenance, and Use of Fumehoods.

(a) A licensee shall install, maintain, and use fumehoods that will keep airborne concentrations within the clearance levels given in CPR Part 3, APPENDIX D-1 (Derived Generic Clearance Levels for Airborne Releases), during administration of radioactive aerosols or releases of radioactive gases that volatilize in containers and vials of radiopharmaceuticals. The fumehood must be equipped with an exhaust duct, or provide for collection and decay or disposal of the aerosol or gas in a shielded and sealed container.

(b) The fumehood shall:
(1) Be located only in a room that is at negative pressure compared to surrounding rooms;
(2) Be situated in a closed laboratory so that no air current can adversely affect its proper function;
(3) Be constructed of corrosion-resistant, non-porous, non-combustible materials such as stainless steel or special composite or polymer materials;
(4) Have an average face velocity of 125-200 fpm and a minimum face velocity of 100 fpm to ensure that no radioactive material contaminant would escape;
(5) Have an exhaust stack with an appropriate filter system;
(6) Be properly maintained for longer usage and to achieve the purpose of an efficient operation; and

(7) Be tested and certified for performance at least once a year, which shall be performed by the RHSO or a qualified individual.

(c) A licensee shall properly implement the procedure for the safe use of fumehoods to ensure protection from inhalation of contaminated airborne substances due to the volatility of same radioactive substances such as compounds of iodine.

(d) A licensee shall use only their fumehood for storage of volatile radioactive materials with the approval of the RHSO.

(e) A licensee shall keep records of the following:
(1) The fumehood airflow measurement conducted at least once a year, with an average face velocity of 125fpm to ensure no contaminant would escape.
(2) The fumehood air changes using a calibrated velometer every six (6) months, for which there should be three (3) to five (5) air changes per hour.

Section 36. Control of Aerosols, Gases, and Other Volatile Substances.

(a) A licensee that administers radioactive aerosols or releases radioactive gases that volatilize in containers and vials of radiopharmaceuticals, shall do so in a room with a system that will keep airborne concentrations within the clearance levels given in CPR Part 3, APPENDIX D-1 (Derived Generic Clearance Levels for Airborne Releases). The system must either be vented to the atmosphere through an air exhaust line or fumehood equipped with an exhaust duct, or provide for collection and decay or disposal of the aerosol or gas in a shielded and sealed container.

(b) A licensee shall administer radioactive aerosols or gases only in a room equipped with fumehood that is at negative pressure compared to surrounding rooms as described in section 35 b(1).

(c) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the time needed after a spill to reduce the concentration in the room to the occupational limit listed in Appendix D of CPR Part 3. The calculation must be based on the highest activity of the gas handled in a single container, the volume of the room, and the measured air exhaust rate.

(d) A licensee shall make a record of the calculations required in paragraph (c) of this section that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

(e) A licensee shall check the operation of exhaust systems each month, and measure the ventilation rates available in areas of use every six months.

Section 37. Storage of Volatiles and Gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shielded container. A licensee shall store a multidose container in a fumehood after drawing the first dosage from it.

Section 38. Waste Management.

(a) General Requirements
(1) Each 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.

(2) The activity and volume of radioactive waste generated shall be kept to the minimum practicable.

(3) Radioactive waste must be managed, i.e., collected, handled, treated, conditioned, transported, stored and disposed of, in accordance with the requirements of this Part and any other applicable Parts of the code.

(4) Different types of radioactive waste must be segregated and treated separately to warrant differences in factors such as radionuclide content, half-life, concentration, volume and physical and chemical properties, taking into account the available options for waste disposal.

(b) Disposal by Release to the Atmosphere

(1) Work with radioactive gases or aerosols shall be done in a fume hood. Fume hood exhaust duct from active laboratories shall be isolated from normal ventilation systems and exhausted to the atmosphere through stacks so as not to re-enter the building or adjacent buildings.

(2) If filtration of exhaust has been deemed necessary in particular circumstances, the appropriate type of filter must be employed for trapping the emission; the installation must have been approved; the assembly tested and the performance continuously monitored.

(c) Discharge of radioactive substances, including waste, to the environment must meet the requirements of Section 29 of CPR Part 3.

(d) Decay-in-Storage – A licensee may hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal as ordinary trash without regard to its radioactivity if it:

(1) Holds radioactive materials for decay a minimum of ten half-lives;

(2) Monitors radioactive material before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels;

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(e) A licensee shall retain a record of each disposal permitted under paragraph (b) to (d) of this section for two years. The record must include the date of the disposal, the date on which the radioactive material was placed on storage, the radionuclide disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name and signature of the individual who performed the disposal.

Section 39. Security and Control of Licensed Radioactive Material.

(a) The licensee shall secure licensed radioactive material from unauthorized removal or access.

(b) The licensee shall maintain constant surveillance, and use devices or administrative procedures to prevent unauthorized use of licensed radioactive material that is in an unrestricted area and that is not in storage.

IV. RADIOPHARMACEUTICALS FOR DIAGNOSIS

Section 40. Uptake, Dilution and Excretion Studies.

A licensee shall only use radiopharmaceuticals for diagnostic purpose involving measurements of uptake, dilution, or excretion studies which have been registered and/or approved by the BFAD.

Section 41. Imaging and Localization Studies.

(a) A licensee shall only use radioactive material in a diagnostic radiopharmaceutical, or from any generator or in a reagent kit for the preparation and diagnostic use of a radiopharmaceutical for imaging and localization studies, which has been approved by the PNRI.

(b) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.

Section 42. Permissible Molybdenum-99 Concentration.

(a) A licensee shall not administer to humans a radiopharmaceutical containing more than 150 Bq of molybdenum-99 per MBq of technetium-99m (0.15 µCi of molybdenum-99 per mCi of technetium-99m).

(b) A licensee that uses molybdenum-99 / technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.

(c) A licensee shall retain a record of each measurement for two years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium-99m, the measured activity of the molybdenum-99, the ratio of the measured activities, the time and date of the measurement, and the name of the individual who made the measurement.

V. RADIOPHARMACEUTICALS FOR THERAPY

Section 43. Usage.

A licensee shall only use a radiopharmaceutical for therapeutic use which has been registered and approved by BFAD. The licensee shall comply with the package insert instructions regarding indications and method of administration.

Section 44. Release of Patients Administered with I-131.

A licensee shall keep under hospital confinement any patient administered with I-131 unless either:

(a) The measured maximum dose rate from the patient is less than 0.025 mSv per hour (2.5 mR/h) at a distance of one meter; and

(b) The activity remaining in the patient is less than 555 MBq of iodine-131.

Section 45. Safety Instructions for Individual's caring for In-patient.

(a) A licensee shall provide radiation safety instructions to all personnel caring for confined patients receiving radiopharmaceutical therapy. The instructions must address the licensee's procedure for:
   (1) Patient control;
   (2) Visitor control;
   (3) Contamination control;
   (4) Waste control; and
   (5) Notification of the RHSO in case of the patient's death or medical emergency.

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

Section 46. Safety Instructions for Out-patient.

(a) A licensee shall provide radiation safety instructions for patient suitable to be considered as outpatient. These instructions are described in APPENDIX I of this Part. Each patient is evaluated and considered to be out-patient on the basis of:
   (1) The patient's home environment;
   (2) The patient and his/her family member's ability to understand the risk involved;
   (3) The likelihood of compliance, by referring physician's opinion, through a self-report questionnaire and through patient interview with the RHSO and the Authorized User.

(b) A copy of the instructions must be given to the outpatient.

Section 47. Safety Precautions for In-patient Individual.

Each in-patient individual receiving radiopharmaceutical therapy shall be provided radiation safety precautions according to Appendix II.

Section 48. Safe Handling of Radioactive Cadavers.

The licensee shall submit to PNRI procedures of safe handling of radioactive cadavers which includes precautionary measures of handling cadavers with remaining administered radioactive materials as stated in Appendix III of this part.

VI. TRAINING AND EXPERIENCE REQUIREMENTS

Section 49. Radiological Health and Safety Officer (RHSO).

The licensee shall designate an individual fulfilling the responsibilities of the RHSO who:

(a) Holds a Bachelor of Science Degree in Medical Technology or allied discipline and is duly licensed by the Philippine Professional Regulations Commission;

(b) Has successfully completed the training courses required by PNRI for a Radiological Health and Safety Officer; and

(c) Has shown proof of knowledge and experience in the licensed institution authorized to use radioactive material in nuclear medicine.

Section 50. Authorized User.

The licensee shall designate an authorized user, upon the endorsement and approval of the Medical Isotopes Committee, who:

(a) Is a physician duly licensed by the Professional Regulations Commission;

(b) Has full working knowledge of the safety requirements of this specific regulation, CPR Part 13, "Licenses for Medical Use of Radiopharmaceuticals". All activities of the authorized user shall be with the knowledge and/or supervision of the RHSO;

(c) Has successfully completed the Radiation Safety in Medical Facilities Course or an equivalent course approved by PNRI;

(d) Has had relevant clinical training and experience in the use of radioactive material in nuclear medicine with particular emphasis on radiation safety procedures and safe handling of radiopharmaceuticals, under the supervision of an authorized user in a medical institution authorized to use radioactive material in nuclear medicine; and

(e) Has received appropriate certification as described in Section 52 of this Part.

Section 51. Authorized Technologist.

The licensee shall appoint an authorized technologist, upon the endorsement and approval of the Medical Isotopes Committee, who:

(a) Holds a Bachelor of Science Degree in Medical Technology or equivalent discipline and is duly licensed by the Philippine Professional Regulations Commission;

(b) Has successfully completed the Radiation Safety in Medical Facilities Course or an equivalent course approved by PNRI; and

(c) Has six (6) months full time experience under the supervision of an authorized technologist in an institution authorized to use radioactive material in nuclear medicine.

Section 52. Certification.

The licensee shall require the authorized user to be a physician who is certified by a PNRI accredited medical organization in the practice of diagnostic and therapeutic nuclear medicine in the Philippines whose certification program includes all the requirements in Section 50.

Section 53. Retraining.

The licensee shall require the RHSO, the authorized user and the authorized technologist to undertake retraining program on radiation safety as appropriate and approved by the PNRI every five years.

VII. RECORDS, REPORTS, AND NOTIFICATIONS

Section 54. Records of Personnel Monitoring.

(a) Each licensee shall maintain records of total exposures of all individuals who are required to wear personnel monitoring devices. Such records shall be kept on clear and legible forms.

(b) Records of personnel monitoring shall be made available to PNRI upon request and shall be kept and preserved until PNRI authorizes their disposition.

Section 55. Records of Surveys.

(a) Each licensee shall maintain records showing the results of surveys incident to the use, storage, and presence of radioactive materials until PNRI authorizes their disposition.

(b) In the absence of personnel monitoring data, records of the results of surveys to determine external radiation doses shall be maintained until PNRI authorizes their disposition.

Section 56. Records of Calibration of Survey Instruments.

(a) A licensee shall retain a record of each survey instrument calibration for two years as per Section 32 of this part. The record must include:
   (1) A description of the calibration procedure; and
   (2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the dose rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

Section 57. Records of Maintenance and Repair.

(a) Each licensee shall maintain records of the maintenance and repair of equipment or instruments at the Nuclear Medicine facility such as dose calibrator, survey instrument, and fumehoods.
(b) The licensee shall retain the records for two years. The records must include:
   (1) The names and signatures of the individuals who performed the maintenance or repair;
   (2) The date of the calibration, maintenance, or repair; and
   (3) A description of the maintenance and repair.

Section 58. Reports of Exposure of Persons who have worked in a Licensee's Facility.

(a) When an individual terminates employment with a licensee, or an individual assigned to work in a licensee's facility but not employed by the licensee completes his work assignment, the licensee shall furnish to such individual**,** a report of the individual's total exposure to radiation during the period of employment or work assignment in the licensee's facility. Such report shall be furnished within 30 days after the exposure of the individual has been determined by the licensee or 90 days after the date of termination of employment or work assignment.

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

Section 59. Notification of Incidents.

(a) Each licensee shall immediately notify PNRI by telephone or by any similarly fast means of communication, of 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 0.05 Sv.

(b) Each licensee shall immediately report to PNRI 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 Becquerels 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 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 60. Notification of Theft or Loss of Licensed Material.

(a) Each licensee shall immediately notify PNRI by telephone, or by any similarly fast means of communication, of any lost, stolen, or missing licensed radioactive materials. The incident must be verified by a written report to PNRI within 48 hours from the time of notification.

(b) In addition to the notification required above, each licensee shall, within 30 days after the occurrence of the incident, make a report in writing to PNRI that shall include the following information:
   (1) A description of the licensed sealed source involved including kind, quantity, chemical, and physical form;
   (2) A description of the circumstances under which the loss or theft occurred;
   (3) A statement of disposition or probable disposition of the licensed sealed source involved;
   (4) Estimated radiation exposures to individuals, circumstances under which the exposures occurred, and the extent of possible hazards to persons in unrestricted areas;
   (5) Actions which have been taken, or will be taken, to recover the source; and
   (6) Procedures or measures, which have been or will be adopted to prevent a recurrence of the circumstances, which led to the loss or theft of licensed sealed sources.

(c) Subsequent to filing the written report, the licensee shall also render periodic progress reports on any substantive information on the loss or theft, which becomes available to the licensee.

(d) Any report filed with PNRI pursuant to this section shall identify the individuals who may have received exposure to radiation and other individuals involved in the incident.

Section 61. Reports and Notification of Medical Events.

(a) A 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 0.05 Sv effective equivalent dose, 0.5 Sv to an organ or tissue, or 0.5 Sv shallow equivalent dose to the skin; and
      (i) The total dosage delivered differs from the prescribed dose by 20 percent or more or falls outside the prescribed dosage range;
      (ii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
   (2) A dose that exceeds 0.05 Sv effective equivalent dose, 0.5 Sv to an organ or tissue, or 0.5 Sv shallow equivalent dose 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 PNRI by telephone no later than the next calendar day after discovery of the medical event.

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

(d) The written report must include:
(i) The licensee's name;
(ii) The name of the prescribing physician;
(iii) A brief description of the event;
(iv) Why the event occurred;
(v) The effect, if any, on the individual(s) who received the administration;
(vi) What actions, if any, have been taken or are planned to prevent recurrence;
(vii) Certification that the licensee notified the patient (or the patient's responsible relative or guardian), and if not, why not;
(viii) Date when it happened.

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

Section 62. Notifications on Specific Changes in the License.

(a) A licensee shall notify the PNRI immediately by telephone or by any similarly fast means of communications within thirty days:
(1) When the Radiological Health and Safety Officer permanently decides to discontinue or has discontinued performance of duties in writing under the license, or
(2) When the licensee's mailing address changes.

(b) The licensee shall mail the report to:

The Director,
Philippine Nuclear Research Institute,
Commonwealth Avenue, Diliman, Q.C.

and marked "Attention: Chief, Nuclear Regulations, Licensing, and Safeguards Division".

VIII. INSPECTION AND ENFORCEMENT; EFFECTIVITY

Section 63. Inspections.

(a) Each licensee shall afford to the PNRI at all reasonable times the opportunity to inspect the radioactive material in his/her possession and the premises, equipment and facilities wherein that radioactive material is used or stored.

(b) Each licensee shall make available to PNRI for inspection records kept pursuant to these rules and regulations at the address specified in the license.

Section 64. Modification and Revocation of License.

(a) The license shall be subject to revision or modification, and the terms and conditions of each license shall be subject to amendments, by reason of amendments to PNRI rules and regulations, or by reason of rules, regulations and orders issued by 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 PNRI.

(c) Except in cases of willful violation or those in which the public health interest or 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 65. Right to Cause the Withholding or Recall of Radioactive Material.

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 health as may be established by PNRI, or who uses such materials in violation of law or regulation of PNRI, or in a manner other than as disclosed in the application and approved by PNRI.

Section 66. Violations.

(a) A notice of violation shall be issued to any person found to have violated any rule, regulation, or order issued by PNRI; or any term, condition, or limitation of any license issued hereunder.

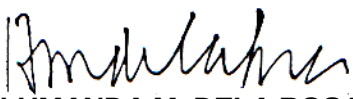
(b) Any license may be modified, suspended, or revoked, after due process, for any violation that PNRI determines to adversely affect the health and safety of the workers, patients and the general public.

(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.

Section 67. 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:



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

Date: November 2, 2005