REGULATORY GUIDE FOR THE PREPARATION OF AN APPLICATION FOR A LICENSE FOR THE MEDICAL USE OF SEALED RADIOACTIVE SOURCES IN BRACHYTHERAPY

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REGULATORY GUIDE FOR THE PREPARATION OF AN APPLICATION FOR A LICENSE FOR THE MEDICAL USE OF SEALED RADIOACTIVE SOURCES IN BRACHYTHERAPY

1. INTRODUCTION

1.1 Purpose of Guide

The purpose of this regulatory guide is to assist the applicant in the preparation of an application for a license for the medical use of sealed radioactive sources in Brachytherapy pursuant to CPR Part 14. The 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 PNRI.

This guide is designed to describe the type and extent of information needed by PNRI to evaluate an application for a license to acquire, receive, possess, handle, store, import, export, transport, use, and dispose radioactive materials for brachytherapy. Additional information may be required by PNRI to ensure that the applicant complies with the requirements of CPR Part 14.

This guide applies to applications for a new license, an amendment to a license, or a license renewal. The application must correctly and adequately address the radiation safety and security measures, programs and procedures that will ensure compliance with CPR Part 14, including other CPRs, as appropriate.

1.2 Management Responsibility

The PNRI believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. It also believes that effective management will result in increased safety and compliance.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation safety records and all information provided to PNRI;
- Knowledge about the contents of the license and application;
- Meticulous compliance with current PNRI regulations and the licensee's operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, and time) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained;
- Development and maintenance of a radiological emergency plan;
- Selection and assignment of a qualified individual to serve as the Radiation Protection Officer (RPO) with responsibility for the overall radiation safety program;
- Selection of management representative(s) with authority to stop unsafe operation;
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions; and
- Obtaining PNRI's prior written consent before transferring control of the license.

1.3 Applicable Regulations

(a) CPR Part 2, “Licensing of Radioactive Materials”
(b) CPR Part 3, “Standards for Protection Against Radiation”
(c) CPR Part 4, “Regulations for the Safe Transport of Radioactive Materials in the Philippines”
(d) CPR Part 14, "Licenses for the Medical Use of Sealed Radioactive Sources in Brachytherapy"
(e) CPR Part 26, “Security of Radioactive Sources”

2. FILING AN APPLICATION

An application for a new license must be filed by completing **PNRI/NRD Form-014**, "Application for a License for the Medical Use of Sealed Radioactive Sources in Brachytherapy" in duplicate copies, including the original copy. The application must include all the information that are necessary to support its intended purpose. Completeness of submitted information will be determined by the PNRI reviewer before the application is docketed. All applications for a license must be notarized.

A copy of the applicant’s registration with the Securities and Exchange Commission must be attached to the application. The corresponding application fee must be remitted upon submission of the application.

3. CONTENTS OF APPLICATION

Item 1. Name and Mailing Address of the Applicant/Licensee

The applicant may be a medical institution or a hospital. The name and signature of the individual who has the authority and responsibility over the proposed activity in the organization shall be affixed in the application, indicating his title or position in the institution/hospital.

The address specified in the application should be the mailing address for correspondence. This may or may not be the same as the address at which licensed material is located and will be used.

The applicant may designate in writing another person to represent him or the organization in conferring with PNRI about the application. The telephone/mobile number, facsimile, and/or e-mail address of the applicant and the designated representative 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 must designate an individual or contact person who can answer questions about the application, usually the Radiation Protection Officer (RPO). The individual's position or title, address, telephone number, fax number, and/or e-mail address (if available) must be specified.

Item 3. **Radioactive Material and Purpose of Use.**

Regulations: Section 7(b) and Section 8(e) of CPR Part 14.

Criteria:

The radioactive material to be used as a sealed source must be of a type, form and quantity which has been approved by PNRI for use in brachytherapy.

Sealed sources used in brachytherapy should be used only for the purposes for which they were designed, according to the manufacturer's written recommendations and instructions. The licensee shall confine his possession and use of radioactive material to the purposes authorized in the PNRI license.

Discussion:

The applicant should specify, for each sealed radioactive source, whether the intended application is for surface, interstitial, intracavitary, or implant therapy or for eye application. If other sources are included in the application for uses other than brachytherapy, the applicant should indicate so.

The applicant needs to submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the source or source shielding. The status of radioactive materials in a brachytherapy facility and the procedure for use should be described. It is essential that sufficient detail be submitted in order to evaluate the status of use of the materials in terms of health, safety and security.

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, chemical/physical form), manufacturer, date of manufacture, date of purchase, model and serial number, number of sealed sources, maximum activity (Bq) in any one source, and purpose of use.

Item 4. Locations of Use.

Regulations: Section 7 (c) and 8(e) of CPR Part 14.

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. 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. A post office box address is not acceptable.

The PNRI must be notified before any changes in the address identified in the license.

Response from Applicant:

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

Item 5. Proposed Workers.

Regulations: Section 7(h) of CPR Part 14

Criteria:

The authorized users, medical physicist, RPO, ARPO, and radiotherapy technologists should be qualified by training and experience in their respective functions relative to the use of radioactive material in brachytherapy.

Discussion:

Proposed workers should be qualified by training and experience to use the radioactive material for the purpose requested, in such a manner as to protect health and minimize danger to life and property. 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 42 to 45 of CPR Part 14.

Response from Applicant:

The applicant should list the name, position/title in the institution, telephone/mobile 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

Proposed workers must have adequate training and experience commensurate with the types and quantities of authorized radioactive material that they propose to acquire, receive, possess, use, transport, import or export and store. Attachments A, B, C, and D should be accomplished by the concerned individual, as appropriate. Certificates of documentary evidence of each individual's relevant training and experience should be submitted to PNRI.

Item 6. Representation in the Radiation Safety Committee.

Regulations: Section 17 of CPR Part 14.

Criteria:

Each medical institution must establish a Radiation Safety Committee represented by an authorized user of each type of PNRI license possessed by the institution, the RPO, a representative of the nursing service, a representative of management, and other staff as appropriate 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 brachytherapy facilty 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(d) of CPR Part 14.

Criteria:

Facilities must be adequate to ensure security of the radioactive sources and to protect health and safety of workers, patients, the public and the environment.

Discussion:

The facilities should be equipped with adequate shielding. 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. Adequate equipment and controls to maintain exposures to radiation of workers within regulatory limits should be provided. A portable radiation area monitor must be placed close to the entrance to the treatment room and electrical interlocks must be installed on the entrance door to the irradiator room.

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;
(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; and
(f) Security provisions to prevent unauthorized access, theft, or unauthorized removal of radioactive sources.

Response from Applicant:

(a) **Location of the facility**

The applicant/licensee should provide a detailed description of the location of the facility, including surrounding structures or adjacent rooms.

(b) **Layout of the facility**

The applicant/licensee should describe the facility and its safety systems, including the materials of construction of the walls and the necessary shielding installed.

The applicant should describe warning systems (e.g., locks, signs, warning lights and alarms, interlock systems) for the treatment room and methods for controlling occupancy for each restricted/controlled area.

(c) **Sketch or drawing**

The applicant should submit annotated plans, elevation drawings or sketches showing location of rooms where radioactive materials will be used and stored. The sketch should identify the isolation room for radioactive patients showing bed location, toilet and bathroom, dimensions, wall thickness, provision for ventilation and classification of adjacent areas.

(d) **Dose rate calculations**

Taking into account existing shielding, calculations of the maximum radiation levels expected in all areas outside the treatment room(s) which could be occupied should be provided.

(e) **Security Provisions**

The applicant should describe the monitoring, surveillance, security and control measures to prevent unauthorized access, theft, loss, unauthorized withdrawal, damage to or tampering with sources and equipment.

Item 8. Equipment/Instruments/Devices.

8.1 Equipment

Regulations: Section 7 (d) of CPR Part 14.

Criteria:

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

Discussion:

The applicant's proposed equipment should be adequate for the purpose requested to protect health and minimize danger to life or property. The applicant should ensure that the equipment conforms to applicable standards of the International Electrotechnical Commission (IEC) or to equivalent national standards.

Response from Applicant:

(a) **Remote After-Loading Brachytherapy Unit.**

The applicant who intends to possess and use low, medium or high dose rate remote after-loading brachytherapy unit should:

i. Specify the type of radioactive material to be used, the manufacturer of the equipment, date of manufacture, model number and serial number of the equipment, date of purchase, and the institution who will provide repair and maintenance service on the equipment.
ii. Indicate the power output of the machine.
iii. Describe the equipment features, including the alarms, electrical interlocks, and automatic source withdrawal interlock.
iv. Indicate the international standards to which the equipment and sources conform (e.g., IEC, ISO).

(b) **Manual After-Loading Device.**

The applicant should submit a description of the source handling devices that will be available including:

i. Source storage and transport container,
ii. Source handling devices and accessories (such as tongs, lead containers, etc.), and
iii. Radiation protection barrier during manual source loading in patient.

8.2 Radiation Measurement Survey Instruments.

Regulations: Sections 7(e) and 37 of CPR Part 14.

Criteria:

The applicant must possess radiation survey instruments required for the proposed authorization. The survey instruments must be sufficiently calibrated and operable.

Discussion:

The applicant/licensee should possess survey instrument(s) sufficiently sensitive to measure the type and energy of radiation used. The licensee needs to have survey instruments for routine use that can measure the radiation levels to which personnel would be subjected during operations. The survey instruments should be calibrated and be operable and capable of measuring radiation levels. For devices using low energy sources, low range instruments with measuring radiation levels of 0-500 µSv/hr should be used. For devices using high energy sources, high range instruments with measuring radiation levels of 0-10,000 µSv/hr should be used.

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 calibration.

8.3 Personnel Monitoring Devices.

Regulations: Sections 7(e) and 38 of CPR Part 14.

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, thermoluminescent dosimeter (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 and TLDs should be sent to PNRI 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. If the facility is engaged in high energy sources, each user must be supplied with direct reading dosimeters in addition to the film badge or TLD. Procedures must require that direct reading dosimeters should have a detector capable of detecting up to 2 mSv (200 mRem)

and doses be recorded daily. Records of personnel monitoring should be kept for two (2) years.

Item 9. Radiation Safety Program.

9.1 As Low As Is Reasonably Achievable (ALARA) Program.

Regulations: Section 15 of CPR Part 14.

Criteria:

Each licensee must develop and implement a written radiation protection program that includes provisions for keeping 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, Radiation 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 to check its effectiveness. The licensee must apply for and must receive a license amendment before it implements any major change in the approved radiation safety program.

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.

Persons engaged in activities under licenses issued by PNRI should, in addition to complying with the requirements set forth in the Code of PNRI Regulations, make every reasonable effort to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable.

License applicants should give consideration to the ALARA philosophy in the development of plans for work with licensed radioactive material. The applicant should establish a written ALARA program for ensuring that occupational radiation exposures are maintained "as low as reasonably achievable (ALARA)". As a minimum, the ALARA program contain:

(a) Management's formal commitment to the ALARA philosophy, recognizing the importance of keeping individual and collective doses ALARA.

(b) The duties of various persons (e.g., radiotherapy technologists, authorized users, Radiological Health and Safety Officer (RPO), licensee management) within the licensee's organization as they apply to ALARA.
(c) Commitment for continuing education and training for all personnel who work with or in the vicinity of the facility.
(d) Commitment to provide that, at intervals not to exceed three (3) months, record of radiation exposures of all personnel will be received and appropriate actions taken.
(e) Commitment to perform a formal annual review by management and the RPO of the ALARA program.

9.2 Radiation Safety Committee (RSC) Duties and Responsibilities.

Regulations: Section 17 of CPR Part 14.

Criteria:

The licensee shall establish a RSC to oversee the medical use of radioactive sources.

Discussion:

Section 17 of CPR Part 14 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 applicant should establish and maintain a Radiation Safety Committee (RSC) to oversee the use of licensed radioactive material throughout the institution and to review the institution's radiation safety program.

The applicant should describe the authorities, duties, responsibilities, and radiation safety activities of the RSC, where applicable, and maintain a copy of these statements until PNRI terminates the license.

If the RSC is already existing in the licensed institution arising from another licensed activity (e.g., nuclear medicine or teletherapy), the applicant may state so in the application and indicate the designated members for this activity.

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

Regulations: Sections 7(f), 7(g) and 16 of CPR Part 14.

Criteria:

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 16 (c) of CPR Part 14, 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 46 to 51 of CPR Part 14.

Criteria:

The applicant must develop a program for training and re-training of workers. Training and experience requirements for authorized users, medical physicists, RPO, and radiotherapy technologists must be in accordance with Sections 46 to 51 of CPR Part 14, as appropriate.

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

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 participants, and the state of learning (background knowledge) of the participants. Strong management support is considered essential to an adequate training program

Personnel must receive instructions during annual refresher training 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 38 of CPR Part 14.

Criteria:

Each licensee shall ensure that workers who work with radiation are provided with suitable and adequate personnel monitoring devices.

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.

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

The monitoring program must require:

(a) That whole-body badges (e.g., film or thermoluminescent dosimeter (TLD)) be provided to personnel who enter controlled areas;
(b) That whole-body badges be processed at intervals required by PNRI;
(c) That pocket dosimeters be operable, calibrated and tested for drift at intervals not to exceed 1 year;
(d) That dosimeters be placed in storage when not used; and
(e) That records of personnel exposures be maintained.

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 of Survey Instruments.

Regulations: Section 37 of CPR Part 14.

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.

Discussion:

Survey meter calibration must only 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.

9.7 Leak Test Program.

Regulations: Section 34 of CPR Part 14.

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 brachytherapy sources in accordance with Section 30 of CPR Part 14. 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. If the source had been leak-tested, then submit the initial leak test certificate and Certificate of Special Form Design Approval, if already available.

9.8 Radiation Survey Program

Regulations: Section 25 of CPR Part 14.

Criteria:

The licensee shall perform radiation surveys on the patient and the area of use immediately after implanting sources in the patient, immediately after removing the last temporary implant source from a patient, before each initial use of a brachytherapy source, or after relocation of a brachytherapy unit.

Discussion:

Radiation surveys should be made on the patient and the area of use immediately after implanting sources in the patient to confirm that no sources had been misplaced and immediately after removing the last temporary implant source from a patient to confirm that all sources had been removed. Radiation surveys should also be performed before each initial use of a brachytherapy source or after relocation of the brachytherapy unit.

Radiation surveys should likewise be performed before the release of any patient who received a permanent implant to determine that the measured dose rate from the patient is less than 0.025 mSv/h at a distance of one meter.

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: Section 29 of CPR Part 14.

Criteria:

Written operating procedures must be developed, implemented and maintained.

Discussion:

The applicant should establish procedures to ensure proper and safe use of brachytherapy sources. The written operating procedures should be directed to and given to occupational workers, defining the responsibilities of each to ensure compliance with the PNRI regulations, the terms and conditions of the license and the commitments made in the license application.

The applicant should submit to PNRI an operating procedure which addresses:

(a) Receipt and storage of radioactive sources;
(b) Radiation safety in handling brachytherapy sources and patients treated with brachytherapy sources;
(c) Periodic and spot-check measurements or inspection of facility and machine;
(d) Installation, maintenance and repair; and
(e) Record keeping

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

Response from Applicant:
Submit a written operating procedure that conforms with the above requirements.

9.10 Radiation Control Procedures

Regulations: Sections 7(l), 27, and 35 of CPR Part 14.

Criteria:
The applicant's operating procedure should be acceptable to PNRI. The brachytherapy treatment room should be constructed and equipped such that access is controlled.

Discussion:
The applicant should submit procedures to minimize exposure of the public to ionizing radiation. Public exposure can be controlled by ensuring that radiation sources are secured (e.g., interlocks are functional, keys to the control panel are secured) to prevent unauthorized access or use. Access by members of the public to areas in and nearby the radiotherapy 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.

These should include procedure for release of patients with permanent implants, procedure for release of patients with temporary implants, procedure for control of public exposure; and procedure for visitor control.

A model radiation control procedure is shown in **Appendix J.**

Response from Applicant:
The applicant should submit procedure on radiation control.

9.11 Emergency Plan and Procedures.

Regulations: Section 27 (a)(4) and (b) of CPR Part 14.

Criteria:
The applicant should develop an emergency plan which includes procedures designed to mitigate or control the consequences of an incident and to minimize radiation exposure of workers and the general public.

Discussion:
A written **emergency plan** that addresses, but not limited to, the following spectrum of incidents should be developed and posted at convenient locations in the brachytherapy control console room:
(a) operator is unable to return the source to its storage position;
(b) any abnormal occurrence in the facility;
(c) failure of the power supply; and
(d) failure of a controlling timer.

The written **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) Identify immediate measures to assess the hazard;
(d) Describe protective actions to contain radioactive material and avoid unnecessary radiation doses to patients, staff and public (such as removal of patients from a brachytherapy unit, return of sources to the shielded position);
(e) Describe the emergency equipment and protective clothing to be used;
(d) Provide instructions posted in a visible area 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;
(f) Indicate measures to prevent access of persons to the affected area during the time that the sources are exposed and normal conditions are restored;
(g) Specify the names and on-duty and off-duty telephone numbers of the responsible persons (i.e., authorized users and RPO) who should be notified; and
(h) Require training and periodic rehearsal of concerned staff.

Appendix K provides Response Actions For Radiological Emergencies Involving A Brachytherapy Source.

Response from Applicant:

The applicant should develop a plan for emergencies that may occur. Emergency procedures should be designed to mitigate or control the consequences of an incident and to minimize radiation exposure of workers and the general public. Copies of written operating and emergency procedures and local rules shall be posted at convenient visible locations in the licensed facility.

9.12 Decommissioning Plan.

Regulations: Sections 7(q) and 41 of CPR Part 14.

Criteria:

The applicant should establish a decommissioning plan for the facility at least twelve (12) months before decommissioning. The decommissioning plan must address the provisions in Section 41 of CPR Part 14.

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 gives guidance on decommissioning a brachytherapy facility.

Response from Applicant:

The applicant should submit to PNRI a decommissioning plan which addresses the items mentioned above.

Item 10. Security of Sealed Sources.

Regulations: Section 35 of CPR Part 14

Criteria:

The applicant using sealed sources for high and medium dose rate brachytherapy units should establish and submit to PNRI a Security Plan. Procedure to assure the security of brachytherapy sources in its possession should be in accordance with the requirements of CPR Part 26, "Security of Radioactive Sources".

Discussion:

Each licensee should ensure the security of radioactive sources in his/her possession. The licensee should control access to the brachytherapy room and secure the radioactive sources from unauthorized access. He must provide adequate physical protection of radioactive sources 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 brachytherapy 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 of radioactive sources, and maintaining records of receipt, transfer, and disposal of radioactive sources.

The applicant/licensee should refer to requirements provided in CPR Part 26 to be able to establish, document, and implement security measures for brachytherapy sources under Security Group B to prevent unauthorized access or theft of radioactive material for possible malevolent use.

Appendix M 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 Sources.

Regulations: Sections 37, 38, 39 and 40 of CPR Part 14.

Criteria:

The applicant should submit a program for the management of disused sealed sources in accordance with Section 37 (b) of CPR Part 14.

Discussion:

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

(a) Transfer to another licensee:
  (1) Notify PNRI of any intention to transfer or decommission the brachytherapy 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:

(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; or

(c) Storage to decay of short half-life disused sealed sources.

For disposal of disused sealed sources, the licensee should 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 management of disused sealed sources is given in **Appendix N**.

Response from Applicant:

The applicant should submit to the PNRI a program for the management of disused sealed sources. If the applicant opts for the return of the source after its useful lifetime, he must submit to PNRI a copy of the contract with the original supplier.

Item 12. Application/License Fee

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 a new 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 other applicable regulatory service fees (e.g., storage license fee, surcharge fee, release certificate fee, authorization to transport fee).

Items 13. Certification.

The application should be certified, signed and dated by an authorized representative of the institution who should be an officer of the institution, usually a Director, President, Chief Executive Officer or Vice President, otherwise a letter from such a person should be included affirming the signing authority of the representative who signed the application in his behalf. Unsigned applications will not be processed and will be returned to the applicant.

Item 14. Acknowledgement.

To attest to the correctness and veracity of statements and information contained in the application for a license, each application should be made under oath or affirmation.

4. AMENDMENTS AND RENEWALS TO A LICENSE

Regulations: Sections 9 and 11 of CPR Part 14

Criteria:

(a) The licensee must amend its license before:

(1) It acquires and uses a brachytherapy source for a clinical procedure other than what is indicated in the license;

(2) It permits anyone to work as RPO, ARPO, or Medical Physicist other than those previously authorized in the license;

(3) It replaces RPO, ARPO or Medical Physicist identified in the license;

(4) It possesses at any one time radioactive sources in excess of the activity authorized in the license;

(5) Making any major change in the brachytherapy unit;

(6) Making any change in the treatment room shielding;

(7) Using the brachytherapy unit in a manner that could result in increased radiation levels in areas outside the brachytherapy treatment room;

(8) Making any change in the location of the brachytherapy unit;

(9) It implements any major change in the approved radiation safety program; or

(10) Any substantial change in any condition of the license takes effect.

(b) The licensee must renew its license at least 30 days before the expiration date and comply with the other requirements for license renewal in accordance with **Section 11** of CPR Part 14.

Discussion:

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 **Section 9** of CPR Part 14, 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.

Response from Applicant:

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 Form-014A** 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 ACTIVITIES

Regulations: Section 12 of CPR Part 14.

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 45 of CPR Part 14**;
(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 radioactive sources, refer to **Section 41** of CPR Part 14 and for decommissioning requirements, refer to **Section 45** of CPR Part 14.

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, including ALARA 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 judgement, 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 radiation safety 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, 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 proper disposal of disused brachytherapy sources.
11. Ensure that the facility has up-to-date copies of PNRI's 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. Significance of radiation dose
    1. Biological effects
    2. Radiation protection standards
C. Sources of radiation
    1. Unsealed (internal hazard)
    2. Sealed (external hazard)
D. Methods of controlling radiation dose
    1. Working time
    2. Working distance
    3. Shielding
    4. Contamination control
E. Locations of use and storage

II. Radiation Detection/Measurement Instrumentation to be Used
A. Radiation monitoring instruments
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. Emergency Procedures

APPENDIX E

MODEL PERPONNEL 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.

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 logarithRSC 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.

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.

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 becquerel 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 before each initial use of brachytherapy source or after relocation of the brachytherapy unit.

2. Measure the ambient dose rates quarterly in all areas where sources are stored.

3. Surveys to be performed should include the following:
   a. Determination of the radiation level at the source housing with the source in the shielded position.
   b. Determination of radiation levels at external surfaces of brachytherapy unit.
   c. Determination of radiation levels in storage room for calibration and check sources.
   d. Determination that the source has returned to the safe storage position after each medical use of the brachytherapy unit.
   e. Determination that the source is in the safe storage position following replacement of the source and following reinstallation of the brachytherapy unit in a new location.
   f. Determination that containers prepared for shipment of disused sealed sources comply with requirements in CPR Part 4, “Regulations for the Safe Transport of Radioactive Materials in the Philippines”.
   g. Calculations to determine the dose received by individuals present in uncontrolled areas, reflecting continuous occupancy (i.e., occupancy factor of 1).
   h. Calculations to demonstrate that the expected dose rates in controlled and uncontrolled areas adjacent to the treatment room(s) meet the regulatory requirements.

4. 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. Measured dose rate at several points in each area expressed in millisievert per hour;
   d. Sketch of the room surveyed; and
   e. Name of RPO/individual performing the survey.

5. Retain record of radiation surveys made following installation of a source for two years.

6. If the results of the surveys indicate any dose rate values that are likely to exceed 0.03 mSv/hr at 10 cm from the surface of the source head, return the source to its shielded position and lock the control console. Do not operate the brachytherapy unit until corrective measures have been undertaken and resumption of operation has been approved by the RPO.

APPENDIX I

MODEL OPERATING PROCEDURES

I. SPOT-CHECKS OF BRACHYTHERAPY UNIT AND FACILITY

1. Perform start-up checks of the brachytherapy 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 brachytherapy unit.

3. Safety spot-checks must be performed on the brachytherapy 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. TESTS, MAINTENANCE AND REPAIR OF BRACHYTHERAPY EQUIPMENT

1. Ensure that acceptance tests will be conducted following installation of a brachytherapy 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 brachytherapy 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 brachytherapy 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. Ensure that only individuals who are specifically authorized and licensed by PNRI shall perform the installation, repair and maintenance operations

III. RECORD KEEPING

1. Keep record of the medical use of brachytherapy 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 brachytherapy 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
   - Training provided (initial and refresher)
   - Waste disposal
   - Transportation
   - Clinical dosimetry records and treatment prescriptions

APPENDIX J

RADIATION CONTROL PROCEDURE

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

2. Conduct a semi-annual physical inventory to account for all sealed sources and devices received and possessed. Each inventory record should be retained for three 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. Date of inventory
   f. Signature of the RPO

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

4. Brachytherapy 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 brachytherapy 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.

7. Maintain records and control receipt, use, storage, transfer, transport and disposal of sealed sources.

APPENDIX K

RESPONSE ACTIONS FOR RADIOLOGICAL EMERGENCIES INVOLVING A BRACHYTHERAPY SOURCE

The response to a radiation emergency may involve different types of hazards, including natural (e.g. storms), technological (e.g. radiation), biological or criminal activity (e.g. theft, sabotage, terrorist attacks). Emergency radiation response activities include radiation monitoring, radionuclide identification, source recovery and assessment of radiological and medical consequences.

Radiation-monitoring activities include environmental and source monitoring, sampling and sample handling,
Radionuclide identification includes in-situ gamma spectrometry and/or laboratory sample analyses.
Source recovery means the activities necessary to render radioactive sources safe and stabilize the situation.
Radiological assessments include evaluating the monitoring data, and using models or other techniques to evaluate the radiological consequences of the emergency, including individual external and internal dose assessment. These activities can be conducted in the field or at competent organizations. The activities also include provision of advice and recommendations on minimizing the consequences of the emergency.
Medical assessments include the evaluation of the medical consequences, the provision of advice or consultation to attending medical staff or assistance with medical care as necessary, assistance in decontamination, decorporation, and the provision of advice on public health issues. The activities also include radiopathology, bioassay and biodosimetry studies as appropriate.

Lost of a Dangerous Source

Operator (Responsible for control of the source):

- Report loss to the appropriate persons, providing a description of the device and threat.
- Conduct a local search and investigate possible means of loss (e.g. returned shipping container, waste, left in patient).
- Check and ensure physical security and control of other sources.
- If the source is found, ensure it is not damaged or leaking; if damaged or leaking, notify officials and ensure it is surveyed for contamination.

Incident Commander (lead first responder → local official):

- Coordinate the response using the Incident Command System (ICS)
- Ensure that all governmental agencies are informed.
- Evaluate all available information; retrace the sequence of events. If illicit trafficking or any criminal act is suspected, notify appropriate law enforcement authorities.
- Obtain radiological assessment assistance to coordinate the radiological response and radiation protection.
- Brief the responders on the risks and provide measures to protect emergency workers, including law enforcement, and control their dose.
- Obtain emergency medical assistance to advise and coordinate with medical facilities on recognition of radiation injuries.
- Obtain public information officer assistance to provide information to the public.
- Promptly inform nearby medical facilities, border crossings and scrap metal dealers to be alert for the source or for radiation-induced injuries. Provide them with a description of the source and its container and indications of radiation injuries (e.g. burns with no apparent cause).
- Initiate public searches if appropriate.

- If potential source is found, confirm the location and establish an inner-cordoned area (safety distance).
- If terrorism, public contamination or exposure, or serious overexposure is indicated, implement the appropriate action guide

Radiological assessment (Radiological assessor → national team):

- Operate under the ICS incident commander.
- Develop search strategy
- Brief incident commander on risks and provide measures to protect emergency workers and control their dose.
- Promptly locate and keep people away from the significant source(s)/contamination.
- Reconstruct/record the doses received and inform those exposed about the risks. Arrange, where appropriate, for long term medical follow-up.

Public information officer/team:

- Operate under the ICS incident commander.
- Promptly make a public announcement describing the source and stressing the hazard and action being taken.
- Initiate media briefings from a single official source.

Emergency medical responder/team:

- Operate under the ICS incident commander.
- Provide medical advice and support to local medical community on recognition of radiation injuries and treatment of contaminated/exposed individuals and on staff risk.

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 Radiation Safety Committee.

APPENDIX L

GUIDANCE FOR DECOMMISSIONING A BRACHYTHERAPY 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 14 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

GUIDANCE FOR THE SECURITY OF RADIOACTIVE SOURCES

1. Establish adequate monitoring, surveillance, and control 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. Control receipt and disposal of radioactive sources and maintain records of receipt, transfer, and disposal of radioactive sources;

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

5. Brachytherapy 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 brachytherapy control panel and that access to the key be restricted to specified personnel;

6. Verify that the interlocks are functional; and

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

APPENDIX N

GENERAL GUIDANCE FOR MANAGEMENT OF DISUSED SEALED SOURCES

1. When importing radioactive sealed sources, it should be negotiated that disused 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. Before declaring the radioactive material as waste, consider whether other organizations can make use of the material.

4. 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.

5. Disused 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.

6. For disused sealed sources with short half-lives, allow them to decay while in storage. During decay, sources will be retained in their original shipping container with the proper labeling. Before disposing the sources, submit to PNRI a report indicating the radiation level in the storage room, activity of the decayed sources and planned method of disposal.

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

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

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE (BRACHYTHERAPY)

INSTRUCTIONS: To complete this application, refer to Part 14 of the Code of PNRI Regulations and the corresponding Regulatory Guide for the Preparation of Application for the Medical Use of Radioactive Material in Brachytherapy. 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 NO. _____
☐ C. RENEWAL OF LICENSE NO. _____

1. NAME AND MAILING ADDRESS OF APPLICANT/LICENSEE

(Attach copy of SEC registration and business permit issued by the responsible government agency.)

Institution/Hospital _____
Address _____
Director/Head of the Institution _____
Telephone Number _____
Mobile Phone No. _____
Fax Number _____
E-Mail Address _____

2. PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Name _____
Position/Title _____
Address _____
Telephone Number _____
Mobile Phone No. _____
Fax Number _____
E-Mail Address _____

3. RADIOACTIVE MATERIAL AND PURPOSE OF USE

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

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

Address (Department/Section, Room No., Building) _____
Telephone Number _____
Fax Number _____
E-Mail Address _____

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. List the names of the members that compose the committee and their position or designation in the Institution, educational degree, address (department, building, room number) in the hospital, and telephone number. Use separate sheet.

7. FACILITIES (Use separate sheets if necessary).

Description of the Facility. 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, warning systems and safety interlock systems and adjacent areas.

Description of Isolation Room for Radioactive Patients. Describe the isolation room and provide a sketch of the room showing bed location, toilet and bathroom, dimensions, materials of construction, wall thickness, provisions for ventilation and description and level of occupancy of the adjacent areas. Provide dose rate and shielding calculations.

8. EQUIPMENT/INSTRUMENTS/DEVICES

8.1 Equipment

(a) **For Remote After-Loading Brachytherapy Unit.**

Type of radioactive source _____

Manufacturer of the equipment _____
Date of manufacture _____
Model number of the equipment _____
Serial number of the equipment _____
Date of purchase _____
Name & Address of institution who will provide repair and maintenance service on the equipment _____
Power output of the machine _____

Equipment features such as alarms, electrical interlocks, and automatic source withdrawal interlock. _____

International standards to which the equipment and sources conform (e.g., IEC, ISO). _____

(b) **For Manual After-Loading Device**

Source storage and transport container _____

Source handling devices and accessories (such as tongs, lead containers, etc.) _____

Radiation protection barrier during manual source loading in patient. _____

8.2 Radiation Detection/Measurement Survey Instruments

Type of Instrument	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 No. of Units _____
☐ TLD No. of Units _____
☐ Pen Dosimeter No. of Units _____
☐ Others 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 of Survey Instruments	☐	
9.7	Leak Test Program	☐	
9.8	Radiation Survey Program	☐	
9.9	Operating Procedures	☐	
9.10	Radiation Control Procedures		
	– Procedure for Release of Patients with Permanent Implants	☐	
	– Procedure for Release of Patients with Temporary Implants	☐	
	– Procedure for Control of Public Exposure	☐	
	– Procedure for Visitor Control	☐	
9.11	Emergency Procedures	☐	
9.12	Decommissioning Plan	☐	

10. SECURITY OF SEALED SOURCES. For Category 2 sources, submit a Security Plan in accordance with CPR Part 26; for Category 4 & 5 sources, e.g., Cs-137 and I-125, submit security measures.

11. MANAGEMENT OF DISUSED SEALED 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 a copy of agreement with the 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:

_____ CTC No. _____ Date/Place Issued _____

_____ 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 & Measurement of Radioactivity					
Radiation Biology					
Nuclear Regulations & Licensing					

2. WORK /CLINICAL EXPERIENCE IN THE USE OF BRACHYTHERAPY SOURCE

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 BRACHYTHERAPY UNIT

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 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 Safety & Protection					
Radiation Detection & Measurement					
Radiation Biology					

2. EXPERIENCE IN THE OPERATION OF A BRACHYTHERAPY 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: _____