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CPR PART 14

LICENSES FOR MEDICAL USE OF RADIOACTIVE SOURCES IN BRACHYTHERAPY

I. GENERAL PROVISIONS

Section 1. Purpose and Scope.

(a) This Part prescribes requirements and provisions for the medical use of sealed radioactive sources in brachytherapy and for the issuance of specific licenses authorizing the medical use of these sources.

(b) This Part also provides requirements for the safety and security of brachytherapy sources.

(c) The requirements and provisions in this Part provide for the protection of health and safety of the public, patients, and workers and are in addition to other requirements in the Code of PNRI Regulations (CPR).

(d) The provisions and requirements of this Part shall be applied in conjunction with the radiation safety requirements of CPR Part 3, radioactive source security requirements of CPR Part 26, and the safe transport requirements of CPR Part 4.

(e) This Part does not relieve the licensee from complying with the applicable requirements of other responsible agencies of government.

Section 2. Definitions.

As used in this Part:

(a) **"Accident"** means any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety;

(b) **"Act"** means Republic Act 2067, otherwise known as the Science Act of 1958, as amended by Administrative Order No. 3589, and Republic Act 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended by P.D. No. 1484;

(c) **"Afterloading"** refers to the process of implanting inactive hollow applicators into the patient in the operating theatre and then loading the source into the applicator after the patient has come out of recovery and has been relocated to the ward. In this technique, no sources are handled in theatre and the sources are typically in place for the whole time of the treatment;

(d) **"ALARA"** (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practicable:
   (1) Consistent with the purpose for which the licensed activity is undertaken, and
   (2) Taking into account the state of technology, the economics of improvements in relation to benefits to the health and safety of the public and other societal and socio-economic considerations;

(e) **"Authorized User"** means a physician who is trained and qualified and is identified as an authorized user in a PNRI license issued pursuant to this Part;

(f) **"Brachytherapy"** means the method of radiation therapy in which an encapsulated source is used to deliver a radiation dose at a very close distance to a target, either by intracavitary, interstitial, intraoperative, surface or mould applications;

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

(h) **"Dedicated check source"** means a radioactive source that is used to check survey instruments or devices for proper operation;

(i) **"Disposal"** means the emplacement of radioactive source in an appropriate facility without the intention of retrieval;

(j) **"Disused radioactive source"** means a radioactive source which is no longer used, and is not intended to be used for the practice authorized by the license;

(k) **"High dose-rate remote afterloader***"* means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed;

(l) **"Incident"** means an event beyond the authorized operating regime but not involving any significant failure in safety provisions or overexposure of workers;

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

(n) **"Low dose-rate remote afterloader"** means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed;

(o) **"Management"** refers to the individual or group of individuals who are responsible for the processes for the conduct and control of the radiation safety program and who are responsible for the license, including the necessary resources to achieve regulatory compliance;

(p) **"Manual brachytherapy"** means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the

tissue volume;

(q) **"Medical institution"** means an organization in which several medical disciplines are practiced, as in a medical hospital;

(r) **"Medical Physicist"** means the individual identified as the medical physicist in a PNRI license issued pursuant to this Part;

(s) **"Medical use"** means the intentional internal or external administration of radiation from sealed radioactive sources to human beings in the practice of medicine**;**

(t) **"Medium dose-rate remote afterloader"** means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed;

(u) **"Output"** means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source for a specified set of conditions;

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

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

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

(y) **"Radiation Safety Officer (RSO)"** means the individual who is designated in a PNRI license issued pursuant to this Part to be responsible for implementing the radiation safety program of the licensee;

(z) **"Radioactive material"** means any material containing radionuclide where both the activity concentration and the total activity exceed the values specified in Appendix A of CPR Part 3;

(aa) **"Radioactive/Sealed 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;

(bb) **"Radiotherapy Technologist"** means an individual authorized in the license issued pursuant to this Part to be responsible in operating the brachytherapy unit;

(cc) **"Remote afterloading"** means the use of a machine to place radioactive sources in applicators, hollow needles or catheters;

(dd) **"Removable contamination"** means contamination that can be removed from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored, where radioactive contamination is expected to accumulate; and

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

Section 3. Interpretations.

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

Section 4. Communication.

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

Section 5. Activities Requiring License.

No person shall acquire, receive, possess, own, use, transfer, import or export sealed radioactive sources for medical use in brachytherapy 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-014, "Application for a License for the Medical Use of Radioactive Sources in Brachytherapy", in duplicate copies.

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

(c) The applicant shall submit a certified true copy of the Securities and Exchange Commission (SEC) registration and a 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. Issuance of License.

An applicant will be issued a license for activities authorized under this Part if:

(a) The applicant has submitted the appropriate information required in the application for a license;

(b) The radioactive sources are in the type, form and quantity authorized in the license and for the purpose authorized by the Act;

(c) The locations and areas where the radioactive sources will be used and stored are in accordance with the safety and security requirements of this Part;

(d) The applicant's proposed equipment and facilities are adequate to protect health and safety of workers, patients, and the public and to minimize danger to life or damage to property, as well as to ensure the security of the radioactive sources;

(e) The applicant possesses appropriate personnel monitoring devices and radiation survey instruments required for the proposed authorization;

(f) The applicant has designated a qualified Radiation Safety Officer (RSO) and assistant RSO (ARSO) who shall both be responsible for implementing the radiation safety program. The RSO and ARSO shall have indicated acceptance of their designations in writing;

(g) The applicant has established and stated in writing the authorities, duties, and responsibilities of the RSO;

(h) The authorized users, medical physicist, and radiotherapy technologists are qualified by training and experience in their respective functions relative to the use of radioactive material in brachytherapy;

(i) The applicant has a program for training and re-training of workers;

(j) The applicant's proposed radiation safety program addresses CPR Part 3, "Standards for Radiation Protection", and the technical requirements of this Part;

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

(l) The applicant's program on the security of radioactive sources is in accordance with the requirements of CPR Part 26, "Security of Radioactive Sources";

(m) The applicant using sealed sources for high or medium dose rate brachytherapy units has established and submitted to PNRI a Security Plan in accordance with Section 28 of CPR Part 26.

(n) The applicant has provided PNRI documents from the manufacturer of the equipment on the maintenance and service to the brachytherapy units;

(o) The applicant has submitted a program for the management of radioactive waste and disused sealed sources in accordance with Section 41 of this Part;

(p) The applicant has shown proof, in writing, for the return of disused sealed sources to

the original supplier or manufacturer in the country of origin; and

(q) The applicant has paid the required license fees and other charges in connection with his license application.

Section 8. Terms and Conditions of License.

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

(b) PNRI may incorporate in any license issued pursuant to this Part at the time of issuance or thereafter by appropriate notification, rule or order, such additional requirements and conditions with respect to the license as it deems appropriate or necessary in order to protect health and safety of the public, as well as ensure the security of the radioactive sources.

(c) No license, 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 other person unless PNRI, after securing full information:
   (1) finds that the proposed transfer, assignment or disposal is in accordance with the regulations of the Code and the provisions of the Act; and
   (2) consents in writing to the proposed transfer, assignment or disposal.

(d) Upon approval of PNRI, pursuant to paragraph c(2) of this section, for the transfer, assignment or disposal of a license, the transferor shall ensure that the transferee is provided with all information required by PNRI pursuant to approval granted.

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

(f) The licensee shall cause each sealed source or device to be tested for contamination and/or leakage prior to its first use and at intervals not to exceed six months, or as may be directed by PNRI.

(g) The licensee shall conduct a semi-annual physical inventory of all sealed sources and brachytherapy sources in its possession. Records of such inventory shall be maintained and made available for inspection by PNRI.

(h) The licensee shall import or export radioactive material specified in the license in accordance with Appendix A, “Requirements on the Import and Export of Radioactive Sources”, of this Part. Shipment and transport of radioactive material shall be in accordance with the requirements of CPR Part 4, "Regulations for the Safe Transport of Radioactive Material in the Philippines".

(i) 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.

(j) The licensee shall maintain and retain records as required in this Part.

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

(l) The licensee shall comply with the termination requirements described in this Part in order to obtain a lawful termination of the license.

(m) The license shall be valid for a period of one (1) year from the date of issuance or as may be determined by PNRI.

Section 9. Amendment of License.

(a) An application for amendment of a license shall be filed in PNRI/NRLSD Form-014A, "Application for Amendment of License", and shall specify in what respect the licensee desires his license to be amended and the grounds for such amendment.

(b) A licensee shall apply for and must receive a license amendment before:
- (1) it acquires and uses a brachytherapy source for a clinical procedure other than what is indicated in the license;
- (2) it permits anyone to work as authorized user or technologist other than those permitted under the license;
- (3) it changes RSO or medical physicist identified in the license;
- (4) it orders and receives radioactive material in excess of the activity authorized in the license;
- (5) making any major change in the brachytherapy unit;
- (6) making any change in the treatment room shielding;
- (7) using the brachytherapy unit in a manner that could result in increased radiation levels in areas outside the brachytherapy treatment room;
- (8) making any change in the location of the brachytherapy unit;
- (9) it implements any major change in the approved radiation safety program; or
- (10) any substantial change in any condition of the license takes effect.

(c) Each application for amendment of license must be accompanied by the corresponding license amendment fee.

Section 10. 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.

(b) At least thirty (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 and the licensee fails to renew its license in accordance with paragraph (b)(1) of this section, the licensee shall refrain from undertaking licensed activities involving the radioactive sources except to keep the radioactive sources under safe and secure storage until the applicable provision of Section 11 is satisfactorily met.

(d) The expiration of the license shall not relieve the licensee of its responsibility to cause the decommissioning of its facility in accordance with Section 45 of this Part, if the license will be terminated.

Section 11. Renewal of License.

(a) If the licensee decides to renew the license, he must submit to PNRI an application for renewal of license not later than thirty (30) days before the expiration date of the

license.

(b) An application for renewal of license that is filed less than thirty (30) days before the stated expiration date of the license shall be subjected to a surcharge equivalent to 25 percent of the required license renewal fee pursuant to the provisions of CPR Part 22, Fees for Radioactive Material Licenses and Other Regulatory Services.

(c) If the licensee submits an application for renewal of license after the specified expiration date, but not later than thirty (30) days after the expiration date, the application must include the following:
   (1) An explanation for the delay in filing the application;
   (2) An assurance that the licensee did not undertake any principal licensed activity involving the radioactive material after the expiration date of the license; and
   (3) An explanation why PNRI should not impose an administrative sanction against the licensee.

(d) If PNRI determines that the licensee's reasons in (c) of this section are acceptable and safety has not been undermined, the application will be accepted and processed provided that the licensee shall not undertake any principal activity involving the licensed radioactive material until PNRI has granted a license. An additional surcharge equivalent to 50 percent of the license renewal fee shall be collected.

(e) If an application for renewal of a license is filed later than thirty (30) days after the expiration date stated in the license, PNRI shall cause the temporary cessation of activity until PNRI has determined whether or not the application shall be accepted and processed. Upon such order, the licensee shall refrain from undertaking any principal licensed activity.

(f) In case a licensee submits an application for renewal of license within the allowed period but decides to terminate all authorized activities under the existing license without transferring his right to possess or own the radioactive material, a new license authorizing for the storage of the radioactive material shall be issued, which will be subject to specific conditions ensuring the safety and security of stored radioactive materials.

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

Section 12. Termination of License.

(a) The licensee shall notify PNRI in writing and request for the termination of the license when he decides not to renew his license accordingly and to terminate all activities involving radioactive material authorized under the license.

(b) A license will be terminated by a written notice to the licensee when PNRI determines that:
   (1) Licensed materials, including accumulated wastes, have been properly disposed of or transferred;
   (2) The site has been verified by PNRI inspectors to be free of contamination in excess of the level specified in CPR Part 3; and
   (3) A radiation survey report has been submitted to confirm the absence of radioactive material or to establish the levels of residual contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The radiation survey report shall specify the instrumentation used and certify that each instrument is properly calibrated and tested.

(c) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive

contamination is found. Upon verification, PNRI will notify the licensee in writing of the termination of license.

(d) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the licensee shall:
   (1) Limit actions involving radioactive material to those activities related to decontamination and undertake the required procedure for the decommissioning of his facility; and
   (2) Continue to control entry to restricted areas until such areas are suitable for release for unrestricted use and PNRI notifies the licensee in writing that the license is terminated

Section 13. Specific Exemptions.

The 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 the Act and will not endanger life, property, and the environment and are otherwise in the public interest.

Section 14. Additional Requirements.

The 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 15. Radiation Safety Program.

(a) Each 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 authorized personnel;
   (4) Procedures for the safety of personnel and the public from radiation exposure;
   (5) Procedures for the security of radioactive sources;
   (6) A commitment by management to keep occupational doses as low as reasonably achievable (ALARA) and the measures to keep radiation exposures ALARA;
   (7) Written procedures for the conduct of licensed activities by individuals qualified by training and experience;
   (8) Continued education and training for all personnel who work with or in the vicinity of radioactive materials;
   (9) Written emergency procedures; and
   (10) Procedures on records management.

(b) Each 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 16. 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, 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 shall:

(1) Establish, implement, and collect in one file all written policy and procedures for:

i. Authorizing the purchase of radioactive material;
ii. Receiving and opening shipments of radioactive material;
iii. Storing radioactive material;
iv. Keeping an inventory record of radioactive material;
v. Using radioactive material safely and ensuring that all users are properly trained;
vi. Taking emergency action if control of radioactive material is lost or in the event of an accident involving radioactive material;
vii. Ensuring the use of personnel monitoring devices as required;
viii. Performing or arranging for leak tests on all sealed sources;
ix. Performing periodic radiation surveys;
x. Performing checks of survey instruments and other safety equipment;
xi. Disposal of disused sealed sources and radioactive wastes;
xii. Decommissioning of its facility;
xiii. Training personnel who work in or frequent areas where radioactive materials are used or stored; and
xiv. Keeping all records and reports required by PNRI, an up-to-date copy of PNRI regulations, a copy of the license and license amendments, and the written procedures required by the regulations;

(2) Establish quality assurance programs that provide, as appropriate, adequate assurance that the requirements relating to protection and safety are satisfied and quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures;

(3) Ensure that radioactive materials are used only by authorized individuals and in a safe manner;

(4) Ensure the safe operating condition of the brachytherapy unit;

(5) Ensure that safety and security culture are fostered and maintained;

(6) Establish personnel exposure levels that, when exceeded, will initiate a prompt investigation by the RSO of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(7) Ensure that the radioactive material and radiation areas are properly secured and their location conspicuously identified by radiation signs;

(8) Perform periodic audits of the radiation safety program and ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, maintained and provided to management for review. He shall ensure that prompt action is taken to correct deficiencies;

(9) Ensure that audit results and corrective actions are communicated to all personnel who use licensed material;

(10) Ensure that a security plan is established in accordance with CPR Part 26;

(11) Investigate, document, and report to PNRI accordingly, overexposures, accidents, losses, thefts, unauthorized orders, receipts, uses, transfers,

disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;
(12) Supervise decommissioning and recovery operations;
(13) Assist the RSC in the performance of its duties; and
(14) Brief management once each year on the radioactive material program.

(c) The licensee shall provide the RSO, where applicable, sufficient authority, organizational freedom, time, resources, and management prerogative to:
(1) Identify radiation safety problems;
(2) Initiate, recommend, or provide corrective actions;
(3) stop unsafe practices;
(4) verify implementation of corrective actions; and
(5) coordinate the establishment, maintenance, drills/exercise of emergency plans and procedures.

(d) The licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the RSO, where applicable, and retain the most recent edition of these statements until the PNRI terminates the license.

Section 17. Radiation Safety Committee (RSC).

The licensee shall ensure that a Radiation Safety Committee (RSC) is established to oversee the medical uses of radioactive materials in the institution. The RSC shall review, on the basis of safety and with regard to the training and experience requirements in Sections 46, 47, and 49 of this Part, and approve or disapprove any individual proposed to be an authorized user, medical physicist or radiotherapy technologist before submitting a license application or request for amendment or renewal of the license.

(a) The RSC must meet the following administrative requirements:
(1) Membership must consist of at least five individuals and must include an authorized user of each type of PNRI license possessed by the institution, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. Other members may be included as the licensee deems appropriate; and
(2) A program must be established for the conduct of meetings, maintenance of records, and submission of reports to PNRI.

(b) To oversee the use of licensed radioactive material, the RSC must:
(1) Review recommendations on ways to maintain individual and collective doses ALARA;
(2) Review quarterly, with the assistance of the RSO, a summary of the occupational radiation dose exposure records of all personnel working with radioactive material, records of radiation level surveys, and all incidents involving radioactive material with respect to cause and subsequent actions taken;
(3) Review annually, with the assistance of the RSO, the inventory and disposition of sealed sources;
(4) Review annually, with the assistance of the RSO, the radiation safety program; and
(5) Submit a report to PNRI on the activities undertaken in b (1) to b (4), accordingly.

III. TECHNICAL REQUIREMENTS

A. Manual Brachytherapy.

Section 18. Radiation Surveys.

(a) The licensee in possession of sealed sources shall measure the ambient dose rates quarterly in all areas where such sources are stored.

(b) Immediately after implanting sources in a patient, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(c) Immediately after removing the last temporary implant source from a patient, the licensee shall make a survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed.

(d) The licensee shall retain a record of each survey for three years.

Section 19. Brachytherapy Sources Inventory.

(a) The licensee shall return brachytherapy sources to the storage area promptly after removing them from a patient, and perform approved inventory control procedures to ensure that all sources taken from the storage area have been returned.

(b) The licensee shall make a record of the use of the brachytherapy sources which must include:
   (1) the names of the individuals permitted to handle the sources;
   (2) the number and activity of sources removed from storage, the time and date they were removed from storage, the patient's name and assigned room, the number and activity of the sources in storage after the removal, and the signature of the individual who removed the sources from storage;
   (3) the number and activity of sources returned to storage, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the signature of the individual who returned the sources to storage; and
   (4) the number and activity of sources permanently implanted in the patient.

(c) The licensee shall retain records of inventory of sources for three years.

Section 20. Safety Instructions During Implant Therapy.

(a) The licensee shall provide radiation safety instructions, initially and at least annually, to all personnel caring for the patient undergoing implant therapy. To satisfy this requirement, the instructions must be commensurate with the duties of the personnel and must include:
   (1) Size and appearance of the brachytherapy sources;
   (2) Safe handling and shielding instructions in case of a dislodged source;
   (3) Patient control;
   (4) Visitor control; and
   (5) Notification of the RSO and other authorities if the patient dies or has a medical emergency.

(b) The licensee shall retain for three years a record of the individuals receiving

instructions required by paragraph (a) of this section, a description of the instructions, the dates of instructions, and the name and title of the individuals who gave the instructions.

Section 21. Safety Precautions During Implant Therapy.

(a) For each patient receiving implant therapy, a licensee shall:
  (1) Isolate the patient from other patients not receiving radiation therapy unless the licensee can demonstrate compliance with the radiation exposure requirements at one meter from the patient with implant;
  (2) Post the patient's door with a "Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room; and
  (3) Authorize visits only with the approval of the authorized user after consultation with the RSO.

(b) The licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:
  (1) Dislodged from the patient; and
  (2) Lodged within the patient following removal of the source applicators.

(c) The licensee shall notify the RSO, or her/his designee, and an authorized user immediately if the patient dies or has a medical emergency.

Section 22. Calibration Measurements of Brachytherapy Sources.

(a) Before the first medical use of a brachytherapy source, a licensee shall have:

  (1) Determined the source output or activity using a dosimetry system that meets the requirements of Section 29 ;

  (2) Determined source positioning accuracy within applicators; and

  (3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory

(c) The licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) The licensee shall retain a record of each calibration.

Section 23. Release of Patients Containing Permanent Implants.

(a) The licensee shall not authorize release from medical confinement of any patient that received a permanent implant until the measured dose rate from the patient is less than 0.025 mSv per hour at a distance of one meter.

(b) The licensee shall provide the released patient, or the patient's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to household members and the public as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv

(0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual.

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female.

Section 24. Release of Patients Treated With Temporary Implants.

(a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed.

(b) The licensee shall retain a record of patient surveys for three years. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as millisievert per hour and measured at one meter from the patient, the survey instrument used, and the initials of the individual who made the survey.

B. Remote Afterloading Brachytherapy.

Section 25. Radiation Surveys for Brachytherapy Facilities.

(a) Radiation surveys shall be performed before each initial use of brachytherapy source or after relocation of the brachytherapy unit to verify that, with the brachytherapy source in the ON position:

(1) Dose rates in the working areas are not likely to cause personnel exposures in excess of three-tenths of the annual equivalent dose limits; and

(2) Dose rates in unrestricted areas are not likely to cause exposure of the public in excess of one-tenth of the equivalent dose limits.

(b) Radiation surveys shall be conducted at the source housing, with the source in the shielded position. The maximum radiation levels at 10 cm from the surface of the source head shall not exceed 0.03 mSv/hr.

(c) If the results of the surveys indicate any dose rate values that are likely to exceed the above limits, the licensee shall cause the source to return to its shielded position and lock the control console. The licensee shall not operate the unit until corrective measures have been undertaken and resumption of operation has been approved by the RSO.

Section 26. Surveys of Patients Treated with a Remote Afterloader Unit.

(a) Before releasing a patient from licensee control, the licensee shall survey the patient and the remote afterloader unit with a portable radiation detection survey instrument

to confirm that the source(s) has been removed from the patient and returned to the safe shielded position.

(b) The licensee shall retain a record of these surveys in accordance with Section 54.

Section 27. Safety Procedures and Instructions for Remote Afterloader Units.

(a) A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room. These procedures must include:

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally**.**

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by paragraph (a)(4) of this section; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

(1) The procedures identified in paragraph (a)(4) of this section; and

(2) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section.

(g) A licensee shall retain a copy of the procedures required by this section.

Section 28. Safety Precautions for Remote Afterloader Units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) The brachytherapy unit shall be equipped with a back-up power supply which will trigger power failure alarms, operate a DC motor to drive the source to its safe storage position, and operate the device which will preserve and save all treatment data.

(e) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of and communication with the patient from the treatment console during irradiation.

(f) For licensed activities where sources are placed within the patient's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(g) A licensee shall:

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require:

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(h) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient has a medical emergency or dies.

(i) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

Section 29. Dosimetry Equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. The system must have been calibrated by a Secondary Standard Dosimetry Laboratory (SSDL).

(b) The calibration must have been performed within the previous two (2) years and after any servicing that may have affected system calibration.

(c) The system must be calibrated using internationally acceptable protocol or equivalent national protocol.

(d) The licensee shall retain a record of each calibration during the useful life of the machine. For each calibration, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated as required by paragraph (a) of this section, the correction factor that was determined from the calibration, the names and signature of the individuals who performed the calibration.

Section 30. Full Calibration Measurements on Remote Afterloader Units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within ± 5 percent;

(2) Source positioning accuracy to within ±1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in Section 29 to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration.

Section 31. Periodic Spot-Checks for Remote Afterloader Units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A qualified medical physicist shall be responsible for measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist.

(c) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of:

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(d) If the results of the checks required in paragraph (c) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section.

Section 32. Additional Technical Requirements for Mobile Remote Afterloader Units.

(a) A licensee providing mobile remote afterloader service shall:
(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by Section 30, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:
(1) Electrical interlocks on treatment area access points;
(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
(3) Viewing and intercom systems;
(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;
(5) Radiation monitors used to indicate room exposures;
(6) Source positioning (accuracy); and
(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b) of this section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section.

Section 33. Installation, Maintenance and Repair Restrictions.

a) The licensee shall ensure that only individuals who are specifically authorized and licensed by PNRI shall perform the following services:
   (1) Installation, replacement, relocation, or removal of sources contained in the afterloading brachytherapy unit.
   (2) Repair and preventive maintenance operations on the afterloading brachytherapy unit, including work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit or the source(s) and result in increased radiation levels.

(b) The licensee shall ensure that acceptance tests will be conducted following installation of the brachytherapy unit to verify that it conforms to technical specifications certified by the manufacturer.

(c) The licensee shall retain records of the installation, adjustment, repair and maintenance of remote afterloader units.

C. Common Requirements for Manual and Remote Afterloading Brachytherapy.

Section 34. Leak Test of Sealed Sources.

(a) The licensee shall:
   (1) Test each sealed source or cause the source to be tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was leak tested within six months before its transfer to the licensee; and

   (2) Test each source for leakage at intervals not to exceed six months, or as may be determined by PNRI.

(b) If the leak test reveals the presence of 185 Bq or more of removable contamination, the licensee shall:
   (1) Immediately ensure that the sealed sources are in the shielded position and cause the brachytherapy unit to be decontaminated; and

   (2) File a report with PNRI, within five days of the leak test, describing the equipment involved, the test results, and the action taken on the leaking source.

(c) The licensee need not perform a leak test on:
   (1) Sources containing only radioactive material with a half-life of less than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 3.7 MBq or less of beta- or gamma-emitting material or 0.37 MBq or less of alpha-emitting material;

(4) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leak-tested within six months before the date of use or transfer; and

(5) Seeds of Iridium-192 encased in nylon ribbon.

(d) The licensee shall retain records of leak test required by this section in accordance with Section 60 of this Part**.**

Section 35. Authorization for Calibration, Transmission, and Reference Sources.

The licensee may receive, possess, and use sealed sources not exceeding 0.555 GBq each for check, calibration, transmission, and reference use.

Section 36. Possession of Survey Instrument.

The licensee shall have in its possession a portable radiation survey instrument capable of measuring dose rates over the range of 1 μSv per hour 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 instruments used before first use, annually, and following repair. The licensee shall:
(1) Calibrate all scales with readings up to 10 mSv per hour with a radiation source;
(2) Take at least two separate readings (at 20% and 80% of full range) on each scale that must be calibrated; and
(3) Conspicuously note in the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(b) When calibrating a survey instrument, the licensee shall consider a scale as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall show a correction chart or graph.

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

(d) The licensee shall retain a record of each survey instrument calibration for three (3) years.

Section 38. Personnel Monitoring.

(a) The licensee shall require authorized users, medical physicists, radiotherapy technologists, and service personnel who work with radiation to wear each an individual monitoring device such as a film badge or a thermoluminescent dosimeter (TLD).

(b) Film badges shall be processed every month and the TLD every three months.

(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 39. Security and Control of Licensed Sealed Sources.

(a) The licensee shall establish and implement written security measures to prevent theft, loss, damage to or unauthorized access to licensed sealed sources in accordance with CPR Part 26.

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

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

(d) For sources in storage, the licensee shall:
   (1) Secure the source in a locked and fixed container or in a device holding the source;
   (2) Ensure that the fixed container or a device holding the source is secured in a locked room to separate the container from authorized access;
   (3) Ensure that access of the room shall be controlled; and
   (4) Ensure that the room shall be equipped with a device to detect unauthorized access to or removal of the source.

(e) For sources in use, the licensee shall ensure that during brachytherapy operation, the RSO and the ARSO shall maintain a continuous and direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part 3 of the Code, except:
   (1) Where the high radiation area is equipped with a control device or an alarm system; or
   (2) Where the high radiation area is locked to protect against unauthorized or accidental entry.

(f) The licensee shall conduct a semi-annual physical inventory of all sealed sources in his/her possession under the license. The records of each inventory shall be maintained for three years from the date of the inventory for inspection by the Institute and shall include the type and quantity of radioactive source, the location of each source, and the date of the inventory.

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

Section 40. Import and Export of Radioactive Sources.

The import and export of radioactive sealed sources shall be in accordance with Appendix A, "Requirements on the Import and Export of Radioactive Sources", of this Part.

Section 41. Management of Disused Sealed Sources.

(a) The licensee shall be responsible for the disposition of all licensed sealed sources listed in his license.

(b) A licensee may have the following management options to consider:
   (1) Transfer the source to another authorized licensee for application elsewhere at the current activity level;
   (2) Return the disused sealed source to the original supplier or manufacturer; or
   (3) Allow the sources containing radionuclides with short half-lives to decay while in storage.

Section 42. Transfer of Disused Sealed Sources to Another Authorized Licensee.

(a) A licensee may transfer disused sealed sources to another person authorized by PNRI to receive such sources.

(b) A licensee shall not transfer disused radioactive sealed sources to another authorized licensee unless:
   1) He has notified and has received authority from PNRI about such transfer;
   2) He has submitted to PNRI appropriate information that includes:
      (i) licensee's name, address and license number;
      (ii) type, form and quantity of disused sealed sources to be transferred; and
      (iii) the name, address and license number of the person to whom the sources will be transferred; and
   3) He has complied with the requirements in CPR Part 4, "Regulations for the Safe Transport of Radioactive Material in the Philippines", on the transport of radioactive material.

Section 43. Return of Disused Sealed Sources to the Original Supplier or Manufacturer.

(a) The licensee shall return the disused sealed sources to the original supplier or manufacturer in accordance with Appendix A of this Part.

(b) The disused sealed sources to be returned to the supplier or manufacturer shall be packaged and shipped, in accordance with CPR Part 4, in the original container, or provisions shall be made to acquire another acceptable container if the original container is not available

Section 44. Storage to Decay of Short Half-Life Spent Sealed Sources.

(a) Licensee may store for decay sealed sources which are allowed by the PNRI.

(b) During decay, sources shall be retained in their original shipping casket and overpacks, each labelled to show the:
   (1) Trefoil radiation warning symbol;
   (2) Radionuclide contained in the source;
   (3) Activity and the date decay storage was commenced; and
   (4) Estimated date when the source may be disposed of as non-radioactive material.

(c) Before disposal of the sources, licensee shall submit to the PNRI a report which indicates the radiation level in the storage room, the activity of the decayed sources and the planned method of disposal.

Section 45. Decommissioning of Licensed Facility.

(a) The licensee shall be responsible for the decommissioning of the licensed facility.

(b) The licensee shall submit to PNRI for approval, not less than twelve months before the start of decommissioning activities, a proposed decommissioning plan which must include:

   (1) A description of planned decommissioning activities;
   (2) A description of the methods to ensure protection of workers and the environment against radiation hazards during decommissioning;
   (3) A description of the planned final radiation survey;
   (4) A description of technical specifications, quality assurance provisions and physical security plan provisions in place during decommissioning;
   (5) An assurance on the availability of adequate funds for completion of decommissioning; and
   (6) A program for the disposition of the radioactive waste after decommissioning.

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

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

VI. EDUCATION, TRAINING AND EXPERIENCE REQUIREMENTS

Section 46. Authorized User.

The licensee shall require the authorized user to be an individual who:

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

(b) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of brachytherapy sources that includes 200 hours of PNRI-approved classroom and laboratory training in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology;

(c) Has had 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Checking survey meters for proper operation;

(3) Preparing, implanting, and removing sealed sources;

(4) Maintaining running inventories of material on hand;

(5) Using administrative controls to prevent the misadministration of radioactive sources; and

(6) Using emergency procedures to control radioactive sources;

(d) Has had 3 years of clinical experience in therapeutic radiology under the supervision of an authorized user in a medical institution. This experience may be obtained concurrently with the supervised work experience required by paragraph (c) of this section; and

(e) Has obtained written certification, signed by a preceptor authorized user, that he has satisfactorily completed the requirements in paragraphs (b), (c), and (d) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of brachytherapy unit for which the individual is requesting authorized user status.

Section 47. Medical Physicist.

The licensee shall require the Medical Physicist to be an individual who:

(a) Holds a Bachelor of Science degree in physics, therapeutic radiological physics, biophysics, medical physics, health physics, physical sciences or engineering; and

(b) Has had at least 200 hours of classroom training that includes Radiation Physics, Radiation Dosimetry, Radiation Protection, Radiation Biology, and Nuclear Regulations and Licensing; and

(c) Has earned units in Physics of Radiotherapy and Practical Attachments in Radiotherapy in the MS degree program in Medical Physics or equivalent; and

(d) Has a six-month training in conventional radiotherapy procedures which shall cover treatment planning; dose calculations; localization and simulation; and quality assurance of brachytherapy equipment, including treatment planning system, under close supervision by a medical physicist , after which certification of completion of training and experience is issued by the medical institution.

Section 48. Radiation Safety Officer (RSO)

The licensee shall require an individual fulfilling the responsibilities of the RSO to be an individual who:

(a) Has a Bachelor of Science Degree in natural or physical sciences or engineering;

(b) Has received at least 200 hours classroom and laboratory training in radiation safety covering as minimum: Radiation Physics and Instrumentation; Radiation Quantities and Measurements, Biological Effects of Ionizing Radiation, Principles of Radiation

Protection, Regulatory Control, Assessment of External and Internal Exposures, Protection Against Occupational Exposure, Medical Exposure in Radiotherapy, Exposure of the Public Owing to Practices, and Intervention in Situations of Chronic and Emergency Exposure; and

(c) Has gained three-month experience under the supervision of an individual identified as RSO in a Medical Institution licensed to use radioactive sources in brachytherapy unit.

Section 49. Radiotherapy Technologist.

A licensee shall require the radiotherapy technologist to be an individual who:

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

(b) Has had at least six (6) months full-time training and experience in the operation of a brachytherapy unit under the supervision of a medical physicist and authorized user; and

(c) Has had 40 hours classroom training in radiation safety.

Section 50. Refresher Course.

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

Section 51. Security Awareness Training.

The licensee shall require each individual who is authorized to handle radioactive sources to have completed a training on security awareness.

V. RECORDS, REPORTS AND NOTIFICATIONS

Section 52. Records of Radiation Surveys.

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

(b) Each licensee shall maintain a record of the surveys after source implant and source removal, as required by Section 18, for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey

Section 53. Records of Inventory of Sealed Sources and Brachytherapy Sources.

(a) Each licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources for three (3) years.

(b) Inventory records shall be made available for inspection by the PNRI and must contain the model number of each source, and serial number if one has been assigned, the

identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

Section 54. Records of Use of Brachytherapy Sources.

(a) Each licensee must record the use of licensed material to reflect proper use and accountability. Records of use must be maintained for three (3) years.

(b) Each licensee using manual brachytherapy sources must keep records of temporary implant brachytherapy sources removed from storage and those returned to storage and record of permanent implants.

Section 55. Records of Calibration Measurements of Brachytherapy Sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by Section 22 for 3 years after the last use of the source.

(b) The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Section 56. Records of Safety Instructions.

(a) Each licensee shall retain a copy of the safety instructions required by Section 27 of this Part until the licensee no longer possesses the brachytherapy unit.

(b) The licensee shall retain the records for three years. The record must include:
(1) A description of the instructions;
(2) The dates of instructions;
(3) The names of the attendees; and
(4) The name(s) and title(s) of the individual(s) who gave the instructions.

Section 57. Records of Periodic Spot-Checks for Remote Afterloader Units.

(a) The licensee shall retain a record of each spot-check for remote afterloader units required by Section 31 for 3 years.

(b) The record must include, as applicable:
(1) The date of the spot-check;
(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) The licensee shall retain a copy of the procedures required by Section 31(b) until the licensee no longer possesses the remote afterloader unit.

Section 58. Records of Calibration of Survey Instruments.

(a) Each licensee shall maintain a record of radiation survey instrument calibration.

(b) The record must include:
(1) The model and serial number of the instrument;
(2) The date of the calibration;
(3) The calibration procedure;
(4) A description of the source used;
(5) The certified exposure rates from the source;
(6) The rates indicated by the instrument being calibrated and the calibration factors deduced from the calibration data;
(7) The results of the calibration; and
(8) The names and signatures of the individuals who performed the calibration.

Section 59. Records of Installation, Maintenance, Adjustment and Repair.

(a) Each licensee shall maintain records of the installation, maintenance, adjustment and repair of the brachytherapy unit for as long as the brachytherapy unit is licensed.

(b) The licensee shall retain the records for three years. The records must include:
(1) The date of each installation, maintenance, adjustment or repair;
(2) A description of the service; and
(3) The names and signatures of the individuals who performed the work.

Section 60. Records of Leak Test.

(a) Each licensee shall retain records of the results of leak tests on sealed sources for three (3) years or until the sealed sources are transferred or disposed of.

(b) The records must contain:
(1) The model number, and serial number if assigned, of each source tested;
(2) The identity of each source radionuclide and its estimated activity;
(3) The measured activity of each test sample expressed in becquerels;
(4) A description of the method used to measure each test sample;
(5) The date of the test;
(6) The name of the individual conducting the test; and
(7) The signature of the RSO.

Section 61. Records of Personnel Monitoring.

(a) Each licensee shall maintain records of total exposures of all individuals who are

required to wear personnel monitoring devices. Such records shall be kept on clear and legible forms.

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

Section 62. Records of Disposal of Radioactive Wastes and Disused Sealed Sources.

Each licensee shall maintain and retain records of disposal of radioactive wastes and disused sealed sources until PNRI authorizes their disposition.

Section 63. Reports of Exposure of Persons Who Have Worked in a Licensee's Facility.

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

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

Section 64. Notification of Incidents.

(a) Each licensee shall notify PNRI within 24 hours by telephone or by any similarly fast means of communication, of any incident involving a radioactive material possessed by the licensee, which may have caused or threatened to cause a single exposure of the whole body of any individual in excess of 0.05 Sv.

(b) Each licensee shall report to PNRI within twenty four (24) hours from the occurrence of a failure of, or damage to, the encapsulation of a sealed source, or upon the detection of 185 Becquerels or more of removable contamination. The report shall be made in writing within 30 days of the occurrence which contains a brief description of the incident and the corrective actions taken.

(c) The notification filed with PNRI pursuant to this section shall specify the names of individuals who have received exposure to radiation and other persons involved in the incident in a separate part of the report.

Section 65. Notification of Theft or Loss of Licensed Material.

(a) Each licensee shall notify PNRI by telephone, or by any similarly fast means of communication, of any lost, stolen, or missing licensed sealed source.

(b) Within 30 days after the notification of the event in (a) above, each licensee shall make a written report to PNRI that shall include the following information:
   (1) A description of the licensed material involved including kind, quantity, chemical, and physical form;

(2) A description of the circumstances under which the loss or theft occurred;
(3) A statement of disposition or probable disposition of the licensed material involved;
(4) Estimated radiation exposures to individuals, circumstances under which the exposures occurred, and the extent of possible hazards to persons in unrestricted areas;
(5) Actions taken, or will be taken, to recover the material; and
(6) Procedures or measures undertaken or will be adopted to prevent a recurrence of the incident.

(c) Subsequent to the occurrence of the incident and its immediate notification to PNRI, the licensee shall also report immediately any substantive information on the incident which may become available to the licensee.

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

Section 66. Notification on Specific Changes in the License.

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

(a) When an authorized user, Radiation Safety Officer, or medical physicist permanently discontinues performance of duties under the license or has a name change; or

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

VI. INSPECTION AND ENFORCEMENT

Section 67. Inspection.

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

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

Section 68. 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 person who wilfully 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 69. 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.

VII. EFFECTIVITY

Section 70. Effective Date.

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

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***

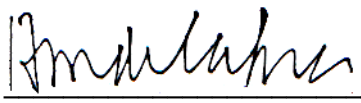
Radionuclide	Category 1* 1000 x D		Category 2** 10 x D	
	(TBq)	(Ci)	(TBq)	(Ci)
Am-241	6.E+01	2.E+03	6.E-01	2.E+01
Am-241/Be	6.E+01	2.E+03	6.E-01	2.E+01
Cf-252	2.E+01	5.E+02	2.E-01	5.E-00
Cm-244	5.E+01	1.E+03	5.E-01	1.E+01
Co-60	3.E+01	8.E+02	3.E-01	8.E+00
Cs-137	1.E+02	3.E+03	1.E+00	3.E+01
Gd-153	1.E+03	3.E+04	1.E+01	3.E+02
Ir-192	8.E+01	2.E+03	8.E-01	2.E+01
Pm-147	4.E+04	1.E+06	4.E+02	1.E+04
Pu-238	6.E+01	2.E+03	6.E-01	2.E+01
Pu-239b/Be	6.E+01	2.E+03	6.E-01	2.E+01
Ra-226	4.E+01	1.E+03	4.E-01	1.E+01
Se-75	2.E+02	5.E+03	2.E+00	5.E+01
Sr-90 (Y-90)	1.E+03	3.E+04	1.E+01	3.E+02
Tm-170	2.E+04	5.E+05	2.E+02	5.E+03
Yb-169	3.E+02	8.E+03	3.E+00	8.E+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**.

Approved:



ALUMANDA M. DELA ROSA, Ph.D.

October 16, 2009
Date