REGULATORY GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES TO MANUFACTURE AND DISPENSE RADIOPHARMACEUTICALS

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REGULATORY GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES TO MANUFACTURE AND DISPENSE RADIOPHARMACEUTICALS

CPR PART 20

I. Purpose of the Guide.

This guide is designed to describe the type and extent of information needed by PNRI to evaluate an application for a license to manufacture and dispense radiopharmaceuticals. This guide applies to all applications for a new license, an amendment to a license, or a license renewal. It is the intent of this regulatory guide to assist the applicant and licensee in understanding the regulatory requirements and the licensing policies that apply to CPR Part 20. The appendices to this guide serve to:

- **Provide additional information on certain subject areas;**
- **Provide a model procedure the applicant may adopt in response to an item on the application form; or**
- **Provide an outline the applicant may use to develop a procedure for review by the PNRI staff.**

1.1. Applicable Regulations.

- **CPR Part 2, "Licensing of Radioactive Materials"**
- **CPR Part 3, "Standards for Protection Against Radiation"**
- **CPR Part 4, "Regulations for the Safe Transport of Radioactive Materials in the Philippines"**
- **CPR Part 20, "Licenses to Manufacture and Dispense Radiopharmaceuticals"**

II. Filing an Application.

Apply for a license by completing NRLSD Form-020, "Application for Radioactive Materials License" (To Manufacture and Dispense Radiopharmaceuticals). All items in the application form should be completed in sufficient detail upon submission for the PNRI to determine that the equipment, facilities, training and experience of individual employees, and radiation safety program are adequate to protect the health and safety of the public as well as employees. The PNRI reviewer/evaluator will determine the completeness of the submissions before the application is docketed. All applications for a new license must be affirmed or notarized.

Retain a copy of the application. The approved license incorporates the statements, representations and supplements in the application as well as the requirements in the regulations. Statements and representations in the application or supporting documentation become enforceable when the license is approved as if they were regulations.

III. Content of an Application.

This portion of the guide explains, item by item, the information requested on NRLSD Form-020. The accuracy and completeness of information in the application allow the PNRI reviewer/evaluator to undertake prompt actions on the application. The applicant may submit an alternative procedure for review by PNRI for its acceptability.

III.1. Applicant's Name and Mailing Address.

The applicant must show proof of business certification and registration issued by the competent government agency such as Security and Exchange Commission (SEC), Board of Investments (BOI), etc. The applicant may be represented by a duly designated official of the company.

The applicant should specify the mailing address for correspondence and the address where material will be used or located.

The telephone, facsimile, and/or e-mail number for each address should be provided for easy and fast means of communication.

III.2. Locations of Use.

Specify each location of use of the radioactive material by the street address, city or other descriptive address to easily locate the facilities. A post office box address is not acceptable. If the radioactive material is manufactured or used at more than one location, give the specific address of each location and describe the intended use, facilities and the equipment.

III.3. Person to be Contacted about the Application.

Provide the name and telephone number of the individual who is knowledgeable of the proposed radioactive material program and can answer questions about the application. This individual will serve as the point of contact during the review of the application and until a license is granted or otherwise. Notify PNRI if this individual is replaced while the application is being reviewed or evaluated.

Any request from PNRI for additional information, or for changes in the application should be addressed by the official of the organization who has the authority and responsibility over the proposed licensed activity.

III.4. Radioactive Material.

Regulation**:** **Sections 41 and 42 of CPR Part 20**

Criteria:

Applicants must assure that the radiopharmaceuticals to be manufactured, dispensed and distributed including sealed sources used for checking, calibration and reference sources are approved by PNRI and registered with the Bureau of Food and Drugs.

Response from Applicant:

The applicant should submit a list of all radioactive materials or radioactive drugs that will be produced, dispensed or used including check sources, calibration sources, and reference sources that will be possessed. Provide the following information, including the purpose of use.

For Unsealed Sources.

1) **Provide the name of the radioisotope, element and mass number, chemical and physical form and the maximum amount to be possessed at any one time and the proposed used.**
2) **For potentially volatile materials (e.g., I-125, I-131, H-3, Kr-85), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form.**

For Sealed Sources.

1) **Identify each radionuclide (element name and mass number) that will be used in each source and the proposed use.**
2) **Provide the manufacturer's (distributor's) name and model number for each sealed source requested.**
3) **Confirm that each sealed source is registered and approved by PNRI.**
4) **Confirm that the activity per source will not exceed the maximum activity listed on the approved license.**

III.5. Authorized Nuclear Pharmacist.

Regulation: **Section 8 (d), Section 25 of CPR Part 20**

Criteria:

The Authorized Nuclear Pharmacist must be board-certified by the Professional Regulatory Commission and possesses adequate training and experience pursuant to CPR Part 20.

Discussion:

The authorized nuclear pharmacist must be qualified to prepare or supervise the preparation of radiopharmaceuticals or radioactive drugs. Any certified pharmacist who cannot be an authorized nuclear pharmacist may work as an authorized personnel under the supervision of the authorized nuclear pharmacist. At least one individual named as an authorized nuclear pharmacist must be physically present when dispensing radiopharmaceuticals.

Response from Applicant:

Provide the following:

1) **Submit the name of each proposed authorized nuclear pharmacist and a copy of the PRC pharmacy licensure or registration for the pharmacist.**
2) **The description of the training and experience demonstrating that the proposed authorized nuclear pharmacist is qualified by training and experience; and written certification, signed by the trainor that the above training and experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.**

III.6. Radiological Health and Safety Officer (RHSO).

Regulation**:** **Section 8 (c), Sections 22, 23 & 24 of CPR Part 20**

Criteria:

Each licensee must appoint a qualified individual to act as the Radiological Health and Safety Officer (RHSO). The RHSO must have adequate training and experience.

Discussion:

PNRI requires that the applicant has identified a responsible person who is qualified by training and experience to oversee the radiation safety program. When selecting an RHSO, the applicant should keep in mind the duties and responsibilities of the position, and select an individual who is qualified and has the time and resources to fulfill those duties and responsibilities. The designated RHSO must indicate his/her acceptance of the designation in writing. Appendix B **outlines the typical duties and responsibilities of RHSO.**

The RHSO needs a level of basic technical knowledge sufficient to understand the work to be performed with radioactive materials at the proposed facility and to be qualified by training and experience to perform the duties required for that position. The training and experience requirements for the RHSO are described in Section 24 of CPR Part 20.

The RHSO should be present daily at the facility and direct the day-to-day radiation safety program. When the RHSO is absent, sick or on vacation, the Assistant RHSO will perform the duties and responsibilities of the RHSO in his/her absence.

Any individual who has sufficient training and experience to be named as an authorized nuclear pharmacist is also considered qualified to serve as the day-to-day RHSO.

Response from Applicant**:** **Provide the following:**

1) **The name of the proposed RHSO and ARHSO who will be responsible for the Radiation Safety Program.**
2) **The specific training and experience of the RHSO and ARHSO.**
3) **Demonstrate that the RHSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organization chart by position, demonstrating day-to-day oversight of the radiation safety activities.**
4) **Accomplish NRLSD Form 020A, "Statement of Training and Experience".**
5) **Specify all other responsibilities of the RHSO besides the regular responsibilities in the CPR. Indicate the percentage of time that the RHSO will be able to devote to the radiation safety program.**

Note: It is important to notify PNRI and obtain a license amendment within thirty (30) days prior to making changes in the designation of the RHSO responsible for the radiation safety program. If the RHSO leaves the organization before an amendment is approved by PNRI, the ARHSO or designate shall be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with the license and PNRI regulations.

III.7. Authorized Personnel.

Regulation: **Section 8 (b) and (f), Section 10 (a) of CPR Part 20**

Criteria:

Authorized personnel must have adequate training and experience commensurate with the types and quantities of licensed material that they propose to use.

Discussion:

If the applicant intends to assign certain individuals to perform functions other than the preparation and distribution of radioactive drugs, these individuals will be designated as authorized personnel who shall be under the supervision of the authorized nuclear pharmacist.

In order to demonstrate adequate training and experience, the proposed authorized personnel should have:

1) **As a minimum, a college degree at the bachelor level, or equivalent training and experience in physical, chemical, biological sciences, or engineering; and**
2) **Training and experience commensurate with the scope of proposed activities. The training should be sufficiently equivalent to that offered by PNRI.**

Response from Applicant:

Submit the names of the proposed authorized personnel and certificates that demonstrate that the training and experience qualifies him/her to use the requested licensed materials.

III.7.1. Safety Instructions for Individuals Working In or Frequenting Controlled Areas.

Regulation: **Section 8 (b), Section 21 (b) of CPR Part 20**

Discussion:

Individuals working with or in the vicinity of licensed material must have adequate safety instruction. For individuals who, in the course of employment are likely to receive in a year an occupational dose of radiation over 1 millisievert (100 millirem), the licensee must provide safety instructions and the individuals must received radiation safety training commensurate with their assigned duties specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training at no more than 12-month intervals. Training should also be performed whenever there is a significant change in hazards, duties, procedure, regulations, or terms of the license.

Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

Response from Applicant:

Submit a description of the radiation safety training program, including topics covered, group of workers, and the method and frequency of training. See Appendix C **of this guide.**

III.8. General Description of Facility.

Regulation: **Section 8 (e) and (h), Section 27 of CPR Part 20**

Criteria:

Facilities and equipment must be adequate to protect health and minimize danger to life or property. They must minimize the possibility of contamination and keep exposures to workers and the public ALARA.

Discussion:

The facility or area where the proposed material will be used 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, including deliveries, will be secured against unauthorized removal.

Response from Applicant:

Submit a diagram of the facility that indicates the type, dimensions, position, and thickness of shielding that will be available for:

1) **Use and storage of Molybdenum-99/Technetium-99m generators. The auxiliary shielding supplied by the manufacturer of the generator may be used. If the generators are to be stored against a wall, however, additional shielding may be necessary depending on the activity of the generators, the type of auxiliary shielding provided, the construction of the wall, and the use of the area on the other side of the wall. The auxiliary shielding provided by the manufacturer shields only three sides of the generator.**
2) **Storage of radioactive drugs.**
3) **Storage of radioactive waste, including decay-in-storage before disposal. Consider both short-term storage at each preparation station as well as long-term storage for decay before disposal. Long-term storage should be designed to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels.**
4) **Preparing and dispensing kit radiopharmaceuticals.**
   - **When working with photon-emitting radionuclides, it is acceptable to specify to use a lead/lead-glass L-block at each preparation station.**
   - **For primarily beta-emitting radionuclides, describe the shielding.**
   - **For high-energy beta-emitters, discuss steps to be taken to minimize bremstrahlung radiation production.**
   - **When using reagent kits and preparing radioactive materials for human use, describe the preparation, steps, shielding needs, and efforts to reduce contamination when using unsealed materials.**
5) **Indicate the intended use of each area in the diagram. Also, indicate the area designated for the receipt of shipments containing radioactive materials during hours when the facility is not staffed. This area should be chosen (and shielded, if necessary) with regards to the potential for radiation levels in supervised areas. In addition, delivery persons and other non-employees should not have access to the main area where licensed material is stored.**

III.8.1. Facilities and Equipment.

Regulation: **Section 8(e) of CPR Part 20**

Discussion:

The adequacy of the site, facilities, and equipment depends on the scope of operations (e.g., the form of radioactive materials possess, how to handle them, the types of radioactive emitters, etc.). Particular attention should be given to operations using large quantities of radioactive materials, preparation involving liquids, gases, and volatile radioactive materials, and the use of low energy photon and low energy beta-emitters.

Response from Applicant: **Provide the following:**

1) **Describe the facilities and equipment to be made available at each location where radioactive material will be stored and used.**
2) **Description of the area(s) assigned for the receipt, shipping, storage, preparation, security and measurement of radioactive materials.**

3) **The type of neighborhood (e.g., commercial, industrial), the type of building construction (e.g., concrete, brick), and the location of other building tenants (if any).**
4) **Diagrams that indicate the use of land along the perimeter of the facility and the use of other buildings and spaces in the neighborhood.**
5) **The security measures to prevent unauthorized access when the facility is closed. Include the type of doors and locks, window barriers (if necessary), intrusion alarm system, etc.**
6) **The location of fume hood stacks, their heights above roof level, and their relationship to the nearest window, air intakes, etc.**
7) **Confirmation that operation of the facility on the site does not conflict with local codes and zoning laws.**
8) **The arrangement made with the local fire department to inform of the operation and to instruct in appropriate emergency procedures.**
9) **If the requested possession limits involve 1 curie of iodine-131 or other potentially volatile radioisotopes, describe the fire protection method that you will use. Curie quantities of iodine-131 should be stored either in an area of the facility that is protected by a sprinkler system or in a fire proof, well or safe.**

III.8.2. Annotated Drawing.

Regulation: **Section 8 (e) of CPR Part 20**

Response from Applicant:

Submit an annotated drawing of the rooms and controlled areas where licensed activities are performed, and other adjacent areas. Note the following:

1) **The scale. Use the same scale (preferably ¼ inch = l foot) for all drawings.**
2) **The direction of north.**
3) **Room numbers and principal use of each room or area (e.g., dispensing area, generator room, lounges, offices, file rooms, storage area, radioactive waste storage, rest rooms, closets, halfway).**
4) **Any shielding available.**
5) **Additional safety equipment (for example, fume hoods, fixed area monitors) including manufacturer and model or serial numbers where appropriate.**

III.8.3. Other Equipment and Facilities.

Regulation: **Section 8 (e) of CPR Part 20**

Response from Applicant:

1) **Describe the equipment and facilities available for the use and/or storage of radioactive material. The equipment and instrumentation must be appropriate, operable, calibrated, and adequately maintained and conforms to that described in the license.**
2) **For dose calibrator quality assurance testing, review** Appendix D **carefully.**
3) **Provide the manufacturer's name, model number, and range of the survey instruments used for quantitative measurements. As an example:**

Manufacturer	Model Number	Range
Geotronics Industries	**OMG-12**	**0.01-50 mR/hr**
Flick Manufacturing Co.	**BBSM-42**	**1-1000 mR/hr**
Lite Scientific, Inc.	**DKM-007**	**1-100000 cpm**

4) **If survey instruments will be sent to a private contractor for calibration, provide the name, address, and license number of the provider. If you plan to perform your own calibration, submit the procedures. Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing".**
5) **Describe the equipment and the methods used to measure the airflow rate. These airflow ratings may change with the seasons or as the equipment ages. Periodic measurements are necessary to ensure continued performance at the same ratings. At a minimum, airflow ratings should be measured at 6-month intervals. Describe the type and frequency of periodic measurements you will make to ensure that the airflow ratings of your ventilation system continue to meet the specifications submitted in your application. Problems should be promptly corrected.**

III.8.4. Additional Response for Multitenant Buildings.

Regulation: **Section 8 (e) and (f) of CPR Part 20**

Response from Applicant:

1) **If radioactive material will be received, stored, or used frequently near a common wall, outline the access agreement with other tenants to allow you to perform the required surveys. Describe any alternate monitoring procedure (e.g., attaching film badges at specified intervals on a common wall).**
2) **State whether air from your suite could be circulated to other areas of the building by the heating/cooling system (e.g., via a common air space above ceiling tile, or by a central return duct). If so, show that rooms where volatile isotopes (e.g., Xenon-133, Iodine 131) are used or stored will be maintained under negative pressure with respect to the rest of the building. Submit a facility diagram that indicates the location and measured airflow ratings of the air supply and air exhaust vents.**
3) **Describe the equipment and the methods that were used to measure the airflow ratings. These airflow ratings may change with the seasons or as the equipment ages. Periodic measurements are necessary to ensure continued performance at the same ratings. At a minimum, airflow ratings should be measured and corrected, if necessary at 6-month intervals. Describe the type and frequency of periodic measurements to ensure that the airflow ratings of the ventilation system continue to meet the specifications submitted in the application.**

III.8.5. Special Equipment for Handling Millicurie Quantities of Liquid Iodine.

Regulation: **Section 8 (e) and (f) of CPR Part 20**

Response from Applicant:

1) **If the operations will involve opening and dispensing millicurie quantities of liquid radioiodine, the facility must be equipped to maintain effluent releases of radioactive iodine at ALARA levels. Most applicants use a charcoal filtration system in conjunction with their fume hood in order to achieve this goal.**
2) **Specify that this work will be performed in a fume hood with adequate airflow. Airflow should be checked at 6-month intervals. Submit your procedures for review.**
3) **Show how to maintain releases to the environment at ALARA levels. Most applicants use a charcoal filtration system (or equivalent), describe the system and indicate the percentage of radioiodine that the system is expected to remove**

from the effluent. Also estimate the concentrations of radioiodine in effluents released to the environment. Appendix M **provides specific guidance on exposures to concentrations of gases. Other precautionary measures, including bioassays, should be described in the appropriate sections of the application.**

III.9. Radiation Safety Program.

Regulation: **Section 21 of CPR Part 20**

Criteria:

Licensees must ensure that the occupational doses and to doses to members of the public are ALARA and must review the content and implementation of their Radiation Safety Program at least annually.

Response from Applicant:

Using the appendix as a guide, as may be applicable, submit procedures on Radiation Safety Program.

Appendix A Model Program for Maintaining Occupational Radiation Exposure ALARA
Appendix B Duties and Responsibilities of RHSO
Appendix C Model Training Program
Appendix D Model Procedure for Calibrating Dose Calibrators
Appendix E Model Personnel Exposure Monitoring Program
Appendix F Model Procedure for Leak-Testing Sealed Sources
Appendix G Model Procedure for Safe Use of Radiopharmaceuticals
Appendix H Model Spill Procedures
Appendix I Model Guidance for Ordering and Receiving Radioactive Material
Appendix J Measuring and Recording Molybdenum Concentration
Appendix K Model Procedure for Area Survey
Appendix L Model Procedure for Safely Opening Packages Containing Radioactive Material
Appendix M Model Procedure for Monitoring, Calculating, and Controlling Air Concentrations
Appendix N Model Procedure for Waste Disposal

III.9.1. Management Control of Licensed Activities.

Regulation: **Section 21 (b) of CPR Part 20**

Discussion:

PNRI holds the licensee responsible for the radiation safety program. It is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Senior management should delegate to the RHSO, in writing, sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding PNRI regulations and license provisions and to terminate unsafe activities involving radioactive material. The licensee maintains the ultimate responsibility for the conduct of licensed activities.

Response from Applicant:

Submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RHSO.

III.9.2. Personnel Monitoring.

Regulation: **Section 26 of CPR Part 20**

Criteria:

Establish and follow written procedures for personnel monitoring. As a minimum, these written procedures must require:

1) **That whole-body badges (i.e., film or thermoluminescent dosimeters) be provided when required.**
2) **That whole-body badges and finger extremity monitors (i.e., film or TLD) be provided to personnel who elute, prepare, assay, or dispense millicurie quantities of radioactive materials.**
3) **That whole-body and extremity badges be exchanged for processing at intervals not to exceed 1 month.**
4) **That whole-body and extremity badges be processed.**
5) **That any pocket dosimeters used to measure exposure from licensed material be operable, calibrated, and tested for drift at intervals not to exceed 1 year. Record of calibration must be maintained for two years.**

Response from Applicant:

Provide procedures and instructions for proper use of personnel monitoring equipment.

III.9.3. Radiation Monitoring Instruments.

Regulation: **Section 28 of CPR Part 20**

Criteria:

Licensees must possess operable and calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments at any time when radioactive material is used.

Response from Applicant:

1) **Describe the radiation detection and measuring instruments you will use for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control. Identify each instrument by type, sensitivity, and range for each type of radiation detected.**
2) **For photon-emitting radionuclides, use the radiation detection instruments described in Section 28 of CPR Part 20.**
3) **When working with beta-emitting radionuclides, describe the instrumentation used to assay beta-emitting radioactive materials for medical use, measure air concentrations, and measure contamination (either removable or fixed).**

III.9.4. Calibration of Survey and Measuring Instruments.

Regulation: **Section 29 of CPR Part 20**

Criteria:

Survey and measuring instruments must be operable and calibrated at all times.

Response from Applicant: **Provide the following:**

1) **Calibrate survey instruments at intervals not to exceed six (6) months and after repair.**
2) **If instrument calibration will be performed by another organization, the application should include the name, address, and license number of the organization.**
3) **If an applicant intends to calibrate survey instruments in-house, the following information should be submitted:**
   - i) **The type (radioisotope, manufacturer, model number and serial number) and exposure rate of the sources to be used for calibration.**
   - ii) **The accuracy* of the source that will be used.**
   - iii) **The specific procedures to be used for calibration, including radiation safety procedures to be followed.**
4) **Maintain records of each calibration for at least 3 years after the calibration. These records should show the date and results of the calibration and the name of organization that provided the service.**
5) **Survey instruments should be identified by type (i.e., ionization chamber, G.M., scintillation counter) and exposure range.**

*_____

Accuracy is the maximum deviation of the source activity from the true value. This information is normally provided by the manufacturer.

III.9.5. Possession, Use, Calibration and Check of Dose Calibrators**.**

Regulation: **Section 30 of CPR Part 20**

Criteria:

Establish and follow written procedures for calibrating instruments used to measure activity of dosages of photon-or beta-emitting radionuclides.

Response from Applicant:

1) **A description of the frequency, reference sources, and procedures that will be used to calibrate dose calibrator and other instrument used to measure the accuracy of photon and beta emitting radionuclides.**
2) **When measuring only photon-emitting radionuclides, make a statement that the dose calibration program describe in** Appendix D **of this guide will be adopted.**

III.9.6. Surveys.

Regulation: **Section 31 of CPR Part 20**

Criteria:

Establish and implement written procedures for performing periodic radiation surveys and contamination monitoring. As a minimum, these procedures should include:

1) **That all areas used for eluting, preparing, assaying, or dispensing radioactive material be surveyed daily.**
2) **That all other areas where radioactive materials are used or stored be surveyed weekly.**
3) **That these surveys for external radiation from photon- and high-energy beta-emitters be performed with survey meter sufficiently sensitive to detect 0.1 millirem per hour of the type of radiation present. If a survey meter cannot detect**

the type of radiation used, other appropriate instrumentation or monitoring techniques must be used.

4) **That the instrumentation or measurement technique used to perform the daily and weekly surveys for or low-energy beta-emitters is sufficiently sensitive to detect contamination.**
5) **That higher than normal readings for any area be investigated and corrected immediately.**
6) **That a series of wipe tests be performed at least weekly in order to detect surface contamination.**
7) **That the method for analyzing the wipe tests be sufficiently sensitive to detect 2000 disintegartions per minute (dpm) per 100 cm^2 for the contaminant involved.**
8) **That areas be either cleaned or posted and restricted from use if the contamination level exceeds 2000 dpm per 100 cm^2.**
9) **That areas be covered, cleaned, or identified to employees if the contamination level exceeds 2 times background but is less than 2000 dpm per 100 cm^2.**
10) **That records of the results of all surveys and wipe tests be maintained for PNRI for inspection, for a period of 3 years.**

Response from Applicant:

1) **Provide a description of the intervals and the procedures to be established and followed for performing routine radiation surveys and contamination monitoring.**
2) **A statement for photon and high-energy beta emitters adopted for area surveys.**

III.9.7. Sealed Source Inventories.

Regulation: **Section 34 (c) of CPR Part 20**

Criteria:

Licensees must conduct periodic inventory of stored radioactive materials.

Response from Applicant:

1) **Conduct inventories at intervals not to exceed 3 months to account for all sealed sources received and possessed under your license.**
2) **Maintain records of the inventories for at least 5 years from the date of the inventory. The records should include the model number of each source and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of inventory, and the signature of the RHSO.**
3) **Register every sealed source with the PNRI Sealed Source Registry prior to delivery or shipment to an authorized buyer. A copy of Registry Certificate shall be available for regulatory inspection.**

III.9.8. Operations.

Regulation: **Sections 41 and 42 of CPR Part 20**

Criteria:

Licensees must assure that the products to be manufactured or distributed are labeled, and packaged in accordance with the licensing requirements of PNRI or registered by the BFAD.

Response from Applicant:

Submit a description of the operations you plan to conduct under your license. The description should specify that:

1) **The facility is approved by PNRI or registered at the BFAD; submit a copy of any permit or license;**
2) **The activities in the facility are limited to the preparation of radiopharmaceuticals for delivery by prescription to PNRI-licensed institutions within a specified geographical area;**
3) **A copy of each customer's current radioactive materials license is maintained to ensure that facilities receive only authorized radiopharmaceuticals;**
4) **The activity is limited to manufacture, dispense and distribute radiopharmaceuticals.**

III.9.9. Product Labels.

Regulation: **Section 41 (c) of CPR Part 20**

Criteria:

Product labels must fulfill the color, symbol, and wording requirements. They must contain sufficient information to prevent errors that lead to misadministration.

Discussion:

The label must include the name of the radioactivity or its abbreviation, quantity of radioactivity, and date and time of assay. The syringe or syringe radiation shield labels should also specify the clinical procedure to be performed or the name of patient in order to prevent errors that lead to misadministration. Labels for containers of radiopharmaceuticals tagged with Technetium-99m should specify the total activity or concentration of Molybdenum-99. An expiration date and time should also be provided to ensure that no single patient dose at the time of administration will contain more than 1 microcurie of Molybdenum-99 per millicurie of Technetium-99m.

If the vial or unit dose syringe can accidentally become separated from the shield in which it is distributed, both the vial or syringe and the shield must bear all the required labeling. Because of the limited surface area on the unit-dose syringe, the syringe label may bear the radiation caution symbol, the words "CAUTION, RADIOACTIVE MATERIAL". All other labels must be complete.

Response from Applicant:

1) **Describe all labels, indicating the colors to be used, that will accompany your products and describe where each label is placed (e.g., on the unit-dose syringe, on the container shield).**
2) **Describe the leaflets and brochures containing radiation safety information that will accompany the product.**

III.9.10. Product Shielding.

Regulation: **Section 41 (b) of CPR Part 20**

Criteria:

The shielding provided for each product to be distributed must be adequate for safe handling and storage at the offices of the clients.

Response from Applicant:

For each radionuclide intended for distribution, provide the following:

1) **State the maximum activity for each type of container (e.g., vial and syringe).**
2) **Describe the type and thickness of the shielding provided for each type of container.**
3) **Indicate the maximum radiation level to be expected at the surface of each type of shielded container when filled with the maximum activity.**

IV. Packaging and Transporting of Radiopharmaceuticals.

Regulation: **Section 8 (g), Section 33 of CPR Part 20**

Criteria:

Establish and implement procedures that ensure compliance with CPR Part 4, "Regulations for the Safe Transport of Radioactive Materials in the Philippines", regarding transportation of licensed radioactive material and ensure that radioactive material is secured at all times against unauthorized removal. Adequate information should be available in the delivery vehicle for drivers, police, or civil authorities in case of traffic accidents, etc.

Response from Applicant:

The applicant should provide a description of the mechanisms or procedures used to assure the following:

1) **Transportation of radioactive material is in accordance with CPR Part 4. Procedures should include:**

    a) **Approved packages**
    b) **Approved labeling**
    c) **Proper surveys**
    d) **Complete and accurate shipping papers**
    e) **Bracing or rigging of packages**
    f) **Security provisions**
    g) **Emergency procedures**

2) **Training program should be developed for drivers and technologists in transportation regulations and emergency procedures. Documentation of this training should minimally include dates, topics discussed, attendees, and instructor's name.**
3) **Step-by-step procedures for packaging and transporting radiopharmaceuticals.**
4) **Quarterly management audits of transportation documentation should be scheduled (i.e., shipping papers, survey reports, etc.).**
5) **Emergency procedures that drivers shall follow in case of an accident involving licensed material in transport shall be maintained in the vehicle during transport. Emergency procedures should minimally include posting the area, maintaining surveillance, and notifying the RHSO. A copy of these procedures must be submitted to PNRI.**
6) **Procedures for handling radioactive waste during transport and the method of storage and final disposal should be established.**

V. Emergency Plan.

Regulation: **Section 9 (d) of CPR Part 20**

Criteria:

Each applicant and licensee must submit to PNRI an Emergency Plan for responding to a release of radioactive material and for responding to the radiological hazards of an accidental releases of source material and to any associated chemical hazards.

An emergency plan responding to a release of radioactive material must include the following information:

1) **A brief description of the licensee's facility and area near the site;**
2) **An identification of each type of radioactive materials accident for which protective actions could be needed;**
3) **A classification system for classifying accidents as alert or site area emergencies;**
4) **Identification of the means of detecting each type of accident in a timely manner;**
5) **A brief description of the means of equipment for mitigating the consequences of each type of accident, including those provided to protect workers on site, and a description of the program for maintaining the equipment;**
6) **A brief description of the methods and equipment to asses releases of radioactive materials; and**
7) **A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the department and the responsibilities of licensee personnel for developing, maintaining, and updating the plan.**

Response from Applicant:

Submit a copy of an Emergency Plan to PNRI.

V.1. Operating and Emergency Procedures.

Regulation: **Section 8 (j) of CPR Part 20**

Criteria:

Operating and emergency procedures must be established and submitted to PNRI as part of the application.

Discussion:

Licensees are responsible for the security and safe possession and use of all licensed material from the time it arrives at their facility until it is used, transferred, and/or disposed. Licensees should develop written procedures to ensure safe possession and use of licensed material and the procedures should also include operational and administrative guidelines. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

Response from Applicant:

Each licensee must develop, implement and maintain operating and emergency procedures containing the following elements:

1) **Instructions for maintaining security during storage and transportation.**
2) **Steps to keep radiation exposures ALARA.**
3) **Use of personnel monitoring and radiation survey equipment.**
4) **Instruction for packaging and transporting licensed materials.**

5) Steps to take and whom to contact when emergency occurs.

VI. Waste Management.

Regulation: **Section 8 (l), Section 35 of CPR Part 20**

Criteria:

Radioactive waste generated as part of the manufacturing and dispensing process must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Response from Applicant:

1) Submit procedures for the collection, storage and disposal of radioactive wastes. See Appendix N**. Be sure to include a specific procedure for all radioactive material when necessary.**
2) Contact PNRI (when necessary) for guidance and obtain advance approval of any methods of waste disposal.

VI.1. Procedures for Retrieving Radioactive Waste from Customers.

Regulation**: Section 8 (i), Section 35 of CPR Part 20**

Criteria:

If you will retrieve radioactive waste from customers, you must:

1) Agree to retrieve only those items (e.g., syringes, and vials) that contain or are contaminated with radioactive materials that you supplied.
2) Agree to provide detailed instructions to customers that will package radioactive waste for return to your facility. These instructions must clearly indicate that you will accept only items that are contaminated or that contain radioactive materials. (The items must contain radioactive material that your facility has supplied to the customer). In addition, the instructions must be adequate to provide for regulatory compliance for packaging and transport of licensed materials and for the radiation safety of drivers.
3) Submit to PNRI a copy of the instructions that you provide to your customers concerning the return of radioactive waste.

Response from Applicant:

Submit a copy of instructions to customers about the return of radioactive waste.

VII. Decommissioning.

Regulation: **Section 9 (d), Section 12 (a), (b)(1); Section 36 of CPR Part 20**

Criteria:

Each 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.

Discussion**:**

All applicants and licensees are responsible for decommissioning their facilities and must provide up-front decommissioning financial assurance or provide a decommissioning funding plan.

PNRI wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. Decommissioning of licensed facilities should be accomplished in a safe and timely manner and that licensees will provide adequate funds to cover all costs associated with decommissioning. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide guarantee that funds will be available.

Response from Applicant:

1) **Describe how the facilities will be decommissioned.**
2) **Provide/submit financial assurance for decommissioning for applicants or holders of a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days, or large sealed source or plated foil users.**

VIII. License Fees.

An application fee paid in full is required for this license, including applications for license amendments and renewals. Note that, in addition to licensing fees, licensees are required to pay the inspection fee and other applicable fees.

VIII.1. Amendments to License.

A licensee must receive a license amendment before changing the scope of the program or any specific condition of the license as specified in Section 10 of CPR Part 20. The appropriate fee must be included.

The licensee shall not implement any amendment until he has received a written verification from the PNRI that the amendment has been approved.

VIII.2. Renewal of License.

An application for the renewal of a license should be filed at least 30 days before the expiration date. This will ensure uninterrupted use of licensed material before the final action on the application has been taken by the PNRI. The application for the renewal should not make reference to information that was submitted.

If you do not wish to renew your license, you must inform PNRI and request for the termination of your license. Any radioactive material that could not be disposed or transferred to another licensee, a license for storage of the material may be requested.

IX. Termination of License.

The licensee may request termination of the license anytime. This notification should include a request to terminate the license. The licensee must certify that all sources have been disposed of properly. Note that a license is not terminated until PNRI takes action to terminate the license. An application for license termination does not relieve the licensee from its obligation to comply with PNRI's regulation and terms and conditions of the license.

X. Certification.

The application must be signed by an authorized representative of the firm, institution/hospital or legal entity who is also authorized to certify that the application contains information that is true and correct to the best of their knowledge and belief. Identify the position/title of the individual who signs the application. Unsigned applications will not be processed and will be returned to the applicant.

XI. Implementation.

The information in this regulatory guide is for your guidance although prescribed regulatory requirements are emphasized in the guide. The PNRI reviews each applicant to ensure that users of radioactive material are capable of complying with PNRI's regulations. This guide provides one set of methods approved by the PNRI for meeting the regulations and represents the minimum acceptable standards.

Appendix A

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

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 is 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. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and 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 is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

B. Radiological Health and Safety Officer (RHSO) Commitment

1. Annual and Quarterly Review:

   (i) Annual review of the radiation safety program. The RHSO 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.
   (ii) Quarterly review of occupational exposures. The RHSO 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 RHSO 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 and the RHSO are committed to implementing the ALARA concept.

3. Cooperative Efforts for Development of ALARA Procedures:

   Workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

   (i) The RHSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
   (ii) The RHSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of these programs.

4. Reviewing Instances of Deviation from Good ALARA Practices:

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

C. Authorized Users Commitment

1. New Methods of Use Involving Potential Radiation Doses

(i) The authorized user will consult the RHSO during the planning stage before using radioactive materials for new uses.
(ii) 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

(i) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
(ii) 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.

D. 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 RHSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RHSO 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 RHSO, 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 RHSO 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 RHSO 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. Re-establishment 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 investigation level, a new higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

Table 1.

Investigational Levels		
	Investigational Levels mSv per month (mrems per month)	
	Level I	Level II
Total dose Equivalent: Whole body; head and trunk; active blood-forming organs; or gonads	2 (200)	4 (400)
Skin of whole body, extremities	20 (2000)	40 (4000)
Lens of eye	6 (600)	12 (1200)

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

_____

***** Investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

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

Appendix B

DUTIES AND RESPONSIBILITIES OF THE RADIOLOGICAL HEALTH AND SAFETY OFFICER (RHSO)

MODEL PROCEDURE

The RHSO 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 RHSO's duties and responsibilities include:

A. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.

B. Ensure that individuals using the material are properly trained, have received refresher training at least annually, and are informed of all changes in regulatory requirements and deficiencies identified during annual management audits or PNRI inspections.

C. Ensure that personnel monitoring devices are used as required and that reports of personnel exposure are reviewed in a timely manner.

D. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.

E. Ensure that proper authorities are notified in case of accident, damage, fire or theft, in accordance with the most recently approved emergency plan.

F. Ensure that audits are performed at least annually to determine that:

1. The licensee complies with PNRI regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, transportation, and use by trained users);
2. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA; and
3. 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.

G. Ensure that the results of the 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.

H. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).

I. Ensure that the receipt, opening and delivery of all packages of radioactive materials at the facility are overseen and coordinated.

J. Ensure that all incidents, accidents, and personnel exposure to radiation more than ALARA levels are investigated and reported to PNRI within the required time limits.

K. Ensure that fume hood flow rates are tested at appropriate intervals and that employees utilize hoods in accordance with the safe use of radiopharmaceuticals.

L. Ensure that licensed material is transported in accordance with all applicable DOTC requirements.

M. Ensure that licensed material is disposed of properly.

N. Ensure that the facility has up-to-date copies of PNRI's regulations, completing a review of new or amended PNRI regulations, and revising licensee procedures, as needed, to comply with PNRI regulations.

O. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provide to PNRI in the licensing process.

Appendix C

MODEL TRAINING PROGRAM

MODEL PROGRAM

Personnel to be instructed:

A. All workers that might receive an occupational dose.

B. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work near radioactive material.

Frequency of instruction:

A. Before assuming duties with, or in the vicinity of, radioactive materials.

B. During annual refresher training.

C. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

A. Applicable regulations and license conditions.

B. Licensee's in-house work rules.

C. Areas where radioactive materials is used or stored.

D. Potential hazards associated with radioactive material.

E. Radiological safety procedures appropriate to the duties of the employee.

F. The employee's obligation to report unsafe conditions to the RHSO.

G. The appropriate response to emergencies or unsafe conditions.

H. The right to be informed of personal radiation exposure and bioassay results.

I. Locations where the licensees have posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence).

Records of Training:

Records of initial and refresher training will be maintained and will include:

A. The name of the individual who conducted the training.

B. The names of the individual who received the training.

C. The date of the training session.

D. A list of the topics covered.

Appendix D

MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

MODEL PROCEDURE

A. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The recommended tolerances of ±5 are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances and must be removed from service.

B. ***Constancy*** means reproducibility in measuring a constant source over a long period. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

1. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit, if it is used.
3. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
4. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
5. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the logbook or posted on the calibrator. The regulation requires repair or replacement if the error exceeds ±10 percent.

C. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

D. ***Linearity*** means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed. The vial or syringe may be in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract the background to obtain the net activity in millicuries. Record the date, time to the nearest minute and net activity. The first assay should be done in the morning at a regular time, for example, 8 a.m.
2. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 370 kBq (10 microcuries). For dose calibrators with a range selection switch, select the range you would normally use for the measurement.
3. Convert the recorded time and date to hours elapsed.
4. On the sheet of semilog graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number and serial number of the dose calibrator. Then plot the data.
5. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed-A-line)/(A-line) = deviation.
6. Put a sticker on the dose calibrator that says when the next linearity is due.

Shield Method

If you decide to use a set of "sleeves" of various thickness to test for linearity, it will first be necessary to calibrate them. The manufacturer provides specific procedures. Note that the decay method must be used upon initial installation. Calibration of the "sleeves" must be performed each time the dose calibrator is returned from repair.

Follow the manufacturer's instructions when performing the linearity test.

E. ***Geometry Independence*** means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that the radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

1. In a small beaker or vial, mix 2.0 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.
2. Draw 0.5 cc of the Tc-99m solution into the syringes and assay. Record the column and millicuries.
3. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
4. Repeat the process until you have assayed a 2.0 – cc volume.
5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume".
6. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity". This will also be necessary if any data points lie outside the 5 percent error lines. Be sure to label the table or graph "syringe geometry dependence", and note the date of the test and the model number and serial number of the calibrator.
7. To test the geometry dependence of a 30 – cc glass vial, draw 1.0 cc of the Tc-99mm solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
8. Remove the vial from the calibrator and using a clean syringe, inject 2.0 cc of the non-radioactive saline or tap water, and assay again. Record the column and millicuries indicated.
9. Repeat the process until you have assayed a 19.0 – cc volume. The entire process must be completed within 10 minutes.
10. Select as a standard the volume closest to that normally used for mixing radiopharmaceuticals kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume".
11. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity". This will also be necessary if any data points lie outside the 5 percent error lines. Be sure to label the table or graph "vial geometry dependence", and note the date of the test and the model number and serial number of the calibrator.

F. ***Accuracy*** means that the indicated millicurie value for a reference source is equal to the millicurie values determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. The regulations require that one must have a principal photon energy between 100 keV and 500 keV, other sources must be at least 1.85 MBq (50 microcuries). Consider using at least one reference source whose activity is within the range of activities normally assayed.

1. Assay a calibrated reference source at the appropriate setting (i.e., use the C0-57 setting to assay C0-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for three determinations.
2. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.
3. Repeat the procedure for other calibrated reference sources.
4. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.
5. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values.
6. Place a sticker on the dose calibrator that indicates when the next accuracy test is due.

G. The RHSO will review and sign the records of all geometry, linearity, and accuracy tests.

Appendix E

MODEL PERSONNEL EXPOSURE MONITORING PROGRAM

MODEL PROGRAM

A. The RHSO 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 record is a film badge, thermoluminiscent dosimeter (TLD), or optically stimulated dosimeter (OSD).

B. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, OSD, or other approved whole body monitor. The device will be processed by a contract service on a monthly basis if they exceed 5 mSv per quarter (500 millirem per quarter). Those licensees whose employees receive exposures of less than 5 mSv a quarter (500 millirem a quarter) may request to extend the exchange frequency upon agency approval. To receive approval provide the following information:

1. Supporting documentation that confirms that no employee will exceed 5 mSv/quarter (500 millirem/quarter); and
2. Proposed frequency of exchange.

C. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or TLD finger monitor. The device will be processed by a contract service on a monthly basis if they exceed 5 mSv per quarter (500 millirem per quarter). Those licensees whose employees receive exposures of less than 5 mSv a quarter (500 millirem a quarter) may request to extend the exchange frequency upon agency approval. To receive approval provide the following information:

1. Supporting documentation that confirms that no employee will exceed 5 mSv/quarter (500 millirem/quarter); and
2. Proposed frequency of exchange.

D. 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, secretarial personnel, etc.

E. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.

F. 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.

G. Licensees are required to review the potential exposures of their employees and to monitor them if there's likelihood that the intake may exceed 10% of the limit in a year. Monitoring as it applies to intake means the implementation of a bioassay program designed to monitor and quantify intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay depending on the isotope or combination of isotopes handled during the monitoring period. Baseline surveys should be completed for all individuals likely to require future monitoring.

Appendix F

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

As a licensee, you must perform leak testing of sealed sources. The PNRI requires tests to determine whether or not there is any leakage from the radioactive source. The leak test should be performed at 6-month intervals unless otherwise authorized in the license.

The options for leak testing are:

A. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.

B. Take the sample using a commercial leak-test kit and send the sample to the kit supplier who reports the results to you.

C. Perform the test and analyze yourself.

For option A:
Specify the name, address, and license number of the consultant or commercial organization.

For option B:
Specify the kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples.

For option C:
Describe the procedure for taking the test sample. Identify the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used. Hand-held survey meters will not normally be considered adequate for these measurements. Include the minimum sensitivity for the instrument used for analysis and a sample calculation for conversion of the measurement data to microcuries. Specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in the application.

MODEL PROCEDURE FOR TAKING TEST SAMPLES

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

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

C. 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:

1. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
2. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
3. For the teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care not to touch the field light, mirror or crosshairs. Wipe the primary and secondary collimators and trimmers.
4. If you are testing radium sources, you should also check for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as describe below. A survey should be done to be sure that sources are adequately shielding during the leak-test period.

MODEL PROCEDURE FOR ANALYZING TEST SAMPLES (Option C)

A. Select an instrument that is sufficiently sensitive to detect 185 Bq (0.005 microcurie). For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a scintillation detector with a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

B. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that is the same isotope and whose activity the supplier certifies. 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 (0.005 microcurie), 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 in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

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

F. If the wipe sample activity is 185 Bq (0.005 microcurie) or greater, notify the RHSO. The source must be withdrawn from use to be repaired or disposed.

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

Appendix G

MODEL RULES FOR SAFE USE OF RADIOPHARMACEUTICALS

MODEL RULES

A. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

B. Wear disposable gloves at all times while handling radioactive materials.

C. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.

D. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

E. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

F. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the RHSO. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in a work place in a designated low-background area.

G. Wear a finger exposure monitor during the elution of generators; during the preparation and assay of radiopharmaceuticals.

H. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

I. Never pipette by mouth.

J. Wipe-test radioactive material, preparation and administration areas daily for contamination and each week where radioactive materials are stored. If necessary, decontaminate or secure the area for decay as appropriate.

K. With a radiation survey meter, survey daily for contamination the generator storage and kit preparation areas. If necessary, decontaminate or secure the area for decay as appropriate.

L. Confine radioactive solutions in shielded containers that are clearly labeled. Multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study or the patient’s name.

M. Assay each dosage in the dose calibrator.

N. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

O. Because sources with even small amounts of radioactivity exhibit a high dose rate on contact, you should consider the use of a cart or other device to move waste and other radioactive material.

Appendix H

MODEL SPILL PROCEDURES

MODEL PROCEDURES

A. Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

4. Survey the area with a low-range radiation detection meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.

5. Report the incident to the RHSO.

6. The RHSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

B. Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry.

5. Notify the RHSO immediately.

6. Decontaminate personnel by removing contaminated clothing. Flush contaminated skin with lukewarm water. Wash the affected area with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

7. The RHSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

C. Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

The table below may be used as a general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented.

Table 1. Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major spill procedure based on the following dividing line. Spills above these millicuries are considered major. Spills of the amounts shown below are considered minor.

Radionuclide	Millicuries
I-125, I-131, Co-60	1
P-32, Co-58, Fe-59, Se-75, Sr-85, In-111, I-123, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99m, Tl-201	100

Radioactive Spill Report

The spill occurred at ____:____ am/pm on ____ - ____- ____ room ____

Instrument used to check for personnel contamination:

Meter model: _____ Meter S/N: _____ Probe model: _____ Probe S/N _____

Personnel present	Personnel contamination results*
_____	_____
_____	_____
_____	_____

* On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a postcleaning contamination wipe-test.

Radioisotopes present or suspected in the spill:
_____ mCi of _____ as _____
_____ mCi of _____ as _____
_____ mCi of _____ as _____

Give a brief description of the accident:
_____
_____
_____

Give a brief description of follow-up actions taken to prevent recurrence:
_____
_____
_____

Name: _____
Date: _____

Radioactive Spill Contamination Survey

The spill occurred at _____ am/pm on _____ - _____ - _____ in room _____

Decontamination completed at _____ am/pm

Location	**Pre-Clean** in mSv/hr (mR/hr)	Post Clean In mSv/hr (mR/hr)	Post Clean in dpm/100 cm^2

Name: _____

Appendix I

MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

MODEL GUIDANCE

A. The Radiological Health and Safety Officer (RHSO) or a designee ensures that the requested materials and quantities are authorized on the license. The material and quantity must also be approved for the requesting authorized user. Checks should be made to ensure that possession limits are not exceeded.

B. The RHSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

1. For routinely used materials:

   (i) Written records identifying the authorized user or department, isotope, chemical form, activity, and supplier
   (ii) Verification that material received was ordered by an authorized user.

2. For occasionally used materials (e.g., therapeutic dosages):

   (i) The authorized user who will perform the procedure will make a written request to confirm that the material received is what was ordered.
   (ii) The person who receives the material will check the physician's request to confirm that the material received is what was ordered.

C. For deliveries during normal working hours, the RHSO shall instruct carriers to deliver radioactive packages directly to specified areas.

Appendix J

MEASURING AND RECORDING MOLYBDENUM CONCENTRATION

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Molybdenum-99 per millicurie of Technetium-99m at the time of administration.

The model procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig". Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of molybdenum photons. The manufacturer will specify the Molybdenum-99 correction factor to convert the measured Molybdenum-99 to total Molybdenum-99.

MODEL PROCEDURE

Each time a generator is eluted, record the following:

A. Date the generator was received.

B. Product of the measured Molybdenum-99 activity and the correction factor noted by the manufacturer.

RECOMMENDED ACTION LEVEL:

An 0.07 action level allows for the quicker decay of the Technetium-99m through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Molybdenum-99 to Technetium-99m would have doubled.

The licensee must notify PNRI if a leaking generator is detected.

Appendix K

MODEL PROCEDURE FOR AREA SURVEYS

AMBIENT DOSE RATE SURVEYS:

A. Surveys – Controlled Areas:

1. In areas such as *in vitro* labs where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey **monthly** with a radiation detection survey meter.

2. In sealed source storage areas, survey **quarterly** with a radiation survey meter.

3. Protective clothing should be surveyed by the wearer after use if significant contamination is possible. Contaminated clothing should be removed before leaving a restricted work area. Hands should be washed and surveyed. Personal clothing should also be surveyed before leaving the controlled areas. Any contamination above expected levels should be reported to the RHSO.

B. Surveys – Supervised Areas:

Quarterly surveys should be accomplished in areas:

- Adjacent to controlled areas
- Through which radioactive materials are transferred
- Where radioactive material is temporarily stored before shipment

More frequent surveys will be necessary if radiation levels are suspected.

REMOVABLE CONTAMINATION SURVEYS:

A. Survey Areas:

In any area where the potential for spreading contamination is likely to occur, (cafeterias, snack bars, furniture and equipment), survey at least **quarterly**. Random wipe testing of floors alone is acceptable for most supervised areas. If such surveys reveal that radioactive contamination is being transferred out of controlled areas, immediate corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.

B. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm to disintegrations per minute or dpm).

C. Immediately notify the RHSO if you find levels which exceed the established action levels. See table below for guidance in establishing your action levels.

RECORDS:

A. Records must include dose rate and contamination survey results as well as actions taken in the case of excessive dose rates or contamination and follow-up survey information.

B. The RHSO will review and initial the record at least **monthly** and promptly in those cases in which action levels were exceeded.

Table 1:

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination		
	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	**Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201**
1. Supervised areas, personal clothing	200	2,000
2. Controlled areas, protective clothing used only in controlled areas, skin	2,000	20,000

C. Maintain records for three (3) years.

Appendix L

MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

MODEL PROCEDURE

A. All shipping packages received and known to contain radioactive material must be monitored for radiation level and radioactive surface contamination.

B. The following procedure for opening each package will be followed:

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RHSO.
3. Measure the exposure rate from the package at 1 meter and at the package surface. If it is more than 0.1 mSv per hour (10 millirems per hour) at 3 feet (1 meter), stop and notify the RHSO. [The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millisievert per hour (millirem per hour) at 1 meter from the package surface].
4. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 2 mSv per hour (200 millirem per hour) at any point on the package. The dose rate from the packages with "White I" labels should be less than 0.05 μSv per hour (0.5 millirem per hour) on the external surface of the package.

Beta-gamma-emitting radionuclides; all radionuclides with half-lives less than ten days	22 dpm/cm^2
All alpha-emitting radionuclides	2.2 dpm/cm^2

5. Open the package with the following precautionary steps:
   (i) Remove packing slip.
   (ii) Open outer package following the supplier's instructions, if provided.
   (iii) Open inner package and verify that the contents agree with the packing slip.
   (iv) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
   (v) If anything is other than expected, stop and notify the RHSO.
6. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NAI(TI) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe samples counts per minute to disintegrations per minute. Note that the dose calibrator is not sufficiently sensitive for this measurement. Take precautions against the potential spread of contamination.
7. Check the user request to ensure that the material received is the material that was ordered.
8. Monitor the packing material and the empty packages for contamination with a radiation survey meter before discarding.
   (i) If contaminated, treat this material as radioactive waste.
   (ii) If not contaminated, remove or obliterate the radiation labels before discarding it.
9. Make a record of the receipt.

Appendix M

MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS

ADEQUACY OF FACILITY FOR HANDLING XENON-133

You must have adequate equipment and operating controls to ensure that radioactivity in air is maintained within regulatory limits. Describe the scope and extent of your operations involving Xenon-133. Include the form in which Xenon-133 will be received (e.g., ampoules containing 1 curie or more, unit vials), the form in which Xenon-133 will be dispensed, and the manipulations involved between receipt and dispensing. This description should include an estimate of the fraction of Xenon-133 lost during storage and manipulation.

It is assumed that you will receive Xenon-133 in unit-dose vials and redistribute the product to your customers upon request.

A. Model Procedure for Calculating Worker Dose from Concentrations of Gases in Work Areas.

1. Collect the following data:

   (i) Estimated number of studies per week;
   (ii) Activity to be administered per study;
   (iii) Estimated activity lost to the work areas per study (you may assume 20 percent loss);
   (iv) Measured airflow supplied by each vent in the imaging room (if different during heating and cooling seasons, use the lesser value);
   (v) Measured airflow exhaust at the storage site (e.g., fume hood); and
   (vi) Maximum permissible air concentrations in controlled and supervised areas. For Xe-133, the maximum permissible values are 0.3 Bq/ml (1×10^{-5} μCi/ml) in controlled areas and 0.011 Bq/ml (3×10^{-7} μCi/ml) in supervised areas. For soluble Tc-99m, the maximum permissible values are 1.48 Bq/ml (4×10^{-5} μCi/ml) in controlled areas and 0.037 Bq/ml (1×10^{-6} μCi/ml) in supervised areas.

2. The following calculations must be made:

   (i) The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
   (ii) The estimated average concentration in controlled areas.

   - The total activity released to the controlled area (activity used each week multiplied by estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable maximum permissible value for a controlled area.

   - If this is not the case, plan for fewer studies. (An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere).

B. Guidance for Calculating Airborne Effluent Concentration

1. Divide the total activity released to a supervised area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable maximum permissible value for a supervised area.

2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the controlled area.

C. Public Dose from Airborne Effluent

1. Estimate the maximum amount of xenon-133 to be released per week, value "A". Your estimate should be based on your total possession limit multiplied by your estimated loss factor.

2. Determine the airflow rate of the exhaust system and describe the methods used for measuring the airflow rates. **The airflow rate should be determined by actual measurement**. Linear airflow (i.e., feet per minute) must be multiplied by the area of the fume hood opening (in square feet) to obtain the airflow rating in cubic feet per minute.

3. Calculate the airflow per week, value "**V**".

4. Calculate the average concentration for supervised areas.

$$\mathbf{C} = A/V \leq 5 \times 10^{-7}\ \mu Ci/ml$$

where:

A = maximum amount of Xe-133 to be released per week, (μCi)
V = airflow concentration per week (ml)
C = average concentration (μCi/ml)

The following gives the amount of Xenon-133 that can be released per week without exceeding an average concentration of 5×10^{-7} mCi/ml:

Exhaust Rate (ft3/min)	Average Release of Xenon-133 per Week (mCi)
100	14.3
500	71.4
1,000	142.7
1,500	214.1

Some Useful Conversions

1 mCi = 10^3 μCi
1 ft^3 = 2.832×10^4 ml
1 ft^3/min = 1.699×10^6 ml/hr

Airflow ratings should be measured periodically to ensure continued compliance. Describe the type and frequency of periodic measurements you will make to ensure that the airflow ratings of your ventilation system continue to meet the specifications submitted in your application.

D. Guidance for Monitoring or Checking Trap Effluent

Charcoal traps can significantly reduce air concentration. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.
2. If you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.
3. The RHSO will establish an action level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, the trap is breaking down and must be replaced.
4. Follow the trap manufacturer's instructions for replacing the trap.

E. Model Procedure for Calculating Spilled Gas Clearance Time

Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, calculations should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

1. Collect the following data:

    (i) **A** - the highest activity of gas in a single container, in microcuries;
    (ii) Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser values), in millicuries per minute;
    (iii) **Q** – the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room. The exhaust should be vented and not re-circulated within the facility. This may be the normal air exhaust or a specially installed exhaust gas exhaust system.
    (iv) **C** – the maximum permissible air concentrations in controlled and supervised areas. For Xe-133, the maximum permissible values are 0.3 Bq/ml (1×10^{-5} μCi/ml) in controlled areas and 0.011 Bq/ml (3×10^{-7} μCi/ml) in supervised areas, and
    (v) **V** – the volume of the room in milliliters.

2. For each room make the following calculations:

    (i) The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
    (ii) The evacuation time **t** = -V/Q x ln (C x V/A)

3. The radiation levels in supervised areas from operations or releases of radionuclides in effluents are restricted.

    - 0.02 mSv (2.0 mrem) in any 1 hour from external sources, and
    - 1 mSv (100 mrem) in a year (Total Effective Dose Equivalent) for individual members of the public.

F. Records

1. Measure ventilation rates in areas of use at intervals not to exceed 6 months.
2. Maintain these records for 3 years.

Appendix N

MODEL PROCEDURE FOR WASTE DISPOSAL

The following general guidance and procedure may be used for disposal of radioactive waste. If you prefer, you may develop your own procedure for review.

OVERVIEW

There are four commonly used methods of waste disposal:

- Release to the environment through the sanitary sewer or by evaporative release;
- Decay-in-storage (DIS)
- Transfer to a burial site or back to the manufacturer; and
- Release as in-house waste

GENERAL GUIDANCE

A. All radioactivity labels must be defaced or removed from containers and packages before disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

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

C. Occasionally monitor all procedures to ensure that no unnecessary radioactive waste is created. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

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

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

A. Regulations for disposal in the sanitary sewer appear in CPR Part 3. There are specific limits based on the total sanitary sewerage release of your facility. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

B. Limits on permissible concentrations in effluents to supervised areas are in CPR Part 3. These limits normally apply at the boundary of the controlled area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

C. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity. Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

A. Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Smaller facilities may find easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.

B. When the container is full, seal it with string or tape and attach an identification tag that includes the date that it was sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

C. Decay the material for at least 10 half-lives.

D. Before disposal as in in-house waste, monitor each container as follows:

1. Check your radiation detection survey for proper operation.

2. Plan to monitor in a low-level [less than 0.5μSv per hour (0.05 millirem per hour)] area.

3. Remove any shielding from around the container.

4. Monitor all surfaces of each individual container.

5. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages). Check to be sure that no radiation labels are visible.

6. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

E. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background [less than 0.5μSv/hr (0.05 mR/hr)] area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer.

A. Retain the records needed to demonstrate that the package qualifies with CPR Part 4.

B. Assemble the package in accordance with the manufacturer's instructions.

C. Measure the dose rate and removable contamination levels.

D. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

MODEL PROCEDURE FOR RELEASE AS IN-HOUSE WASTE

Waste from in-vitro kits is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

PHILIPPINE NUCLEAR RESEARCH INSTITUTE
Department of Science and Technology
Diliman, Quezon City

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
(Manufacture and Dispense Radiopharmaceuticals)

INSTRUCTIONS: Accomplish this application and submit two copies, including supplementary documents, personally to the Nuclear Regulatory Division (NRD), Philippine Nuclear Research Institute. Use additional sheets, if necessary.

1. **THIS IS AN APPLICATION FOR** (check appropriate box):

   ☐ a. New License

   ☐ b. Amendment to License No. _____

   ☐ c. Renewal of License No. _____

2. **NAME AND MAILING ADDRESS OF APPLICANT**

   Institution/Hospital: _____

   Address: _____

   _____

   Telephone No(s).: _____

   Fax No.: _____

   E-mail Address: _____

3. **LOCATIONS OF USE**

   Name of Department: _____

   Room No(s).: _____

   Street: _____

   Fax No.: _____

   E-mail Address: _____

4. **NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION**

   Name: _____

   Official Designation: _____

   Address: _____

   _____

   Telephone No(s).: _____

   Fax No.: _____

   E-mail Address: _____

5. **RADIOACTIVE MATERIAL** (List must include all radioactive materials to be used and /or stored). Use separate sheets, if necessary.

5.1 **For unsealed sources**

Isotope (Element, Mass Number)	Chemical/Physical Form	Maximum Amount to be possessed at any one time (becquerels)

5.2 **For sealed sources**

Isotope (Element, Mass Number)	Chemical/Physical Form	Maximum Amount to be possessed at any one time (becquerels)

* 1 millicurie = 3.7 x 10^7 becquerels

6. **PURPOSE(S) FOR WHICH EACH RADIOACTIVE MATERIAL LISTED IN ITEM 5 WILL BE USED**

For Items 7-11, use separate sheets

7. **INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE**

7.1 **Radiological Health and Safety Officer (RHSO)**. Accomplish Attachment A (NRLSD/LRE-008A form) and submit certificates of relevant training and experience and official designation/appointment signed by the management).

7.2 **Nuclear Pharmacist (s)/Technologist(s)**. Accomplish Attachment A (NRLSD/LRE-008A form) and submit certificates of relevant training and experience and official designation/appointment signed by the management.

8. **TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS**

9. **FACILITIES AND EQUIPMENT**

9.1 **Description of facilities** (Include sketch/drawing of room, layout of laboratory, hot laboratory, specifications of fume hood, etc.; and street address (If different from Item 3) where radioactive materials will be dispensed, compounded and stored.

9.2 **Radiation Monitoring Instruments**

Type of Instrument	Manufacturer	Model No.	Serial No.	Type of Radiation Detected	Sensitivity Range (mR/hr.)	Window thickness (mg./sq. cm.)	Use (detection, measuring, etc.

9.3 **Personnel Monitoring Devices**

☐ Film Badge No. of Units: _____ ☐ TLD (describe type of TLD) No. of Units:

☐ Pen Dosimeter No. of Units: _____ Brand, Serial Nos. & Range of dosimeter:

☐ Finger Dosimeter No. of Units: _____ Brand, Serial Nos. & Range of dosimeter:

9.4 **Other Equipment/Instruments** to be used in the lab (list all available equipment /instruments to be used in the lab., e.g. dose calibrator, alarm ratemeter, Geiger counter, multi-channel analyzer, high energy gamma detector, etc.)

10. **RADIATION SAFETY PROGRAM**

		Description attached	Previously submitted on
10.1	ALARA Program	☐	
10.2	Personnel Training Program	☐	
10.3	Duties & Responsibilities of RHSO and Pharmacist	☐	
10.4	Personnel Monitoring Program	☐	
10.5	Procedure for Ordering/Receiving and Opening Packages	☐	
10.6	General Procedure for Safe Use of Radioactive Materials	☐	
10.7	Emergency Procedures (spillage or contamination, transport, etc.)	☐	
10.8	Decontamination Procedure	☐	
10.9	Procedure for Retrieving Radioactive Wastes from Customers	☐	
10.10	Precautionary Measures for Handling of Liquid Radioiodine	☐	
10.11	Operations	☐	
10.12	Product Labels	☐	
10.13	Product Shielding (syringes & vials)	☐	
10.14	Procedure for Safe Transport of Radiopharmaceuticals (this includes packaging, labelling, swipe test of packages)	☐	
10.15	Procedure for Survey Instrument Calibration	☐	
10.16	Procedure for Dose Calibrator Calibration/ Tests	☐	
10.17	Procedure for Determining Molybdenum Concentration	☐	
10.18	Procedure for Area Survey	☐	
10.19	Air Concentration Monitoring/Control	☐	

10.20	Independent Audit Program	☐	_____
10.21	Radioactive Material Storage Procedure	☐	_____

11. **RADIOACTIVE WASTE MANAGEMENT PROGRAM**. Describe how the generated wastes, wastes from the users/clients, unneeded/depleted sources will be disposed of.

12. **FILING FEE**: (for new license application only) _____ OR No.: _____ Date: _____

LICENSE FEE: _____ OR No.: _____ Date: _____

13. ***CERTIFICATION***: **THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS APPLICATION ON BEHALF OF THE APPLICANT NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH THE APPLICBLE REQUIREMENTS IN THE CODE OF PNRI REGULATIONS AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF HIS/ITS KNOWLEDGE AND BELIEF**.

_____
Signature Over Printed Name

_____ _____
Date Position & Title