

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

**LICENSES FOR COMMERCIAL PROVIDERS OF NUCLEAR TECHNICAL SERVICES**

**CPR PART 25**

**I. GENERAL PROVISIONS**

**Section 1. Purpose and Scope.**

- (a) This Part prescribes the licensing requirements that will qualify commercial service providers to perform technical services for PNRI licensed users of radioactive materials relative to the operations of devices/equipment that contain radioactive materials.
- (b) The regulations of this Part shall apply to organizations who provide technical services, such as, but not limited to, transport of radioactive materials; installation, calibration, repair or maintenance of nuclear devices/equipment; hazards evaluation or contamination/decontamination survey; decommissioning of radiation facilities/devices, and other related nuclear services to PNRI licensees.
- (c) The requirements of CPR Parts 3 and 4 shall apply where applicable.
- (d) The relevant requirements of other Parts of the CPR are in addition to the specific provisions of this Part, as may be deemed appropriate.
- (e) 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 achievable:
  - (1) consistent with the purpose for which the licensed activity is undertaken; and
  - (2) taking into account the state of technology, the economics of improvement to benefit the health and safety of the public and the workers and other societal and socio-economic considerations;
- (c) "**Ancillary Personnel**" means those individuals whose assigned duties involve exposure to radiation and/or radioactive material incidental to providing services under

the supervision of and direction of the RHSO or authorized personnel, and who are likely to receive in a year an occupational dose greater than 1 millisievert;

- (d) **“Assistant Radiological Health and Safety Officer (ARHSO)”** means an individual who will perform the duties and responsibilities of a RHSO, in the absence of the RHSO designated in the license;
- (e) **“Authorized Personnel”** means those individuals who are authorized to undertake the services specified in the license;
- (f) **“Commercial Service Provider”** means any organization providing technical services for commercial gain;
- (g) **“Licensee”** means a holder of a valid license issued pursuant to this Part;
- (h) **“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;
- (i) **“PNRI”** means the Philippine Nuclear Research Institute and its duly authorized representative;
- (j) **“Quality Assurance”** means planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality specified in the license;
- (k) **“Radiological Health and Safety Officer (RHSO)”** means the individual who is qualified to be the Radiological Health and Safety Officer in accordance with Section 16 of this Part; and
- (l) **“Nuclear Technical Services”** means the installation, repair, maintenance, calibration, hazards evaluation, contamination surveys, decontamination, decommissioning of facilities and equipment, modification and other related services performed or undertaken on the devices/equipment containing radioactive materials.

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

### **Section 3. Interpretation.**

Except as specifically authorized by the Director in writing, no interpretation of the meaning of the regulations in this Part by any officer or employee of PNRI other than a written interpretation by the Director will be recognized to be binding upon PNRI.

### **Section 4. Communication.**

All communication and reports concerning an application, the license 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.**

No person shall engage in providing commercial nuclear technical services for PNRI-licensed users of radioactive materials except in accordance with a license issued by PNRI pursuant to this Part.

### **Section 6. Application for a License.**

- (a) An application for a license pursuant to this Part shall be filed by completing NRLSD Form 025, "Application for Radioactive Material License (Nuclear Technical Services)".
- (b) Each applicant shall show proof of authority/permit to conduct business under its business name issued by the responsible government agency.
- (c) Each applicant shall show proof of technical and financial qualification to undertake such proposed technical services.
- (d) The application shall include the submission of all safety and technical requirements specified in this Part, as may be required, 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) Each application for a license must be affirmed and notarized upon submission to PNRI.

### **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 PNRI determines that the application, as submitted, contains the vital facts and information that are needed to initiate a review and evaluation of the license application.

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

PNRI shall approve an application for a license which will be valid for a period of one (1) year if:

- (a) The applicant has satisfactorily complied with the requirements for the intended authorization(s) described in Chapter III of this Part;
- (b) The applicant has designated a Radiological Health and Safety Officer (RHSO) and Assistant RHSO who are both qualified by training and experience to perform their duties and responsibilities;
- (c) The personnel designated in the application to perform the authorized services are qualified by training and experience;
- (d) The applicant has established a program for training and re-training of authorized and ancillary personnel;

- (e) The applicant possesses the appropriate tools, instruments, devices and facilities for the services to be provided;
- (f) The applicant meets the requirements of CPR Part 3, "Standards for Protection Against Radiation" and CPR Part 4, "Rules and Regulations for the Safe Transport of Radioactive Materials in the Philippines";
- (g) The applicant has submitted a Quality Assurance Program governing its operation as a commercial service provider;
- (h) The applicant has established measures acceptable to PNRI for the safety and security of radioactive materials in its possession;
- (i) The applicant's operating and emergency procedures are acceptable to PNRI; and
- (j) The applicant has paid all fees and charges, as may be applicable.

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

- (a) Each license issued pursuant to this Part shall be subject to the provisions of the Act and applicable regulations of the CPR, and the specific conditions prescribed in the license.
- (b) No license issued pursuant to this Part, and no right 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 any right under the license to any person unless PNRI, after being notified and provided full information, approves in writing to the proposed transfer or assignment.
- (c) Each licensee shall provide PNRI all information necessary to track the location and use of sealed sources and devices upon request.
- (d) Each licensee shall confine the use and possession of licensed radioactive material to the locations and purposes authorized in the license.
- (e) Each licensee shall notify and must receive the written approval of PNRI for a temporary jobsite other than that authorized in the license.
- (f) Each licensee who is engaged to provide decommissioning services for another licensed facility must notify PNRI in writing at least sixty (60) days prior to commencement of decommissioning activities.
- (g) Each licensee shall submit a report of services rendered and results of such services on a quarterly basis.
- (h) Each licensee shall only undertake an activity authorized in his/her license under a contractual agreement with the recipient of the technical services.

**Section 10. Amendment of License.**

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

- (1) Before it permits anyone to work as the Radiological Health and Safety Officer (RHSO), Assistant RHSO or authorized personnel designated in the license;
  - (2) Before it implements any major change in the approved radiation protection and safety program;
  - (3) Before it changes or modifies the service facility identified in the license;
  - (4) Before any material change in any specific condition of the license takes effect;  
or
  - (5) Before it acquires radioactive material other than what is authorized in the license.
- (b) Each licensee shall apply for a license amendment not later than thirty (30) days after the RHSO and/or Assistant RHSO permanently discontinues performance of his/her assigned duties and responsibilities under the license and shall correspondingly submit the necessary supporting documents for the new RHSO/Assistant RHSO.

### **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 if the requirements of (b) are not met. After the expiration date, the licensee must cease or discontinue engaging in all authorized activities described in the license and initiate the procedure for termination of license.
- (b) At least thirty (30) days before the expiration date specified in the license, the licensee shall either;
- (1) Submit an application for renewal of the license; or
  - (2) If the licensee decides not to renew the license, notify PNRI in writing and request that the license be terminated.
- (c) In case the licensee has filed an application for renewal of his/her license in proper form in accordance with (b)(1) of this section, such existing license shall not expire until final action has been taken by PNRI.
- (d) An application for renewal of license that is filed less than thirty (30) days before the stated expiration date of the license, but not after the expiration date, shall be imposed a surcharge equivalent to 25 percent of the required renewal license fee.
- (e) Each application for renewal of license in accordance with this section must include the corresponding license renewal fee and other applicable regulatory fees.

### **Section 12. License Renewal after the Expiration Date.**

- (a) If the licensee submits an application for renewal of license after the specified expiration date, but not exceeding thirty (30) days after the expiration date, the application must include the following information in writing:
- (1) An explanation for the delay in filing the application and why PNRI should not undertake any administrative sanctions against the licensee;
  - (2) An assurance that the licensee did not undertake any principal licensed activity involving radioactive material after the expiration date of the license; and
  - (3) A request that the license will be renewed under the previous authority.
- (b) If PNRI determines that the licensee's reasons in (a) of this section are acceptable and that safety has not been undermined, the application will be accepted and processed,

provided that the licensee shall not undertake any principal activity involving the licensed radioactive material until PNRI has granted the license. An additional surcharge equivalent to fifty (50) percent of the renewal license fee shall be collected.

- (c) If the licensee has not filed an application for renewal of license under the conditions stated in this section, or, if PNRI deems that the licensee's reply with respect to (a) and (b) of this section, are unacceptable, the license is deemed to have expired. PNRI shall order the licensee to initiate or cause the termination of its license in accordance with the prescribed procedure for the termination of license in the CPR.

### **Section 13. Termination of License.**

- (a) Each licensee shall notify PNRI in writing and request for the termination of the license within sixty (60) days after a decision has been made by the licensee to permanently discontinue all licensed activities identified in the license, or twenty four (24) months after the licensee ceased from undertaking all licensed activity.
- (b) A license will be terminated by PNRI through written notification to the licensee when PNRI determines that, the site has been verified by PNRI inspectors to be free of contamination, that clearance can be given for unrestricted use and the required records are complete and up-to-date.

### **Section 14. Additional Requirements and Exemptions.**

PNRI may, by rule, regulation, or order, impose upon any licensee such requirements, in addition to those established in this Part, or may, upon its own initiative or upon application by the applicant/licensee, allow specific exemptions from the requirements of a license, as it deems appropriate or necessary to protect the health and safety of the public or to minimize danger to life or property pursuant to the Act.

## **II. TECHNICAL REQUIREMENTS**

### **Section 15. Radiation Protection and Safety Program.**

- (a) Each licensee shall develop and implement written radiation protection and safety program that includes provisions for keeping doses ALARA in accordance with the provisions of CPR Part 3.
- (b) The program must include a description of functions and program 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 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.
- (c) Each licensee shall review at least annually the content and implementation of its radiation protection and safety program.

**Section 16. Radiological Health and Safety Officer (RHSO).**

- (a) The licensee shall appoint a RHSO who shall be responsible for radiation safety and compliance with the relevant regulatory requirements for providing technical services as identified in the license. The RHSO must confirm, in writing, of his/her acceptance of the appointment. The RHSO shall ensure that radiation safety activities are performed according to approved safety policies and procedures and should have the authority to stop any activity that may endanger health and safety.
- (b) The licensee shall appoint an Assistant RHSO who shall act as the temporary RHSO in the absence of the RHSO designated in the license.
- (c) The RHSO shall be responsible for ensuring the following:
  - (1) Activities involving licensed material that the RHSO considers unsafe are stopped;
  - (2) Radiation exposures are as low as is reasonably achievable (ALARA);
  - (3) Development, distribution, implementation, and maintenance of operating and emergency procedures are updated;
  - (4) Possession, installation, relocation, use, storage, repair and maintenance of sealed sources, devices and radioactive wastes are consistent with the conditions of the license, individual Sealed Source and Device Registration Certificate(s), and the manufacturer's specific recommendations and instructions;
  - (5) Evaluations of occupationally exposed individuals are performed to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of the allowable limits or personnel monitoring devices are provided;
  - (6) Licensed radioactive materials are properly secured;
  - (7) Documentation is maintained to demonstrate, by measurement or calculation, that the total effective equivalent dose to the individual member of the public that is likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
  - (8) Proper authorities are notified of incidents such as damage to sealed sources/devices, loss of licensed material, fire, theft, etc.;
  - (9) Unusual occurrences are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
  - (10) Radiation protection and safety program audits are performed and documented at least annually;
  - (11) When PNRI identifies violations of licensee requirements or program weaknesses, the licensee develops, implements, and documents corrective actions;
  - (12) Licensed material is transported in accordance with CPR Part 4 and all applicable transport requirements of other government authorities concerned;
  - (13) Licensed material is disposed of properly;
  - (14) Appropriate records are maintained;
  - (15) Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner;
  - (16) Monitoring and surveys of all areas in which radioactive material is used are performed;
  - (17) Ordering, receipt, surveys, and delivery of radioactive material are proper;
  - (18) Proper packaging, labeling, surveys, etc. of all shipments of radioactive material leaving the institution;
  - (19) Implementation of personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and

- developing corrective actions for those exposures approaching maximum dose limits;
  - (20) Training of personnel;
  - (21) Administration of waste management program;
  - (22) The inventory and leak testing of sealed sources;
  - (23) Decontamination activities are performed properly;
  - (24) Appropriate investigation of any incidents and adequate response to any emergencies;
  - (25) Liason with the PNRI; and
  - (26) Records that are necessary to support the license and satisfy PNRI regulations are maintained.
- (d) The RHSO/Assistant RHSO shall immediately inform the licensee and PNRI if he/she decides to terminate his/her responsibilities as RHSO.
- (e) The RHSO/Assistant RHSO shall be present during the performance of any licensed activity.

#### **Section 17. Statements of Authority and Responsibilities.**

- (a) The licensee shall provide the RHSO sufficient authority, organizational flexibility, 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 actual authorities, duties and responsibilities of the RHSO and submit a copy to PNRI.

#### **Section 18. Qualification and Training of RHSO and ARHSO.**

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

- (a) Holds a Bachelor of Science Degree in Engineering or at least graduated from any four (4) year course and is duly licensed by the Philippine Professional Regulations Commission;
- (b) Has successfully completed a Radiation Safety Officer (RSO) Course conducted by PNRI or an equivalent course conducted by an accredited training provider. Training syllabus and modules shall be submitted to PNRI for review and evaluation; and
- (c) Has completed a training course on Safety in the Use of Nuclear Equipment and Devices conducted by PNRI or an equivalent course conducted by an accredited training provider. Training syllabus and modules shall be submitted to PNRI for review and evaluation.

#### **Section 19. Authorized and Ancillary Personnel.**

- (a) Each authorized personnel designated by the licensee must be qualified by training and experience for the services to be performed.



- (b) Each authorized personnel who supervises or directs the activities of ancillary personnel shall inform or provide appropriate training to these individuals about radiation hazards and the appropriate precautions they should take when working in the vicinity of radioactive materials.
- (c) Each ancillary personnel shall be provided direct reading personnel monitoring devices when performing his/her duties involving radioactive material.

## **Section 20. Training for Authorized Personnel.**

The designated authorized personnel must have minimum qualifications for each specific type of services to be rendered as described below.

- (a) Installation and associated technical services of devices/equipment and components containing radioactive materials including the making of diagnostic radiation output measurements to verify performance associated with the installation or service:
  - (1) Completed a training course on Safety in the Use of Nuclear Equipment and Devices conducted by PNRI or an equivalent course conducted by an accredited training provider. Training syllabus and modules shall be submitted to PNRI for review and evaluation;
  - (2) Completed the manufacturer's training program on the handling, maintenance and services for the type of devices/equipment containing radioactive material being used;
  - (3) Completed a specialized training program relevant to the technical service to be provided; and
  - (4) Three months of actual work experience for the type of service to be provided.
- (b) Sales of devices/equipment and components containing radioactive materials to end users:
  - (1) Completed a training course on Safety in the Use of Nuclear Equipment and Devices conducted by PNRI or an equivalent course conducted by an accredited training provider. Training syllabus and modules shall be submitted to PNRI for review and evaluation; and
  - (2) Certification of knowledge or familiarity with the rules which govern the possession, installation, and use of devices/equipment containing radioactive materials.
- (c) Diagnostic radiographic/fluoroscopic facility and shielding design:
  - (1) Completed a training course on Safety in the Use of Nuclear Equipment and Devices conducted by PNRI or an equivalent course conducted by an accredited training provider. Training syllabus and modules shall be submitted to PNRI for review and evaluation;
  - (2) Certification on training in shielding design; and
  - (3) One year of actual work experience in diagnostic radiographic/fluoroscopic facility and shielding design for the specific type of devices/equipment application.
- (d) Radiation instrument calibration:
  - (1) Must hold and show proof of certificate of training on Secondary Standard Dosimetry or on-the-job training on radiation instrument calibration or

- participated in the Intercomparison Program given by the International Atomic Energy Agency and other Member States; and
- (2) Three (3) months of actual work experience on radiation instrument calibrations.
- (e) Personnel dosimetry service:
- (1) Participated in Intercomparison Programs for dosimetry reliability and accuracy given by the International Atomic Energy Agency and other Member States; and
  - (2) Three (3) months of actual work experience on personnel dosimetry services.
- (f) Radiation surveys, monitoring, decontamination, decommissioning and other related nuclear services:
- (1) Completed a training course on Safety in the Use of Nuclear Equipment and Devices conducted by PNRI or an equivalent course conducted by an accredited training provider. Training syllabus and modules shall be submitted to PNRI for review and evaluation;
  - (2) Three months of actual work experience performing area radiation surveys, monitoring, decontamination, decommissioning, or in other types of service to be provided.

#### **Section 21. Retraining.**

The licensee shall require the RHSO, ARHSO and authorized personnel to undertake retraining program on safety and security as appropriate and approved by PNRI every five (5) years.

#### **Section 22. Possession of Sealed Sources or Unsealed Sources Incident to Performing Services.**

- (a) Each licensee providing such services as leak test, environmental analyses, instrument and/or dosimetry calibration shall specify the sealed source that will be used for each type of service with all the necessary technical data.
- (b) Each licensee that provides services for devices containing sealed sources shall state that possession of sealed sources is incidental to performing services relative to installation, radiation surveys, removal, disposal, relocation, repair, maintenance, source exchange or retrieval, transportation, training, or leak test sample acquisition.
- (c) Each licensee that may use unsealed sources for the purpose of performing services and has stated its possession of unsealed sources is incidental to performing commercial services shall consider this condition during an emergency.

#### **Section 23. Personnel Monitoring and Alarm Ratemeter.**

- (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 dosimeter or similar device and either a film badge or a thermoluminescent (TLD) badge.
- (b) Pocket dosimeter shall have a range from 0 to almost 2 mSv and shall be charged to zero at the start of each shift. Each film badge or TLD shall be assigned to and worn by only one individual.

- (c) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters shall be read, and exposures recorded after every use. Records of pocket dosimeter readings shall be kept for two years.
- (d) Pocket dosimeters or electronic personal dosimeters shall be checked and calibrated with validity not to exceed one year by facilities accredited by PNRI. If the individual's pocket dosimeter is discharged beyond its range, his/her film badge or TLD shall be immediately sent for processing.
- (e) Personnel monitoring devices shall be worn by personnel performing installation, repair, maintenance, decommissioning, and other related services on the devices/equipment containing radioactive material.
- (f) If the individual uses an audible alarm ratemeter, each ratemeter must:
  - (1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each use;
  - (2) Be set to give an alarm signal at a preset dose rate of 1 mSv/hr;
  - (3) Require special means to change the preset alarm functions; and
  - (4) Be calibrated at periods not to exceed one year. Acceptable ratemeters must give an alarm signal within plus or minus 20 percent of the true radiation dose rate.

#### **Section 24. Possession and Calibration of Survey Instrument.**

- (a) Each licensee shall have in his/her possession a portable radiation survey instrument capable of measuring dose rates over the range of 0 to 10 mSv per hour.
- (b) Each licensee shall calibrate or cause the calibration of its survey instrument before first use, following repair and every year thereafter. If the licensee will engage the calibration services of another person or firm, the licensee shall submit that person's or firm's qualification and calibration procedures for review.
- (c) Each licensee shall retain a record of each survey instrument calibration for two years.

#### **Section 25. Requirements for Transport.**

- (a) Each licensee shall transport radioactive material in accordance with CPR Part 4, "Rules and Regulations for the Safe Transport of Radioactive Materials in the Philippines".
- (b) Each licensee shall ensure that labeling, marking, placarding, such as radiation warning signs, symbols, stickers, etc. are in accordance with transport regulations.
- (c) Each licensee shall ensure compliance with other relevant transport requirements of other government authorities.

#### **Section 26. Transfer of Sealed and Unsealed Sources.**

- (a) Each licensee shall notify PNRI of any possession and use of sealed and unsealed sources transferred from its client/user incident to services provided thereto.

- (b) Each licensee shall submit the name, type, activity, and serial number for each sealed source that it will receive, possess, use, or service from its client/user.
- (c) Each licensee shall notify PNRI before it transfers radioactive material back to its client/user.

### **Section 27. Safety and Security of Radioactive Material.**

- (a) When appropriate, each licensee shall:
  - (1) Provide a secured storage area for devices/equipment containing radioactive materials in its possession, or incidental to performing services;
  - (2) Ensure that stored radioactive materials are protected and secured to prevent any theft, unauthorized transfer, or possession, and assure that the likelihood of unnecessary exposure to any member of the public is diminished; and
  - (3) Keep a record of all pertinent information regarding the stored radioactive material.
- (b) The licensee shall ensure that the security measures are appropriate for the category of radioactive materials in use at the facility and are consistent with the administrative and technical requirements prescribed by PNRI.

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

### **Section 28. Types of Services Provided by Commercial Service Providers.**

- (a) Each licensee is limited to provide the following types of commercial services:
  - (1) Installation, relocation, removal from services, disposal of radioactive waste, radiation surveys, routine and preventive maintenance, adjustment of equipment, training of personnel or repair of devices containing licensed material, calibration, waste treatment and processing;
  - (2) Installation, relocation, removal from service, disposal of radioactive waste, radiation surveys, routine or preventive maintenance, adjustment, training of personnel or repair of large irradiators described in CPR Part 15;
  - (3) Installation, radiation surveys, routine and preventive maintenance, adjustment or repair of remote afterloaders, teletherapy, or gamma stereotactic radiosurgery units that require access to the sealed source(s), driving units, or other electronic components that could expose the sealed source, reduce the shielding or compromise the radiation safety of the device or safety systems;
  - (4) Calibration of survey instruments and personnel dosimetry equipment;
  - (5) Monitoring services;
  - (6) Leak testing of sealed sources, including analyzing the leak test smears;
  - (7) Environmental sample analysis;
  - (8) Training of personnel using sealed and unsealed sources;
  - (9) Calibration of dose calibrators;
  - (10) Waste management services including treatment and conditioning;
  - (11) Decontamination and decommissioning services; and
  - (12) Quality assurance program implementation.

- (b) Each licensee who shall provide the services described in (a)(1), (a)(2), (a)(3), (a)(8), (a)(10), (a)(11), or (a)(12) of this section shall submit a program, including procedures and instructions, that describes how it will perform the services it intends to provide under the license.
- (c) Each licensee who shall provide the services described in (a)(4), (a)(5), (a)(6), (a)(7), or (a)(9) shall submit the procedures for such services described.
- (d) Each licensee shall submit the names, functions and responsibilities of all authorized personnel involved in the performance of activities.
- (e) Each individual, who participates in the conduct of services where radiation is present, must be provided with proper and adequate personnel monitoring devices.
- (f) Each licensee shall assure that adequate radiation monitoring instruments and all necessary testing, measuring and repair equipment for the authorized activities are adequate and calibrated.
- (g) Each licensee shall submit to PNRI quarterly report on services rendered to any PNRI-licensed client/user.
- (h) Each licensee shall ensure that after completion of services provided, all devices/equipment serviced operate correctly and safely, and will not cause any unnecessary exposure of radiation to workers and the public.
- (i) Each licensee shall ensure that the installation, repair, maintenance and other nuclear services is in accordance with manufacturer's instructions for the said devices/equipment.
  - (1) Ensure that the replacement parts match those specified by the manufacturer and can identify all spare parts replaced during the repair of a particular devices/equipment.
  - (2) If an alternative method will be used, the licensee shall demonstrate that the method is equivalent and takes into account all risks to concerned parties and users and is fully documented.
- (j) Each licensee shall undertake audit and review of the installation, repair, maintenance, and other related nuclear service process, taking any action as necessary.
- (k) If the devices/equipment failed or injured a patient or user, as a result of defective repair and maintenance, both the owner of the devices/equipment and the licensee who provides services could be liable to the injured person within the penal provisions of the Act.
- (l) Each licensee shall undertake to participate in intercomparison programs for dosimetry reliability and accuracy, if appropriate. A dose quality assurance program shall be submitted for review and evaluation by the PNRI.
- (m) Each licensee shall ensure that the qualifications of trainers (training staff/providers), the methodology used, course syllabus, modules and facilities for training or practical exercises must be submitted to PNRI for accreditation.

#### **IV. RECORDS, REPORTS AND NOTIFICATIONS**

##### **Section 29. Records of Radiation Protection and Safety Program.**

- (a) Each licensee shall maintain records of the radiation protection and safety program and shall include:
  - (1) The provisions of the program; and
  - (2) Results of audits and other reviews of program content and implementation.
- (b) The records required by this Section shall be retained for three (3) years or until PNRI orders otherwise.

##### **Section 30. Records of Personnel Monitoring.**

- (a) Each licensee shall maintain records showing the total exposures of all personnel. Such records shall be kept on clear and legible forms in accordance with the instructions required by PNRI.
- (b) Records of personnel monitoring shall be kept and preserved until PNRI authorizes their disposition.

##### **Section 31. Records of Surveys.**

- (a) Each licensee shall maintain records showing the results of surveys incident to the use of radioactive materials.
- (b) In support of records of personnel monitoring, records of result of surveys to determine external radiation doses shall be maintained until PNRI authorizes their disposition.

##### **Section 32. Records of Disposition of Sealed Sources.**

Records of disposition of sealed sources shall be maintained and retained until PNRI authorizes their disposition.

##### **Section 33. Reports of Thefts or Loss of Radioactive Material.**

- (a) The licensee shall immediately notify PNRI by telephone or by any other fast means of communication, of any loss or theft of radioactive material within 24 hours and make a written report within 30 days after the notification which include the following:
  - (1) Description of the sealed source involved i.e. isotope, quantity, chemical and physical forms;
  - (2) Description of the circumstances under which the loss or theft occurred;
  - (3) Estimated radiation exposure to individuals, if any;
  - (4) Actions to recover the source; and
  - (5) Measures to be adopted to prevent recurrence of the circumstances which led to the loss or theft of the sealed source.

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

#### **Section 34. Records and Reports of Service Rendered.**

- (a) Each licensee shall submit quarterly a report and record of all services rendered to its PNRI-licensed or prospective licensed clients/users. The report shall describe:
  - (1) Name, PNRI licensed number, and address of the licensed client/user, if applicable;
  - (2) Kind or type of devices/equipment;
  - (3) All activities performed, including, but not limited to, the initial status of the devices/equipment and the reason for the request of their services;
  - (4) Details of replacement of parts or components, repair and/or modification of any component of the devices/equipment;
  - (5) Status of the devices/equipment after the completion of the services rendered and its safety implications;
  - (6) Result of calibration of the devices/equipment before being put back to operation, if needed;
  - (7) The satisfactory acceptance of the licensed client/user of the completed services;
  - (8) Date service/repair was done and the name of the person who performed/conducted service/repair of the devices/equipment; and
  - (9) For dosimetry providers, submit dose evaluation reports for licensed clients/users to PNRI.
- (b) Each licensee shall ensure that all records relating to the repair, maintenance and other related nuclear services are accurate, detailed and readily accessible.

#### **Section 35. Notification of Incidents.**

- (a) Each licensee shall notify PNRI within 24 hours by telephone, or by any other fast means of communication, of any incident involving a licensed activity, licensed facility, source material, or any other radioactive material possessed by the licensee that may have caused, or threatens to cause:
  - (1) Exposure of the whole body of any individual in excess of 0.05 Sv; or
  - (2) Release of radioactive material in the facility.
- (b) Any report filed with PNRI shall specify the names of individuals who have received exposure to radiation and other persons involved in the incident, including telephone numbers and addresses as may be practicable.

#### **Section 36. Notification on Specific Changes in the License.**

- (a) A licensee shall notify the PNRI immediately by telephone or by similarly fast means of communication and by letter within thirty (30) days:
  - (1) When the RHSO, Assistant RHSO and any authorized personnel permanently discontinues performance of duties under the license or has a name change;
  - (2) When the licensee's mailing address changes; or

- (3) When there is a change of the authorized storage location of radioactive materials.
- (b) The licensee shall mail the report to:  
**The Director**  
Philippine Nuclear Research Institute  
Commonwealth Avenue, Diliman  
Quezon City 1101  
Attention: Chief: Nuclear Regulations, Licensing and Safeguards Division

## **V. ENFORCEMENT AND EFFECTIVITY**

### **Section 37. Inspections.**

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

### **Section 38. Modification and Revocation of License.**

- (a) The terms and conditions of each license issued pursuant to the regulations in this Part shall be subject to amendment, revision or modification by reason of amendments to these regulations and the Act, or by reason of rules, regulations and orders issued by the Institute in accordance with the terms of the Act.
- (b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application, or for violation of, or failure by the licensee to observe, any of the terms and conditions of the license or any of the provisions of the Act, or any of the rule, regulation or order of the Institute.
- (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.
- (d) A license maybe modified by PNRI, or upon the request of the licensee, when:
  - (1) The licensee decides to discontinue any specific licensed activity authorized in the license or to undertake another licensed activity prescribed in this Part;
  - (2) PNRI determines that the licensee can no longer perform the specific licensed activity authorized in the license; or
  - (3) The licensee has ceased to perform a licensed activity during a two (2) year period.

### **Section 39. 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 radioactive materials in violation of law or regulation of the PNRI, or in any manner other than as disclosed in the application therefore or approved by PNRI.

**Section 40. Violations.**

Any person who shall willfully violate, attempt to violate or conspire 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 and Section 25 of Republic Act No. 2067, as amended.

**Section 41. 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:

(Signed)

**ALUMANDA M. DELA ROSA, Ph.D.**

Director, PNRI

Date: December 15, 2005