REGULATORY GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR MEDICAL USE OF RADIOACTIVE SOURCES IN TELETHERAPY

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REGULATORY GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR MEDICAL USE OF RADIOACTIVE SOURCES IN TELETHERAPY

1. INTRODUCTION

1.1 Purpose of Guide

The purpose of this regulatory guide is to assist an applicant in the preparation of an application for a license for the medical use of radioactive sources in teletherapy unit and Gamma Stereotactic Radiosurgery (GSR) unit pursuant to CPR Part 12. This guide discusses the relevant specific regulatory requirements and provisions that must be addressed by the applicant. If the applicant cannot provide the information as specifically suggested in this guide, he may submit an alternate method to comply with the regulatory requirements subject to the approval of the PNRI.

This guide also describes the information that must be submitted to PNRI to facilitate the evaluation of the application. Additional information may be required by PNRI to ensure that the applicant complies with the requirements of CPR Part 12. The appendices to this guide present model procedures and regulatory guidance which the applicant may adopt in response to an item in the application form.

1.2 Applicable Regulations.

a. CPR Part 3, “Standards for Protection Against Radiation"
b. CPR Part 4, “Safe Transport of Radioactive Materials in the Philippines"
c. CPR Part 12, “Licenses for the Medical Use of Sealed Radioactive Sources in Teletherapy”

2. FILING AN APPLICATION

An application for a new license must be filed in duplicate in **PNRI/NRD Form-012, "Application for a License for Medical Use of Radioactive Sources in Teletherapy"**. The application must include all information that are necessary to support the intended purpose of the application. Completeness of submitted information will be determined by the PNRI reviewer before the application is docketed.

The **PNRI/NRD Form-012**, together with this guide, can also be used for an application for license amendment and renewal, especially when major and significant changes from the original application will be made. The corresponding application fee must be remitted upon submission of the application.

3. CONTENTS OF APPLICATION

Item 1 - Name and Mailing Address of Applicant.

The applicant may be an institution, hospital, firm or a government agency. The name of the individual who has the authority and responsibility in the organization over the proposed activity should be signified in the application, indicating his title or position in the institution. The applicant may designate in writing another person to represent the organization in conferring with PNRI about

the application. The address specified here should be the mailing address for correspondence. This may or may not be the same as the address where licensed material is located and will be used. The telephone number, mobile phone number, facsimile number, and/or e-mail address of the applicant should be provided for easy and fast means of communication. The applicant should demonstrate or provide evidence of authenticity of business name issued by the Securities and Exchange Commission and a copy of business permit issued by the responsible government agency.

Item 2 - Person to be Contacted About the Application.

The applicant should designate an individual who can answer questions about the application. The individual's name, position or title, address, telephone and mobile phone numbers, fax number, and/or e-mail address should be specified. This person is typically the proposed Radiation Protection Officer (RPO), unless the applicant has named a different person as the contact.

Item 3 - Radioactive Material and Purpose of Use.

Regulations: Section 7 (b) of CPR Part 12.

Criteria:

The regulations require that an applicant must use radioactive material for the purpose stated in Section 7(b) of CPR Part 12. The radioactive material to be used as a sealed source must be of a type, form and quantity which has been approved for the intended purpose by the PNRI or by a licensing authority of the country of origin of the source.

Discussion: The applicant must indicate the specific teletherapy sealed source radionuclide, the chemical/physical form (i.e., sealed source or unit (device) identified by manufacturer and model number), the total amount in Becquerels (Bq), and maximum number of sources or activity possessed at any one time. The applicant should correlate the radioactive source(s) with the unit to be used. The amount and type of information necessary will vary according to the type of use.

An applicant may request a possession limit adequate to allow for the possession of a spare source, to accommodate the total quantity of material in the licensee’s possession during replacement of the source in the teletherapy or gamma stereotactic radiosurgery (GSR) unit. The maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer. However, an applicant may request a maximum activity for the source in the shipping container that exceeds the maximum activity allowed in the teletherapy unit provided that he presents a certification that the source transport container is approved for the requested activity.

Response from Applicant:

The applicant should submit a list of all radioactive sources and other radioactive materials to be used in his licensed activity, including check, calibration and reference sources. Information on each of the sealed sources should include the**:** isotope (element and mass number), manufacturer of the source, date of manufacture, date of purchase, model and serial number of the source, number of sealed sources, maximum activity (Bq) in each source, and the purpose of use (i.e., for teletherapy or GSR).

Item 4 - Location(s) of Use.

Regulations: Section 7 (b) of CPR Part 12.

Criteria:

Locations at which the radioactive source will be used and stored must be found acceptable by PNRI for the radioactive source requested in the application. The licensee shall confine its possession and use of radioactive source to the locations authorized in the license.

Discussion:

The licensee should specify the street address, city, or other descriptive address (e.g., on South Expressway, 1 kilometer east of the intersection of South Expressway and Bicutan) for each facility. The descriptive address should be sufficient to allow a PNRI inspector to easily find the facility location. A post office box address is not acceptable. If the radioactive material is to be used at more than one location under the license, the specific address (e.g., street, building, and department) must be provided for each facility. The PNRI must be notified before any changes in the address identified in the license.

Response from Applicant:

The applicant should describe the actual location(s) of use of the radioactive source, specifying the name of department, room number, building, street address, or other descriptive address, telephone number, fax number, if different from Item 1. A location map or building plan should be included.

Item 5 - Proposed Workers.

Regulations: Sections 7(d) and (e), 44 to 47 of CPR Part 12.

Criteria:

The applicant and/or proposed users must be qualified by training and experience to use the radioactive source for the purpose requested in such a manner as to protect health and minimize danger to life and property.

Discussion:

The individuals who will be listed as authorized users, medical physicist, RPO, ARPO, and radiotherapy technologists in the license must be recommended by the Radiation Safety Committee (RSC). Their qualifications must be reviewed by the RSC based on the requirements specified in Sections 44 to 47 of CPR Part 12.

Response from Applicant:

The applicant should list the name, position/title in the institution, telephone/cellphone number, and names of other affiliated institutions of the persons listed below who will use or supervise the use of radioactive source:

Authorized Users (Physicians)
Medical physicist
Radiation Protection Officer (RPO)
Assistant Radiation Protection Officer
Radiotherapy technologists

The applicant should have Attachments A, B, C, and D accomplished by concerned staff, as appropriate, and submitted together with the Application Form. Certificates of documentary evidence of each individual's qualification, relevant training and experience should also be submitted.

Item 6 - Representation in the Radiation Safety Committee.

Regulations: Section 18 (a)(1) of CPR Part 12.

Criteria:

Each medical institution must establish a Radiation Safety Committee represented by at least 5 members to oversee the use of radioactive material in the whole institution.

Discussion:

The applicant must be represented by at least 5 members in the Radiation Safety Committee (RSC) established in the medical institution where the teletherapy facility is located or affiliated. The RSC must consist of the following members: an authorized user (physician) and the RPO 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 RPO. Other members may be included as the licensee deems appropriate.

Response from Applicant:

The applicant should list the names of the representatives to the RSC. Information must be given of their position or title in the institution, educational degree, address in the institution (department, building, room number), and telephone number.

Item 7 - Facilities.

Regulations: Section 7(c) of CPR Part 12.

Criteria: Facilities must be adequate to ensure the safety and security of the radioactive sources and to protect health and safety of workers, patients, and the public and minimize danger to life or property.

Discussion:

The facility should be equipped with adequate shielding. If the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation, it may be necessary to restrict use of the teletherapy unit's primary beam. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit (e.g., electrical or mechanical stops). The overall plan and design of the facility must ensure that radiation levels can be maintained within regulatory limits and that licensed materials will be secured against theft or unauthorized removal.

Response from Applicant:

The applicant should describe the proposed facilities and provide the following on the facility diagrams:

(a) Drawings, which should be to scale and indicating the scale used;
(b) Location, room numbers, and principal use of each room or area where radioactive source is used or stored;
(c) Location, room numbers, and principal use of each adjacent room (e.g., office, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms;
(d) Calculations of the maximum radiation levels expected in each adjacent area; and
(e) Shielding provisions, including information about the type, thickness, and density of any necessary shielding, including a description of any portable shields to be used.

The applicant must provide a description of the layout of the facility and its safety systems, including the materials of construction of the wall and the shielding to be installed. He must describe:

(a) the **viewing and intercom system**. If a shielded viewing window will be used, the thickness, density, and type of material to be used should be specified. If a close circuit television system (or other electronic system) will be used for viewing the patient, the

back-up system that will be used in case the electronic system malfunctions should be specified; and

(b) the **warning systems** (e.g., locks, signs, warning lights and alarms, interlock systems) for the treatment room and methods for controlling occupancy for each restricted area.

Item 8. Equipment/Instruments/Devices.

8.1 Equipment: Teletherapy or GSR Unit

Regulations: Section 7 (c), (g), and (n) of CPR Part 12.

Criteria:

The applicant's proposed equipment must be adequate for the purpose requested to protect health and safety of workers, patients, and the public and minimize danger to life or property. The technical specifications for the equipment must conform with relevant international standards or its equivalent national standards

Discussion:

The applicant should ensure that the equipment conforms to applicable standards of the International Electrotechnical Commission (IEC) or to equivalent national standards. The equipment should be verified to have been leak tested within the past six months.

Response from Applicant:

The applicant should:

(a) Specify the type of equipment to be used, the manufacturer of the equipment, date of manufacture, model and serial number, and date of purchase;
(b) Indicate the power output of the equipment;
(c) Describe the equipment features, including the alarms and electrical interlocks;
(d) Submit certificate of conformance of all performance specifications and tests with standards of the IEC;
(e) Submit proof of accreditation of the company that will install the teletherapy unit, as well as the qualifications of the individuals who will install the equipment; and
(f) Specify the institution who will provide repair and maintenance service on the equipment.

8.2 Radiation Detection/Measurement Survey Instruments.

Regulations: Section 7(i) of CPR Part 12.

Criteria:

The applicant must possess a sufficiently calibrated and operable portable radiation survey instrument capable of measuring dose rates over the range or 2 μSv to 10 mSv per hour.

Discussion:

The licensee should possess survey instrument(s) sufficiently sensitive to measure the type and energy of radiation used. The radiation survey instruments should be calibrated or caused to be calibrated for the radiation measured. They are considered calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent.

Response from Applicant:

The applicant should specify the type of radiation survey instruments to be used, brand, model and serial numbers, type of radiation that can be detected or measured, sensitivity range,

window thickness, intended use, i.e., for monitoring or measurement of radiation level, and date of initial use.

8.3 Personnel Monitoring Devices.

Regulations: Section 21 of CPR Part 12; Section 29 of CPR Part 3.

Criteria:

Each licensee must ensure that his personnel are provided with suitable and adequate personnel monitoring devices.

Discussion:

The licensee should provide occupational workers working in controlled areas with suitable and adequate personnel monitoring devices (e.g., pen dosimeters, TLD, film badges). The pocket dosimeters should be operable, calibrated, and tested for drift at intervals not to exceed 1 year. Record of calibration must be maintained for two years. Film badges should be worn so that the part of the body likely to receive the greatest dose will be monitored. These badges should be sent to PNRI at intervals not to exceed 1 month and the TLDs every 3 months for processing.

Response from Applicant:

The applicant should indicate the type of personnel monitoring devices (i.e., film badge, TLD, pen dosimeter) that will be provided to workers and the number of units of each device to be provided.

Item 9. Radiation Safety Program.

9.1 Radiation Protection Program and As Low As Reasonably Achievable (ALARA) Program.

Regulations: Sections 7(j) and 16 of CPR Part 12.

Criteria:

Section 16 of CPR Part 12 states that each licensee must develop and implement a written radiation protection program that includes provisions for keeping doses ALARA. Section 18 (b) of CPR 12 provides that the RSC must review recommendations on ways to maintain individual and collective doses ALARA

Discussion:

Applicants should develop and implement a radiation protection program that includes provisions of Section 14 of CPR Part 3. It is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly.

License applicants should develop and implement an ALARA program that, as a minimum, must:

(a) Describe its organization;
(b) Contain management's formal commitment to the ALARA philosophy, recognizing the importance of keeping individual and collective doses ALARA;
(c) Specify the duties of various persons (e.g., authorized users, Radiological Health and Protection Officer (RPO), technologists, licensee management) within the licensee's organization as they apply to ALARA;
(d) Provide continuing education and training for all personnel who work with, or in the vicinity of, radioactive material;
(e) Establish Investigational Levels (IL) and identify what should be done if radiation exposure exceeds the IL; and

(f) Include a formal annual review by management and the RPO of the ALARA program and review of the doses received by workers.

The radiation safety program must be reviewed annually by the RSC with the assistance of the RPO as required by Section 18(b)(5) of CPR 12. The licensee must apply for and must receive a license amendment before it implements any major change in the approved radiation safety program as required in Section 9(b)(7) of CPR Part 12.

Appendix A shows a model ALARA program.

Response from Applicant:

The applicant should establish a written radiation safety program which includes a radiation protection program and an ALARA program which takes into account the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures.

9.2 Radiation Safety Committee (RSC) Duties and Responsibilities.

Regulations: Section 18 of CPR Part 12.

Criteria:

Section 18 of CPR Part 12 states that the licensee shall establish a RSC to oversee the medical use of radioactive sources.

Discussion:

Section 18(b) of CPR Part 12 states that to oversee the medical use of radioactive material in a medical institution, the RSC must (a) review recommendations to maintain individual and collective doses ALARA; (b) review and recommend the individuals who will be listed as authorized user, RPO, medical physicist, and radiotherapy technologists in the license; (c) review quarterly, with the assistance of the RPO: (1) a summary of the occupational radiation dose exposure records of all workers in the radiation facility and records of radiation level surveys and (2) all incidents involving radioactive source with respect to cause and actions taken; and (d) review annually, with the assistance of the RPO, the radiation safety program.

Appendix B further identifies the duties and responsibilities of the RSC.

Response from Applicant:

The licensee shall designate members of the RSC and may state so in the application if the RSC is already existing in the licensed institution arising from another licensed activity (e.g., nuclear medicine or brachytherapy).

9.3 Radiation Protection Officer (RPO) Authorities, Duties, and Responsibilities.

Regulations: Section 7 and 17 of CPR Part 12.

Criteria:

Section 7(e) and (f) of CPR Part 12 states that the applicant must designate a qualified RPO and ARPO who shall be responsible for implementing the radiation safety program. The applicant must establish and state in writing the authorities, duties and responsibilities of the RPO on matters affecting radiation safety. .

Discussion:

The RPO is responsible for day-to-day oversight of the radiation safety program. In accordance with Section 17 of CPR Part 12, the licensee must provide the RPO sufficient authority, organizational freedom, time and resources to perform his or her duties. Additionally, the

RPO must have sufficient commitment from management to fulfill his duties and responsibilities in ensuring that radiation safety activities are being performed in accordance with regulatory requirements and approved procedures.

Appendix C contains a model RPO Delegation of Authority.

Response from Applicant:

The applicant must submit to the PNRI a written acceptance by the RPO of its responsibility in ensuring that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the course of the daily operation of the radiation facility. The applicant must submit to the PNRI a description of the authorities, duties, responsibilities, and radiation safety activities of the RPO.

9.4 Training Program.

Regulations: Sections 44 to 48 of CPR Part 12

Criteria:

The applicant must develop an adequate training program for all workers. Training and experience requirements for authorized users, medical physicists, RPO, and radiotherapy technologists must be in accordance with Sections 44 to 48 of CPR Part 12, as appropriate.

The licensee shall ensure that workers are provided with appropriate training in protection and safety, as well as periodic retraining as required in Section 48 of CPR Part 12 in order to ensure the necessary level of competence.

Discussion:

A training program that provides necessary instructions must be written and implemented. All training activities must be tailored to meet the needs of the individuals in attendance. Topics of the training should depend on the purpose of the training, the audience, and the state of learning (background knowledge) of the audience. Strong management support is considered essential to an adequate training program

Personnel must receive during annual refresher training, instructions before assuming duties with, or in the vicinity of, radioactive materials and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Refresher training should include topics with which the individual is not involved frequently and requires reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Records of worker training should be maintained for at least 3 years. The training records should include the date of the instruction or training, name of instructor, scope of instruction provided and name/signature of each participant.

Appendix D shows a model training program.

Response from Applicant:

The applicant must submit to PNRI a training program for its personnel.

9.5 Personnel Monitoring Program.

Regulations: Section 29 of CPR Part 3; Section 21 of CPR Part 12

Criteria:

Each licensee shall ensure that his workers are provided with suitable and adequate personnel monitoring devices. Section 29 of CPR Part 3 requires that the licensee shall be

responsible for arranging for the assessment of the occupational exposure of workers, on the basis of individual monitoring.

Discussion:

The licensee shall establish a personnel monitoring program that requires personnel who enter a controlled area to wear adequate personnel monitoring devices (e.g., film badge, pocket dosimeter, or thermoluminescent dosimeter (TLD), alarm rate meter). Individual monitoring shall not be required for individuals regularly employed in a supervised area or who enters a controlled area only occasionally. The nature, frequency and precision of individual monitoring will be determined with consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures.

Appendix E shows a model personnel monitoring program.

Response from Applicant:

The applicant should submit a copy of the personnel monitoring program to the PNRI. The program must cover assessment of individual radiation doses, description of the responsibilities of each individual responsible for monitoring workers exposed to radiation, and description of the monitoring methods.

9.6 Calibration.

9.6.1 Calibration of Survey Instruments

Regulations: Section 33 of CPR Part 12.

Criteria:

The licensee must maintain sufficiently calibrated and operable radiation survey instruments. The licensee shall calibrate or cause the calibration of its survey instruments before first use, annually and following any repair in accordance with Section 33 of CPR Part 12.

Discussion:

Survey meter calibration must be performed by persons who are qualified to perform calibrations. An applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration. When calibrating a survey instrument, a point is considered calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent.

Appendix F shows a model procedure for calibrating survey instruments.

Response from Applicant:

If instrument calibration will be performed by an organization other than the applicant, the applicant should submit a description of the radioactive sources and the procedures used by the organization for calibrating survey instruments. The application must include the name, address and license number of the organization who will do the calibration.

If an applicant wishes to calibrate its survey instruments, he should do so in-house and submit the following information:

(a) Type (radioisotope, manufacturer, model number and serial number) of the source to be used for calibration;
(b) Activity of the source;
(c) Specific procedures to be used for calibration, including radiation safety procedures to be followed; and
(d) Name and pertinent experience of the individual who will perform instrument calibration.

9.6.2 Calibration of Teletherapy Unit/Sources

Regulations: Section 37.3 of CPR Part 3; Sections 26 and 27 of CPR Part 12.

Criteria:

CPR Parts 3 and 12 require that each licensee shall ensure that:

(a) The calibration of sources used for medical exposure be traceable to a Standards Dosimetry Laboratory;

(b) Radiotherapy equipment must be calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions and in accordance with the conditions of the license; and

(c) Full calibration measurements on each teletherapy/GSR unit are carried out by the Medical Physicist before the first medical use, following repair or after any maintenance procedure that may have an effect on the dosimetry, following replacement of the sources, and at intervals not to exceed one year.

Discussion:

Section 27 of CPR Part 12 requires that full calibration of radiation sources, including radioactive material, equipment and accessories, must be performed before first medical use, whenever spot-check measurements (if required) indicate that the output differs by more than 3% from the output obtained at the last full calibration corrected mathematically for decay, following replacement of the sources or reinstallation of the unit in a new location, following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly, and at intervals not exceeding one year. The calibration must have been performed using a dosimetry system calibrated within the previous two years by an accredited calibration laboratory. The licensee shall retain records of each calibration for the duration of the use of the teletherapy/GSR source.

Response from Applicant:

The applicant must submit a procedure for the calibration of its teletherapy/GSR unit and sources.

9.7 Leak Test Program.

Regulations: Section 34 of CPR Part 12.

Criteria:

The licensee in possession of any sealed source or device containing more than 3.7 Bq of beta or gamma emitters shall test the source or cause the source to be tested for leakage before its first use and at intervals not to exceed **six months** or at such other intervals as are specified on the label or in the leaflet or brochure that accompanies the source or device, or as approved by the PNRI.

Discussion:

Licensees must perform leak testing of sealed sources, e.g., calibration, transmission, reference, or teletherapy sources in accordance with Section 34 of CPR Part 12. Each sealed source is supplied by distributors with a certificate which indicates the results and date of the last leak test performed on the source. Without a certificate, the source may not be used until a leak test has been performed and the results of the test have been received showing that the source is not leaking or contaminated. Thereafter, the source must be tested for leakage and contamination

at intervals not to exceed **six months**, or as may be determined by PNRI. Sources that are stored and not being used need not be leak-tested. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak-tested within 6 months before the date of use or transfer.

Records of leak tests must be retained for the duration of use of the source. The records must contain the identity of each source radionuclide and its estimated activity, the manufacturer, model number and serial number of each source tested, the measured activity of each test sample, a description of the method used to measure each test sample, the date of the test and the name of the person who performed the test.

A description of a leak test program for sealed sources is given in **Appendix G**.

Response from Applicant:
The applicant must submit a proposed leak test program.

9.8 Radiation Surveys.

Regulations: Sections 20 of CPR Part 3; Section 29 of CPR Part 12.

Criteria:
The licensee shall perform radiation surveys before mechanical use, after each installation of a teletherapy source, or after making any major change in teletherapy unit, treatment room shielding, location of the unit or any change that could result in increased radiation levels in areas outside the teletherapy treatment room. Section 20 of CPR Part 3 requires that the licensee shall ensure that surveys are made to evaluate: a) the magnitude and extent of radiation levels; b) the activities of radioactive material; and c) the potential radiological hazards. For licensed radioactive material that is not in storage in a controlled area, the licensee shall control and maintain constant surveillance as required in Section 20 of CPR Part 3.

Discussion:

Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess radiological conditions.

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect workers and the public from external and internal exposure. Also the frequency of the survey depends on the type of survey. Licensees should perform surveys after the patient's release and prior to the release of the room for unrestricted use. Licensees should be cognizant of the requirement to perform surveys to demonstrate that the public dose limits are not exceeded.

Record of radiation measurements should be retained for two years. It must include the date of the survey, a plan of each area that was surveyed, the measured dose rate (mSv/hr) at several points in each area, the survey instrument used, and the signature of the individuals who made the survey.

Guidance for radiation surveys is shown in **Appendix H**.

Response from Applicant:
No response is necessary.

9.9 Operating Procedures.

Regulations: Sections 23, 24, 26 to 29 of CPR Part 12.

Criteria:

Written operating procedures must be developed, implemented and maintained.

Discussion:

Operating procedures must be developed, implemented and maintained to ensure proper and safe use of teletherapy/GSR sources and teletherapy/GSR unit. The procedures should provide reasonable assurance that only appropriately trained personnel will handle and use the teletherapy sources and unit. Start-up checks of the teletherapy unit shall be performed prior to operation following a normal shutdown and machine function checks shall be performed periodically.

Teletherapy units should be provided with safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel. The design of safety interlocks should be such that operation of the installation during maintenance procedures, if interlocks are bypassed, could be performed only under direct control of the maintenance personnel using appropriate devices, codes or keys. Repair and preventive maintenance work on the teletherapy unit shall be performed only by individuals who are specifically qualified or authorized by the PNRI.

The written operating procedures must be made available to all users by maintaining a current copy of the procedures at each location of use or, if not practicable, posting a notice describing the procedures and the location of procedure storage.

The procedures should address the following:

(a) Radiation safety in handling teletherapy sources;
(b) Inspection, maintenance and repair of teletherapy unit;
(c) Full calibration measurements on each teletherapy/GSR unit;
(d) Periodic spot checks of teletherapy/GSR units, sources, and treatment facilities;
(e) Conduct of area radiation level surveys;
(f) Calibration of survey instruments;
(g) Radioactive waste management; and
(h) Recordkeeping.

A model operating procedure is shown in **Appendix I**.

Response from Applicant:

Submit a written operating procedure that conforms with the above mentioned description.

9.10 Safety and Security of Sealed Sources.

Regulations: Section 16 of CPR Part 3; Section 43 of CPR Part 12

Criteria:

Each licensee shall ensure the safety and security of the sources in his/her possession. He shall establish clear lines of responsibility for protection and safety of the sources. The licensee shall control access to the teletherapy room. The licensee shall secure the radiation sources from unauthorized access.

Discussion:

Licensees must provide adequate physical protection of materials and facilities on site and during transportation of radiation sources. Physical protection of radiation sources involve instrumentation systems, administrative procedures and structures installed to provide adequate monitoring, surveillance and control measures to ensure unauthorized removal of radiation sources from its authorized location. Access by members of the public to areas in and nearby the teletherapy department shall be considered when designing and shielding storage and use locations. This shall include access by other members of the hospital staff, including housekeeping, maintenance, porters and medical staff who may have legitimate reasons to be in the department.

Teletherapy units should be provided with safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel. The design of safety interlocks should be such that operation of the installation during maintenance procedures, if interlocks are bypassed, could be performed only under direct control of the maintenance personnel using appropriate devices, codes or keys.

Radiation sources may be secured by maintaining a system of accountability which can be done by conducting physical inventories, controlling receipt and disposal of radiation sources, and maintaining records of receipt, transfer, and disposal of radiation sources.

Appendix J gives information on ensuring the safety and security of radiation sources.

Response from Applicant:

The applicant must:

(a) Submit procedures for the safety and security of their radiation sources;
(b) Register every sealed source and teletherapy unit with the PNRI Sealed Source Registry. A copy of the Registry Certificate should be available for regulatory inspection; and
(c) Propose adequate security measures to prevent loss or theft of radioactive material.

9.11 Emergency Procedures.

Regulations: Section 59 of CPR Part 3; Section 35 of CPR Part 12.

Criteria:

The licensee shall post at convenient visible location in the licensed facility copies of written operating and emergency procedures and local rules as required in Section 35 of CPR Part 12. The emergency procedures must be designed to mitigate or control the consequences of an incident and to minimize radiation exposure of workers and the general public.

Discussion:

Emergency procedures that address the following spectrum of incidents should be developed, implemented, and maintained:

(a) leaking or damaged source;
(b) unit malfunction and/or damage; and
(c) operator is unable to turn the primary beam of radiation off with controls outside the treatment room.

The emergency procedures should:

(a) Specify when they are to be implemented;
(b) Describe step-by-step actions that are to be taken and by whom;
(c) Describe the emergency equipment and protective clothing to be used;
(d) Provide instructions to the staff to avoid overexposure to radiation;
(e) Require that the radiation area/room be secured (i.e., door locked, guard posted) and an appropriate sign posted to alert others to the problem; and

(f) Specify the names and on-duty and off-duty telephone numbers of the authorized users and RPO who should be notified.

Appendix K shows a model emergency procedure for teletherapy.

Response from Applicant:
The applicant should submit proposed procedures to be followed in case of occurrence of a radiological and non-radiological incident.

9.12 Decommissioning Plan.

Regulations: Section 7(o) of CPR Part 12; Section 42 of CPR Part 12.

Criteria:
Section 7(o) of CPR Part 12 requires that the applicant must establish a decommissioning plan for the facility. The decommissioning plan must address the provisions in Section 42(b) of CPR Part 12.

Discussion:
The licensee shall immediately notify PNRI, in writing, and request for the termination of the license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. Licensee shall satisfactorily decommission his facilities before the license can be terminated. A decommissioning plan should address the following:

(a) Availability of adequate financial resources to cover the anticipated costs of decommissioning, including an allowance for contingencies;
(b) Description of the planned decommissioning activities;
(c) Description of the radiation protection measures to assure protection of workers and the environment from the hazards of radiation during decommissioning;
(d) Description of decontamination methods and planned final radiation surveys to ensure that the facility is safe for unrestricted use after decommissioning;
(e) Program for the disposition of the radioactive sources after decommissioning; and
(f) Documentation and record keeping.

Appendix L provides guidance on how to perform the decommissioning of a teletherapy facility.

Response from Applicant:
The applicant must submit to the PNRI a decommissioning plan.

Item 10. Security of Sealed Radioactive Sources.

Regulations: Section 43 of CPR Part 12

Criteria:
Each licensee shall ensure the security of sources in his/her possession. The licensee shall control access to the teletherapy room. The licensee shall secure radioactive sources from unauthorized removal.

Discussion:
Licensees must provide adequate physical protection of materials and facilities on site and during transportation of radioactive sources. Physical protection of radioactive sources involve instrumentation systems, administrative procedures and structures installed to provide adequate monitoring, surveillance and control measures to prevent unauthorized removal of radioactive

sources from its authorized location. Access by members of the public to areas in and nearby the teletherapy department shall be considered when designing and shielding storage and use locations. This shall include access by other members of the hospital staff, including housekeeping, maintenance, porters and medical staff who may have legitimate reasons to be in the department.

Radioactive sources may be secured by maintaining a system of accountability which can be done by conducting physical inventories, controlling receipt and disposal, and maintaining records of receipt, transfer, and disposal of radioactive sources.

Appendix J gives information on ensuring the security of radioactive sources.

Response from Applicant:
The applicant must submit a security plan in accordance with CPR Part 26.

Item 11. Management of Disused Sealed Radioactive Sources.

Regulations: Sections 39, 40 and 41 of CPR Part 12.

Criteria:
A program should be established for the disposal of disused sealed radioactive sources.

The licensee shall be responsible for the disposition of all licensed sealed sources listed in his license. Disused sealed sources must be disposed of in accordance with Sections 39 to 41 of CPR Part 12.

Discussion:
The program should describe the method of disposal of disused sealed sources by considering the following management options:

(a) Transfer to another licensee (Section 40 of CPR Part 12):
  (1) Notify PNRI of any intention to transfer or decommission the teletherapy equipment prior to initiating any action;
  (2) Submit to the PNRI a Certificate of Transport and secure an **Authority to Transport**; and
  (3) Transfer the radioactive source in accordance with the requirements of CPR Part 4; or

(b) Return to the original supplier or manufacturer (Section 41 of CPR Part 12):
  (1) In the purchase contract, make an arrangement with the supplier for the return of the source after its useful lifetime;
  (2) Submit a copy of the contract to the PNRI;
  (3) Pack and ship the disused sealed sources in the original shipping container. If the original container is not available, provisions should be made to acquire a new container, the design and specifications of the package of which have been approved by the PNRI;
  (4) Submit to the PNRI a Certificate of Transport and secure an **Authority to Transport**. If the sources are to be shipped outside the Philippines, secure, in addition, a **Shipment Approval Certificate**; and
  (5) Transport the sources in accordance with the requirements of CPR Part 4.

For disposal of disused sealed sources, the licensee shall submit information that includes his name, address and license number; isotope (element and mass number), type, form, and activity of the sources to be transferred; and the name, address and license number of the person to whom the sources will be transferred.

Guidance for the management of disused sealed sources is given in **Appendix M**.

Response from Applicant:

The applicant should submit to the PNRI a program for the management of disused sealed sources and radioactive waste. The applicant must make an arrangement with the supplier for the return of the source after its useful lifetime and submit to PNRI a copy of the contract.

Item 12. Application/License Fees.

The applicant should refer to **CPR Part 22**, "Fees and Charges for Radioactive Material Licenses and Other Related Regulatory Fees", to determine the amount of application or license fee to be paid. The application fee must be paid upon submission of the application. For an initial license, the license fee may be paid upon notification of approval of the license or upon issuance and release of the license. For amendments to a license, the licensee shall not implement any amendment until he has received a written approval from PNRI and after payment of the amendment fee. For a license renewal, the required license fee must likewise accompany an application for renewal of a license. The applicant must indicate the amount of application fee or license fee paid, the official receipt numbers and date the fees were paid.

In addition, licensees are required to pay the inspection fee and other applicable fees (e.g., storage license fee, surcharge fee, release certificate fee, authority to transport fee).

Item 13. Certification.

The application must be certified and signed by an authorized representative of the institution who must be an officer of the institution, usually a Director, President, Chief Executive Officer or Vice President. Certification is made that the application contains information that is true and correct to the best of their knowledge and belief. Unsigned applications will not be processed and will be returned to the applicant. All new applications must be notarized.

Item 14. Acknowledgement.

All new applications must be notarized.

4. AMENDMENTS AND RENEWALS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information in the original application is to be modified or changed, the licensee must submit an application for a license amendment, in accordance with **Sections 9 of CPR Part 12**, before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date.

Applications for license amendment, in addition to the following, must provide the appropriate fee. For renewal and amendment requests applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request.
- Submit duplicate copies of the Application Form **PNRI/NRD-012A** or a letter requesting amendment or renewal.
- Provide the license number.
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, PNRI's guidance, the licensee's organization, or radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

5. TERMINATION OF LICENSE

Regulations: Section 13 of CPR Part 12.

Criteria: The licensee must do the following:

(a) Notify PNRI, in writing, within 30 days of:
  (1) the expiration of its license;
  (2) a decision to permanently cease licensed activities at the entire site (regardless of contamination levels);
  (3) a decision to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to PNRI requirements;
  (4) no principal activities having been conducted at the entire site under the license for a period of 24 months; and
  (5) no principal activities having not been conducted for a period of 24 months in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to PNRI requirements;

(b) Submit decommissioning plan;
(c) Conduct decommissioning, as required by **Section 42 of CPR Part 12**;
(d) Submit to PNRI information and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey); and
(e) Before a license is terminated, send the records important to decommissioning to PNRI.

Discussion:

A licensee who decides to cease licensed activities must, before informing PNRI, determine whether residual radioactivity is present at the facility and whether the levels make the building or outdoor area unsuitable for release according to PNRI requirements. A licensee's determination that a facility is not contaminated is subject to verification by PNRI inspection.

For guidance on the disposition of licensed material, refer to **Sections 39 to 41** of CPR Part 12 and for decommissioning requirements, refer to **Section 42** of CPR Part 12.

Response from Applicant:

The licensee is not required to submit a response to the PNRI during the initial application. However, when the license expires or at the time the licensee ceases operations, then any necessary decommissioning activities must be undertaken, information relevant to decommissioning must be submitted to PNRI, and other actions must be taken as summarized in the Criteria.

APPENDIX A

MODEL ALARA PROGRAM

A. Management Commitment

1. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution.

2. We will perform a formal annual review of the radiation safety program, includingALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

3. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing the changes.

4. In addition to maintaining doses to individuals as far as below the limits as reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

B. Radiation Safety Committee (RSC) Commitment

1. Review of Proposed Users and Uses
   a. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of radioactive materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
   b. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

2. Delegation of Authority
   a. The RSC will delegate authority to the RPO for enforcement of the ALARA concept.
   b. The RSC will support the RPO when it is necessary for the RPO to assert authority. If the RSC has overruled the RPO, it will record the basis for its action in the minutes of the quarterly meeting.

3. Review of ALARA Program
   a. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
   b. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded.
   c. The RSC will evaluate our institution’s overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RPO, authorized users, and workers as well as those of management.

Table 1.

Investigational Levels		
	Investigational Levels (mSv per quarter)	
	Level I	Level II
Whole body; head and trunk; active blood-forming organs; or gonads	2	4
Extremities (hands and feet) or the skin	20	40
Lens of eye	6	12

C. Radiation Protection Officer (RPO) Commitment

1. Annual and Quarterly Review:
   a. Annual review of the radiation safety program. The RPO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
   b. Quarterly review of occupational exposures. The RPO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA.

2. Education Responsibilities for ALARA Program:
   The RPO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management, RSC, and the RPO are committed to implementing the ALARA concept.

3. Cooperative Efforts for Development of ALARA Procedures:

   Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
   a. The RPO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
   b. The RPO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of these programs.

4. Reviewing Instances of Deviation from Good ALARA Practices:

   The RPO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RPO will implement changes in the program to maintain doses ALARA.

D. Authorized User's Commitment

1. New Methods of Use Involving Potential Radiation Doses:
   a. The authorized user will consult the RPO during the planning stage before using radioactive materials for new uses.
   b. The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

2. Authorized User's Responsibility to Supervised Individuals:
   a. The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

b. The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and maintaining exposures ALARA.

Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RPO. The investigational levels that we have adopted are listed in **Table 1**. These levels apply to the exposure of individual workers.

The RPO will review and record results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in **Table 1**.

1. Personnel doses less than Investigational Level I:
   Except when deemed appropriate by the RPO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.
2. Personnel doses equal to or greater than Investigational Level I but less than Investigational Level II:
   The RPO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first management meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate.
3. Personnel dose equal to or greater than Investigational Level II:
   The RPO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation.
4. Reestablishment of investigational levels to levels above those listed in Table I.
   In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

Signature of Certifying Official**

I hereby certify that this institution has implemented the ALARA Program as set forth above.

_____
Signature

_____
Name (Print or type)

_____
Title

_____
Date

** The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

APPENDIX B

RADIATION SAFETY COMMITTEE DUTIES AND RESPONSIBILITIES

Duties:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures.
2. Ensure that licensed material is used in compliance with the PNRI regulations and license conditions.
3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program.
4. Establish a table of investigational levels for individual occupational radiation exposures.
5. Identify program problems and solutions.

Responsibilities:

1. Be familiar with all pertinent PNRI regulations, the license conditions, the license and the amendments. Ensure that the radioactive material license is amended, if required, before any changes in facilities, equipment, policies, procedures, and personnel.
2. Review the RPO's summary report of the radiation safety program at least annually. The review should be sufficient to determine that all activities are being conducted safely, in accordance with PNRI regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review should include an examination of records, reports from the RPO, and results of PNRI inspections, written safety procedures, and the adequacy of the management control system.
3. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
4. Support the RPO when it is necessary for the RPO to assert authority. If the RSC has overruled the RPO, it will record the basis for its action in the minutes of the quarterly meeting.
5. Perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.
6. Delegate authority to the RPO on the responsibility for ensuring the safe use of radiation.
7. Hold meetings every six months or whenever necessary and prepare, distribute and maintain the minutes of all meetings.

APPENDIX C

RADIATION PROTECTION OFFICER (RPO) DUTIES AND RESPONSIBILITIES

The RPO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RPO shall:

1. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RPO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or PNRI inspections.
3. Ensure that personnel monitoring devices are used as required and that reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least **annually** to ensure that:
    a. The licensee is abiding by PNRI regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, transportation, and use by trained users);
    b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA; and
    c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with PNRI requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least 3 years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material.
9. Ensure that all incidents, accidents, and personnel exposure to radiation more than the ALARA levels are investigated and reported to PNRI within the required time limits.
10. Ensure that licensed material is disposed of properly.
11. Ensure that the facility has up-to-date copies of PNRI's regulations, completing a review of new or amended PNRI regulations, and revising licensee procedures, as needed, to comply with PNRI regulations.
12. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to PNRI in the licensing process.
13. Establish, implement, and document all written policy and procedures for:
    a. Authorizing the purchase of radiation sources;
    b. Receiving and opening shipments of radiation sources;
    c. Storing radioactive material;
    d. Keeping an inventory of radioactive material;
    e. Using radioactive material safely;
    f. Performing periodic radiation surveys;
    g. Performing or arranging for leak tests on all sealed sources;
    h. Performing checks of survey instruments and other safety equipment; and
    i. Decommissioning of its facility.
14. Assist the RSC in the performance of its duties.
15. Brief management once each year on its radioactive material program.

APPENDIX D

MODEL TRAINING PROGRAM

The following training program will be adopted and provided to individuals who frequent areas where radioactive material is used or stored in order to avoid radiological health protection problems. Training will be in lecture format with a written outline of the presented scope provided to the individuals. Supporting handouts, audio/video tape may also be utilized. Training will be provided initially before assigning duties involving radioactive material and following changes in duties or procedures or potential radiation hazards. **Refresher training** which covers all of the topics below will be provided at intervals not to exceed 12 months.

Training for Individuals Involved in the Use of Radioactive Material

Training for authorized users, medical physicists, RPOs, and technologists may contain the following topics, commensurate with their duties:

1. Basic radiation biology, e.g., interaction of ionizing radiation with cells and tissues;
2. Basic radiation protection to include concepts of time, distance, and shielding;
3. Concept of maintaining exposure ALARA;
4. Risk estimates, including comparison with other health risks;
5. Posting requirements in CPR Part 3;
6. Proper use of personnel dosimetry (when applicable);
7. Access control (including visitor control) procedures;
8. Proper use of safety devices and radiation shielding;
9. Patient release procedures;
10. Size and appearance of different types of sources;
11. Operating instructions;
12. Computerized treatment planning system;
13. Dosimetry protocol;
14. Detailed pretreatment quality assurance checks;
15. Correct positioning of sources to ensure that treatment is to the correct site;
16. Emergency procedures (including emergency response drills);
17. Previous incidents, events, and/or accidents; and
18. Initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model-specific and includes:
    - Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms; and
    - Hands-on training in actual operation of the device under the direct supervision of an experienced user including “dry runs” (using dummy sources) of routine patient set-up and treatment and implementation of the licensee’s emergency procedures;

Training for Ancillary Personnel

The training program for ancillary personnel (e.g., clerical, janitorial and housekeeping, dietary, security) whose duties may require them to work in the vicinity of radioactive material will include instructions commensurate with potential radiological health protection problems present in the work place. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel. Topics of instruction may include the following:

I. Fundamentals of Radiation Safety
   A. Characteristics of radiation

B. Units of radiation dose and quantity of activity
C. Conversions and calculations which are basic to the use and measurement of activity.
D. Significance of radiation dose
    1. Biological effects
    2. Radiation protection standards
        a) Occupational
        b) Public
        c) Embryo/Fetus
E. Sources of radiation
    1. Unsealed (internal hazard)
    2. Sealed (external hazard)

F. Methods of controlling radiation dose
    1. Working time
    2. Working distance
    3. Shielding
    4. Contamination control

G. Locations of use and storage

II. Radiation Detection/Measurement Instrumentation to be Used

A. Radiation monitoring instruments
    1. Operation
    2. Calibration
    3. Limitation
B. Use of personnel monitoring equipment
    1. Film badges
    2. Thermoluminescent dosimeters (TLDs)
    3. Pocket dosimeters

III. Safety Equipment to be Used
A. Storage containers
B. Personnel protective equipment (i.e., gloves, lab coats)
C. Shielding

IV. Control of Radioactive Material, Signs and Labels
A. Areas of use and restricted access
    1. Locks and security
    2. Supervision and control
B. Survey techniques and occasions for conducting surveys
    1. Area monitoring
    2. Contamination monitoring
C. Sign recognition and relative hazard
    1. Caution-Radioactive Material
    2. Caution- Radiation Area
    3. Caution-High Radiation Area

V. Requirements of Pertinent State Regulations
A. Obligation of individual to report unsafe conditions
B. Right of individual to be informed of exposures
C. Access to regulations and radioactive material license

VI. Terms and conditions of the Radioactive Material License, active amendments and any correspondence submitted in support of the license application

VII. The Licensee's Written Operating Procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing)

VIII. Emergency Procedures

IX. Decontamination and release of facilities and equipment

X. Manufacturer's Instruction Manuals for Sources/Devices

APPENDIX E

MODEL PERSONNEL EXPOSURE MONITORING PROGRAM

1. The RPO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of records is a film badge, or thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).

2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, or other approved whole body monitor. The TLD will be processed by PNRI every three months while the film badge will be processed on a monthly basis if they exceed 5 millisievert per quarter. Those licensees whose employees receive exposures of less than 5 millisievert a quarter may request to extend the exchange frequency upon PNRI approval. To receive approval, provide the following information:
   a. Supporting documentation that confirms that no employee will exceed 5 mSv/quarter; and
   b. Proposed frequency of exchange.

3. All individuals who are exposed to radiation on an occasional basis will not normally be issued exposure monitors. Examples of such personnel are service personnel who deliver packages, and secretarial personnel who do not work with patients.

4. Submit the name, address, and license number of the company who will process the personnel monitoring devices.

5. Instructions will be given to all employees about how and where dosimetry devices are to be stored when not in use. The storage place should be cool and dry.

6. Maintain records of exposure of all individuals required to wear personnel monitoring device. These records should be made available to PNRI during inspections.

APPENDIX F

MODEL PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated before first use, annually and following repair.

PRE -CALIBRATION

The following conditions shall be established before exposing the instrument to a source for adjustment and calibration:

The instrument should be free of significant radioactive contamination.

1. The meter shall be adjusted to zero, or the point specified by the manufacturer, using the adjustment or adjustments provided.
2. The batteries or power supply shall comply with the instrument manufacturer's specification.
3. The instrument shall be turned on and allowed to warm up for the period specified by the manufacturer.
4. Electronic adjustments such as high voltage shall be set, as applicable, to the manufacturer's specifications.
5. Geotropism shall be known for orientation of the instrument in the three mutually perpendicular planes, and this effect shall be taken into account during calibration and performance testing.
6. The performance of any internal sampling time based in digital readout instruments should be verified as being within the manufacturer's specifications.

MODEL PROCEDURE FOR PRIMARY CALIBRATION

1. The source must be approximately a point source.
2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.
3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.
4. The source should be of sufficient strength to give an exposure rate of about 0.30 mSv/hr at 100 cm. Minimum activities of typical sources are 3145 MBq. of Cesium-137 or 780 MBq. of Cobalt-60.
5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.
6. A record must be made of each survey meter calibration.
7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent. A correction chart or graph must be conspicuously attached to the instrument if the difference is greater than 10 percent. Any instrument with an exposure rate that differs from the calculated exposure rate by more than 20 percent must be repaired and can not be considered calibrated.
8. Three kinds of scales are frequently used on survey meters:
    a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be separated by at least 50 percent of scale rating.

b. Meters that have a multi-decade logarithms scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be separated by at least 50 percent of the decade.
c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be separated by at least 50 percent of the decade.

9. Readings above 10 mSv/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.
10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.
11. The report of a survey meter calibration should indicate the procedure used and the data obtained and should be retained for two years. The description of the calibration will include:
    a. The owner or user of the instrument;
    b. A description of the instrument that includes:
        manufacturer
        model number
        serial number,
        and type of detector;
    c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;
    d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
    e. The reading indicated with the instrument in the "battery check" mode;
    f. The angle between the radiation flux field and the detector. For external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel or perpendicular to the central axis of the detector. For instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument;
    g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
    h. The apparent exposure rate from the check source; and
    i. The name of the person who performed the calibration and the date on which the calibration was performed.
12. The following information will be attached to the instrument as a calibration sticker or tag:
    a. The proper deflection in the battery check mode.
    b. The apparent exposure rate from the check source.
    c. The name of the person who performed the calibration and the date on which the calibration was performed.
    d. For each scale or decade, one of the following as appropriate:
        i. The average correction factor,
        ii. A graph or graphs from which the correction factor for each scale or decade may be deduced, or
        iii. An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative.
13. To check reproducibility, the instrument should be exposed to a radiation field three or more times under identical conditions. The readings obtained should normally not deviate from the mean value by more than +/- 10 percent.
14. The response of an instrument may vary as a function of such parameters as energy, temperature, pressure, humidity, and source/detector geometry. Primary calibration should be accomplished with known values of these parameters and under the conditions specified by the manufacturer.

MODEL PROCEDURES FOR SPECIAL CONDITIONS

1. If the instrument is to be used under conditions that vary significantly from those for which the instrument is designed, the instrument should be adjusted, calibrated, and used only for the special conditions. Examples of such conditions are radiation energy, temperature and pressure, or source/detector geometry. When an instrument is calibrated for special conditions, an identification label shall be attached, in addition to any required calibration labels, to indicate its restriction to the special use. If instrument is also to be used within its design limits, the adjustments made during primary calibration shall remain the same, and instrument readings for the special conditions shall be corrected using correction factors obtained from appropriate labels or graphs. Only one parameter should be varied at a time during calibration for the special conditions, but the interrelationships of the variables should be known.

2. Radiation Energy.
   a. Calibration shall be performed with a standard source or source-providing radiation fields similar to those in which the instrument will be used. Where instruments will be used in radiation fields of widely differing energies, the response of the instrument at several energies over the energy range shall be determined.
   b. The response of the instrument to various energies of radiation shall be:
      i. Plotted as a function of energy; This type of graph is commonly called an energy dependence or spectral sensitivity curve.
      ii. normalized to the response to a specific energy obtained during the primary calibration; and
      iii. provided with the instrument.
3. Temperature, Pressure, and Humidity
   a. Instruments to be used outside the manufacturer's recommended temperature range or at temperatures which differ by more than 30 degrees from the calibration temperature shall be calibrated over the temperature range at which they will be used. Care must be taken to ensure that instruments are not exposed to temperatures that will damage detector or electronic components.
   b. If the manufacturer has not stated operating limits for humidity or atmospheric pressures, the instruments shall be calibrated at the approximate humidity or pressure expected to be encountered in use. Care must be taken to ensure that an instrument is not damaged by exceeding its pressure or humidity limits.

4. Detector Directional Dependence

If an instrument is to be used in a detector orientation relative to the source that is different from that used during primary calibration, correction factors should be developed.

DISCRIMINATION AGAINST UNWANTED RADIATION

If adjustments or changes are made which might alter the instrument response to unwanted ionizing radiation, the discrimination against unwanted radiation should be determined for all unwanted radiation that may be encountered.

PERIODIC PERFORMANCE TEST

To assure proper operation of the instrument between calibrations, the instrument shall be tested with the check source during operation and before each intermittent use.

Reference reading shall be obtained on each instrument when exposed to a check source in a constant and reproducible manner at the time of, or promptly after, primary calibration. If at any

time the instrument response to the check source differs from the reference reading by more than +/- 20 percent, the instrument shall be returned to the calibration facility for calibration or for maintenance, repair, and re-calibration, as required. Reference readings should be obtained for one point on each scale. The check source should accompany the instrument if it is specific to that instrument.

PRIMARY CALIBRATION FREQUENCY

All instruments shall receive a pre-calibration inspection and the primary calibration prior to first use. Primary calibration will be required at least annually even when the performance test requirements outlined in PERIODIC PERFORMANCE TEST above are met. Where instruments are subjected to extreme operational conditions, hard usage, or corrosive environment, calibration that is more frequent should be scheduled. Re-calibration shall be scheduled after any maintenance or adjustment of any kind has been performed on the instrument.

CALIBRATION FREQUENCY FOR SPECIAL CONDITIONS

Calibration for special conditions need be performed only once unless:

1. the instrument is modified or physically altered,
2. the special conditions are changed, or
3. the primary calibration is altered, provided that the conditions in PRIMARY CALIBRATION FREQUENCY are met.

PERFORMANCE TEST FREQUENCY

A performance check shall be made prior to each use, during intermittent use conditions and several times a day during continuous use.

APPENDIX G

LEAK-TEST PROGRAM

Perform leak test of sealed sources at six-month intervals unless otherwise authorized in the license. The options for leak-testing are:

1. Use a commercially available leak-test kit. Identify each kit to be used by designating the kit supplier and the kit model number. Only leak-test kits that are identified will be authorized. Identify also the individuals who will perform the leak-test (using kits).

2. Engage the services of a consultant or commercial organization licensed by PNRI to take the necessary test samples, evaluate the samples and report the results to you. Specify the name, address, and license number of the consultant or commercial organization.

3. Be licensed by PNRI to perform leak-test, including taking and evaluating the smears. The following information must be included:
   a. A description of the instrumentation to be used in evaluating the smears, including its sensitivity and accuracy.
   b. A description of the calibrating and standardizing procedures with sample calculation showing conversion of results to the required microcurie units. Survey instruments are generally not designed for such measurements and not acceptable for this use.
   c. A description of the material to be used in taking the smears and the points on the equipment that will be smeared.
   d. The radiation safety procedures to be followed during the smearing process, the method for handling and disposing of the smears.
   e. A description of the pertinent training and experience of each person who will take or evaluate the smears.

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES:

1. Make a list of all sources to be tested. This must include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few becquerels, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints.
   b. For larger sealed sources and devices (survey meter calibrator) take the wipe near the radiation port and on the activating mechanism.

4. Analyze the samples as follows:
   a. Select an instrument that is sufficiently sensitive to detect 185 Bq. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate.

b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 185 Bq, a different instrument must be used.

c. Assay the wipe sample. It must be the same geometry relative to the detector as was the certified check source.

d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in Bq on the wipe sample.

e. Continue the same analysis procedure for all wipe samples.

f. If the wipe sample activity is 185 Bq or greater, notify the RPO. The source must be withdrawn from use to be repaired or discarded.

g. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample, description of method used to test each sample, date of test, and signature of RPO. Maintain records for 5 years.

APPENDIX H

GUIDANCE FOR RADIATION SURVEYS

1. Perform radiation surveys using a portable calibrated survey meter after:
   a. each installation of a teletherapy source;
   b. making any major change in the teletherapy unit;
   c. making any change in the treatment room shielding; and
   d. making any change in the location of the teletherapy unit.

2. Surveys to be performed should include the following:
   a. Verification 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 0.1 mSv per hour and 0.02 mSv per hour, respectively.
   b. Verification that 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, the dose rates in restricted areas and in unrestricted areas are not exceeded.
   c. Determination of radiation levels at external surfaces of teletherapy unit.
   d. Determination of radiation levels in storage room for calibration and check sources.
   e. Determination that the source has returned to the safe storage position after each medical use of the teletherapy unit.
   f. Determination that the source is in the safe storage position following replacement of the source and following reinstallation of the teletherapy unit in a new location.
   g. Determination that containers prepared for shipment of spent sealed sources comply with requirements in CPR Part 4, “Regulations for the Safe Transport of Radioactive Materials in the Philippines”.
   h. Calculations to determine the dose received by individuals present in uncontrolled areas, reflecting continuous occupancy (i.e., occupancy factor of 1).
   i. Calculations to demonstrate that the expected dose rates in controlled and uncontrolled areas adjacent to the treatment room(s) meet the regulatory requirements.

3. Lock the control console in the OFF position if results of the surveys indicate that acceptable limits are exceeded.

4. Specify the parameters (equations, constants, assumptions, etc.) used to perform the calculations. These parameters must include, as applicable, such factors as distance to each area of concern; the type and thickness of material used in barriers and shields; the transmission factor of the barriers or shields; the maximum source strength; beam orientation; maximum field size; scatter angle; scatter ratio; contributions from primary leakage and scattered radiation.

5. The survey record should include, as applicable:
   a. Date of survey;
   b. Measuring device used (manufacturer, model and serial number, date of last calibration);
   c. Sketch of the room surveyed; and
   d. Name of RPO/individual performing the survey.

6. Retain record of radiation surveys made following installation of a source for the duration of the license.

APPENDIX I

MODEL OPERATING PROCEDURES

I. SPOT-CHECKS OF TELETHERAPY UNIT AND FACILITY

1. Perform start-up checks of the teletherapy unit prior to operation following a normal shutdown.

2. The medical physicist must establish procedures for periodic output spot-checks that must be performed on the teletherapy unit.

3. Safety spot-checks must be performed on the teletherapy facility once in each calendar month to ensure proper operation of electrical interlocks, electrical or mechanical stops, beam condition indicator lights, viewing systems, and electrically assisted treatment room doors.

4. A quality assurance program which contains routine checks and procedures must be established to ensure optimal accuracy in the delivery of prescribed therapeutic radiation to the patient undergoing treatment and to minimize the radiation risks to others.

5. Operators must follow the Manufacturer's Operating Manual, and any additional procedures that the physician and the medical physicist may develop in operating the equipment. These procedures must be part of the technical documentation and must be permanently available at the control panel of the equipment.

II. FULL CALIBRATION OF TELETHERAPY UNIT

1. Full calibration measurements must be performed on the teletherapy unit at intervals not exceeding one year.

2. The teletherapy physicist must complete acceptance testing and calibration prior to clinical use when the equipment is new, repaired or received maintenance, or radioactive source is replaced.

3. Arrangements must be made to have access to a calibrated dosimetry system which will be used to perform calibration measurements on the teletherapy unit.

4. The medical physicist must implement a QA program for all dosimetry and associated measuring instruments.

III. TESTS, MAINTENANCE AND REPAIR OF TELETHERAPY EQUIPMENT

1. Ensure that acceptance tests will be conducted following installation of a teletherapy unit to verify that the equipment conforms to technical specifications certified by the manufacturer.

2. Ensure that acceptance testing of the machine is performed after repairs or maintenance that has the potential to alter the radiation output.

3. Perform maintenance checks on the teletherapy equipment once in each calendar month.

4. Notify the medical physicist anytime there is repair regardless of its importance.

5. A summary of the repair and maintenance of teletherapy equipment and treatment planning equipment must be documented in the user's logbook by the service engineer and transferred to the medical physicist.

6. Full details of the repair and maintenance must be recorded in a service logbook, which must be readily accessible at the equipment. Ensure that a system is in place for the equipment service records to be transferred to the physicist.

7. Whenever the qualified and authorized service engineer services, repairs or modifies the therapy or planning equipment:
   a. a warning notice to the effect 'DO NOT USE - MAINTENANCE IN PROGRESS' must be prominently displayed at the equipment console;
   b. the chief radiation oncologist must also be informed;
   c. the repair and maintenance must be in accordance with the manufacturer's recommendations;
   d. appropriate entries must be entered into the service log book; and
   e. the medical physicist must be informed at the completion of the service work.

8. Where maintenance or service work on the teletherapy equipment or treatment planning equipment may affect the accuracy of the dosimetry or the safe operation of the equipment, the medical physicist must assess whether any specific tests or measurements are to be made and whether that equipment is operating satisfactorily.

9. The medical physicist must ensure regular performance constancy tests, dosimetry and service maintenance of all operational parts of the teletherapy equipment.

IV. RECORD KEEPING

1. Keep record of the medical use of teletherapy source indicating the activity of the source, date of use, and patient's name. Give a description of the treatment planning target volume and the doses delivered to it, the doses to other relevant organs, the dose fractionation, and the overall treatment time.

2. Keep record of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatments.

3. Keep record of the quarterly physical inventory conducted to account for all sealed sources and devices received and possessed. Each inventory record should be retained for five years. The inventory records must contain:
   a. Identity of each source radionuclide (element and mass number, chemical and physical form)
   b. Model and serial number
   c. Nominal activity of each source
   d. Location of each source
   e. Signature of the RPO

4. Keep record of the ambient dose rates measured quarterly in all areas where the teletherapy sources are stored. The RPO will review and initial the survey records at monthly and also promptly in those cases in which action levels were exceeded. Retain record of the survey results for two years.

5. Maintain also the following records:
   - Copy of the license

- Dosimetry (current and prior work history)
- Instrument QC tests and calibration
- Tests of leakage of radiation from radiation sources
- Incident and accident investigation reports
- Audits and reviews of radiation safety program
- Installation, maintenance and repair work
- Facility modification
- Full calibration and periodic output check of equipment
- Training provided (initial and refresher)
- Waste disposal
- Transportation
    - Package documentation
    - Package surveys
    - Transfer/receipt documents
    - Details of shipments dispatched
- Clinical dosimetry records and treatment prescriptions

APPENDIX J

GUIDANCE FOR THE SAFETY AND SECURITY OF RADIATION SOURCES

1. Establish measures to prevent theft, loss, unauthorized withdrawal, damage to or tampering with sources and equipment;

2. Conduct quarterly physical inventory to account for all sealed sources and devices received and possessed. Each inventory record should be retained for five years. The inventory records must contain:
   a. Identity of each source radionuclide (element and mass number, chemical and physical form)
   b. Model and serial number
   c. Nominal activity of each source
   d. Location of each source
   e. Signature of the RPO;

3. Lock equipment when not in use and secure sealed sources in a locked room or storage container;

4. Teletherapy units should be provided with safety interlocks or other means designed to prevent unauthorized clinical use. Safety interlocks should be designed such that operation of the unit can be performed only by use of a key at the teletherapy control panel and that access to the key be restricted to specified personnel;

5. Verify that the interlocks are functional;

6. Restrict access to the controlled area. Post appropriate signs and instructions to control entry of visitors, maintenance or housekeeping staff or unauthorized personnel.

APPENDIX K

GUIDANCE IN THE ESTABLISHMENT OF EMERGENCY PROCEDURES

Emergency procedures should cover at least:

- The persons responsible to take actions
- The responsibilities
- A set of concise instructions posted in a visible area
- The availability or quick access to the persons responsible to carry out the actions
- Equipment and tools necessary to carry out the procedure
- Training and periodic rehearsal

Emergency procedures should also include:

- Immediate measures to assess the hazard;
- Protective actions to contain radioactive material and avoid unnecessary radiation doses to patients, staff and public (such as removal of patients from a teletherapy unit, return of sources to the shielded position); and
- Measures to prevent access of persons to the affected area during the time that the sources are exposed and normal conditions are restored.

The types of situations which need to be planned for include:

Leaking sources

Measures should be conducted to prevent dispersion of contamination and access of persons to the contaminated area.

Accidental Medical Exposures (Due to delivery of therapeutic treatment to the wrong patient, wrong treatment site, or with the wrong dose; equipment failure)

Formal procedures should be developed to report and deal with the situation. The medical physicist should undertake an investigation which should include: a) a calculation or estimation of the doses received and their distribution within the patient; b) corrective measures required to prevent recurrence of the incident; and c) method to implement any corrective measures. Following the investigation, a report of the incident should be made to the Medical Isotope Committee.

APPENDIX L

GUIDANCE FOR DECOMMISSIONING A TELETHERAPY FACILITY

1. Ensure the availability of financial resources to cover the anticipated costs of decommissioning. The costs of decommissioning must cover not only the works but also licensing fees, monitoring costs and long term maintenance, depending on the regulatory requirements.

2. Establish the group who will be responsible for the decommissioning activity. Designate duties and responsibilities. Provide personnel monitoring device for each member of the group.

3. Ensure that unauthorized personnel are denied access to the area to be decommissioned.

4. Survey the facility to be decommissioned for exposure levels and contamination, if any. Keep a record of dose rate and contamination survey results. It must include the following information:
   a. Radioactive and hazardous materials present.
   b. Date, area surveyed, and equipment used.
   c. Name or initials of the person who made the survey.
   d. Radiation and contamination levels.

5. Remove any radioactive material and place it in a safe storage container. Make sure that you are equipped with protective clothing or device.

6. Perform another survey of the area to determine any presence of radioactivity. Decontaminate, if necessary.

7. Dispose radioactive wastes in accordance with the provisions in Part 12 and Part 3 of the CPR.

8. After determining that the area is acceptable for unrestricted use, submit a report to PNRI and attach the results of all surveys conducted

APPENDIX M

GENERAL GUIDANCE FOR DISPOSAL OF SPENT SEALED SOURCES

1. When importing radioactive sealed sources, it should be negotiated that spent sealed sources should be returned to the manufacturer.

2. Prior to the import of a sealed source containing radioactive material which 10 years after receipt will have an activity greater than 100 MBq:
   a. require the supplier, as a condition of any contract for purchase, to receive the source back after its useful lifetime within one year from time the recipient requested such return, provided that the recipient seeks to return the source to the supplier not later than 15 years after purchase; and
   b. submit to the PNRI a copy of relevant parts of the contract or acceptance document and obtain its written agreement prior to entering the contract or accepting the source.

3. Do not dismantle any sealed source.

4. Before declaring the radioactive material as waste, consider whether other organizations can make use of the material.

5. Transfer the material after confirming with PNRI that the organization to which it will be transferred has the necessary authority to hold the material. Secure from PNRI an Authority to Transport.

6. Spent sealed sources should be shipped back to the manufacturer in the original transport container or in a properly labeled and shielded transport container whose design is approved by PNRI. Secure from the PNRI an Authority to Transport and a Shipment Approval Certificate.

7. Transport of spent sealed sources should be in accordance with the CPR Part 4, “Regulations for the Safe Transport of Radioactive Material in the Philippines”.

GENERAL GUIDANCE FOR MANAGEMENT OF RADIOACTIVE WASTE

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal as in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF RADIOACTIVE WASTE BY DECAY-IN-STORAGE

Short-term storage should be designed to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage area must be in a secure location.

1. Consider using separate containers for different types of waste. Because the waste will be surveyed with all shielding removed, the containers in which the waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it and attach an identification tag that includes the date sealed, and the longest-lived radionuclide in the container. The container may then be transferred to the decay-in-storage area.

3. Prior to disposal as in-house waste, monitor and record the monitoring of each container as follows:
   a. Choose a survey instrument that is appropriate for the type and energy of the radiation being measured.
   b. Check the radiation detection survey meter for proper operation.
   c. Plan to monitor in a low-level radiation (0.0005 mSv/hr) area away from all sources of radioactive material, if possible.
   d. Remove any shielding from around the storage container.
   e. Monitor, at contact, all surfaces of each individual container.
   f. Remove or deface any radioactive material labels.
   g. Discard as in-house waste only those containers that cannot be distinguished from background. Record the disposal date, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
   h. Return to the storage area containers that can be distinguished from background radiation levels for further decay or transfer to an authorized byproduct material recipient.

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

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE (TELETHERAPY)

INSTRUCTIONS: To complete this application, refer to Part 12 of the Code of PNRI Regulations and the corresponding Regulatory Guide for the Preparation of Application for the Medical Use of Sealed Radioactive Sources in Teletherapy. Submit an original and one copy of the completed application, with the specified license fee and all required attachments, to the Nuclear Regulatory Division of the Philippine Nuclear Research Institute, Commonwealth Avenue, Diliman, Quezon City.

This is an application for: (Check appropriate box)

☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

1. NAME AND MAILING ADDRESS OF APPLICANT. (Attach SEC registration and business permit issued by the responsible government agency.)

Institution/Hospital _____
Address _____
Director/Head of the Institution _____
Telephone/Mobile Number _____
Fax Number _____
E-Mail Address _____

2. PERSON TO BE CONTACTED ABOUT THIS APPLICATION.

Name _____
Position/Title _____
Address _____
Telephone/Mobile Number _____
Fax Number _____
E-Mail Address _____

3. RADIOACTIVE MATERIAL AND PURPOSE OF USE.

Isotope (Element/ Mass Number)	Manufacturer	Date of Manufacture	Date of Purchase	Source Model/ Serial Number	No. of Sealed Sources	Maximum Activity in each Sealed Source	Purpose of Use

4. LOCATIONS OF USE. (Attach location map or building plan.)

Address _____
Telephone Number _____
Fax Number _____

5. PROPOSED WORKERS.
(Accomplish Attachments A, B, C and D for the training and experience of each person named below and submit certificates of relevant trainings.)

Worker	Name	Position/Title	Other Affiliated Institutions
Authorized Users (Physicians)			
Medical Physicist			
Radiation Protection Officer (RPO)			
Assistant RPO			
Radiotherapy Technologists			

6. REPRESENTATION IN THE RADIATION SAFETY COMMITTEE (RSC).

Identify the members of the RSC, indicating their position/title, department in the hospital, and telephone/mobile number.

7. FACILITIES. (Use separate sheets.)

Describe the facilities and submit annotated plans and drawings or sketches of rooms where radioactive material will be used and stored, indicating wall thickness, materials of construction, shielding, conduits or ventilation ducts. Describe the viewing systems, safety interlock systems, warning systems, and adjacent areas.

8. EQUIPMENT/INSTRUMENTS/DEVICES.

8.1 **Equipment.** Describe the equipment features, including the alarms and electrical interlocks; Submit certificate of conformance of all performance specifications and tests with standards of the IEC; Submit proof of accreditation of the company and the qualification of the individuals who will install the teletherapy unit.

Equipment	Manufacturer	Date of Manufacturer	Model/ Serial Number	Date of Purchase	Power Output	Institution to Perform Service & Maintenance

8.2 Radiation Detection/Measurement Survey Instruments

Type of Instrument (GM, Scintillation, IC, etc.)	Model No. /Serial No.	Manufacturer	Radiation Detected (α,β,γ, etc.)	Sensitivity Range (mSv/h)	Window Thickness (mm)	Intended Use	Date of Initial Use

8.3 Personnel Monitoring Devices

☐ Film Badge ☐ TLD ☐ Pen Dosimeter ☐ Others

No. of Units _ No. of Units _ No. of Units _

9. RADIATION SAFETY PROGRAM. (Check appropriate space and attach the required information. Additional specific procedures may be required as may be deemed necessary).

		Description Attached	Remarks
9.1	ALARA Program	☐	_____
9.2	RSC Duties & Responsibilities	☐	_____
9.3	RPO Authorities, Duties and Responsibilities	☐	_____
9.4	Training Program	☐	_____
9.5	Personnel Monitoring Program	☐	_____
9.6	Calibration	☐	_____
	9.6.1 Calibration of Survey Instruments	☐	_____
	9.6.2 Calibration of Teletherapy Unit/Sources	☐	_____
9.7	Leak Test Program	☐	_____
9.8	Radiation Surveys	☐	_____
9.9	Operating Procedures	☐	_____
9.10	Safety and Security of Radioactive Sources	☐	_____
9.11	Emergency Procedures	☐	_____
9.12	Decommissioning Plan	☐	

10. SECURITY OF SEALED SOURCES. Submit a Security Plan in accordance with CPR Part 26.

11. MANAGEMENT OF DISUSED RADIOACTIVE SOURCES.

Submit a detailed description of methods of disposal of disused sealed sources. If disused sealed sources are to be returned to original supplier or manufacturer, submit copy of agreement with original supplier or manufacturer.

12. APPLICATION FEE _____ Official Receipt No. _____
Date: _____

LICENSE FEE _____ Official Receipt No. _____
Date: _____

13. CERTIFICATION.

The applicant understands that all statements and representations made in this application are binding upon the applicant. The applicant or any official executing this certification on behalf of the applicant certifies that this application is prepared in conformity with the applicable requirements in the Code of PNRI Regulations and that all information contained herein are true and correct to the best of his knowledge and belief.

_____
Signature of Certifying Official Over Printed Name

_____
Title/Position of Certifying Official

_____
Date

14. ACKNOWLEDGEMENT.

{Republic of the Philippines}
{ }

Before me, a Notary Public for and in the above jurisdiction, personally appeared the following persons:

Name_____CTC No._____Date/Place Issued _____
Name_____CTC No._____Date/Place Issued _____

both known to me to be the same persons who executed the foregoing application and all attachments, and acknowledged to me the same to be their free and voluntary act and deed.

_____
Notary Public

Doc. No. _ Page No. _____
Book No. _____
Series of _____

ATTACHMENT A

TRAINING AND EXPERIENCE OF PROPOSED AUTHORIZED USER

NAME : _____
NAME OF INSTITUTION: _____
EDUCATIONAL DEGREE : _____

1" x 1" ID PHOTO

1. TRAINING RECEIVED IN BASIC RADIATION SAFETY

(Enclose certificates of training and use additional sheets if necessary.)

Field of Training	Location of Training	Date of Training	Duration of Training (Hours)		
			Lecture	Laboratory	On -the-Job
Radiation Physics & Instrumentation					
Radiation Protection					
Mathematics & Calculations Pertaining to the Use of Radioactive Materials & Measurement of Radioactivity					
Radiation Biology					
Nuclear Regulations & Licensing					

2. WORK /CLINICAL EXPERIENCE IN THE USE OF RADIOACTIVE SOURCE IN A TELETHERAPY/GAMMA STEREOTACTIC RADIOSURGERY UNIT

Radioactive Source (Element & Mass No.)	Maximum Activity (Becquerels)	Where Experience was Gained	Duration of Experience (Months)	Type of Use

3. RELEVANT TRAININGS (Submit certificates of relevant trainings.)

Title of Training	Place of Training	Date of Training

4. CERTIFICATION. (Indicate the name of the Body that certified you to practice therapeutic radiology or similar disciplines and submit a copy of the certification).

Certifying Body	Date of Certification

I CERTIFY THAT THE INFORMATION GIVEN ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE.

_____
Signature of Proposed Authorized User

_____
Date

Endorsed by: _____
Chairman, Radiation Safety Committee

Date: _____

ATTACHMENT B

TRAINING AND EXPERIENCE OF PROPOSED MEDICAL PHYSICIST

NAME: _____
NAME OF INSTITUTION: _____
EDUCATIONAL DEGREE: _____

1" x 1" ID PHOTO

1. TRAINING RECEIVED IN BASIC RADIATION SAFETY
(Enclose certificates of training and use additional sheets if necessary.)

Field of Training	**Location of Training**	**Date of Training**	**Duration of Training** (Hours)		
			Lecture	**Laboratory**	**On-the-Job**
Radiation Physics and Instrumentation					
Radiation Dosimetry					
Radiation Protection					
Radiation Biology					
Radiation Therapy					

2. EXPERIENCE WITH RADIATION AND RADIOACTIVE MATERIAL

Radioactive Source (Element & Mass No.)	**Maximum Activity** (Becquerels)	**Where Experience was Gained**	**Duration of Experience** (Months)	**Type of Use of Radioactive Source**

3. EXPERIENCE WITH A TELETHERAPY/GAMMA STEREOTACTIC RADIOSURGERY UNIT
(e.g., full calibration measurements, output spot checks, etc.)

Equipment (Brand Name, Model/Serial Numbers)	**Radioactive Source** (Element & Mass No.)	**Activity of the Source** (Becquerels)	**Experience Gained**	**Place where Experience was Gained**	**Duration of Experience** (Months)

4. RELEVANT TRAININGS (Submit certificates of relevant trainings.)

Title of Training	**Place of Training**	**Date of Training**

I CERTIFY THAT THE INFORMATION GIVEN ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE.

_____
Signature of Proposed Medical Physicist

_____
Date

Endorsed by: _____
Chairman, Radiation Safety Committee

Date: _____

ATTACHMENT C

TRAINING AND EXPERIENCE OF PROPOSED RADIATION PROTECTION OFFICER

NAME: _____
NAME OF INSTITUTION: _____
EDUCATIONAL DEGREE: _____

1" x 1" ID Photo

1. TRAINING IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

(Enclose certificates of training and use additional sheets if necessary.)

Field of Training	Location of Training	Date of Training	Duration of Training (Hours)		
			Lecture	Laboratory	On-the-Job
a. Radiation Physics and Instrumentation					
b. Radiation Protection					
c. Mathematics Pertaining to the Use of Radioactive Materials and Measurement of Radioactivity					
d. Radiation Biology					
e. Nuclear Regulations and Licensing					

2. EXPERIENCE WITH RADIATION AND RADIOACTIVE MATERIAL

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use

3. EXPERIENCE WITH RADIOTHERAPY EQUIPMENT, SURVEY INSTRUMENTS AND MONITORING DEVICES

Equipment (Brand Name, Model/Serial Numbers)	**Radioactive Source** (Element & Mass No.)	**Activity of the Source** (Becquerels)	**Where Experience was Gained**	**Duration of Experience**

4. RELEVANT TRAININGS (Submit certificates of relevant trainings.)

Title of Training	Place of Training	Date of Training

I CERTIFY THAT THE INFORMATION GIVEN ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE.

_____
Signature of Proposed RPO

_____
Date

Endorsed by: _____
Chairman, Radiation Safety Committee
Date: _____

ATTACHMENT D

TRAINING AND EXPERIENCE OF PROPOSED RADIOTHERAPY TECHNOLOGIST

NAME : _____
NAME OF INSTITUTION: _____
EDUCATIONAL DEGREE : _____

1" x 1" ID PHOTO

1. TRAINING RECEIVED IN BASIC RADIATION SAFETY
(Enclose certificates of training and use additional sheets if necessary.)

Field of Training	**Location of Training**	**Date of Training**	**Duration of Training** (Hours)		
			Lecture	**Laboratory**	**On-the-Job**
Radiation Physics & Instrumentation					
Radiation Protection					
Radiation Detection & Measurement					
Radiation Biology					

2. EXPERIENCE IN THE OPERATION OF A TELETHERAPY/GAMMA STEREOTACTIC RADIOSURGERY UNIT

Equipment (Brand Name, Model/Serial Numbers)	**Radioactive Source** (Element & Mass No.)	**Activity of the Source** (Becquerels)	**Where Experience was Gained**	**Duration of Experience** (Months)

3. RELEVANT TRAININGS (Submit certificates of relevant trainings.)

Title of Training	**Place of Training**	**Date of Training**

I CERTIFY THAT THE INFORMATION GIVEN ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE.

_____
Signature of Radiotherapy Technologist

_____
Date

Endorsed by: _____
Chairman, Radiation Safety Committee
Date: _____