

CPR PART 12. LICENSES FOR MEDICAL USE OF SEALED RADIOACTIVE SOURCES IN TELETHERAPY

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I

General Provisions

SECTION 1. Purpose and Scope — This part prescribes requirements and provisions for the medical use of sealed radioactive sources in teletherapy and for the issuance of specific licenses authorizing the medical use of this material. The requirements and provisions in this Part provide for the protection of the public health and safety, and are in addition to other requirements in the Code of PAEC Regulations[*] (CPR or Code). The relevant requirements of parts 2, 3 and 4 of the Code apply to applicants and licensees subject to this Part unless specifically stated otherwise.

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, and Republic Act 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended;
- b. Address of use means the building or buildings that are identified on the license and where radioactive material may be received, used or stored;
- c. ALARA (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practicable:
 - Consistent with the purpose for which the licensed activity is undertaken,
 - Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety and other societal and socio-economic considerations, and
 - In relation to utilization of nuclear energy in the public interest;
- d. Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material;
- e. Authorized Technologist means an individual authorized to operate a teletherapy unit in a license issued by the Institute for the medical use of sealed sources in teletherapy units;
- f. Authorized User means a physician who is identified as an authorized user in a license issued by the Institute that authorizes the medical use of sealed radioactive sources in teletherapy units;
- g. Dedicated check source means a radioactive source that is used to assure the proper operation of a survey instrument over several months or years;
- h. Institute means the Philippine Nuclear Research Institute and its duly authorized representative;
- i. Licensee means a holder of a valid license issued by PNRI for medical use of sealed sources in a teletherapy unit;

- j. Management means the chief executive officer or that person's representative;
- k. Medical Institution means an organization in which several medical disciplines are practiced;
- l. Medical use means the intentional external administration of radiation from sealed radioactive material to human beings in the practice of medicine;
- m. Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of conditions;
- n. Person means (1) Any individual, firm, partnership, association, trust, estate, private or public body, whether corporate or not, or any government agency other than the Institute, 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;
- o. Physician means a medical doctor licensed or authorized by the Professional Regulatory Commission to prescribe drugs in the practice of medicine in the Philippines;
- p. Radiological Health and Safety Officer means the individual identified as the Radiological Health and Safety Officer (RHSO) in the license;
- q. Sealed source means any radioactive material that is encased in a capsule to prevent leakage or escape of the radioactive material;
- r. Teletherapy means the external beam treatment in which the source of radiation is at a remote distance from the patient;
- s. Teletherapy Physicist means the individual identified as the teletherapy physicist in a PNRI license for medical use of sealed source in a teletherapy unit.

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

SECTION 3. Interpretations — Except as specifically authorized by the Director in writing, no interpretation of the meaning of the regulations in this Part by any officer or employee of the Institute other than a written interpretation of the Director will be recognized to be binding upon the Institute.

SECTION 4. License Required — No person shall acquire, receive, possess, use, transfer or import sealed radioactive source for medical use in a teletherapy unit except in accordance with the requirements and provisions of this Part.

SECTION 5. Application for License, Amendment or Renewal —

- a. If the application is for medical use in a facility cited in a medical institution, only the institution's management may apply.
- b. If the application is for medical use of the radioactive material in a facility not cited in a medical institution, any person may apply.
- c. An application for a license for medical use of sealed radioactive material for use in a teletherapy unit must be made by completing Form NRLSD/LRE-005, "Application for Radioactive Material License (Teletherapy).
- d. An application for a license amendment or renewal may be submitted as an original and one copy in letter format.

SECTION 6. License Issuance — The Institute will issue a license for the medical use of sealed radioactive material in a teletherapy unit for a term of one year if:

- a. The applicant has filed Form NRLSD/LRE-005, "Application for Radioactive Material License (Teletherapy)" in accordance with the instructions in Section 5;
- b. The Institute finds the applicant equipped and committed to observe the safety standards established in this Part and in other Parts of the Code for the protection of the public health and safety;
- c. The applicant meets the relevant requirements of Part 2 and Part 3 of the Code;
- d. The applicant has paid all applicable fees in connection with his application; and
- e. The applicant's decommissioning and disposal plans for the facility and radioactive material had been approved by the Institute.

SECTION 7. License Amendments — A licensee shall apply for and must receive a license amendment:

- a. Before it receives and uses radioactive source for a teletherapy procedure permitted under this Part but not permitted by the license that was issued pursuant to this Part;
- b. Before it permits anyone to work as an authorized user or authorized technologist under the license;
- c. Before it changes RHSO or teletherapy physicist;
- d. Before it orders and receives radioactive material in excess of the activity authorized in the license;
- e. Before any major change in equipment or teletherapy unit;
- f. Before making any change in the treatment room shielding.
- g. Before making any change in the location of the teletherapy unit;
- h. Before using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
- i. Before it implements any major change in the approved radiation safety program; or
- j. Before substantial change in any condition of the license takes effect.

II

General Administrative Requirements

SECTION 11. ALARA Program —

- a. Each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA. The radiation protection program shall also address the provisions of Section 21 of Part 3 of the Code.
- b. To satisfy the requirement of paragraph (a) of this section:
 - At a medical institution, the management, the RHSO, and all authorized users must participate Isotopes Committee (MIC) and approved by the Institute.
 - For facilities that are not cited in medical institutions, the management and all authorized users must participate in the program submitted by the RHSO and approved by the Institute.

c. The program must include a description of the organization, notice to workers of the program's existence, functions and responsibilities to help keep dose equivalents ALARA, a review of summaries of occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for all personnel who work with, or in the vicinity of, radioactivity material. The purpose of the review is to ensure that reasonable effort is made to maintain individual and collective occupational doses ALARA.

SECTION 12. Radiological Health and Safety Officer

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

b. The Radiological Health and Safety Officer shall:

- Investigate, document, and report to the Institute 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;
- 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 safety;
 - vi. Taking emergency action if control of radioactive material is lost;
 - vii. Performing periodic radiation surveys;
 - viii. Performing checks of survey instruments and other safety equipment;
 - ix. Disposing of radioactive material;
 - x. Training personnel who work in or frequent areas where radioactive material is used or stored;
 - xi. Keeping a copy of all records and reports required by the Institute regulations, a copy of Parts 2, 3 and this Part of the CPR, a copy of each licensing request, the license and license amendments, and the written policy and procedures required by the regulations.
- Brief Management once each year on the radioactive material program;
- Establish preliminary personnel exposure investigational levels that, when exceeded, will initiate an investigation by the RHSO of the cause of the exposure;
- Establish higher personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the RHSO of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence; and
- Assist the MIC in the performance of its duties.

SECTION 13. Medical Isotopes Committee (MIC). — Each medical institution licensee shall establish a MIC to

oversee the medical use of radioactive materials. This includes uses for nuclear medicine teletherapy and brachytherapy.

a. The Committee must meet the following administrative requirements:

- Membership must consist of at least five (5) individuals and must include an authorized user and the RHSO of each type of use permitted in the license, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RHSO. Other members may be included as the licensee deems appropriate.
- The Committee must establish a program for the conduct and maintenance of meetings, reports, records and actions.

b. To oversee the use of licensed material, the Committee must:

- Review recommendations on ways to maintain individual and collective doses ALARA;
- Review, on the basis of safety and with regard to the training and experience requirements in Sections 51, 52, 53 and 54 of this part, and approve or disapprove any individual who is to be listed as an authorized user, the RHSO, or a Teletherapy, Physicist, before submitting a license application or request for amendment or renewal;
- Review quarterly, with the assistance of the RHSO, a summary of the occupational radiation dose exposure records of all personnel working with radioactive material and records of radiation level surveys;
- Review quarterly, with the assistance of the RHSO, all incidents involving radioactive material with respect to cause and subsequent actions taken; and
- Review annually, with the assistance of the RHSO, the radiation safety program.

SECTION 14. Teletherapy Physicist — Each licensee shall appoint a teletherapy physicist whose functions shall include:

- a. radiation dosimetry;
- b. the physical aspects of treatment planning;
- c. supervision of quality control;
- d. radiation protection;
- e. advice on the choice of teletherapy equipment and radiation shielding design; and
- f. conduct of calibration of teletherapy unit and survey equipment.

SECTION 15. Statements of Authority and Responsibilities —

- a. The licensee shall provide the RHSO and the MIC where applicable, sufficient authority, organizational freedom, and management prerogative, to:
 - Identify radiation safety problems;
 - Initiate, recommend, or provide corrective actions; and
 - Verify implementation of corrective actions.
- b. The licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the RHSO and the MIC, where applicable, and maintain the most current edition of these statements

until the Institute terminates the license.

III

Technical Requirements

SECTION 21. Use of Sealed Source in a Teletherapy Unit — The regulations and provisions of this part govern the medical use of a sealed source of Cobalt-60 or Cesium-137 in a teletherapy unit.

SECTION 22. Installation, Maintenance and Repair Restrictions — Only persons specifically authorized and licensed by the Institute pursuant to Section 31 of Part 2 of the CPR to perform teletherapy unit maintenance and repair shall:

- a. Install or remove a teletherapy sealed source or relocate a teletherapy unit that contains a sealed source; or
- b. Maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, or result in increased radiation levels.

SECTION 23. Safety Instructions —

- a. The licensee shall post safety instructions at the teletherapy unit console which must inform the operator of:
 - The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation ON to begin a treatment or after a door interlock interruption;
 - The procedure to be followed if the operator is unable to turn the primary beam of radiation OFF with controls outside the treatment room, or any other abnormal operation occurs; and
 - The names and telephone numbers of the authorized users and RHSO to be immediately contacted if the teletherapy unit or the console operates abnormally.
- b. The licensee shall provide periodic instructions on the topics identified in paragraph (a) of this section to all individuals who operate a teletherapy unit.
- c. The licensee shall retain for two years the record of individuals receiving instruction required by paragraph (b) of this section, a description of the instruction, the dates of instruction, and the name and title of the individual who gave the instruction.

SECTION 24. Safety Precautions —

- a. The licensee shall control access to the teletherapy room by a door at each entrance.
- b. The licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:
 - Prevent the operator from turning the primary beam of radiation ON unless each treatment room entrance is closed;
 - Turn the primary beam of radiation OFF immediately when an entrance door is opened; and
 - Prevent the primary beam of radiation from being turned ON following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.
- c. The licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.
- d. The licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status;

- A radiation monitor must provide visible indication of a teletherapy unit malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the teletherapy room.
 - A radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.
 - A radiation monitor must be checked with a check source for proper operation each day before the teletherapy unit is used for treatment of patients.
 - A licensee shall maintain a record of the check required by paragraph (d) (3) of this section for two years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.
 - If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument to monitor for any malfunction of the source mechanism that may result in an exposed or partially exposed source. The survey instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in paragraph (d) (4) of this section.
 - The licensee shall promptly repair or replace the radiation monitor if it is inoperable.
- e. The licensee shall construct or equip in each teletherapy room a system that will permit continuous observation of the patient from the teletherapy unit console during irradiation.

SECTION 25. Dosimetry Equipment —

- a. The licensee shall have available for use or shall have made arrangements for available use a calibrated dosimetry system. To satisfy this requirement, one of the following two conditions must be met:
- The system must have been calibrated by an accredited calibration laboratory. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration.
 - The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been inter-compared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by an accredited calibration laboratory. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by, e.g., IEAA/WHO SSDL. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating Cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a Cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating Cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a Cesium-137 source.
- b. The licensee shall have available for use or shall have made arrangements for available use a dosimetry system for constancy-check measurements. To satisfy this requirement, the system maybe compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The constancy-check system may be the same used to meet the requirement in paragraph (a) of this section.
- c. The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs

(a) and (b) of this section, the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or accredited radiologic physics center.

SECTION 26. Full Calibration Measurements —

(a) The license authorized to use a teletherapy unit for medical use shall perform or cause to be performed full calibration measurements on each teletherapy unit:

- Before the first medical use of the unit;
- Before medical use under the following conditions;
 - i. Whenever constancy-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - ii. Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - iii. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
- At intervals not exceeding one year.

b. To satisfy the requirement of paragraph (a) of this section, full calibration measurements with the use of a dosimeter calibrated in an SSDL facility must include determination of:

- The output within + 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
- The coincidence of the radiation field and the field indicated by the beam localizing device;
- The uniformity of the radiation field and its dependence on the orientation of the useful beam;
- Timer constancy and linearity over the range of use;
- On-off error; and
- The accuracy of all distance measuring and localization devices in medical use.

c. The licensee shall use the dosimetry system described in Section 25(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

determined in paragraph (b) (1) of this section for physical decay for intervals not exceeding one month for Cobalt-60 or six months for Cesium-137.

e. Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (d) of this section must be performed by the licensee's teletherapy physicist or equivalent.

f. A licensee shall retain a record of each calibration for the duration of the use of the teletherapy unit source. The record must include the date of the calibration, the manufacturer's name, model number, and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy,

the calculated on-off error, the estimated accuracy of each distance measuring or localization device, the name of the individual performing the calibration and the signature of the teletherapy physicist.

SECTION 27. Periodic Spot-Checks —

a. The licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

- Timer constancy, and timer linearity over the range of use;
- On-off error;
- The coincidence of the radiation field and the field indicated by the beam light localizing device;
- The accuracy of all distance measuring and localization devices used for medical use;
- The output for one typical set of operating conditions measured with the dosimetry system described in Section 25(b) of this part; and
- The difference between the measurement made in paragraph (a) (5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

b. The licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the teletherapy physicist. The physicist need not actually perform the spot-check measurements.

c. The licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for two years.

d. The licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month that assure proper operation of:

- Electrical interlocks at each teletherapy room entrance;
- Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
- Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;
- Viewing systems;
- Treatment room doors from inside and outside the treatment room; and
- Electrically assisted treatment room doors with the teletherapy unit electrical power turned off;

e. The licensee shall arrange for prompt repair of any system identified in paragraph (d) of this section that is not operating properly and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

f. The licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section for five years. The record must include the date of the spot-check, the manufacturer's name, model number and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the

instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

SECTION 28. Safety Checks for Teletherapy Facilities —

- a. The licensee shall promptly check all systems listed in Section 27(d) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by Section 7 (e) through (h).
- b. If the results of the checks required in paragraphs (a) of this section indicate the malfunction of any system specified in Section 27(d), 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.
- c. The licensee shall retain for five years a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and door, and the signature of the RHSO.

SECTION 29. Radiation Surveys for Teletherapy Facilities —

- a. Before mechanical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by Section 7(e) through (h), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with Section 34 of this part to verify that:
 - The maximum and average dose rates at one meter from the teletherapy source with the source in the OFF position and the collimators set for a normal treatment field do not exceed .1 mSv (10 millirem) per hour and .02 mSv (2 millirem) per hour, respectively; and
 - With the teletherapy source in the ON position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:
 - i. Dose rates in restricted areas are not likely to cause personnel exposures in excess of the limits specified in Section 24(b) of CPR Part 3; and
 - ii. Dose rates in unrestricted areas do not exceed the limits specified in Section 24(d) of CPR Part 3.
- b. If the results of the surveys required in paragraph (a) of this section indicate any dose rates in excess of the respective limit specified in that paragraph, the licensee shall lock the control console in the OFF position and not use the unit;
 - Except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or
 - Until the licensee has received a specific exemption pursuant to Section 71 of CPR Part 3.
- c. A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source and the instrument

used to measure radiation levels, each dose rate measured around the teletherapy source while in the OFF position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millisievert (or millirem) per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the RHSO.

SECTION 30. Modification of Teletherapy Unit or Room Before Beginning a Treatment Program — a. If the survey required by Section 29 (a) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by Section 24 of CPR Part 3, before beginning the treatment program the licensee shall:

- Either equip the unit with stops or and additional radiation shielding to ensure compliance with Section 29 (b);
- Perform the survey required by Section 29 (a) again;
- Include in the report required by Section 29(c) the results of the initial survey, a description of the modification made to comply with paragraph (a) (1) of this section, and the results of the second survey; and
- Have the approval of the RHSO to begin the treatment program.

SECTION 31. Reports of Teletherapy Surveys, Checks, Tests, and Measurements — The licensee shall mail a copy of the records required in Sections 27, 28, and 29, and the reference output from the teletherapy source expressed as Centigray per hour at 80 cm SSD, or as applicable, at the position of dose maximum from the source and determined during the full calibration required in Section 26, to the PNRI within thirty days following completion of the action that initiated the second requirement.

SECTION 32. Five-Year Inspection —

- a. The licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.
- b. This inspection or servicing may only be performed by persons specifically licensed to do so by the Institute pursuant to Section 31 (d) of CPR Part 2.
- c. The licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license, license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

SECTION 33. Possession of Survey Instrument — Any person licensed to use a teletherapy unit for medical use shall have in its possession a portable radiation survey instrument capable of measuring dose rates over the range 0 to 10 mSv (0 to 1,000 millirem) per hour.

SECTION 34. Calibration and Check of Survey Instruments —

- a. The licensee shall calibrate or cause the calibration of its survey instruments used to show compliance with this Part before first use, semi-annually, and following repair. The licensee shall:
 - Calibrate all scales with readings up to 10 mSv (1,000 millirem) per hour with a radiation source;
 - Take at least two separate readings (at 20% and 80% of full range) on each scale that must be calibrated; and

- 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. HSDaTC

c. The licensee shall check each survey instrument for proper operation with the dedicated source 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 two years. The record must include:

- A description of the calibration procedure; and

- The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the calibration factors deduced from the calibration data, and the signature of the individual who performed the calibration.

SECTION 35. Authorization for Calibration and Reference Sources —

a. The licensee in possession of any sealed source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. The licensee in possession of a sealed source shall:

- Test the source or cause the source to be tested for leakage before its first use unless the licensee has its certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

- Test the source for leakage at intervals not to exceed six months.

c. To satisfy the leak test requirements of this section, the licensee must:

- Take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample; and

- Measure the sample so that the leakage test can detect the presence of less than 185 Bq (0.005 microcurie) of removable contamination.

d. The licensee shall retain leakage test records for five years. The records must contain the model number, and serial number if assigned, of each source tested the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels (microcuries), a description of the method used to measure each test sample, the date of the test, the name of the individual conducting the test, and the signature of the RHSO.

e. If the leakage test reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination, the licensee shall:

- Immediately withdraw the sealed source from use and store it in accordance with requirements in Parts 2 and 3 of the CPR; and

- File a report within five days of the leakage test with the Institute, describing the equipment involved, the test

results, and the action taken on the leaking source.

f. The licensee need not perform a leakage test on the following sources:

- Sources containing 4 MBq (100 microcurie) or less of beta or gamma-emitting material or 0.4 MBq (10 microcurie) or less of alpha-emitting material; and
- 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.

g. The licensee in possession of sealed sources shall conduct a quarterly inventory of all such sources in its possession. The licensee shall retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the RHSO.

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

i. The licensee shall retain a record of each survey required in paragraph (h) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in millisievert (or millirem) per hour, the survey instrument use, and the signature of the RHSO.

SECTION 37. Management of Spent Sealed Sources —

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

b. The licensee may have the following management options to consider:

- Transfer the source to another authorized user or licensee for application elsewhere at the current activity level; or
- Return of the spent sealed source to the original supplier or manufacturer.

SECTION 38. Transfer of Spent Sealed Sources to Another Authorized User — No licensee shall transfer spent sealed sources to another authorized user or licensee unless:

a. He has notified and has received authority from the Institute about such transfer;

b. He has submitted to the Institute appropriate information that includes:

- licensee's name, address and license number;
- type, form and quantity of material to be transferred; and
- the name, address and license number of the person to whom the sources will be transferred; and

c. He has complied with the requirements in CPR Part 4 on the transport of radioactive material.

d. A Certificate of Transport has been issued by the Institute.

SECTION 39. Return of Spent Sealed Sources to the Original Supplier or Manufacturer — Licensee shall transfer to the original supplier or manufacturer its spent sealed sources on conditions that:

a. The sources are packaged and shipped in a container, the design and specifications of which have been approved by the Institute; and

b. Transfer is in accordance with transport requirements and the export license issued by the Institute, if the radioactive material is to be shipped abroad.

SECTION 40. Decommissioning of Spent Teletherapy Units —

a. All Licensees shall be responsible for the decommissioning of their spent teletherapy units or facilities.

b. The licensee shall submit to the institute for approval a proposed decommissioning plan which must include:

- Description of planned decommissioning activities;
- Description of methods to assure protection of workers and the environment against radiation hazards during decommissioning;
- Description of the planned final radiation survey;
- Assurance on the availability of adequate funds for completion of decommissioning; and
- program for the disposition of the radioactive source after decommissioning.

c. The licensee shall submit to the Institute, 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.

IV

Training and Experience Requirements

SECTION 51. Authorized User — The licensee shall require the authorized user of a sealed source in a teletherapy unit to be a physician who:

- a. Is in the active practice of therapeutic radiology;
- b. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of a sealed source in a teletherapy unit, comparable with the course syllabi offered by the Philippine Nuclear Research Institute;
- c. Has had relevant clinical training and experience in the use of a sealed source in a teletherapy unit under the supervision of an authorized user in a program conducted by a medical institution; and
- d. Has received appropriate certification as described in Section 55 of this part.

SECTION 52. Training For Teletherapy Physicist — The licensee shall require the teletherapy physicist to be an individual who:

- a. Has formal training in radiological physics, radiation, dosimetry, radiation protection, treatment planning as well as practical experience in radio therapy applications; and
- b. Has completed one year of full time work experience under the supervision of a teletherapy physicist in a reputable medical institution.

SECTION 53. Training for RHSO — The licensee shall require an individual fulfilling the responsibilities of the RHSO as provided in Section 12 to be an individual who has had classroom and laboratory training and experience as follows:

a. 200 hours of classroom and laboratory training that includes:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Radiation biology; and
- Nuclear regulation and licensing; and

b. One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the RHSO in an Institute license that authorizes the medical use of sealed sources in a teletherapy unit.

SECTION 54. Training for Authorized Technologist — The licensee shall require the authorized technologist to be an individual who:

- a. Holds a Bachelor of Science Degree in Radiologic Technology, Medical Technology or related discipline and is duly licensed by the Philippine Professional Regulations Commission;
- b. Has had at least one year training and experience in the operation of a teletherapy unit under the supervision of an authorized technologist/user; and
- c. Has had classroom training on radiation safety, radiation detection and radiological emergency procedures.

SECTION 55. Certification — The licensee shall require the authorized user of sealed sources for teletherapy to be a physician who:

- a. Is certified by the Philippine College of Radiology in the practice of therapeutic radiology, radiation oncology, or similar disciplines; or
- b. Is certified by a competent authority in a foreign country where his or her training and experience were acquired in the practice of therapeutic radiology, radiation oncology, or similar disciplines.

V

Records, Reports and Notifications

SECTION 61. Records, Reports and Incident Reporting — The licensee shall keep records and make reports and notifications of incident to the Institute in accordance with the applicable Sections of Parts 2, 3 and 4 of the CPR.

SECTION 62. Notification on Specific Changes in the License —

- a. The licensee shall notify the Institute immediately by telephone or by similarly fast means of communications and by letter within thirty days:
 - When an authorized user or Radiological Health and Safety Officer permanently discontinues performance of duties under the license or has a name change, or
 - When the licensee's mailing address changes.
- b. The licensee shall mail the resort to:

The Director Philippine Nuclear Research Institute Don Mariano Marcos Avenue Diliman, Quezon City and marked "Attention: Head, Licensing, Review and Evaluation".

VI

Exemptions and Additional Requirements

SECTION 71. Specific Exemptions — The Institute may, upon application by the licensee or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property and are otherwise in the public interest.

SECTION 72. Additional Requirements — The Institute may, by rule, order, or regulation impose upon any licensee such requirements, in addition to those established in these regulations, as it deems appropriate or necessary to protect the health and safety of the public or to minimize danger to life or property.

VII

Enforcement

SECTION 81. Violations —

- a. A notice of violation shall be issued to any person found to have violated any rule, regulation, or order issued thereunder, or any term, condition, or limitation of any license issued thereunder.
- b. Any license may be modified, suspended, or revoked, after due process, for any violation which the Institute determines to adversely affect the health and safety of the workers and the public.
- c. Any person who willfully violates, attempts to violate, or conspires to violate any rule or regulation or order issued hereunder, may be guilty of a crime, and upon conviction, may be punished by a fine or imprisonment or both as provided by Sections 64 and 65 of Republic Act No. 5207 and Section 25 of Republic Act No. 2067, as amended.

VIII

Effectivity

SECTION 91. 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. However, licenses in effect on that date shall remain valid until the expiration date given on that license. Applications for amendments and renewals of existing licenses and applications for new licenses received after that date will be considered under these regulations.

Adopted: Oct. 1994

Date Filed: 9 November 1994

(SGD.) CARLITO R. ALETA

Director

[*] The "Code of PAEC Regulations" established by PAEC Administrative Order No. 1, Series of 1981, consists of all rules and regulations promulgated or to be promulgated by the Philippine Atomic Energy Commission implementing the various provisions of Section 16-a of RA 2067, as amended and RA 5207, as amended. The Philippine Atomic Energy Commission was reorganized and renamed Philippine Nuclear Research Institute by virtue of Executive Order No. 128, issued in 1987.

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