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Republic of the Philippines
Department of Science and Technology
**PHILIPPINE NUCLEAR RESEARCH INSTITUTE**
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# LICENSES TO MANUFACTURE AND DISPENSE RADIOPHARMACEUTICALS

# CPR PART 20

## I. GENERAL PROVISIONS

### *Section 1. Purpose and Scope.*

(a) This Part prescribes requirements and provisions for the issuance of specific licenses to persons who manufacture and dispense radiopharmaceuticals.

(b) The requirements and provisions of this Part are in addition to, and not in substitution for, other relevant requirements of the CPR.

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

### *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 exposure to radiation as far below the dose limits as is practicable;

(1) Consistent with the purpose for which the licensed activity is undertaken; and
(2) Taking into account the state of technology, the economics of improvements in relation to benefits to public health and safety and other societal and socio-economic considerations;

(c) **"Authorized Nuclear Pharmacist"** means an individual who is authorized under the license issued pursuant to this Part to prepare and dispense radiopharmaceuticals;

(d) **"Authorized Personnel"** means those individuals who have functional responsibilities in the license issued pursuant to this Part;

(e) **"BFAD"** means the Bureau of Food and Drugs;

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

(g) **"Dispense"** means the procedure for preparing specific dose of radiopharmaceutical or radioactive drug for individual recipient patients from a produced solution;

(h) **"Distribute"** means the delivery of radiopharmaceuticals or radioactive drugs to prospective client users under a commercial arrangement in accordance with transport regulations and the standards for radiation protection;

(i) **"Export"** means shipment of radioactive material from the Philippines to another country;

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

(k) **"Manufacture"** means the process of producing radiopharmaceuticals or radioactive drugs from a raw or bulk source and includes the requisite packaging for transport and delivery to client users;

(l) **"Nuclear Pharmacy**" means a field of practice involving the preparation and dispensing of radiopharmaceuticals;

(m) **"Person"** means (i) any individual, firm, partnership, association, trust, estate, private or public body, whether corporate or not, or government agency other than PNRI, any province, city, municipality, or any political subdivision of the Republic of the Philippines or any political entity in the Philippines and (ii) any legal successor, representative, agent or agency of the foregoing;

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

(o) **"Radiological Health and Safety Officer (RHSO)"** means the individual who is identified as the Radiological Health and Safety Officer under a license issued pursuant to this Part;

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

(q) **"Sale"** means the transfer of ownership of radioactive material to licensed persons under a commercial arrangement.

**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. Interpretations.*

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 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 PNRI Director. Communication, reports and license applications may be mailed to the Philippine Nuclear Research Institute, Commonwealth Avenue, Diliman, Quezon City, Metro Manila or may be faxed to PNRI through Fax No. (632) 9201646 or (632) 9208796.

***Section 5. Activities Requiring License.***

No person shall manufacture and dispense radiopharmaceuticals except in accordance with a license issued by PNRI pursuant to this Part.

***Section 6. Application for New License, Amendment, or Renewal of License.***

(a) An application for a license pursuant to this Part shall be filed by completing NRLSD Form-020, "Application for Radioactive Material License (To Manufacture and Dispense Radiopharmaceuticals)".

(b) The application shall be accepted and processed only when PNRI has determined the completeness of the submitted information, and payment of the application fee has been made.

(c) An application for a license amendment or renewal may be submitted as an original and one copy in a letter format.

***Section 7. Completeness and Accuracy of Information.***

(a) Information required by the regulations, orders, or license conditions to be provided or maintained by the licensee shall be complete and accurate in all material respects.

(b) Information required in the application for a license shall be deemed complete if the application, as submitted, contains the vital facts and information that are needed to assure that safety is being complied with.

(c) Each licensee shall notify PNRI about any information, relative to a regulated activity, that the licensee has identified as having a significant implication to public health and safety. Notification shall be provided to PNRI within two (2) working days of identifying the information. This requirement is not applicable where the information is already required to be submitted to PNRI by other reporting requirements.

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

PNRI shall approve an application for a license pursuant to this Part for a term of one (1) year if:

(a) The applicant has specified in his application the appropriate authorization(s) described in Chapter III of this Part;

(b) The applicant has identified the qualifications of personnel who will be authorized in the manufacture and dispensing of radiopharmaceuticals;

(c) The applicant has designated a qualified Radiological Health and Safety Officer (RHSO) and an Assistant RHSO who shall be responsible for implementing the radiation safety program. The Assistant RHSO shall take the place of RHSO in his absence;

(d) The applicant has designated an authorized nuclear pharmacist whose qualifications and experiences are specified in Section 25;

(e) The applicant has provided a radiation facility wherein there are adequate dispensing equipment and ventilation/exhaust system appropriate for the type and activity of the radioactive material;

(f) Specific procedures for dispensing, storage and transportation of radioactive materials, disposal of radioactive wastes, use of fume hoods, radiation protection program, and qualification of technical staff, are submitted;

(g) The applicant has established procedures for transport of radioactive material in accordance with the requirements of CPR Part 4, "Safe Transport of Radioactive Materials in the Philippines";

(h) The location of the facility indicated in the license application is acceptable to PNRI;

(i) The procedures for the storage/disposal of radioactive wastes are acceptable to PNRI;

(j) The applicant's operating and emergency procedures are acceptable to PNRI; and

(k) The applicant has paid all applicable fees in connection with his license application.

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

(a) Each license shall be subject to the provisions of this Part and relevant regulations of the CPR and orders of PNRI;

(b) Each licensee shall submit to PNRI on a quarterly basis a report of the amount of radiopharmaceuticals manufactured and/or dispensed;

(c) A copy of each of the existing license and applicable regulations of the Code shall be kept and made available at each location of use indicated in the license; and

(d) Each licensee shall submit to PNRI for approval a Radiological Emergency Response Plan and a decommissioning plan.

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

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

(a) Before it permits anyone to work as an authorized pharmacist, authorized personnel and RHSO under the license;

(b) Before it prepares or dispenses radioactive material other than those specified in the license;

(c) Before it possesses at any one time radioactive material in excess of the activity authorized in the license;

(d) Before it implements any major change in the approved radiation safety program;

(e) Before it changes or modifies the areas of use identified in the license; and

(f) Before any material change in any condition of the license takes effect.

***Section 11. Expiration and Renewal of License.***

(a) Each license shall expire at the end of the day of the expiration date stated in the license, unless the licensee has filed an application for renewal of the license not less than thirty (30) days before the expiration date.

(b) If an application for renewal has been filed at least thirty (30) days before the expiration date, the existing license expires at the end of day on which PNRI makes a final determination to deny the application for renewal or at the expiration date stated in the determination.

(c) However, in no case shall an application for renewal of a license be accepted and processed if it is filed more than thirty (30) days after the expiration date stated in the existing license or after the existing license has been determined by PNRI to have expired.

(d) Each application for license renewal must be accompanied by the corresponding license fee.

***Section 12. Termination of License.***

(a) For the purpose of terminating a license, each licensee shall notify PNRI in writing within sixty (60) days when a decision has been made to decommission his facility or to permanently cease licensed activities at the site identified in the license.

(b) Until PNRI notifies the licensee in writing that his license is terminated, the licensee shall:

(1) Limit activities involving licensed material related to decommissioning in accordance with Section 36 of this Part; and
(2) Control entry to restricted areas.

(c) A license will be terminated by written notice to the licensee when PNRI determines that:

(1) Licensed materials, including accumulated wastes, have been properly disposed of or transferred;
(2) A radiation survey has been performed by the licensee which demonstrates that the premises are suitable for unrestricted use; and
(3) The site has been verified by PNRI inspectors to be free of contamination in excess of regulatory levels.

***Section 13. Application for Exemptions.***

PNRI may, upon application by the licensee or upon its own initiative, grant such exemptions from the regulations in this Part as it determines are authorized by law and will not endanger life or property and are otherwise in the public interest.

***Section 14. Additional 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.

## II. TECHNICAL REQUIREMENTS

***Section 21. Radiation Safety Program.***

(a) Each licensee shall develop and implement a written radiation safety program that includes provisions for keeping doses ALARA in accordance with the provision of CPR Part 3.

(b) The program must include a description of the organization, notice to workers of the program's existence, functions and responsibilities to help keep dose equivalents ALARA, a review of summaries of 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, radioactive material.

***Section 22. Radiological Health and Safety Officer.***

(a) The licensee shall appoint a qualified RHSO and assistant RHSO who both shall be responsible for implementing the radiation safety program. The assistant RHSO shall act in the absence of the RHSO. The licensee, through the RHSO, shall ensure that radiation safety measures are being observed in accordance with approved procedures and regulatory requirements in the daily performance of the licensee's licensed activities.

(b) The Radiological Health and Safety Officer shall:
- (1) Investigate, document, and report to PNRI overexposures, accidents, losses, thefts, and other deviations from approved radiation safety practice and implement corrective actions as necessary;
- (2) Ensure that radiation areas are properly secured and the location conspicuously identified by radiation signs;
- (3) Establish, implement, and collect in one file all written policies and procedures for:
  - (i) Monitoring the performance of fume hoods;
  - (ii) Supervising and coordinating the receipt, opening and delivery of all shipments of radioactive material arriving at the facility;
  - (iii) Supervising the distribution and processing of personnel monitoring devices;
  - (iv) Conducting training programs for the handling of radioactive material;
  - (v) Supervising and coordinating the radioactive waste disposal program;
  - (vi) Supervising the safe storage of all radioactive materials not in current use;
  - (vii) Ensuring that sealed sources are leak tested at proper frequencies;
  - (viii) Maintaining an inventory of all radioactive materials including wastes and limiting the quantity of radionuclides at the facility to the amounts authorized by the license;
  - (ix) General surveillance over all activities involving radioactive material, including routine monitoring and surveys; and
  - (x) Ensuring compliance with PNRI rules and regulations.
- (4) Keep copies of all records and reports required by the regulations of the Code, a copy of Parts 2, 3, 4, and this Part of the CPR, a copy of each licensing application, the license and license amendments, and all other orders, bulletins and issuances from PNRI.

***Section 23. Statements of Authority and Responsibilities.***

(a) The licensee shall provide the RHSO 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.

***Section 24. Training for RHSO.***

The designated RHSO shall have:

(a) Completed 200 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity;
(4) Radiation biology; and
(5) Radiopharmaceutical chemistry;

(b) Experience in handling unsealed radioactive material and should include:

(1) Ordering, receiving, and unpacking radioactive materials safely, including performing related radiation surveys;
(2) Calibrating dose calibrators and survey meters;
(3) Performing emergency procedures to contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests; and
(4) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and preparing technetium-99m-labelled radiopharmaceuticals.

(c) Completed a special training program in Radiological Health and Safety based on his duties and responsibilities as RHSO. This program shall be approved by PNRI and administered by the licensee.

***Section 25. Training for an Authorized Nuclear Pharmacist.***

Each licensee authorized to manufacture and dispense radiopharmaceuticals shall appoint an authorized nuclear pharmacist who:

(a) Has a current board certification by the Professional Regulatory Commission as a pharmacist, medical technologist, chemist or other related fields;

(b) Has satisfactorily completed 700 hours of training and instructions in a structured educational program consisting of both:

(1) Didactic training in the following areas:
    (i) Radiation physics and instrumentation;
    (ii) Radiation protection;
    (iii) Mathematics pertaining to the use and measurement of radioactivity;
    (iv) Chemistry of radioactive material for medical use; and
    (v) Radiation biology; and
(2) Supervised experience in a nuclear pharmacy involving the following:
    (i) Shipping, receiving, and performing related radiation surveys;
    (ii) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
    (iii) Calculating, preparing and calibrating patient dosages;
    (iv) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(c) Has obtained written certification that the above training and experience have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

***Section 26. Personnel Monitoring.***

(a) The licensee shall not permit any individual authorized in the license to perform licensed activities during operations unless each individual wears a direct reading pocket dosimeter or similar device and either a film badge or a thermoluminescent dosimeter (TLD).

(b) Pocket dosimeters shall have a range from zero to at most 2 mSv (200 mrem) and shall be recharged at the start of each shift. Each film badge or TLD shall be assigned to and worn by only one individual.

(c) Pocket dosimeters shall be read and exposures recorded for each daily use. Records of daily pocket dosimeter readings shall be kept for two years.

(d) Pocket dosimeters shall be checked at intervals not to exceed one year for correct response to radiation.

(e) If the individual's pocket dosimeter is discharged beyond its range, his film badge or TLD shall be immediately processed.

(f) Pocket dosimeter, film badge or TLD shall be provided to every personnel who elutes, prepares, assays, or dispenses radioactive material.

(g) Personnel engaged in elution of Technetium 99m pertechnetate from generators and/or preparation of labeled pharmaceuticals with kits shall have the exposures to their fingers or hands monitored using appropriate dosimeters.

***Section 27. Site Description.***

Each licensee shall:

(a) Have a facility that indicates the type and thickness of shielding for:

(1) Use and storage of molybdenum-99/technetium-99m generators;
(2) Storage of radiopharmaceuticals;
(3) Storage of radioactive waste, including decay in storage before disposal; and
(4) Preparing and dispensing kit radiopharmaceuticals.

(b) Assure that the radiation levels of the proposed facility are maintained within regulatory limits and that licensed materials shall be secured against unauthorized removal.

(c) Describe the equipment and methods to measure the airflow ratings of the air exhaust vents of the facility.

***Section 28. Possession of Radiation Detection and Measuring Instruments.***

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

(a) A low-level survey meter with a thin window capable of detecting 0.001 mSv/hr (0.1 milliroentgen per hour) for performing accurate contamination surveys;

(b) A high-level survey meter, such as ionization type, capable of reading up to 10 mSv/hr (1roentgen per hour) in order to measure exposure rates that may exist in the vicinity of molybdenum-99/technetium-99m generators;

(c) Dose calibrators to assay radiopharmaceuticals; and

(d) A sodium iodide well crystal and either a gamma spectrometer or a multichannel analyzer to analyze swipe tests, perform quality control tests, etc.

***Section 29. Calibration of Survey and Measuring Instrument.***

(a) Each licensee shall calibrate or cause the calibration of its survey and measuring instruments before first use, following repair and every six (6) months thereafter.

(b) Each licensee shall retain a record of each instrument calibration for two years.

(c) If the licensee shall engage the calibration services of other persons, the qualification of the person and the procedures to be used for calibration must be submitted to PNRI.

***Section 30. Possession, Use, Calibration, and Check of Dose Calibrators.***

(a) The licensee authorized to dispense radiopharmaceuticals as described in Section 42 of this Part shall have in his possession a dose calibrator and use it to measure the amount of activity of the radiopharmaceutical being prepared.

(b) The 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 (50 μCi) of any other photon-emitting radionuclide;
(2) Test each dose calibrator for accuracy upon installation and at least quarterly 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 (50 μCi).
(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 (10 μCi); 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) The licensee shall also perform appropriate checks and tests required by this section following change of position, adjustment or repair of the dose calibrator.

(d) The 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 (10 μCi) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(e) The 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 initials 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 31. 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 all areas where radiopharmaceuticals are routinely prepared.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical 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 0.001 mSv/hr (0.1millirem per hour).

(d) A licensee shall establish radiation dose rate trigger 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 a trigger level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared 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 of 2000 disintegrations per minute.

(g) A licensee shall establish removable contamination trigger 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 trigger level.

(h) A licensee shall retain a record for each survey for two (2) years. The surveys must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in mSv/hr (millirem per hour) or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instruments used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

***Section 32. Control of Gases, and other Volatilized Substances.***

Each licensee shall release gases that volatilize in containers or radiopharmaceuticals in a room or dedicated compartment with a system that will keep airborne concentrations of radioactive particles within the limits. The system must either be vented to the atmosphere through a fume hood equipped with an exhaust duct.

***Section 33. Packaging and Transporting of Radiopharmaceuticals.***

Each licensee shall:

(a) Ensure that transport of radioactive material is in accordance with CPR Part 4.

(b) Have written procedures for packaging and transporting radiopharmaceuticals to customers;

(c) Ensure that the packaging and containers of radioactive material meet design and fabrication requirements;

(d) Ensure that the radioactive material is secured at all times against unauthorized removal;

(e) Provide adequate information available in the delivery vehicle for drivers, police, or civil authorities in case of traffic accidents, etc.

***Section 34. Storage of Radioactive Material.***

(a) Each licensee shall have a storage area for radioactive material.

(b) Each licensee shall keep a record of all pertinent information regarding the stored radioactive material.

(c) Each licensee shall conduct quarterly inventory of stored radioactive materials.

***Section 35. Waste Management.***

(a) The licensee shall hold radioactive materials with a physical half-life of less than 65 days for decay in storage before disposal in ordinary trash provided that:

(1) Radioactive wastes to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.
(2) Before disposal as ordinary waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
(3) Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

(b) The licensee shall retain a record of each disposal permitted under paragraph (a) of this section for 2 years. The record must include the date of the disposal, the date on which radioactive material was placed on storage, the radionuclides disposed, the survey instrument used, the background dose rate, the maximum dose rate measured at the surface of each waste container, and the name and signature of the individual who performed the disposal.

(c) Each licensee shall submit to PNRI a copy of his agreement with a licensed supplier indicating that the spent sealed sources will be returned to the original supplier or manufacturer. The spent sealed sources shall be shipped in accordance with the packaging and shipping requirements specified in CPR Part 4 and the IAEA Safety Standards Series No. 1 (ST-1, Revised), “Regulations for the Safe Transport of Radioactive Materials”, as may be applicable.

***Section 36. Decommissioning of Licensed Facility.***

(a) The licensee shall submit a decommissioning plan for approval by PNRI not later than twelve (12) months before the schedule for initiating the decommissioning.

(b) A proposed decommissioning plan must include:

(1) A description of the site or area to be decommissioned;
(2) A description of the decommissioning procedures;
(3) A description of the methods to be used to ensure protection of workers and the environment against radiation hazards during decommissioning; and
(4) A description of the planned final radiation survey.

(c) As a final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed radioactive materials, including accumulated wastes, by submitting a report to PNRI; and
(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of the survey to PNRI.

## III. REQUIREMENTS FOR SPECIFIC ACTIVITIES AUTHORIZED IN THE LICENSE

***Section 41. Authority to Manufacture, Prepare and Dispense Radiopharmaceuticals.***

For this authority to be included in the license, the applicant shall:

(a) Submit evidence that the applicant is registered by the Bureau of Food and Drugs and licensed by PNRI;

(b) Submit information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees;

(c) Satisfy the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”, the name of the radioactive drug or its abbreviation; and the quantity of the radioactivity at a specified date and time;
(2) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label; and

(d) Assure that the radioactive drugs for medical use will be prepared by authorized nuclear pharmacist or an individual under the supervision of an authorized nuclear pharmacist;

(e) Assure the possession and use of instrumentation for measuring the radioactivity of radioactive drugs. Measure, by direct measurement or by combination of

measurements and calculations, the amount of radioactivity in dosages of radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustment when necessary; and
(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(f) Perform bioassay on individuals who work with H-3, I-125, or I-131 if the following limits are exceeded in a three (3) month period: 5 MBq (0.135 mCi) in an open room, or 50 MBq (1.35 mCi) in a fume hood.

***Section 42. Authority to Dispense and Distribute Radiopharmaceuticals.***

For this authority to be included in the license, the applicant shall:

(a) Assure that the products to be distributed either manufactured, labeled, and packaged complied with the licensing requirements of PNRI and registered by the Bureau of Food and Drugs;

(b) Submit to PNRI a copy of permit or registration issued by BFAD;

(c) Assure that the activities of the facility are limited to the preparation of radiopharmaceuticals for delivery to licensed medical institutions; and

(d) Assure that the activity of the facility is limited to repackaging, distribute, or preparing radiopharmaceuticals by tagging reagent kits with radionuclide eluted from generator by following the procedures on the labels of the reagent kit or the generator or both.

## IV. RECORDS, REPORTS AND NOTIFICATIONS

***Section 51. Records and Reports of Incidents.***

(a) The licensee shall keep records and make reports and notification of incidents to PNRI in accordance with the notification requirements of Parts 2, 3, and 4 of the Code.

(b) The licensee shall notify PNRI within 24 hours of any loss or theft of radioactive material and make a written report within 30 days after the notification.

***Section 52. Notification on Specific Changes in the License.***

(a) The licensee shall notify PNRI, in writing, within thirty (30) days:
(1) When the Radiological Health and Safety Officer and the authorized nuclear pharmacist will be replaced or permanently discontinues performance of duties under the license; or
(2) When the licensee's mailing address changes.

(b) The licensee shall mail or fax the report to:

**The Director**
**Philippine Nuclear Research Institute**
**Commonwealth Avenue, Diliman, Quezon City 1101**

Attention: Chief, Nuclear Regulations, Licensing and Safeguards Division

***Section 53. Records and Reports of Manufacture, Sale, Distribution or Transfer of Radioactive Material.***

(a) The licensee shall submit to PNRI, on a quarterly basis, a summary report of the manufacture and sale of radioactive material. The licensee shall keep records of sale of radioactive material identifying the name and address of each person to whom radioactive material is sold stating the kinds and quantities of radioactive material sold, the date of each sale, and the total activity of radioactive material involved.

(b) Record of the sale shall be maintained for a period of two years after the event is included in a summary report to PNRI.

## V. ENFORCEMENT AND EFFECTIVITY

***Section 61. Inspections.***

(a) Each licensee shall afford to PNRI at all reasonable times the opportunity to inspect the radioactive material in his 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, upon reasonable notice, records kept pursuant to these rules and regulations at the address specified in the license.

***Section 62. 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 thereunder.

(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 and the 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 63. 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.**
Acting Director, PNRI

Date: February 18, 2002