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Republic of the Philippines
Department of Science and Technology
PHILIPPINE NUCLEAR RESEARCH INSTITUTE
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LICENSES FOR LARGE IRRADIATORS

CPR PART 15

I. GENERAL PROVISIONS

Section 1. Purpose and Scope.

(a) This Part prescribes:
  (1) requirements for the issuance of a **license** authorizing the use of radioactive sources in large irradiators used to irradiate objects or materials using gamma radiation;
  (2) **radiation safety** requirements in connection with the construction, installation, operation, and decommissioning of an irradiator; and
  (3) **security** requirements for the irradiator and the radioactive sources.

(b) This Part applies to **panoramic** irradiators that have either dry or wet storage of the radioactive sources and to **underwater** irradiators in which both the source and the product being irradiated are underwater.

(c) This Part covers irradiators whose dose rates exceed 5 grays per hour at one (1) meter from the radioactive sources in air or in water, as applicable for the irradiator type.

(d) The regulations in this Part do not apply to self-contained dry-source-storage irradiators (those in which both source and the **material** subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

(e) The requirements of **CPR Parts 3, 4, and 26** shall be in addition to the provisions of this Part, as may be applicable.

(f) Nothing in this Part relieves the licensee from complying with applicable requirements of other government authorities governing the siting, zoning, land use, and building requirements for industrial facilities.

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) **"Authorized personnel"** means those individuals authorized in the license to:
(1) Work with ionizing radiation;
(2) Operate and control access to the irradiator;
(3) Perform operational inspection and maintenance checks on the irradiator; and
(4) Perform periodic contamination detection tests on the irradiator;

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

(d) **"Construction"** includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of a warehouse or auxiliary structures, and other similar tasks;

(e) **"Containment"** means either:
(1) The confinement of radioactive material in such a way that it is prevented from being dispersed into the environment or is only released at a specified rate, or
(2) The device used to effect such confinement;

(f) **"Decommissioning"** means removing a facility or site safely from service and reducing residual radioactivity to a level that permits:
(1) Release of the property for unrestricted use and termination of the license; or
(2) Release of the property under restricted conditions and termination of the license.

(g) **"Doubly encapsulated radioactive source"** means a radioactive source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

(h) **"Facility Management"** refers to the individuals working in the irradiator who are responsible for the processes in the conduct and control of a radiation safety program.

(i) **"Fully shielded"** means the condition in which the source is stored so that the dose rate from leakage radiation measured at 30 cm. from the accessible surface of the radiation shield shall not exceed an average of 0.025 mSv/h. Radiation dose rates of up to 0.2 mSv/h averaged over any 100 square centimeter area are allowed, provided these contributions do not raise the average radiation dose rate to more than 0.025 mSv/h over a one meter square area parallel to the accessible surface of the radiation shield;

(j) **"Import"** means the physical transfer into the Philippines or to a recipient in an importing State, originating from an exporting State, of one or more radioactive source(s) covered by these Regulations;

(k) **"Inventory"** means a physical check of all sources possessed, by specifically and uniquely identifying each individual source using appropriate means such as serial numbers;

(l) **"Irradiator"** means a facility that uses radioactive sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays per hour exist at one meter from the radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the radioactive source and the area subject to irradiation are contained within a device and are not accessible to personnel;

(m) **"Irradiator operator"** means an individual who meets the qualification required in **Section 20(a)** and is authorized in the license to operate the irradiator;

(n) **"Large Irradiator"** means an irradiator designed for industrial and large-scale applications which contain more than 10,000 curies of radioactive material and which are not self-shielded;

(o) **"Non-routine operations"** means activities that are not performed on a regular basis, which may include the following:
(1) Source loading, unloading and repositioning
(2) Troubleshooting the control console
(3) Clearing stuck source racks
(4) Investigating/remediating removable contamination/leaking sources
(5) (Re)installing source cables
(6) Any other activity during which personnel could receive radiation doses exceeding PNRI limits;

(p) **"Panoramic dry-source-storage irradiator"** means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials;

(q) **"Panoramic irradiator"** means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators in which the source remains partially shielded during irradiations;

(r) **"Panoramic wet-source-storage irradiator"** means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored underwater in a storage pool;

(s) **"Permit to Construct"** means a document that permits the commencement of construction activities;

(t) **"PNRI"** means the Philippine Nuclear Research Institute and/or its duly authorized representatives;

(u) **"Pool irradiator"** means any irradiator at which the sources are stored or used in a pool of water, including panoramic wet-source-storage irradiators and underwater irradiators;

(v) **"Product"** means the object or material being irradiated;

(w) "**Product conveyor system**" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place;

(x) "**Qualified experts**" means those individuals who, by virtue of certification by appropriate boards, professional licenses or academic qualifications and experience, are duly authorized by PNRI to install, maintain, service and conduct acceptance testing of the irradiator;

(y) "**Radiation room**" means that region of the irradiator that is enclosed by radiation shields and is made inaccessible when the source is in use;

(z) **"Radioactive source"** means any 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 or power reactor;

(aa) **"Radiation Safety Officer (RSO)"** means an individual who is trained and qualified in accordance with **Section 20(b)** of this Part and identified as the RSO in a license issued pursuant to this Part;

(bb) **"Safety"** means measures intended to minimize the likelihood of accidents with radioactive sources and, should such an accident occur, to mitigate its consequences;

(cc) **"Security"** means measures to prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources;

(dd) **"Self-contained dry-source-storage irradiator"** means an irradiator in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel;

(ee) **"Underwater irradiator"** means an irradiator in which the sources always remain shielded underwater and humans could not access the radioactive sources and the space subject to irradiation without entering the pool; and

(ff) **"Vehicle"** means a conveyance used for land, sea, or air transport.

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 **PNRI** in writing, no interpretation of the meaning of the regulations 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, transfer, import, construct, or operate an irradiator, for the purpose of irradiating objects or materials using gamma radiation, except in accordance with a license issued by PNRI pursuant to this Part.

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

(a) The applicant shall file an application for a new license or renewal of license pursuant to this Part on **PNRI/NRLSD Form-015**, "Application for a License for Large Irradiators", in duplicate copies.

(b) Each license application must be duly affirmed and notarized and shall be signed by the applicant or an individual duly authorized to act for and on his behalf upon submission to PNRI.

(c) The applicant shall submit a certified true copy of the Securities and Exchange Commission (SEC) registration and current business permit issued by the responsible local government agency.

(d) PNRI, may, at any time after the filing of the application, require further information necessary to enable the PNRI to determine whether the application should be granted or denied.

(e) For license renewals, licensee shall provide a complete and up-to-date application, if many outdated documents are referenced or there have been significant changes in regulatory requirements, the licensee's organization, or radiation protection program.

(f) The application will be accepted and processed only when it is deemed by PNRI to be complete in substance and form and accompanied by proof of payment of the corresponding application fee or license renewal fee.

Section 7. Requirements Before Commencement of Construction.

The applicant shall secure from PNRI a **Permit to Construct** before starting the construction of a new irradiator. The applicant shall meet the following requirements:

(a) The applicant shall submit the organizational set-up and list of contractors; the site suitability information which includes purchase of a site, site surveys or soil testing, site preparation, and site excavation; irradiator design in accordance with **Section 32**; engineering and civil works drawings and specifications; construction plans and the schedule of activities for construction; and initial technical information relevant to the irradiator;

(b) The applicant shall define adequately the schedule of construction activities according to specified phases of construction;

(c) The applicant shall describe adequately the construction activities under each phase according to the approved schedule; and

(d) The applicant shall assure PNRI that the proposed construction activities will not pose any undue risk to the safety of the public based on the information and data available and submitted.

Section 8. Issuance of License.

A **License** for the use of radioactive sources in a large irradiator shall be issued if:

(a) The applicant has submitted to PNRI:

(1) A **report** which shows that all phases of construction activities have been performed and completed in accordance with the applicant's quality assurance program and the requirements of **Section 24** to **Section 32** were met;
(2) A **report** which gives assurance that the construction monitoring and acceptance testing described in **Section 33** were performed and the safety features of the irradiator are operable; and
(3) A safety assessment applied to the stages of design, construction, operation, maintenance and decommissioning of the irradiator;

(b) The radioactive sources that will be used for irradiation are ready and available for loading into the designated location in the irradiator;

(c) The radioactive sources meet the design and performance criteria in **Section 23**.

(d) The locations at which the radioactive sources will be used and stored are found acceptable by the PNRI;

(e) The applicant has described the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities;

(f) A qualified Radiation Safety Officer (RSO) and Assistant Radiation Safety Officer (ARSO), who have accepted their functions and responsibilities in writing, have been designated;

(g) The proposed irradiator operators, RSO, ARSO and authorized personnel meet the training and experience requirements in **Section 20**;

(h) An adequate **training program** for radiation safety officers, irradiator operators, and authorized personnel has been submitted to and approved by PNRI;

(i) The applicant has verified that the personnel who will load or unload the radioactive sources are trained and qualified and the procedures to be used are adequate. If the applicant intends to contract for source loading or unloading at its irradiator, the loading or unloading must be done by an organization specifically authorized by the PNRI to load or unload irradiator sources;

(j) The technical specifications and written operating procedures of the irradiator, including the relevant radiation safety aspects, are adequately established;
(k) The proposed **Quality Assurance program** for the operation phase is adequate to protect health and minimize danger to life or property;

(l) The applicant possesses appropriate personnel monitoring devices, personal protective equipment and radiation survey instruments;

(m) The applicant has provided a description of the access control systems required by **Section 24**, the radiation monitors required by **Section 27**, the method of detecting leaking sources required by **Section 39,** including the sensitivity of the method, and a diagram of the irradiator that shows the locations of all required interlocks and radiation monitors;

(n) The applicant has submitted procedures for leak testing of radioactive sources;

(o) The applicant has submitted its **inspection and maintenance program**, including the frequency of the operational checks required by **Section 40**;

(p) The applicant has submitted an **emergency plan** that shall provide reasonable assurance that adequate protection and protective measures can and shall be taken in the event of any emergency that could result in significant radiological consequences;

(q) The applicant has established and submitted to PNRI a **Security Plan** for Category 1, Security Group A radioactive sources in accordance with **Section 28 of CPR Part 26**, "Security of Radioactive Sources";

(r) The licensee has submitted a **Physical Protection Program**. The program shall identify the vital equipment, vital areas, and isolation zone and shall address tests, inspections, and other means to provide and ensure protection against potential sabotage and associated radiological consequences.

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

(t) The applicant has submitted a program for the management of disused radioactive sources and radioactive waste in accordance with **Section 46** of this Part;

(u) The applicant has provided the PNRI with a copy of the agreement for the return of disused radioactive sources to the original supplier or manufacturer;

(v) The applicant has submitted a proposed **initial decommissioning plan** for approval by PNRI;

(w) The applicant has submitted proof of financial security to fulfill the obligations for decommissioning and liability for damage to life or property arising from the operation of the irradiator; and

(x) The applicant has paid all applicable fees as determined by PNRI.

Section 9. Terms and Conditions of License.

(a) The license shall be valid for a period as may be determined by the PNRI, but not more than **5 years**.

(b) Each license shall be subject to the provisions of this Part, the specific conditions of the license, and applicable rules, regulations and orders of PNRI.

(c) No license issued or granted pursuant to the regulations in this Part nor any right granted under the license shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person unless PNRI, after securing full information:
   (1) finds that the transfer, assignment or disposition 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 disposition.

(d) The licensee shall confine the use and possession of the radioactive sources to the locations and purposes authorized in the license.

(e) The licensee shall monitor occupational exposures to radiation and shall supply and require the use of individual monitoring devices by personnel.

(f) The licensee shall cause each radioactive source to be tested for contamination and/or leakage pursuant to **Section 39** of this Part.

(g) The licensee shall conduct an annual physical inventory to account for all radioactive sources and devices received and possessed.

(h) The licensee shall ensure that all radioactive sources are properly stored and adequately secured in accordance with **CPR Part 26** to prevent unauthorized access, use, or diversion.

(i) The licensee shall have the right to import radioactive source specified in the license in accordance with this Part, except as otherwise provided.

(j) The licensee shall, at any time before the expiration of the license, upon the request of PNRI, submit written statements to enable the PNRI to determine whether the license should be modified, suspended, or revoked.

(k) The licensee shall keep and make available a copy of his license and applicable regulations of the Code at authorized locations indicated in the license.

(l) The licensee shall notify PNRI immediately in writing following the filing of a voluntary or involuntary petition for bankruptcy under existing Philippine laws.

(m) The licensee shall have its **final decommissioning plan** submitted to PNRI for approval not less than **12 months** before the start of decommissioning activities.

Section 10. Amendment of License.

(a) An application for amendment of a license shall be filed by completing PNRI/NRLSD **Form-015A**, "Application for Amendment of License", in duplicate copies, duly affirmed and notarized, and accompanied by the corresponding license amendment fee. The application 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 acquires and uses a radioactive source other than what is permitted in the license;
   (2) it permits anyone to work as RSO, ARSO, irradiator operator, or authorized personnel other than those permitted under the license;
   (3) it replaces the RSO, ARSO, irradiator operator, or authorized personnel;
   (4) it orders and receives radioactive sources in excess of the activity authorized in the license;
   (5) making any major change in the irradiator;
   (6) making any change in the radiation room shielding;
   (7) it implements any major change in the approved radiation safety program; or
   (8) any substantial change in any condition of the license takes effect.

Section 11. Specific Conditions for Expired License.

(a) Each license shall expire at the end of the day of the expiration date specified in the license unless the licensee has filed an application for renewal of the license in accordance with **Section 12** of this Part.

(b) At least **30 days** before the expiration date specified in the license, the licensee shall:
   (1) Submit an application for renewal of the license; or
   (2) Notify PNRI in writing and explain the reasons if the licensee decides not to renew the license.

(c) If the license has expired, the licensee shall not undertake licensed activities involving radioactive sources until the applicable provision of **Section 12** is satisfactorily met.

(d) The expiration of the license shall not relieve the licensee of its responsibility to cause the decommissioning of its irradiator in accordance with **Section 47** of this Part, if the license will be terminated.

Section 12. Renewal of License.

(a) If the licensee decides to renew the license, he must submit to PNRI an application for renewal of license at least **30 days** before the expiration date of the license.

(b) An application for renewal of license that is filed **less than 30 days** before the stated expiration date of the license shall be subjected to a surcharge equivalent to **25 percent** of the required license renewal fee.

(c) If the licensee submits an application for renewal of license after the specified expiration date, but **not exceeding 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 the 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. A surcharge equivalent to **50 percent** of the license renewal fee shall be collected.

(e) If an application for renewal of a license is filed **more than 30 days after the expiration date** stated in the license, PNRI shall cause the temporary cessation of any principal licensed activity until PNRI has determined whether or not the application shall be accepted and processed.

(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 sources.

(g) Each application for renewal of license must be accompanied by the corresponding license renewal fee and other outstanding regulatory fees.

Section 13. Termination of License.

(a) The licensee shall notify PNRI, in writing, and request for termination of the license when he decides to:
   (1) transfer the radioactive sources to another licensee; or
   (2) permanently cease all activities involving radioactive sources authorized under the license.

(b) Before the license can be terminated, the licensee shall:
   (1) Discontinue all activities involving licensed radioactive sources;
   (2) Transfer or dispose of all licensed radioactive sources which are in his possession, including accumulated waste, in accordance with the regulations;
   (3) Decontaminate or decommission the irradiator in accordance with **Section 47**;
   (4) Conduct a radiation survey or other means to confirm that the premises are suitable for unrestricted use; and
   (5) Assure that the required records are complete and up-to-date.

(c) To be relieved of the responsibilities for the radioactive sources and other conditions in his license, the licensee shall submit to PNRI:
   (1) His request that the license be terminated;
   (2) A certified statement that he no longer has in his possession any radioactive source requiring a license;
   (3) A listing of the radioactive sources transferred or disposed of and to whom the sources were transferred or the method of disposal;
   (4) The statement of a **Qualified Expert** that the irradiator is not contaminated; and
   (5) An agreement that his record and facility will be available for inspection by PNRI at a mutually agreeable date.

(d) PNRI will inform the licensee and formally terminate the license upon verification that the above requirements were satisfactorily complied with.

Section 14. Specific Exemptions.

PNRI may, upon application by the licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this Part as it determines are authorized by law and will not result in undue hazard to life, property and the environment.

Section 15. Additional Requirements.

PNRI may, by rule, order, or regulation impose upon any 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, property and the environment.

II. ADMINISTRATIVE REQUIREMENTS

Section 16. Radiation Safety Program.

(a) The applicant or licensee shall develop, document, and implement a radiation safety program containing the following elements:
   (1) Description of the organizational structure and individuals responsible for ensuring implementation of the radiation safety program;
   (2) Description of equipment and facilities adequate to protect personnel, the public and the environment;
   (3) Specific assignments and duties of RSO, irradiator operator, and authorized personnel;
   (4) A commitment by management to keep occupational doses as low as reasonably achievable (ALARA) and the measures to keep radiation exposures ALARA;
   (5) Procedures for the conduct of licensed activities by individuals qualified by training and experience;
   (6) Continued education and training for all personnel who work with or in the vicinity of radioactive sources;
   (7) Written operating procedures and emergency plan;
   (8) Security plan; and
   (9) Procedures on records management.

(b) The licensee shall review and assess the radiation safety program and its implementation at least **annually** together with the RSO. The purpose of the review is to ensure that reasonable effort is made to maintain individual and collective occupational doses ALARA.

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

(a) The licensee shall designate a qualified RSO and an ARSO, who shall have consented and accepted in writing, to be responsible for implementing the radiation safety program. The ARSO shall take the place of the RSO in his absence. The licensee shall provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. The licensee, through the RSO, shall ensure that radiation safety measures are being observed in accordance with regulatory requirements and approved procedures in the performance of the licensee's authorized activities.

(b) The Radiation Safety Officer's duties and responsibilities shall include the following:
   (1) Keeping exposures ALARA;
   (2) Developing, maintaining, distributing, and implementing up-to-date operating and emergency procedures;
   (3) Ensuring that individuals associated with irradiator operations are properly trained and evaluated;
   (4) Ensuring that non-routine operations for irradiators are consistent with the limitations in the license, the Radioactive Source and Device Registration Certificate, and the manufacturer's written recommendations and instructions;

(5) Analyzing potential safety consequences or non-routine operations before conducting any such activities that have not been previously analyzed;
(6) Ensuring non-routine operations are performed by the manufacturer or person specifically authorized by the PNRI to perform those operations;
(7) Ensuring that personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained by the licensee;
(8) Maintaining documentation that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or provide personnel monitoring devices;
(9) Notifying proper authorities of incidents such as damage to or malfunction of irradiators, fire, loss or theft of licensed materials;
(10) Investigating emergencies and abnormal events involving the irradiators (e.g., malfunctions or damage), identifying cause(s), implement appropriate and timely corrective action(s);
(11) Performing radiation safety program audits at least every **12 months** and developing, implementing, and documenting timely corrective actions;
(12) Ensuring the security of radioactive sources in accordance with CPR Part 26;
(13) Ensuring transport of licensed material in accordance with **Chapter V** of this Part;
(14) Ensuring proper disposal of licensed material;
(15) Maintaining appropriate records associated with irradiator operations;
(16) Maintaining an up-to-date license and timely submission of amendment and renewal requests; and
(17) Ensuring that when the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented.

Section 18. Statement of Authority, Duties and Responsibilities of the RSO.

(a) The licensee shall provide the RSO, where applicable, sufficient authority, organizational freedom, time, resources, and management prerogative to:
(1) Stop unsafe activities;
(2) Identify radiation safety and security problems;
(3) Initiate, recommend, or provide corrective actions; and
(4) Verify implementation of corrective actions.

(b) The licensee shall establish and state in writing the authority, duties, responsibilities, and radiation safety activities of the RSO.

Section 19. Quality Assurance.

The licensee shall establish and implement suitable quality assurance programs for the design, construction, operation, maintenance and decommissioning of the irradiator that provide, as appropriate:

(a) adequate assurance that the relevant provisions of this Part are complied with;

(b) adequate assurance that the safety and security requirements are being satisfied; and

(c) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of the safety and security measures.

Section 20. Training and Experience.

(a) **Irradiator Operator**

(1) The licensee shall ensure that the i**rradiator operator** has:

(i) a Bachelor of Science Degree in Engineering or Physical Science;

(ii) completed the Irradiator manufacturer's course for operators specific to the irradiator to be used;

or

received instructions on:

- Radiation physics and instrumentation;
- Radiation safety applied to irradiators;
- Radiation detection and measurements;
- The operation of the irradiator;
- Licensee operating and emergency procedures that the operator is responsible for performing;
- Case histories of accidents or problems involving irradiators; and
- The regulatory requirements;

(iii) passed a written test given by the manufacturer or a training provider authorized by PNRI, on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the operator is responsible for performing and other operations necessary to safely operate the irradiator; and

(iv) received on-the-job training or simulator training in the operation of the irradiator. The irradiator operator shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(2) The licensee shall conduct safety reviews and emergency drills for irradiator operators at least **annually**. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

(i) Changes in operating and emergency procedures since the last review, if any;

(ii) Changes in regulations and license conditions since the last review, if any;

(iii) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(iv) Relevant results of inspections of operator safety performance; and

(v) Relevant results of the facility's operational quality assurance program.

(3) The licensee shall evaluate the safety performance of each irradiator operator at least **annually** to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator, and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(b) The **Radiation Safety Officer** or **ARSO** shall be an individual who has:

(1) a Bachelor of Science Degree in Engineering or Physical Science;

(2) successfully completed a Radiation Safety Officer Course offered by PNRI or by a PNRI accredited training provider which shall cover at least **40 hours** training on the following topics:

- Radiation physics and instrumentation
- Radiation safety and security of radioactive sources
- Radiation detection and measurements
- Radiation biology
- Nuclear regulations and licensing
- Emergency planning and response

(3) a thorough knowledge of radiation safety at irradiators with respect to practical and operational matters and PNRI regulatory and licensing requirements applicable to the irradiator; and

(4) three (3) months of full time work experience at the applicant's irradiator or at another irradiator of a similar type, which may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed.

(c) **Authorized personnel** who have not received the training required for irradiator operators or RSO shall have received training on basic radiation safety and machine operation; instructed in precautions they should take to avoid radiation exposure; and trained and tested on how to respond to alarms. Such personnel shall be retested at least **once a year**.

Section 21. Retraining.

(a) The licensee shall establish and implement a refresher and retraining program approved by PNRI for its RSO, ARSO, irradiator operators, and authorized personnel.

(b) The licensee shall ensure that training will be reinforced regularly and updated when necessary. Annual review of staff training needs shall be undertaken. Arrangements shall be made to ensure that all new staff receive the required training and that the training needs of staff affected by any internal reorganization are reviewed and effected.

Section 22. Security Awareness Training.

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

III. DESIGN AND PERFORMANCE REQUIREMENTS

Section 23. Design and Performance Criteria for Radioactive Sources.

The licensee shall assure that radioactive sources meet the following requirements:

(a) Radioactive sources shall have a Sealed Source and Device Registration Certificate from its country of origin.

(b) Radioactive sources shall be doubly encapsulated and encapsulation shall be of a material resistant to general corrosion and to localized corrosion, if to be used in irradiator pools.

(c) Radioactive sources shall contain radioactive material that is as non-dispersible and as insoluble, as practical, if to be used in a wet-source-storage irradiator.

(d) A prototype of the radioactive source must be leak tested and found leak-free after each of the following tests:
   (1) *Temperature*. The test source must be held at -40^0C for 20 minutes, 600^0C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600^0C to 20^0C within 15 seconds.
   (2) *Pressure*. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.

(3) *Impact*. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

(4) *Vibration*. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity.

(5) *Puncture*. A 50-gram weight and pin, 0.3 cm pin diameter, must be dropped from a height of 1 meter onto the test source.

(6) *Bend*. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 Newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

Section 24. Access Control.

(a) Panoramic irradiators shall meet the following:

(1) Each entrance to a radiation room must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

(2) Each entrance to a radiation room must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(3) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in paragraph (b) of this section. The monitor may be located in the entrance (normally referred to as the maze), but not in the direct radiation beam.

(4) Before the sources move from their shielded position, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(5) Each radiation room must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

(6) Each radiation room must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been subsequently closed within a preset time.

(7) Each entrance to the radiation room and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators must also have a sign stating "**Very high radiation area**," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(8) If the radiation room has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(b) Underwater irradiators must have a personnel access barrier around the pool that can be locked to prevent access when the irradiator is not attended. Only **irradiator operators** and **facility management** may have access to keys to the personnel access barrier. There must be an **intrusion alarm** to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily on site) who is prepared to respond or summon assistance.

Section 25. Shielding.

(a) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator shall not exceed **0.02 mSv per hour** at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 0.02 mSv per hour shall be locked, roped off, or posted to prevent access.

(b) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator when the source is in the fully shielded position shall not exceed 0.02 mSv per hour.

(c) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded shall not exceed 0.02 mSv per hour and at 5 centimeters from the shield shall not exceed 0.2 mSv per hour.

Section 26. Fire Protection.

(a) The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting personnel who are prepared to summon assistance promptly. If a fire is detected, the sources must automatically become fully shielded and the product positioning and ventilation systems to shut down.

(b) The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

Section 27. Radiation Monitors.

(a) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that could be carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically before radiation from the source could cause any individual to receive a radiation dose exceeding **1 mSv**. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

(b) Underwater irradiators which are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

Section 28. Control of Source Movement.

(a) The mechanism that moves the sources of a panoramic irradiator must require a key to operate. Only one key may be in use at any time, and only operators or facility management may possess it. The lock must be designed so that the key may not be removed if the source is in an unshielded position. The door to the radiation room must require the same key.

(b) The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when they are exposed.

(c) The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

(d) Each control for a panoramic irradiator must be clearly labeled as to its function.

(e) Controls (source position lights and operating lights) for a panoramic irradiator must be color-coded or illuminated as follows:
   (1) Red represents emergency or critical information;
   (2) Yellow or orange represents caution, no emergency but some function taking place to be aware of; and
   (3) Green or blue represents normal or safe functioning or information.

Section 29. Irradiator Pools.

(a) Irradiator pools must either:
   (1) Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or
   (2) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

(b) Irradiator pools must have no outlets more than **0.5 meter** below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

(c) A means must be provided to replenish water losses from the pool.

(d) An audible and visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(e) Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a **conductivity** of **20 microsiemens per centimeter** or less and with a clarity so that the sources can be seen clearly.

(f) A physical barrier, such as a railing or cover, must be used around irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(g) If hollow poles, hollow long-handled tools, or tools with a density less than that of water are to be used in irradiator pools, they must have vent holes to allow water to enter them readily and fill voids to prevent radiation streaming or they must have sufficient

bends so that the radiation dose rate on the handling areas of the tools do not exceed 0.02 mSv per hour.

Section 30. Source Rack Protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack mechanism. A collision alarm system on the protective barrier must cause an alarm at the control console notifying the operator that a collision between the barrier and product conveyor has occurred.

Section 31. Power Failures.

(a) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position and the irradiator shut down.

(b) The lock on the door of the radiation room of a panoramic irradiator must not be deactivated by a power failure.

(c) During a power failure, the area of any irradiator where sources are located may be entered only using an operable and calibrated radiation survey meter.

Section 32. Design Requirements for Irradiators.

Irradiators must meet the design requirements of this section prior to the start of the construction of the specific component, but do not have to be met prior to submitting a license application.

(a) **Panoramic irradiators** shall meet the following design requirements:

(1) **Shielding**. The licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entrance ways to meet the radiation shielding requirements of **Section 25**. If the irradiator will use more than **2×10^{17} becquerels** of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(2) **Foundations**. The licensee shall design the foundation to ensure that it is adequate to support the weight of the facility considering soil characteristics.

(3) **Radiation monitors**. The licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by **Section 27(a).** The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor could cause a radiation overexposure to any person. For pool irradiators, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(4) **Access control**. The licensee shall verify from the design and logic diagram that the access control system will meet the requirements of **Section 24.**

(5) **Fire protection**. The licensee shall verify that the design and locations of the smoke and heat detectors and fire extinguishing system are appropriate to detect and extinguish fires. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(6) **Source return**. The licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

(7) **Seismic**. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake.

(8) **Wiring**. The licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

(b) **Pool irradiators** shall meet the following design requirements:

(1) **Pool Integrity**. The licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on radioactive sources, that it has no penetrations that do not meet the requirements of **Section 29(b),** and that metal components are metallurgically compatible with other components in the pool.

(2) **Water handling system.** The licensee shall verify that the design of the water purification system is adequate to meet the requirements of **Section 29(e).** The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(3) **Radiation monitors**. The licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by **Section 27(a).** The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor could cause a radiation overexposure to any individual. For pool irradiators, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(4) **Source rack**. The licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of radioactive sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

Section 33. Construction Monitoring and Acceptance Testing.

The requirements of this section must be met prior to loading radioactive sources:

(a) For panoramic irradiators:

(1) **Shielding**. The licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(2) **Foundations**. The licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(3) **Radiation monitors**. The licensee shall verify the proper operation of the monitor to detect sources carried on product conveyor system and the related alarms and interlocks required by **Section 27(a).**

(4) **Source rack**. The licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss-of-power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in **Section 30** are met for protection of the source racks and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

(5) **Access control**. The licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(6) **Fire protection**. The licensee shall verify the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall also verify the operability of the fire suppression or extinguishing system.

(7) **Source return**. The licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

(8) **Computer systems**. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

(9) **Wiring**. The licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

(b) For pool irradiators:

(1) **Pool integrity**. The licensee shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of **Section 29(b).**

(2) **Water handling system**. The licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(3) **Radiation monitors**. The licensee shall verify the proper operation of the radiation monitors and the related alarms and interlocks. For under-water

irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by **Section 27(b).**

(c) The licensee shall ensure that acceptance testing following installation of the irradiator to verify that it conforms to technical specifications certified by the manufacturer will be conducted by **Qualified Experts**.

IV. TECHNICAL REQUIREMENTS

Section 34. Operating Procedures.

(a) The licensee shall have and follow written operating procedures for:
- (1) Operation of the irradiator, including entering and leaving the radiation room;
- (2) Use of personnel dosimeters;
- (3) Surveying the shielding of panoramic irradiators;
- (4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
- (5) Leak testing of sources;
- (6) Operational inspection and maintenance checks required by **Section 40**;
- (7) Loading, unloading and repositioning sources, if the operations will be performed by the licensee; and
- (8) Inspection of movable shielding required by **Section 24 (a) (8),** if applicable.

(b) The licensee may revise operating procedures without PNRI approval only if all of the following conditions are met:
- (1) The revisions do not reduce the safety of the irradiator;
- (2) The revisions are consistent with the outline or summary of procedures submitted with the license application;
- (3) The revisions have been reviewed and approved by the Radiation Safety Officer; and
- (4) The operators are instructed and tested on the revised procedures before they are put into use.

Section 35. Personnel Monitoring.

(a) Irradiator operators, while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator, and authorized personnel who enter high radiation areas, shall wear either a film badge, direct reading dosimeter or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a direct reading dosimeter, which may be a pocket dosimeter. For groups of visitors, only two individuals are required to wear dosimeters.

(c) The licensee shall maintain records of exposures of all individuals required to wear personnel monitoring devices. Such records shall be made available to PNRI during inspections.

(d) In case of loss of the monitoring device, the licensee shall perform and document an evaluation of the dose the individual received and add it to the worker's dose record.

Section 36. Possession of Survey Instrument.

The licensee shall have in its possession a calibrated and operable radiation measurement survey instrument capable of measuring dose rates over the range **0.01 to 10 mSv per hour**.

Section 37. Calibration and Check of Survey Instruments.

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

(b) If the radiation dose rate exceeds 20% of calculated radiation dose rate, the survey instrument must be replaced or calibrated more frequently, or as the PNRI may require.

(c) Portable radiation survey meters must be of a type that do not saturate and read zero at high radiation dose rates.

(d) The licensee shall check each survey instrument for proper operation with a dedicated source at the start of each day of use.

(e) The licensee shall retain a record of each survey instrument calibration for two years.

Section 38. Radiation Surveys.

(a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed **three** (**3) years** and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(b) Water from the irradiator pool or other potentially contaminated liquids must be monitored for radioactive contamination before release to unrestricted areas. The radioactive release rate must not exceed those specified in **Appendix D-2 of CPR Part 3.**

(c) Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.0005 mSv per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.0005 mSv per hour.

(d) The radiation survey shall be conducted by an individual who is qualified by training and experience to measure ionizing radiation, to evaluate safety techniques, to advise on protection needs, and who has a good knowledge and understanding of

the operating characteristics, including the limitations, of the radiation detection instrumentation and measuring devices that are used in the survey.

Section 39. Detection of Leaking Sources.

(a) Each **dry-source-storage** radioactive source shall be tested for leakage at intervals not to exceed **6 months** using a leak test or method approved by the PNRI. The test must be capable of detecting the presence of **200 becquerels** of radioactive material and must be performed by a person authorized by the PNRI to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall remove the leaking source from service and have it decontaminated, repaired, or disposed of by a service provider authorized by the PNRI to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination.

Section 40. Inspection and Maintenance.

(a) The licensee shall establish and implement an adequate inspection and maintenance program that includes, as a minimum, each of the following at the frequency specified in the license or license application:
   (1) Operability of each aspect of the access control system;
   (2) Functioning of the source position indicator;
   (3) Operability of the radiation monitor for radioactive contamination in pool water using a radiation check source, if applicable;
   (4) Operability of the over-pool radiation monitor at underwater irradiators;
   (5) Operability of the product exit monitor;
   (6) Operability of the emergency source return control;
   (7) Leak-tightness of systems through which pool water circulates (visual inspection);
   (8) Operability of the heat and smoke detectors and extinguisher system (but without turning extinguishers on);
   (9) Operability of the means of pool water replenishment;
   (10) Operability of the indicators of high and low pool water levels required by **Section 29(d);**
   (11) Operability of the intrusion alarm, if applicable;
   (12) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources;
   (13) Condition of the barrier to prevent products from hitting the sources or source mechanism;
   (14) Amount of water added to the pool to determine if the pool is leaking;

(15) Electrical wiring on required safety systems for radiation damage; and conductivity measurements and analysis.

(b) Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay by **authorized personnel** or **authorized service provider**.

(c) The licensee shall maintain a record of the maintenance and repair performed on the irradiator for the duration that it is in use.

Section 41. Pool Water Purity.

(a) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below **20 microsiemens per centimeter** under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

Section 42. Attendance During Operation.

(a) Both an **irradiator operator** and an **authorized personnel** shall be present onsite:
(1) Whenever the irradiator is operated using an automatic product conveyor system; and
(2) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(b) At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received training on how to respond to alarms must be onsite.

(c) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training on how to avoid radiation exposure and respond to alarms. Static irradiations may be performed without a person present at the facility.

Section 43. Entering and Leaving the Radiation Room.

(a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:
(1) Visually inspect the entire radiation room to verify that no one else is in it; and

(2) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator shall not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool radiation monitor is operating with backup power.

Section 44. Irradiation of Explosive or Highly Flammable Materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the PNRI. Authorization will not be granted unless the licensee can demonstrate in the license application or application for amendment that detonation of the explosive material would not rupture the radioactive sources, injure personnel, damage safety systems, or cause radiation overexposure of personnel.

(b) Irradiation of more than traces of highly flammable material (flash point below 60^{o}C) is prohibited in panoramic irradiators unless the licensee has received prior authorization from the PNRI. Authorization will not be granted unless the licensee can demonstrate in the license application or application for amendment that a fire in the radiation room could be controlled without damage to radioactive sources or safety systems and without radiation overexposure of personnel.

Section 45. Security of Radioactive Sources.

(a) The licensee shall ensure that the radioactive sources are stored in a secure container within a secure storage area whenever the sources are not being used, serviced, transported or otherwise personally supervised and accompanied.

(b) The licensee shall establish **a Security Plan** in accordance with **Appendix V** of **CPR Part 26**.

(c) The licensee shall control and restrict access to controlled areas to authorized operators and authorized personnel.

(d) The licensee shall ensure that only trained individuals have authorized access to licensed radioactive source. Access can be controlled by providing keys, lock combinations and security badges only to authorized trained personnel.

(e) The licensee shall implement the following key control measures:
   (1) A record shall be kept of all individuals having access to, or possession of, keys concerned with the management of radioactive sources; and
   (2) Arrangements shall be made for:
      (i) Checking and custody of keys, particularly to minimize the possibility of duplication;
      (ii) Changing of combination settings at suitable intervals; and
      (iii) Changing of locks, keys or combination whenever there is evidence or suspicion that they have been compromised or when staff that has held access no longer needs access.

(f) The licensee shall conduct background checks to ensure that persons engaged in the management of sources are trustworthy and reliable.

(g) The licensee shall establish measures to prevent theft, loss, unauthorized withdrawal, damage to or tampering with sources and equipment.

(h) The irradiator room shall be subject to continuous detection of unauthorized intrusion attempt, either by personal surveillance or a remotely monitored intruder alarm. Every unauthorized access to the source shall be detected in a timely manner.

(i) The licensee shall perform **physical inventory** of radioactive sources on an **annual** basis.

(j) The licensee shall ensure the confidentiality of information, the unauthorized disclosure of which could compromise the security measures.

(k) The licensee shall have pre-arranged procedures with law enforcers regarding intelligence information and use of secure communications as well as the reactions to an increased threat.

(l) The licensee shall prepare and appropriately exercise emergency plans to respond to the loss of authorized control of radioactive sources.

(m) The licensee shall maintain records and control receipt, use, storage, transfer, transport and disposal of radioactive sources.

Section 46. Management of Disused Radioactive Sources and Radioactive Wastes.

(a) The licensee shall return the disused radioactive sources to the original supplier or manufacturer in accordance with **Appendix A, "Requirements on the Import and Export of Radioactive Sources",** of this Part.

(c) Radioactive wastes shall be disposed of in accordance with the requirements of **Chapter VI of CPR Part 3**.

Section 47. Decommissioning.

(a) The licensee shall submit to the PNRI for approval, not less than **twelve months** before the start of decommissioning activities, a **final decommissioning plan** which must include:
   (1) A description of planned decommissioning activities;
   (2) A description of methods to ensure protection of workers and the environment against radiation hazards during decommissioning;
   (3) A description of the planned final radiation survey;
   (4) An assurance on the availability of adequate funds for completion of decommissioning; and
   (5) A program for the disposition of the radioactive waste after decommissioning.

(b) The licensee shall submit to PNRI, upon completion of decommissioning, a report of the results of the radiation survey performed.

(c) The licensee shall demonstrate that the premises are suitable for unrestricted use and occupancy after decommissioning.

V. TRANSPORT OF RADIOACTIVE SOURCES

The licensee shall comply with the requirements of **CPR Part 4** for the safe transport of radioactive sources and with any existing national legislation for all activities involving transport of radioactive sources.

Section 48. Import and Export of Radioactive Sources.

The licensee shall ensure that the import and export of radioactive sources are in accordance with **Appendix A** of this Part.

Section 49. Receipt of Radioactive Source.

(a) The licensee shall have a detailed exchange of information with the source supplier prior to each shipment of radioactive source to be dispatched to the licensee. For each package, this information shall include:
   (1) The nuclide, number and activity of sources;
   (2) A description of the source construction and performance tests, including leakage tests;
   (3) Special form approval certificate;
   (4) A description of the container;
   (5) Approval certificate for Type B container or statement of compliance with CPR Part 4 for other containers;
   (6) Details of any special arrangements required, including multilateral approvals, where necessary; and
   (7) A copy of the transport documents, to be sent to the licensee by fax or e-mail before dispatch.

(b) The licensee shall have an agreement with the supplier on the transport route and responsibility for each stage of the journey.

(c) Arrangements shall be made, where necessary, for:
   (1) Special handling equipment during transfer from one mode of transport to another, or between vehicles;
   (2) Checking radiation dose rates from the package or container;
   (3) Checking that correct transport labels are attached to the package or container;
   (4) Ensuring that the package or container is securely attached to the vehicle and that the vehicle is correctly labeled; and
   (5) Dealing with border controls; and security of the consignment during transport, particularly during delays or overnight stops.

Section 50. Loading and Unloading of Sources.

(a) The licensee shall make an evaluation of source loading and unloading procedures to ensure that the exposure of individuals is kept as low as reasonably achievable.

(b) The licensee shall make an assessment of any safety hazards associated with the loading and unloading work.

Section 51. Security of Sources in Transport.

(a) The licensee shall establish a **Source Transport Security Plan** which must include:
   (1) A description of the isotope, activity including date of measurement, and radiation level of the radioactive sources;
   (2) A description of the conveyance;
   (3) A description of how the personnel background checks required by this Part are going to be conducted;
   (4) A detailed description of the proposed technical and administrative security measures;
   (5) Communication arrangements made among the consignor, operator of the vehicle transporting the radioactive source, and the recipient of the radioactive source;
   (6) Planned route, if in a single transport; and
   (7) Any other requirement that may have a bearing on security including provisions of CPR Part 26, as applicable.

(b) The licensee shall conduct background checks, verify, and document that the carrier:
   (1) Use package tracking systems;
   (2) Implement methods to assure trustworthiness and reliability of transport personnel;
   (3) Maintain constant control and/or surveillance during transit; and
   (4) Have the capability for immediate communication to summon appropriate response or assistance.

(c) The licensee shall ensure that each radioactive source is stored at all times during transport in a secure container that is locked and sealed and transported in an enclosed and secured vehicle.

(d) The licensee shall ensure timely detection of unauthorized access to the source through:
   (1) A security device equipped in the transport vehicle which will be activated to prevent theft; and
   (2) An audible and visible alarm that will sound upon detection of unauthorized entry or attack to the vehicle.

(e) The licensee shall ensure response to a security threat through:
   (1) Radio communication between the personnel in the conveyance and a security office or organization;
   (2) Security-trained transport operatives; and
   (3) Additional guards or a response force, as appropriate, depending on the threat assessment.

(f) The licensee shall ensure that before undertaking the transport of radioactive sources, carriers are fully aware of the procedures to be followed in the event of an accident.

VI. EMERGENCY PLANNING, PREPAREDNESS AND RESPONSE

Section 52. Safety Assessment.

(a) The licensee shall prepare a safety assessment applied to the stages of design, construction, operation, maintenance and decommissioning of the irradiator.

(b) The licensee shall incorporate:
  (1) defense-in-depth measures to cope with identified events, and evaluate the reliability of the safety systems (including administrative and operational procedures, and equipment and facility design); and
  (2) the operational experience and lessons learned from accidents and errors in the training, maintenance and quality assurance programs.

(c) The safety assessment shall be documented and revised by an independent expert when:
  (1) modification of a radiation source or its facility is made;
  (2) operational experience or information on accidents or errors indicates that the safety assessment should be reviewed; and
  (3) techniques are modified in such a way that safety may be compromised.

Section 53. Emergency Planning, Preparedness and Response.

(a) The licensee shall make an assessment of the consequences of any reasonably foreseeable accident, occurrence or incident and shall draw up an emergency plan to restrict, so far as is reasonably achievable, any resulting exposures.

(b) The emergency plan shall be specific to each situation and should include, as appropriate:
  (1) Identification of the reasonably foreseeable accidents, incidents or occurrences and their predicted consequences;
  (2) Communication procedures, including an emergency call-out list;
  (3) Recommended actions for specified situations; including the identification of persons able to implement and take responsibility for stated parts of the plan, and positive identification of situations requiring evacuation together with the procedures for implementation;
  (4) A statement regarding immediate life-saving actions;
  (5) Statutory responsibilities and the names of persons able to take actions to satisfy them;
  (6) Availability of emergency equipment, including a list of equipment that should be available, and its location;
  (7) Availability of first aid equipment, including a list of equipment that should be available, and its location, and the names of persons trained to use it; and
  (8) Where appropriate, an outline of the post-emergency procedures designed to restore normal operating conditions.

(c) The licensee shall establish emergency procedures which should be posted visibly in places where their need is anticipated.

(d) The licensee shall follow emergency or abnormal event procedures, appropriate for the irradiator type, for:
  (1) Sources stuck in the unshielded position;
  (2) Personnel overexposure;
  (3) A radiation alarm from the product exit portal monitor or pool monitor;
  (4) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
  (5) A low or high water indicator level, an abnormal water loss, or leakage from the source storage pool;
  (6) A prolonged loss of electrical power;
  (7) A fire alarm or explosion in the radiation room;

(8) An alarm indicating unauthorized entry into radiation room, area around pool, or another alarmed area;
(9) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
(10) The jamming of automatic conveyor systems, product totes or carriers.

(e) Emergency procedures shall be described in concise, easily followed instructions. They shall identify situations requiring emergency action, specify the immediate action to be taken to minimize radiation exposure to persons in the vicinity of the irradiator, and foresee the development of a written contingency plan for effecting entry to the radiation room.

(f) The licensee shall inform staff of any contingency plan that might affect their area of work, and their role if the plan has to be implemented, and shall arrange for staff training and emergency drills appropriate to each situation.

(g) The licensee shall review the contingency plan at intervals not more than 12 months, following relevant operational changes and after an accident in similar facilities and with similar sources.

(h) The licensee shall make arrangements to:
(1) Ensure the safety of the persons in the site in the event of a radiological emergency; and
(2) Provide useful, timely, truthful, consistent and appropriate information to the public.

(i) The licensee shall ensure at all times the availability of means of communication necessary for protective actions to be taken within the irradiator and to off-site responders.

(j) The licensee shall provide emergency response procedures in case of false and true alarms and highlight responsibilities of security guards and other responders.

(k) Liaison shall be maintained with relevant off-site services or agencies, such as the ambulance, fire, police, hospital services, local and national authorities, as appropriate to each accident situation. The licensee shall initiate the emergency procedures, and coordinate the initial response of the emergency services and other bodies, and inform the PNRI and all relevant parties.

(l) The licensee shall provide emergency and first aid equipment which shall be inventoried regularly and tested for good working order at appropriate intervals.

(m) Drills and practical exercises shall be conducted to test the effectiveness of an emergency response plan and to ensure that all persons concerned know what action to take in an emergency.

VII. RECORDS, REPORTS AND NOTIFICATIONS

Section 54. Records and Retention Periods.

The licensee shall maintain the following records for the periods specified:

(a) A copy of the license application and the license authorizing the licensee to operate the irradiator until a new license is issued.

(b) Name of the individual authorized and responsible for the radiation safety program until 5 years after the individual terminates work.

(c) Records of an individual's training, tests, and safety reviews provided to meet the requirements of **Section 20** until 5 years after the individual terminates work.

(d) Records of the annual evaluations of the safety performance of irradiator operators for 5 years after the evaluation.

(e) An up-to-date copy of the operating and emergency procedures and records of changes in procedures retained for 5 years from the date of the change.

(f) Film badge, pocket dosimeter or TLD results until the PNRI terminates the license.

(g) Records of radiation surveys for 5 years from the date of survey.

(h) Records of radiation survey meter calibrations and pool water conductivity meter calibrations until 5 years from the date of calibration.

(i) Records of the results of leak tests and the results of contamination checks for 5 years from the date of each test.

(j) Inventory of radioactive sources for 5 years.

(k) Records on the design checks and the construction control checks until the license is terminated.

(l) Records of inspection and maintenance checks for 5 years.

(m) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve radiation safety equipment for 5 years after repairs are completed.

(n) Records of incident and investigation reports until PNRI terminates the license.

(o) Records of training provided (initial and refresher) until PNRI terminates the license.

(p) Transportation:
  (1) Package documentation;
  (2) Package surveys;
  (3) Transfer/receipt documents; and
  (4) Details of shipment dispatched until 5 years after the transport.

(q) Records of the receipt and transfer of all licensed radioactive sources until 5 years after transfer or disposal.

(r) Records of disposal of all licensed radioactive sources until PNRI terminates the license

(s) Records related to decommissioning of the irradiator until the site is released for unrestricted use.

Section 55. Incident Notification and Reporting.

(a) The licensee shall notify the PNRI within **24 hours**, by telephone or by any similarly fast means of communication, of the following:
   (1) The theft or loss of radioactive source; and
   (2) Events involving radioactive source possessed by the licensee that may have caused or threaten to cause radiation overexposure, excessive concentrations or levels of radiation, loss of one day or more of operation of the irradiator, or property damage.

(b) The licensee shall report leaking radioactive sources, damaged radioactive sources, and pool water contamination in excess of the concentrations listed in **Appendix D-2 of CPR Part 3**. The report must describe the radioactive source involved if known, the extent of the leakage or contamination, the cause or circumstances leading to the leak or contamination to the extent that they are known, and corrective actions taken up to the time the report is made.

(c) The licensee shall submit a written report to the PNRI within **30 days** from the occurrence of the following events if not reported under paragraphs (a) or (b) of this section:
   (1) Sources stuck in an unshielded position;
   (2) Fire or explosion in a radiation room;
   (3) Damage to source racks;
   (4) Failure of the cable or drive mechanism used to move the source racks;
   (5) Inoperability of the access control system;
   (6) Detection of radiation by the product exit portal monitor;
   (7) Abnormal or unusual radioactive contamination;
   (8) Structural damage to the pool liner or walls; and
   (9) Abnormal water loss or leakage from the source storage pool.

(d) The reports filed with PNRI shall specify the names of individuals who have received exposure to radiation and other persons involved in the incident.

Section 56. Reports of Exposure of Individuals Who Have Worked in an Irradiator.

When an individual terminates employment with a licensee, or an individual assigned to work in an irradiator 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 irradiator. Such report shall be furnished within 30 days after the exposure of the individual has been determined by the licensee or 90 days after the date of termination of employment or work assignment.

Section 57. Notification on Specific Changes in the License.

The licensee shall notify the PNRI immediately by telephone or by any similarly fast means of communication and by letter within 30 days:

(a) When the Radiation Safety Officer permanently discontinues performance of duties under the license; or

(b) When the licensee's name or mailing address changes.

VIII. INSPECTION AND ENFORCEMENT

Section 58. Inspection.

(a) Each licensee shall afford to PNRI inspectors the opportunity to inspect, at all reasonable times, the radioactive sources in his possession, activities, and the premises, equipment and facilities wherein 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 59. Violations.

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

(b) Any license may be modified, suspended, or revoked, after due process, for any willful violation that PNRI determines to adversely affect the health, interest or 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, as amended.

Section 60. Modification, Suspension 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 PNRI in accordance with the terms of the Act.

(b) Any license may be modified, suspended, or revoked, 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 rule, regulation or order of the 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 may be modified, as determined by PNRI or upon the request of the licensee, when:

(1) The licensee decides to discontinue any specific activity authorized in the license;
(2) The licensee decides to undertake an activity in addition to or other than what is specified in the license;
(3) PNRI determines that the licensee can no longer perform the licensed activity;

(4) The licensee has changed the address or location of the facility formerly authorized in his license; or

(5) The licensee has ceased to perform a licensed activity during a two (2) year period.

IX. EFFECTIVITY

Section 61. Effective Date.

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

Approved:

ALUMANDA M. DELA ROSA, Ph.D.

July 28, 2008
Date

APPENDIX A

REQUIREMENTS ON THE IMPORT AND EXPORT OF RADIOACTIVE SOURCES

These requirements on the import and export of **Categories 1 and 2** radioactive sources are in conformance with the import and export provisions in Parts 4 and 26 of the Code of PNRI Regulations (CPR), the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and the IAEA Guidance Document on the Import and Export of Radioactive Sources. These requirements do not apply to radioactive sources within military or defense programs.

I. Import of Radioactive Sources.

(a) Licensees intending to import radioactive sources in Categories 1 and 2 of **Table 1** shall apply to PNRI for an authorization and must receive such authorization prior to import.

(b) The application shall include the following information:
- (1) name of the exporter and photocopy of exporter's valid license issued by the competent authority of the exporting country;
- (2) exporter location and legal address or principal place of business;
- (3) radionuclide data, activity, and uses of the radioactive source(s);
- (4) name of licensed local distributor and photocopy of distributor's valid license issued by PNRI; and
- (5) the provisions for return or disposal of the radioactive source once it becomes disused, including copies of any contracts with distributor and exporter to re-export for return and proper management of the source.

(c) Licensees shall ensure that the exporter of the radioactive sources is authorized by the Competent Authority of the exporting country to export such sources to the Philippines in accordance with laws and regulations of that country.

(d) Licensees shall provide the Competent Authority of the exporting country with the following information in writing:
- (1) name of the recipient;
- (2) recipient location and legal address or principal place of business;
- (3) radionuclide data, activity and reference date;
- (4) intended purpose and proposed use(s) of the radioactive source; and
- (5) a suggested timeframe for a decision on the request to import.

(e) A licensee who is only authorized by PNRI to import, sell or distribute radioactive sources shall import these sources only if the recipient or consignee in the Philippines has a valid PNRI license to receive the source and is capable to manage the source consistent with **Section 11 of CPR Part 26.**

(f) Licensees shall ensure that the Exporting Country allows the re-entry of spent or disused sources if, in the framework of that Country's national laws, it has approved that spent or disused sources be returned to a manufacturer authorized to manage the spent or disused sources.

(g) Licensees shall secure from the PNRI:

(1) A **request for release** which is submitted to the Bureau of Customs Officer to allow the release of the radioactive source shipment from the customs cargo hold area; and
(2) An **Authority to Transport** Certificate wherein PNRI gives approval to transport the radioactive source shipment to the recipient location.

(h) Licensees shall ensure that the import of radioactive sources is in accordance with CPR Part 4, "Regulations for the Safe Transport of Radioactive Materials in the Philippines".

II. Export of Radioactive Sources.

(a) Licensees intending to export radioactive sources in Categories 1 and 2, particularly **disused or spent sources**, shall apply to PNRI for an authorization and must receive such authorization prior to exportation.

(b) The application for export shall include:
(1) copies of agreements or contracts to re-import the source once it becomes disused;
(2) confirmation letter from the Competent Authority of the importing country that the recipient is authorized to receive and possess the radioactive source or sources to be exported in accordance with its laws and regulations; and
(3) a copy of the recipient's valid authorization issued by the Competent Authority of the importing country.

(c) Licensees involved in the export of radioactive sources in Categories 1 and 2 of Table 1 shall ensure that the importing country has the appropriate technical and administrative capability, resources and regulatory infrastructure needed for the management of the radioactive sources.

(d) Licensees shall take into consideration the risk of diversion or malicious acts involving radioactive sources by verification of the following information:
(1) whether the recipient has been engaged in illegal procurement of radioactive materials;
(2) whether an import or export authorization for radioactive sources has been denied to the recipient or importing country; or
(3) whether the recipient or importing country has diverted, for purposes inconsistent with the Code of PNRI Regulations, any import or export of radioactive sources previously authorized.

(e) Licensees intending to export Category 1 and 2 sources shall notify the Competent Authority of the importing country, and should receive confirmation of such notification at least 7 days in advance of each shipment.

(f) Licensees shall notify the Competent Authority of the importing country with the following information in advance, as applicable:
(1) estimated date of export,
(2) name and address of the exporting facility,
(3) name and address of the recipient,
(4) radionuclide, activity, and reference date,
(5) aggregate activity level, and
(6) number of radioactive sources and their unique identifiers (e.g., physical and chemical form).

(g) Licensees shall provide PNRI with a copy of the above notification and secure from PNRI a written authorization to transport the radioactive source(s).

(h) Licensees shall show proof to PNRI that the exported radioactive sources have been received by the authorized recipient.

III. Transfer of Radioactive Sources.

Licensees involved in the import and export of radioactive sources shall ensure that transfers are undertaken with a valid written authorization from PNRI.

IV. Transport of Radioactive Sources.

(a) Licensees involved in the import or export of radioactive sources shall ensure that the transport of radioactive sources, either domestically or internationally, is in compliance with the requirements of **CPR Part 4**, "Regulations for the Safe Transport of Radioactive Materials in the Philippines ", and all applicable national and international governmental regulations.

(b) Licensees shall ensure that the import or export of radioactive sources is conducted in a manner consistent with existing relevant international standards relating to the transport of radioactive materials.

(c) Licensees shall ensure that the transport of radioactive sources through the territory of a transit or transshipment country is conducted in a manner consistent with existing relevant international standards relating to the transport of radioactive materials, in particular paying careful attention to maintaining continuity of control during international transport.

(d) If the conditions in **II(c)** with respect to a particular export cannot be satisfied, that export may be authorized by PNRI in exceptional circumstances if an alternative arrangement has been made to ensure the source will be managed in a safe and secure manner.

TABLE I. ACTIVITIES CORRESPONDING TO THRESHOLDS OF CATEGORIES***

Radionuclide	Category 1* 1000 x D		Category 2** 10 x D	
	(TBq)	(Ci)	(TBq)	(Ci)
Am-241	6.0E+01	2.0E+03	6.0E-01	2.0E+01
Am-241/Be	6.0E+01	2.0E+03	6.0E-01	2.0E+01
Cf-252	2.0E+01	5.0E+02	2.0E-01	5.0E-00
Cm-244	5.0E+01	1.0E+03	5.0E-01	1.0E+01
Co-60	3.0E+01	8.0E+02	3.0E-01	8.0E+00
Cs-137	1.0E+02	3.0E+03	1.0E+00	3.0E+01
Gd-153	1.0E+03	3.0E+04	1.0E+01	3.0E+02
Ir-192	8.0E+01	2.0E+03	8.0E-01	2.0E+01
Pm-147	4.0E+04	1.0E+06	4.0E+02	1.0E+04
Pu-238	6.0E+01	2.0E+03	6.0E-01	2.0E+01
Pu-239b/Be	6.0E+01	2.0E+03	6.0E-01	2.0E+01
Ra-226	4.0E+01	1.0E+03	4.0E-01	1.0E+01
Se-75	2.0E+02	5.0E+03	2.0E+00	5.0E+01
Sr-90 (Y-90)	1.0E+03	3.0E+04	1.0E+01	3.0E+02
Tm-170	2.0E+04	5.0E+05	2.0E+02	5.0E+03
Yb-169	3.0E+02	8.0E+03	3.0E+00	8.0E+01

***** "**Category 1 sources**", if not safely managed or securely protected, would be likely to cause permanent injury to a person who handled them, or were otherwise in contact with them, for more than a few minutes. It would probably be fatal to be close to this amount of unshielded radioactive material for a period of a few minutes to an hour. These sources are typically used in practices such as **Co-60 irradiators** and **teletherapy**.

****** "**Category 2 sources**, if not safely managed or securely protected, could cause permanent injury to a person who handled them, or were otherwise in contact with them, for a short time (minutes to hours). It could possibly be fatal to be close to this amount of unshielded radioactive material for a period of hours to days. These sources are typically used in practices such as **industrial gamma radiography**, **high dose rate brachytherapy** and **medium dose rate brachytherapy**.

***** Categorization** is provided by activity levels for radionuclides that are commonly used. These are based on D-values which define a dangerous source i.e., a source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. A more complete listing of radionuclides and associated activity levels corresponding to each category, and a fuller explanation of the derivation of the D-values, may be found in **Appendix I of CPR Part 26**.