CPR Part 16

LICENSES FOR THE USE OF RADIOACTIVE SOURCES CONTAINED IN INDUSTRIAL DEVICES

TABLE OF CONTENTS

	I. GENERAL PROVISIONS	Page
Section 1.	Purpose and Scope	1
Section 2.	Definitions	1
Section 3.	Interpretations	3
Section 4.	Communication	3
Section 5.	Activities Requiring License	3 3 3 3
Section 6.	Application for New and Renewal of License	3
Section 7.	Issuance of License	4
Section 8.	Terms and Conditions of License	5
Section 9.	Amendment of License	5
Section 10.	Expiration of License	6
Section 11.	Renewal of the license	6
Section 12.	Termination of License	7
Section 13. Section 14.	Decommissioning	8 8
Section 15.	Additional Regulatory Requirements Application for Exemptions	8
Section 15.	Application for Exemptions	O
	II. GENERAL ADMINISTRATIVE REQUIREMENTS	
Section 16.	Radiation Safety Program	8
Section 17.	Radiation Safety Officer (RSO) and Assistant RSO (ARSO)	9
Section 18.	Training and Experience Requirements for RSO and ARSO	9
Section 19.	Authorized Operator of the Industrial Device Containing Radioactive Source	9
Section 20.	Retraining	10
Section 21.	Lease and/or Rental of Portable Gauge	10
	III. TECHNICAL REQUIREMENTS	
Section 22.	Personnel Monitoring Devices	10
Section 23.	Possession and Calibration of Survey Instruments	11
Section 24.	Installation, Maintenance and Repair	11
Section 25.	Leak Testing of Radioactive Sources	11
Section 26.	Transport of Radioactive Sources Contained in Industrial Device	12
Section 27.	Operating and Emergency Procedures	12
Section 28.	Portable Gauge at Temporary Jobsite	12
Section 29.	Labels and Markings	12
Section 30.	Posting	13

IV. SECURITY OF RADIOACTIVE SOURCES

Section 31. Section 32.	, ,	13 13
V. WA	STE MANAGEMENT AND DISPOSAL OF LICENSED RADIOACTIVE SO	URCE
Section 33. Section 34.	Transfer of Licensed Radioactive Source	13 13
Section 35.	Return of Disused Radioactive Sources to the Original Supplier or Manufacturer	14
	VI. RECORDS, REPORTS AND NOTIFICATIONS	
Section 36. Section 37. Section 38. Section 39. Section 40. Section 41.	Records of Occupational Exposure Records of Tests Records of Surveys	14 14 15 15 15
Section 42 Section 43.	Utilization Logs for Portable Gauge	15 16
Section 44. Section 45.		16 16
	VII. INSPECTION AND ENFORCEMENT	
Section 46. Section 47 Section 48. Section 49.	Inspections Violations Modification and Revocation of License Right to Cause the Withholding or Recall of Radioactive Source	17 17 17 18
	VIII. EFFECTIVITY	
Section 50.	Effective Date	18

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

CPR PART 16

LICENSES FOR THE USE OF RADIOACTIVE SOURCES CONTAINED IN INDUSTRIAL DEVICES

I. GENERAL PROVISIONS

Section 1. Purpose and Scope.

- (a) This Part prescribes the requirements for the issuance of licenses for the use of radioactive sources contained in industrial devices and radiation safety requirements for persons using these industrial devices.
- (b) The requirements of this Part apply to radioactive sources contained in portable gauges and gauges mounted in fixed locations.
- (c) The provisions and requirements of this Part shall be applied in conjunction with the radiation safety requirements of CPR Part 3 "Standards for Protection Against Radiation," CPR Part 26 "Security of Radioactive Sources," and CPR Part 4 "Regulations on the Safe Transport of Radioactive Materials in the Philippines."
- (d) This Part does not relieve the licensee from complying with applicable requirements of other responsible agencies of government.

Section 2. Definitions.

As used in this Part:

- (a) "Accounting" means physically checking that all sources are present in their expected location; this may be satisfied by an appropriate radiation survey;
- (b) "Act" means Republic Act No. 2067, otherwise known as the Science Act of 1958, as amended by Republic Act No. 3589, and Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended by Presidential Decree No. 1484;
- (c) "ALARA" (as low as reasonably achievable) means making every reasonable effort to maintain exposures 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 improvement to benefit the health and safety of the public and workers and other societal and socioeconomic considerations;

- (d) "Assistant Radiation Safety Officer (ARSO)" means the individual who is identified in the license issued pursuant to this Part to perform the duties and responsibilities of the RSO in his/her absence;
- (e) "Authorized Operator" means an individual trained and qualified to use and operate the industrial device and identified as authorized operator in the license issued pursuant to this Part;
- (f) "CPR" or "Code" means the Code of PNRI Regulations;
- (g) "**Decommissioning**" for purposes of this CPR, means removing an industrial device safely from service and reducing residual radioactivity that permits:
 - (1) Release of an industrial device for unrestricted use and termination of the license; or
 - (2) Release of an industrial device for restricted conditions and termination of the license;
- (h) "Disused Source" means a radioactive source which is no longer used, and is not intended to be used, for the practice for which a license has been granted;
- (i) "Inventory" means to physically check all radioactive sources possessed, by specifically and uniquely identifying each individual source using appropriate means such as serial numbers;
- (j) "Fixed Gauge" means a device that contained a radioactive source installed at a fixed location solely for the intended purpose;
- (k) "Lease" means a contract transferring a portable gauge from one licensee to another for a certain term and usually for a specified rent;
- (I) "PNRI" means the Philippine Nuclear Research Institute and its duly authorized representative(s);
- (m) "Portable Gauge" means a device containing a radioactive source that can be moved from one place to another solely for the intended purpose;
- (n) "Radiation Safety Officer (RSO)" means an individual identified in the license issued pursuant to this Part to be responsible for implementing the radiation safety and security program of the licensee;
- (o) "Radioactive Source" means a radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It also means any radioactive material released if the radioactive source is leaking or broken, but does not mean material encapsulated for disposal, or nuclear material within the nuclear fuel cycles of research and power reactors;
- (p) "Recording Level" means a level of dose, exposure or intake specified by the PNRI at or above which values of dose, exposure or intake received by workers are to be entered in their individual exposure records;
- (q) "Safety" means measures intended to minimize the likelihood of accidents with radioactive sources and, should such accident occur, to mitigate its consequences;
- (r) "Security" means measures to prevent unauthorized access or damage to, and loss, theft, unauthorized transfer of radioactive sources:

- (s) "Storage Area" means any location, facility or vehicle which is used to store, transport, or secure an industrial device when it is not in use, and which is locked and has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the industrial device; and
- (t) "Temporary Jobsite" means a location where portable gauges are used and where the gauges may be stored other than those location(s) of use authorized in the license.

Note: Terms defined in the Act and in other Parts of the Code shall have the same meaning when used in this Part to the extent that such terms are not specifically defined 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 the PNRI.

Section 4. Communication.

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

Section 5. Activities Requiring License.

No person shall acquire, receive, possess, own, use, transfer, export, or import radioactive sources contained in industrial devices or any industrial device containing radioactive sources except in accordance with a license issued by PNRI pursuant to this Part.

Section 6. Application for New License and Renewal of License.

- (a) An application for a new license and a renewal of license pursuant to this Part shall be filed on PNRI/NRD Form 016, "Application for a License for the Use of Radioactive Sources Contained in Industrial Devices" in duplicate copies.
- (b) Each application for a license pursuant to this Part shall be duly affirmed and notarized and shall be signed by the applicant or a person duly authorized to act for and on his behalf upon submission to PNRI.
- (c) The applicant shall show proof of authenticity of business name issued by the Securities and Exchange Commission and the current business permit issued by the responsible government agency.
- (d) The application shall adequately describe the necessary information required in the application form in accordance with the technical, safety, and security requirements specified in this Part.
- (e) The PNRI may, at any time after the filing of the application, require further information to enable PNRI to determine whether the license should be granted or denied.

- (f) For license renewal, licensee shall provide a complete and up-to-date application e.g. radiation safety program, licensee's organization, etc.
- (g) The application will be accepted and processed only when PNRI has determined the completeness, in substance and form, of the submitted information, and payment of corresponding fees prescribed in CPR Part 22" Fees and Charges for Radioactive Material Licenses and Other Related Regulatory Services," have been made.

Section 7. Issuance of License.

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

- (a) The application is for a purpose authorized by the Act;
- (b) The locations and areas where the radioactive source will be used and stored are in accordance with the safety and security requirements of the Code;
- (c) The applicant's proposed equipment and facilities relative to the use of radioactive source are adequate to ensure the security of the radioactive sources, as well as to protect public health and minimize danger to life or property;
- (d) The applicant's proposed operators are qualified by training and experience to use the radioactive source for the purpose requested in such a manner as to protect public health and minimize danger to life or property;
- (e) The applicant has designated a qualified Radiation Safety Officer (RSO) and Assistant Radiation Safety Officer (ARSO), who shall both consent and agree in writing, and shall ensure the effective implementation of the radiation safety and security programs in accordance with approved procedures and regulatory requirements;
- (f) The applicant has established and stated in writing the authorities, duties, responsibilities of the RSO on matters affecting radiation safety and security;
- (g) The applicant has submitted a radiation safety program and is found to be adequate for the activities requested;
- (h) The applicant has established and submitted to PNRI Source Security Measures in accordance with the requirements of CPR Part 26;
- (i) The applicant has submitted acceptable procedures for the transport of radioactive sources in accordance with the requirements of CPR Part 4;
- (j) The applicant has ensured that disused sources shall be returned to the original supplier or manufacturer in the country of origin;
- (k) The applicant has submitted written and approved operating and emergency procedures according to Section 27 of this Part;
- (I) The applicant has submitted to PNRI the maintenance and service information documents about the industrial device and associated equipment as provided by the device manufacturer or supplier;
- (m) The applicant has submitted the decommissioning and waste management program for the radioactive sources;

(n) The applicant has paid all applicable fees in accordance with CPR Part 22.

Section 8. Terms and Conditions of License.

- (a) The license shall be valid for a period as may be determined by PNRI;
- (b) Each license issued shall be subject to the applicable provisions of the Act, specific conditions of the license and to relevant rules, regulations and orders of PNRI.
- (c) The PNRI may incorporate in any license issued pursuant to this Part, at the time of issuance or thereafter by appropriate notification, rule or order, such additional requirements and conditions with respect to the license as it deems appropriate or necessary in order to protect health and safety, as well as ensure the security of the source.
- (d) 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.
- (e) Each licensee shall confine his possession and use of the radioactive source described in the license to the location(s) and purpose(s) authorized in the license.
- (f) The shipment and transport of the radioactive source shall be in accordance with the requirements of CPR Part 4.
- (g) A copy of the existing license and applicable regulations of the Code shall be kept and made available at each location indicated in the license.
- (h) Each licensee shall conduct an inventory at least on a semi-annual basis of all radioactive sources and devices received and possessed. Records of such inventory shall be retained for three (3) years and made available for inspection by PNRI.
- (i) Each licensee, if required by PNRI, shall submit and follow the emergency plan as approved by PNRI.
- (j) Each licensee shall notify PNRI immediately in writing following the filing of a voluntary or involuntary petition for bankruptcy under existing Philippine laws.
- (k) Each licensee authorized to possess and use portable gauges shall immediately notify PNRI of contractual conditions with another entity regarding the use of the portable gauge;
- (I) Each licensee shall undertake an accounting of licensed radioactive sources.

Section 9. Amendment of License.

(a) An application for amendment of license shall be filed in PNRI/NRD Form 016A – "Application for Amendment of License", and shall specify in what respect the licensee desires his license to be amended and the grounds for such amendment.

- (b) A licensee shall apply for and must receive a license amendment before:
 - (1) It receives and uses an industrial device that contains a radioactive source or device other than what is indicated in the license:
 - (2) It replaces the RSO and ARSO designated in the license;
 - (3) It orders and receives radioactive source in excess of the activity authorized in the license;
 - (4) It changes or modifies the areas or locations of use or storage of licensed radioactive source within the premises of the facility identified in the license;
 - (5) It relocates the portable gauge to a temporary jobsite or storage facility;
 - (6) It implements any major change in the approved radiation safety program; and
 - (7) Any substantial change in any conditions of the license takes effect.
- (c) The corresponding license amendment fee prescribed in CPR Part 22 shall be paid upon filing of the application.

Section 10. Expiration of License.

- (a) Each license shall expire at the end of the day of the expiration date stated in the license. Pending any licensee action on the disposition of the license and the licensed radioactive source after the expiration date, the licensee shall keep all radioactive sources under safe and secure storage in accordance with the security plan/security measures.
- (b) If the licensee fails to file an application for the renewal of his license thirty (30) days after the expiration date, PNRI shall require the licensee to Show Cause why an Order to place the radioactive source(s) under temporary regulatory custody shall not be issued.
- (c) If the licensee fails to notify PNRI about the renewal of his expired license and the disposition of the licensed radioactive sources later than thirty (30) days from the expiration date, the PNRI shall order to place the radioactive material under temporary regulatory custody until the licensee resolves the issue.
- (d) If the license is deemed to have expired and will not be renewed, the licensee shall cease to engage in any licensed activity involving the radioactive source, except to keep the radioactive source under safe and secure storage until the disposition of the radioactive source is determined by PNRI.
- (e) The discontinued use of radioactive source(s) as a result of the expiration of the license shall not relieve the licensee of the responsibility to cause the decommissioning of the Industrial device and termination of the license.

Section 11. Renewal of License.

- (a) If the licensee decides to renew the license, the licensee must submit to PNRI an application for renewal of license in proper form, at least thirty (30) days before the expiration date of the license.
- (b) An application for renewal of license that is filed less than thirty (30) days before the stated expiration date of the license shall be subjected to a surcharge equivalent to twenty-five (25) percent of the required license renewal fee as required in CPR Part 22.
- (c) 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:

- (1) An explanation for the delay in filing the application;
- (2) An assurance that the licensee did not undertake any principal licensed activity involving the radioactive source after the expiration date of the license; and
- (3) An explanation why PNRI should not impose an administrative sanction against the licensee.
- (d) If PNRI determines that the licensee's reasons in (c) of this Section are acceptable and 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 source until PNRI has granted a license. Surcharge equivalent to fifty (50) percent of the license renewal fee shall be collected in addition to the prescribed renewal fee as required in CPR Part 22.
- (e) If an application for renewal of a license is filed more than thirty (30) days after the expiration date stated in the license, the PNRI shall cause the temporary cessation of activity until PNRI has determined whether or not the application shall be accepted and processed. Upon such order, the licensee shall not undertake any principal licensed activity.
- (f) In case a licensee submits an application for renewal of license within the allowed period but decides to terminate all authorized activities under the existing license without transferring his right to possess or own the radioactive source, a new license authorizing for the storage of the radioactive source shall be issued, which will be subject to specific conditions ensuring the safety and security of stored radioactive source.
- (g) Each application for renewal of license must include the payment of the corresponding prescribed license renewal fee and other outstanding regulatory fees.

Section 12. Termination of License.

- (a) The termination of a license may be initiated at any time at the request of the licensee.
- (b) Before the license can be terminated, the licensee shall implement decommissioning procedures according to its decommissioning plan and shall:
 - (1) Discontinue all activities involving licensed radioactive sources;
 - (2) Transfer or dispose of all licensed radioactive sources which are in the licensee's possession in accordance with the regulations;
 - (3) Assure that no contamination levels in excess of the limits for supervised areas exist in the facilities: and
 - (4) Assure that the required records are complete and up-to-date.
- (c) To be relieved of the responsibility for the radioactive sources(s) and the other conditions of the license, the licensee shall submit a letter to PNRI containing:
 - (1) A certified statement that the licensee no longer has in his possession any radioactive source that requires a license;
 - (2) A listing of the radioactive source transferred or disposed of and the person(s) to whom the source was transferred and the method of disposal for each item;
 - (3) A certified statement that the facilities are not contaminated; and
 - (4) A statement that the licensee agrees that records and facilities will be available for inspection by PNRI at a mutually agreeable date within three (3) months after termination of the license.

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

Section 13. Decommissioning.

- (a) Each licensee shall be responsible for the decommissioning of industrial device and submit to PNRI a decommissioning plan prior to the issuance of a license which must include the following:
 - (1) Purpose of decommissioning;
 - (2) Description of planned decommissioning activities;
 - (3) Description of methods to assure protection of workers and the environment against radiation hazards during decommissioning;
 - (4) Description of the radiation survey to be undertaken before, during and after the decommissioning activities;
 - (5) Assurance on the availability of adequate funds for completion of the decommissioning; and
 - (6) Program for disposition of the decommissioning waste and other radioactive waste (e.g. disused sources).
- (b) Licensee shall cause the decommissioning of the licensed industrial device if the licensee decides to discontinue any further use of radioactive sources in the facility.
- (c) Licensee shall submit to PNRI, upon completion of decommissioning, a report of the results of the radiation surveys undertaken.
- (d) Licensee shall demonstrate that the premises can be cleared for unrestricted use and occupancy after decommissioning.

Section 14. Additional Regulatory Requirements.

The 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.

Section 15. Application for Exemptions.

The 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.

II. GENERAL ADMINISTRATIVE REQUIREMENTS

Section 16. Radiation Safety Program.

- (a) Each licensee shall establish and implement a radiation safety program that includes provisions for keeping doses ALARA in accordance with Section 7 of CPR Part 3.
- (b) The program must include the following:
 - (1) A description of the organization and a notice to workers of the program's existence;

- (2) Definition of functions and responsibilities to help keep doses ALARA;
- (3) Radiation safety procedures and safety measures; and
- (4) Continuing education and training program for the RSO, ARSO and all authorized operators.
- (c) Each licensee shall review at least annually, the contents and implementation of its radiation safety program.

Section 17. Radiation Safety Officer (RSO) and Assistant RSO (ARSO).

- (a) The licensee shall designate a RSO and Assistant RSO, who shall both be qualified in accordance with Section 18 of this Part. The RSO shall be responsible for implementing the radiation safety program and shall ensure that radiation safety activities are being performed in accordance with licensee's approved procedures and regulatory requirements. The Assistant RSO shall perform the duties and responsibilities of the RSO in his/her absence.
- (b) The licensee shall establish the authority, duties, and responsibilities of the RSO, in writing.
- (c) The licensee shall provide the RSO sufficient authority, organizational freedom, time, resources and management prerogative to:
 - (1) Identify radiation safety problems;
 - (2) Initiate, recommend, or provide corrective actions;
 - (3) Stop unsafe practices;
 - (4) Verify implementation of corrective actions; and
 - (5) Coordinate the establishment, maintenance, drills/exercise of emergency plan and procedures.

Section 18. Training and Experience Requirements for RSO and ARSO.

The individual fulfilling the responsibilities of the RSO or ARSO shall have successfully completed:

- (a) Adequate training conducted by PNRI or an equivalent course approved by PNRI.
- (b) The manufacturer's training program on the use and operation of the nuclear gauge(s) described in the license application; and
- (c) Appropriate experience in the operation and safety in the use of industrial devices containing radioactive sources.

Section 19. Authorized Operator of the Industrial Device Containing Radioactive Source.

- (a) The authorized operator of the industrial device containing the radioactive source shall be under the supervision of a RSO in the implementation of the radiation safety program.
- (b) Before being permitted to use the radioactive source contained in an industrial device, the authorized operator shall have completed the following:
 - (1) Manufacturer's training program on the technical and safe operation of the industrial device; and
 - (2) Adequate training conducted by PNRI or its equivalent.

(c) Each licensee shall keep records of the training of each authorized operator and shall maintain the records for three (3) years from the date the training was completed.

Section 20. Retraining.

The licensee shall require the RSO, ARSO and authorized operators to undertake a refresher course on radiation safety, as appropriate and approved by PNRI, every three (3) years.

Section 21. Lease and/or Rental of Portable Gauge.

- (a) No licensee shall lease and/or rent portable gauge without the prior written approval of PNRI, in accordance with Section 9 (b)(1) of this Part.
- (b) Before leasing or renting radioactive source and portable nuclear gauge to a person licensed by the PNRI, the licensee/lessor shall verify that the lessee's license is valid and authorizes receipt of the type, form and quantity of radioactive source or portable gauge. The licensee/lessor shall ensure that an operable calibrated survey instrument is made available to the lessee.
- (c) The lessor shall indicate in the request for PNRI approval of the transfer or lease, the following information:
 - (1) Name, address and license number of lessee;
 - (2) Description of portable gauge, radioactive source, and instruments made available to lessee including serial numbers;
 - (3) Duration of rental or lease;
 - (4) Date when the lease agreement will be concluded; and
 - (5) Copy of lease agreement.
- (d) Within ten (10) days after the completion of each lease or rental of portable gauge, the licensee/lessor shall inform and submit a report to the PNRI.

III. TECHNICAL REQUIREMENTS

Section 22. Personnel Monitoring Devices.

- (a) Each licensee shall make available the use of personnel monitoring devices such as film badge, thermoluminescent dosimeter (TLD), or pen dosimeter, as may be required by PNRI.
- (b) For fixed gauges that are remotely located, personnel monitoring devices shall be worn only by personnel during repair and maintenance of the gauge or nearby equipment.
- (c) For portable gauges and fixed gauges located near operators, personnel monitoring devices shall always be worn by the authorized operator during use of the gauge.
- (d) Licensees who intend to maintain and service their own portable and fixed gauge shall require its personnel who will perform these procedures to use and wear personnel monitoring devices.

Section 23. Possession and Calibration of Survey Instruments.

- (a) The licensee shall possess an appropriate, calibrated and operable survey meter capable of detecting Beta, β and Gamma, γ radiation.
- (b) A licensee shall calibrate or cause the calibration of the survey instruments before its first use, annually, or following repair, and maintenance of the instruments or as may be determined by PNRI. Records of the results of each instrument calibration shall be maintained for three (3) years after the date of calibration.
- (c) If the licensee shall engage the services of another person or firm for the calibration of his/her instrument, the licensee shall verify from PNRI, prior to accepting the services, that the service provider is licensed by PNRI.

Section 24. Installation, Maintenance and Repair.

- (a) Only persons specifically authorized or licensed by the PNRI in accordance with CPR Part 25 "Licenses for Commercial Providers of Nuclear Technical Services" shall:
 - (1) Install, remove or relocate industrial device that contained radioactive source; or
 - (2) Maintain or repair industrial device that involves work on the source shielding or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.
- (b) Each licensee shall record all the necessary data on installation and maintenance carried out with the device.
- (c) Each licensee shall ensure that the radiation readings surrounding the equipment are within the levels indicated in the radiation profile illustrated in the user's manual provided by the manufacturer.

Section 25. Leak Testing of Radioactive Source.

- (a) A licensee in possession of a radioactive source contained in an industrial device shall test the source for leakage before its first use and annually thereafter, or as recommended by the manufacturer. If the licensee has a certificate from the supplier indicating that the source was leak tested within twelve (12) months before it was delivered to the licensee, the leak test before first use is not required.
- (b) If the licensee performs the entire leak-test procedure himself/herself, the licensee shall describe and submit the procedure for taking the test sample and the instrumentation that will be used for measurement for approval by PNRI.
- (c) If the licensee avails itself of or engages the services of a service provider licensed by PNRI for leak testing of sealed sources, the name, address and PNRI license number of the service provider shall be specified and submitted to PNRI.
- (d) If the licensee intends to use a commercial leak-test kit, the kit model number and the name, address, and license number of the kit supplier shall be specified.

Section 26. Transport of Radioactive Source Contained in an Industrial Device.

The licensee shall not transport or cause the transport of any radioactive source contained in an industrial device outside of the confines of his/her facility or other authorized location, or deliver or cause the delivery of any radioactive source contained in an industrial device to a carrier, unless the licensee is authorized by PNRI and complies with the requirements of CPR Part 4 and the rules and regulations of other government agencies that govern the means of transport.

Section 27. Operating and Emergency Procedures.

- (a) A licensee shall provide each personnel who is authorized to operate the device with written operating and emergency procedures.
- (b) The licensee's operating and emergency procedures shall address the following topics, where applicable:
 - (1) Use of personnel monitoring devices;
 - (2) Step-by-step procedures for the use of the industrial device;
 - (3) Storage of the portable gauge when not in use;
 - (4) Transport procedures of portable gauge to and from work sites; and
 - (5) Emergency procedures in case of device malfunction, fire, theft, or loss of radioactive materials, civil disturbances or transport accident.
- (c) A licensee shall post at convenient visible location in the licensed facility copies of operating and emergency procedures and local rules. Telephone numbers of RSO and other key personnel responsible for response in the event of an emergency shall be included.

Section 28. Portable Gauge at Temporary Jobsite.

- (a) Whenever a radioactive source contained in a portable gauge is used at a temporary jobsite, each personnel authorized to operate the device shall observe the operating and emergency procedures required in Section 27 of this Part.
- (b) Transport of the portable gauge and associated equipment to and from a temporary jobsite must be in accordance with approved transport procedure and the requirements of CPR Part 4 and must be secured in accordance with the requirements of CPR Part 26.
- (c) The licensee shall ensure that portable gauges containing radioactive sources are safely and securely stored at temporary jobsite.
- (d) When a vehicle is used for storage of the portable gauge, the necessary security measures must meet the specific requirements of CPR Part 26.

Section 29. Labels and Markings.

- (a) The licensee shall assure that all labels and markings affixed to the device at the time of receipt are firmly and permanently attached thereon and shall comply with all instructions and precautions provided by such labels. The durable and clearly visible label must provide sufficient information such as the radioactive source(s) contained in the portable gauge, activity, and the date for which the activity is estimated.
- (b) Labeling of transport containers for portable gauge.

- (1) Each licensee shall ensure that each container of portable gauge that contains a radioactive source bears a durable, clearly visible label bearing the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information such as the radioactive source(s) contained in the portable gauge, activity, and the date for which the activity is estimated.
- (2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers, remove or deface the radiation symbol and the radioactive source label.

Section 30. Posting.

All areas in which industrial devices are located shall be conspicuously posted with signs bearing the radiation symbols and the words: "CAUTION OR DANGER RADIATION AREA" and those which are high radiation areas shall be conspicuously posted with signs having the radiation caution symbol and words: "CAUTION or DANGER HIGH RADAITON AREA".

IV. SECURITY OF RADIOACTIVE SOURCES

Section 31. Security Program.

The licensee shall establish physical security measures for fixed and portable gauges in its possession in accordance with the requirements of CPR Part 26.

Section 32. Security Awareness Training.

The licensee shall require each person who is authorized to handle radioactive sources to have completed a security awareness training course in accordance with CPR Part 26.

V. WASTE MANAGEMENT AND DISPOSAL OF LICENSED RADIOACTIVE SOURCE

Section 33. General Requirements.

- (a) Each licensee shall dispose disused sources in accordance with a waste management program approved by PNRI.
- (b) Each licensee shall dispose its disused radioactive sources by either:
 - (1) Transfer to licensed end-user upon written consent by PNRI; or
 - (2) Return to the original supplier or manufacturer in accordance with a prior agreement with the supplier.

Section 34. Transfer of Licensed Radioactive Source.

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

- (b) No licensee shall transfer disused sources to another licensee unless:
 - (1) He has notified and has received authorization from PNRI about the transfer;
 - (2) He has submitted to PNRI appropriate information that includes;
 - (i) licensee's (transferee) name, address and license number; and
 - (ii) type, form and quantity of radioactive material to be transferred.

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

- (a) Each licensee shall keep current its special agreement for the return of disused sources to the original supplier or manufacturer of the source in the country of origin. A copy of such agreement including any updates shall be submitted to PNRI.
- (b) The disused radioactive sources shall be shipped in accordance with the packaging and shipping requirements specified in CPR Part 4.

VI. RECORDS, REPORTS AND NOTIFICATIONS

Section 36. Records of Radiation Safety Program.

- (a) Each licensee shall maintain records of the radiation 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 37. Records of Occupational Exposure.

- (a) The licensee shall maintain the exposure records for each worker for whom assessment of occupational exposure is required by this Part.
- (b) The exposure record shall include:
 - (1) information on the general nature of the work involving occupational exposure;
 - (2) doses, exposure and intakes that exceed the relevant recording level, and the data upon which the dose assessments have been based, including the doses, exposures, and intakes received if any, if the worker is occupationally exposed while in the employ of another; and
 - (3) records of any doses, exposures or intakes received as a result of emergency interventions or accidents, which shall include references to reports of any relevant investigations.
- (c) Records of personnel monitoring shall be kept and preserved for three (3) years or until PNRI authorizes their disposition.

Section 38. Records of Tests.

Each licensee shall maintain records showing the results of tests after maintenance and repair of industrial device in compliance with the requirements of this Part. The records must show the results and date of performance of the tests after the maintenance and repair, and the names of the individuals performing the tests. Each record shall be retained for three (3) years or until the radioactive source is properly transferred or disposed of.

Section 39. Records of Surveys.

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

Section 40. Records of Disposal/Transfer of Radioactive Sources.

Records of disposal/transfer of radioactive sources shall be retained for three (3) years or until the radioactive source is properly transferred or disposed of.

Section 41. Reports of Exposure of Persons Using Industrial Device.

- (a) When an individual terminates employment with a licensee, or an individual assigned to use the industrial device 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 thirty (30) days after the exposure of the individual has been determined by the licensee or ninety (90) days after the date of termination of employment or work assignment.
- (b) At the request of an 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 42. Utilization Logs for Portable Gauge.

- (a) Each licensee shall maintain current logs, showing for each portable gauge the following:
 - (1) a description (or make and model number) of the portable gauge or transport container:
 - (2) the identity of the authorized operator to whom assigned; and
 - (3) the facility or temporary jobsite where used and dates of use including date returned to storage after use.
- (b) The logs required by this Section shall be kept available for three (3) years from date of the recorded event, for inspection by PNRI at the address specified in the license.

Section 43. Report of Theft or Loss of Radioactive Source.

- (a) Each licensee shall immediately notify PNRI by telephone or by any other fast means of communication within twenty-four (24) hours, of any lost, stolen, or missing radioactive source.
- (b) In addition to this notification required in this Section, each licensee shall, within thirty (30) days after the occurrence of the incident, make a report in writing to PNRI that shall include the following information:
 - (1) Description of the radioactive source involved (i.e. isotope, quantity, chemical, and physical forms);
 - (2) Description of the circumstances under which the loss or theft occurred;
 - (3) A statement of disposition or probable disposition of the radioactive source involved:
 - (4) Any report filed with PNRI pursuant to this Section shall identify the individuals who may have been exposed to radiation or may be involved in the incident.
 - (5) Actions which have been, taken or will be taken, to recover the material; and
 - (6) Procedures/Measures to be adopted to prevent recurrence of the circumstances which led to the loss or theft of the sealed source.
- (c) Subsequent to filing the written report, the licensee shall also report immediately to PNRI any additional information, which becomes available to the licensee.

Section 44. Notification of Incidents.

- (a) Each licensee shall immediately notify PNRI within twenty-four (24) hours by telephone, or by any fast means of communication, of any incident involving the radioactive source contained in industrial device possessed by the licensee that may have caused or threatened to cause:
 - (1) Exposure of the whole body of any individual in excess of 0.05 Sv; or
 - (2) The release of radioactive source inside or outside of a controlled area, so that, if an individual is present in the area for twenty-four (24) hours, the individual could have received an intake in excess of one occupational annual limit on intake.
- (b) Each licensee shall immediately report to PNRI the occurrence of a failure of, or damage to, the encapsulation of the sealed source, upon the detection of 185 Bq or more of removable contamination. A written report, which shall be submitted not more than thirty (30) days from the occurrence of the incident, shall contain a brief description of the event and the disposition of the source.
- (c) The notification filed with PNRI pursuant to this Section shall specify the names of individuals who have received or may have received exposure to radiation and other persons involved in or present during the incident in a separate part of the report.
- (d) Each licensee shall immediately report to PNRI the occurrence of fire, labor strike, bankruptcy, floods, and other natural calamities, involving the radioactive source contained in the industrial device.

Section 45. Notification on Specific Changes in the License.

(a) Each licensee shall notify PNRI immediately by telephone or by similarly fast means of communication and by letter within thirty (30) days:

- (1) When the RSO, ARSO and any authorized personnel permanently discontinue 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 Metro Manila

Attention: Chief, Nuclear Regulations Division

VII. INSPECTION AND ENFORCEMENT

Section 46. Inspections.

- (a) Each licensee shall afford to PNRI at all reasonable times the right to inspect, announced or unannounced, the radioactive source(s) in his/her possession and the premises, device/equipment and facilities wherein that radioactive source 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 47. 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 48. 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 PNRI in accordance with the terms of the Act.
- (b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application, or for violation of, or failure by the licensee to observe, any of the terms and conditions of the license or any of the provisions of the Act, or any of the rule, regulation or order of 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.
- (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 49. Right to Cause the Withholding or Recall of Radioactive Source.

The PNRI may cause the right to 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.

VII. EFFECTIVITY

Section 50. Effective Date.

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

APPROVED:

(SGD) ALUMANDA M. DELA ROSA, Ph.D.

Director, PNRI

Date: August 12, 2011