

**[ PNRI, November 09, 1994 ]**

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

**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:
  - 1. Consistent with the purpose for which the licensed activity is undertaken,
  - 2. 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
  - 3. 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:
1. At a medical institution, the management, the RHSO, and all authorized users must participate Isotopes Committee (MIC) and approved by the Institute.
  2. 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:
1. 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;
  2. 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.
- 3. Brief Management once each year on the radioactive material program;
  - 4. Establish preliminary personnel exposure investigational levels that, when exceeded, will initiate an investigation by the RHSO of the cause of the exposure;
  - 5. 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
  - 6. 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:
  - 1. 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.
  - 2. 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:
  - 1. Review recommendations on ways to maintain individual and collective doses ALARA;
  - 2. 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