Radioactive Material License Guide

Nuclear Pharmacy

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LICENSING GUIDE FOR NUCLEAR PHARMACIES

INTRODUCTION

General:

This guide describes the type and extent of information needed by the Registrations & Certifications Section - Radiation to evaluate an application for a specific license for the possession and use of radioactive material. This type of license is provided for under Sections 324 and 325 of the Louisiana Radiation Regulations. The applicant should carefully study the regulations and this guide and submit all information requested. Please remember that any necessary information that is not submitted will delay completion of the review of your application.

Purpose of Appendices to Guide:

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through J to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and then decide if the model procedures are appropriate for its specific radiation safety needs.

Applicable Regulations:

The following Louisiana Radiation Regulations apply to nuclear pharmacy programs and should be used in conjunction with this guide. The applicant should carefully study the regulations and this guide and submit all the information requested. This guide does not substitute for understanding the requirements of the regulations.

A. Chapter 1 - General Provisions

B. Chapter 2 - Licensing of Radioactive Material

C. Chapter 4 - Standards for Protection Against Radiation

D. Chapter 7 - Use of Radionuclides in the Healing Arts

E. Chapter 10 - Notices, Instructions and Reports to Workers; Inspections

Please note that this guide is intended only for general guidance in preparation of the license application and should not be considered a substitute for the applicant's safety evaluation of the proposed use of radioactive material. The applicant must insure that the application correctly and adequately describes the radiation safety measures and procedures to be followed in order to provide adequate protection.

AS LOW AS REASONABLY ACHIEVABLE: (ALARA)

The applicant should, in addition to complying with the requirements set forth in the Louisiana Radiation Regulations, make every reasonable effort to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas as low as reasonably achievable (ALARA). The term "as low as in reasonably achievable" means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socio-economic considerations, and in relation to the utilization of ionizing radiation in the public interest.

ALARA IN NUCLEAR PHARMACIES:

Each licensee must have a formal ALARA program (see Section 705 of the Louisiana Radiation Regulations). The success of an ALARA program depends on the cooperation of each person who works at the licensee's facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources.

The RSO and management should audit the byproduct material program to ensure the continued safe use of byproduct material.

Please submit a copy of your ALARA program to the Department. A model ALARA management program is contained in Appendix J to this guide. Applicants should consider the ALARA philosophy in the development of plans for work with radioactive materials.

License Fees:

A fee is required for all initial applications and for licenses that are required to be reissued. The applicant should refer to the fee schedule in LAC 33:XV.Chapter 25 to determine the amount of the fee that must accompany the application. Review of the application will not begin until the proper fee is received by the Department. If you have any questions concerning the fee or the amount to submit, please do not hesitate to contact the Registrations and Certifications Section - Radiation.

Filing an Application:

A license application for radioactive material should be submitted on Form DRC-11, "Application for Radioactive Material License". The applicant should complete all items on the application form in sufficient detail for the Department to determine that the applicant's equipment, facilities, personnel training and qualifications, and radiation protection program are adequate to protect health and to minimize danger to property.

Only a single copy of the application and all attachments needs to be submitted to the Department. One copy should be retained by the applicant, since the license will require as a condition that the institution follow the statements and representations set forth in the application and any supplements. It is also a requirement of Section 1011 of the Louisiana Radiation Regulations to make a copy of your operating procedures available to employees.

Since the space on Forms DRC-11 and 13 is usually not sufficient to contain all of the required information, additional sheets should be appended. Each separate sheet or document submitted with the application should be identified by a heading indicating the appropriate item number. When completed, Form DRC-11 should be signed and dated by a representative of the institution's management.

CONTENTS OF APPLICATION

This portion of the guide explains, item by item, the information requested on Form DRC-11. The appendices to this guide serve several different purposes, i.e., to provide additional information on certain subject areas, to provide a model procedure the licensee may adopt in response to an item on the application form, or to provide an outline the applicant may use to develop a procedure for review by the Department staff.

Form DRC-11

Item 1 - Enter the name of the applicant, the telephone number, fax number, mailing address, and email address to which correspondence should be directed.

Item 2 - Indicate whether this is an application for a new license, an amendment, or a renewal.

Item 3 - If the mailing address in Item 1 is a post office box or if different from the location where medical radioisotopes will be used and/or stored then enter the street address where medical radioisotopes will be primarily used. A post office box address is not acceptable.

Item 4 - The Radiation Safety Officer (RSO) is the person designated responsible for the day-to-day radiation safety program. The RSO maintains all records required by the Louisiana Radiation Regulations and is the primary contact with the Department on matters pertaining to the license and the use of radioactive materials. The RSO should have the authority to enforce radiation safety policy, suspend activities deemed unsafe, and require and direct remedial action when necessary.

Submit a complete resume of the education and experience of each radiopharmacist, with a confirmation that each is licensed in the State of Louisiana. If persons other than radiopharmacists are to handle or process radioactive material, a description of the minimum training that will be provided to them should be submitted with their job descriptions. (See Appendix A)

Item 5 - Personnel Monitoring:

A. Chapter 4 of the Louisiana Radiation Regulations requires licensees to provide radiation monitoring for occupationally exposed individuals who might receive a dose in excess of 10 percent of the limits in Section 410 of the Louisiana Radiation Regulations.

B. If pocket chambers or dosimeters are to be used, then complete the requested information in Item 5.B of Form DRC-11.

C. The need for bioassays should be thoroughly considered if the chemical or physical form or if procedures and equipment used make it likely that radioactive material will be ingested, inhaled, or absorbed through the skin, e.g., therapeutic doses of liquid iodine-131. Describe your procedure for performing bioassays, i.e., schedule, action levels, actions to be taken, equipment to be used, calibration of equipment, count standard in lucite neck phantom, and conversion of count rate to activity units.

Please describe your personnel occupational exposure monitor program. See APPENDIX B of this guide.

Item 6 - Contamination Surveys and Area Surveys:

Describe your routine radiation survey program, including the areas to be surveyed, acceptable levels of contamination, and provisions for maintaining survey records. For delivery operations, include a description of vehicle survey procedures (See Appendix C).

Item 7 - Leak Test:

Indicate the company performing leak testing and at what intervals. If you will performing your own analysis, see Appendix D.

Item 8 - Waste Disposal:

Describe in detail how the pharmacy will handle and dispose of its own radioactive waste. Specifically address generator disposal and indicate how any releases to the environment or a sanitary sewer system will be controlled within regulatory limits. SEE APPENDIX E.

Item 9a - Health Physics Program:

The applicant should submit radiation safety procedures that will be followed by all persons using the radioactive material and should include the following items:

a. Procedures for the control and management of the radiation safety program, including a description of the duties and authority of the RSO. Also, indicate the daily staffing pattern, including the number of pharmacists and technicians per shift and the number of hours per person to be worked per day. Explain how the RSO will be contacted should a problem occur during routine operations.

b. Procedures for ordering radioactive material, receiving materials during normal business hours and at times other than normal business hours, and notifying responsible person(s) upon receipt of radioactive material. The procedures should be adequate to ensure that possession limits are not exceeded, that radioactive material is secured against unauthorized removal at all times, written directions to delivery firms, where to leave packages when facility is open and when it is closed, securing area after delivery, posting of delivery instructions, if damaged package, whom to contact and how, and that radiation levels in unrestricted areas to not exceed the limits specified in Chapter 4.

c. Procedures for examining incoming packages for leakage, contamination, or damage, and for safely opening packages. The monitoring should be performed as soon as practicable after receiving the package of radioactive material (see LAC 33:XV.455 and Appendix F). The procedures may vary depending upon the quantity of radioactive material received, but as a minimum should include instructions for surveying packages, wearing gloves while opening packages, and checking packing material for contamination after opening.

d. Method of restricting access to areas where radioactive materials are handled and stored.

e. General instructions to be followed by laboratory personnel and/or trainees while working with radioactive material. These instructions should:

    1. Outline general laboratory procedures to be followed when handling radioactive material (See Appendix G).

    2. Prescribe limitations, conditions, and laboratory equipment for handling gaseous or volatile radioactive material such as Xe-133, I-131, etc. For example, explain what materials and what operations should be confined to radiochemical fume hoods or glove boxes. Indicate what shielding or remote handling equipment will be employed when hard beta and/or gamma emitting materials are used.

    3. Explain procedures for storing radioactive material, labeling containers, and identifying areas where radioactive material is used. Describe the location and method for handling and storing contaminated articles and glassware.

4. Explain what records will be kept on radioactive material use and disposal.

5. Outline procedures for monitoring personnel for radiation exposure and maintaining exposure records. The procedures should indicate when extremity monitoring will be used.

6. Describe the bioassay procedures to be followed if millicurie amounts of I-125 or 131, or hydrogen-3 will be used in non-encapsulated form.

7. Describe procedures for operational and maintenance checks of fume hoods and glove boxes, including their exhaust systems and the monitoring procedures for release to the atmosphere.

8. Describe emergency procedures to be followed in the event of a radioactive material spill, a fire, or other emergency. Address emergency procedures for accidental releases of gases if bulk quantities of xenon-133 or xenon-127 are to be authorized. Also, address vehicle accident procedures, instructions to be carried on vehicles, and any emergency kits.

Procedures for Preparing and Dispensing Radiopharmaceuticals

In addition to the information required by the application, the applicant should also submit procedures for preparing and dispensing radiopharmaceuticals. These procedures should include at least the following:

A. A description of the methods for preparing, performing quality control testing on, and dispensing the various types of radiopharmaceuticals. Describe those to be bought in bulk and subdivided, those to be made from kits, etc.

B. A sample of the labeling to be put on the product and on the shipping container.

C. The method to be used to assure that the radiopharmaceutical is authorized to be received by the recipient.

D. The method of providing the proper dose at the time of use and the method for calculating the dose expiration time.

E. Records to be kept of radiopharmaceuticals prepared and dispensed.

F. A sample of the prescription form to be used.

G. Records of the receipt and transfer of radioactive material.

H. Procedures for eluting Tc-99m generators and testing for Mo-99 breakthrough. Method for determining compliance with Mo-99 contamination requirements, including calculation of dose expiration time. Include procedures for checking for aluminum breakthrough.

I. Quality control checks to be used for assure proper doses are dispensed. Include your procedures for sterility, pyrogenicity testing and radiochemical purity.

J. Confirmation that only FDA-approved suppliers will be used.

K. Additional procedures for handling radioiodine, radioxenon, or other products that require special precautions.

L. A description of the method to be used for shipping and transporting radioactive material, and a statement that such procedures are in accordance with the U. S. Department of Transportation Regulations.

Item 9b - Physical Facilities:

Submit a detailed, scaled drawing of the facility, and indicate the type of construction (e.g., wood, brick, etc.). On the diagram, show 1) the areas for use/storage of Mo-99/Tc-99m generators, 2) the area for storage of radiopharmaceuticals, 3) the area for storage of waste (decay in storage and waste picked up from customers), and 4) the area for preparing and dispensing kit radiopharmaceuticals. If the building is multi-story, indicate the location of the radiopharmacy and the provisions for surveys of adjacent areas. Designate on the sketch restricted and unrestricted areas (e.g., restrooms, break room, clerical offices). Indicate the type and proximity of neighboring facilities. If-I-125 and/or I-131 will be processed, include a detailed description of the hood and filter system to be used to prevent the spread of iodine inside or outside the facility. Also, show air flow patterns on the facility drawing, indicating locations of intake and exhaust. Describe the method for stack sampling and filter exchange.

Item 10 - Health Physics Instrumentation:

List all radiation monitoring or measuring instruments that will be available. List the manufacturer's name and model number of each instrument, number of instruments available, the type of radiation detected (e.g., beta, gamma), the range (mR/hour, counts per minute), window thickness if applicable, and how used (measuring or surveying). Describe the method, frequency, and standard used for the maintenance and calibration of radiation detection and survey instruments. These procedures should be included even if the service of an individual or company is employed. See Appendix H for model procedure.

Item 11 - General Instrumentation:

List the manufacturer and model number of all instruments used in conjunction with the requested procedures. This would include rectilinear scanners, gamma cameras, and dose calibrators. Submit your procedure for calibrating the dose calibrator. SEE APPENDIX I for requirements.

Item 12 - Medical Supplements:

Not applicable.

Item 13 - Industrial Radiography Supplement

Not applicable.

Item 14 - List the name and company affiliation of any individuals who assisted in the completion of the license application.

THE APPLICATION MUST BE DATED AND SIGNED BY THE INDIVIDUAL AUTHORIZED TO SIGN ON BEHALF OF THE INSTITUTION. SUBMIT ONLY THE ORIGINAL.

FORM DRC-13

Sealed Sources:

In the space provided or on a separate attachment, give the proposed inventory of calibration, reference, and medical radioisotopes in the form of sealed sources. Indicate
if the sources will be owned or leased either on a long term or case-by-case basis. If the model numbers of the sealed sources are not available, then indicate the type of sources such as plaques, needles, seeds, tubes, or wire.

Radiological Qualifications and Training:

Complete the required information for all technologists listed under Item 4 of Form DRC-11. This information may be submitted on a separate attachment if desired, but the attachment should be clearly referenced.

Schedule of Radioactive Materials:

You may state only the section number of Chapter 7 (Sections 729 and/or 731) for which you are requesting licensure.

For routine human use not listed in Sections 729 and 731, and for non-human use, list each radionuclide to be used. Provide the chemical and physical form and the maximum quantity in millicuries and/or microcuries to be possessed. List the manufacturer, model number, and quantity for all sealed sources.

ADDENDUM TO PERMIT APPLICATION: The attached "Addendum to Permit Application" must be completed for all new licenses and renewals.

The Addendum to Permit Application per LAC 33:I.1701 which can be found at:
http://www.deq.louisiana.gov/portal/tabid/240/Default.aspx

APPENDIX A

I. Introduction

Every nuclear pharmacy shall have one nuclear pharmacist who shall be named on the nuclear pharmacy license as a Nuclear Pharmacist-in-Charge. A Nuclear Pharmacist-in-Charge may not be in charge of more than one nuclear pharmacy. This person will be responsible for the radiopharmacy's compliance with state and federal laws and regulations pertaining to all aspects of the practice of nuclear pharmacy. The Nuclear Pharmacist-in-Charge should have the autonomy to suspend pharmacy operations should a condition exist which would compromise radiation safety.

Acceptable training of nuclear pharmacy personnel is outlined below.

II. Nuclear Pharmacist

Every licensed nuclear pharmacy in Louisiana which receives, prepares, possesses, uses, transfers, owns, acquires and/or distributes radioactive materials must be staffed with a person or persons classified as a nuclear pharmacist. The nuclear pharmacist must be named as an authorized user by the Department and licensed by the Louisiana Board of Pharmacy. Minimum acceptable training and experience are:

A. Successful completion of formal training in basic radioisotope handling techniques from an accredited college or university program. The minimum of 200 hours of didactic and laboratory training (involving theory, background and practical applications) to include:

1. Radiation physics and instrumentation - 85 hours

2. Radiation protection - 45 hours

3. Mathematics of radioactivity - 20 hours

4. Radiation biology - 20 hours

5. Radiopharmaceutical chemistry - 30 hours

B. A minimum of 500 hours of supervised training under the direction of nuclear pharmacist. This training must include the proper receipt, handling, preparation, usage, dispensing, transfer and/or distribution of radioactive materials.

C. Licensure by the Louisiana Board of Pharmacy.

Previous approval as an authorized user by another Agreement State or the NRC and successful pharmacist licensure in the State of Louisiana will be accepted in lieu of the requirements of Sections A and B. Board certification in nuclear pharmacy by the Board of Pharmaceutical Specialty, American Pharmaceutical Association or Board certification in radiochemistry and radiopharmacy by the American Board of Science in Nuclear Medicine are also recognition of training and will satisfy requirements A and B.

III. Nuclear Pharmacy Technician

The non-pharmacist authorized user is classified as a nuclear pharmacy technician who meets the minimum hiring criteria based upon the following:

A. Training in basic radioisotope handling techniques, including the minimum of 200 hours of didactic and laboratory hours from an accredited college or university program.

B. Successful completion of a minimum of one year on-the-job training in radiation safety at the nuclear pharmacy. The supportive personnel will be under the supervision of the Nuclear Pharmacist-in-Charge. The in-house experience should include all radiation safety aspects as previously documented with the expressed exception of the dispensing of a radiopharmaceutical.

Board Certification of Nuclear Medicine Technology by the ARRT is recognition of training and will satisfy requirement A and will reduce requirement B to a term of four months on-the-job training.

APPENDIX B

Model Personnel External Exposure Monitoring Program

Model Program

1. The RSO will promptly review all exposure reports 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 or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

APPENDIX C

Model Procedure for Area Surveys

You may use the following model procedure to perform area surveys.

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas

a. In radiopharmaceutical elution and preparation areas, survey at the end of each day of use with a radiation detection survey meter.

b. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

c. Action levels should be 0.1 mR/hr or twice background.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

a. In radiopharmaceutical elution and preparation areas, survey weekly for removable contamination.

b. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm2 of removable contamination (200 dpm/100 cm2 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.

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. ***Keep a record of dose rate and contamination survey results. It must include the following information:***

   a. ***The date, area surveyed, and equipment used.***

   b. ***The name or initials of the person who made the survey.***

   c. ***A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO.***

   d. ***Measured dose rates in mR/hr or contamination levels in dpm/100 cm2 as appropriate.***

   e. ***Actions taken in the case of excessive dose rates or contamination and followup survey information.***

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

Table C-1

Recommended Action Levels in dpm/100 cm2 for Surface Contamination by Radiopharmaceuticals

		P-32, Co-57, Fe-59 Co-60, Se-75, Sr-85 In-111, I-123, I-125	*Cr-51, Co-57 Ga-67, Tc-99m, Hg-197, Tl-201*
1.	*Unrestricted areas, personal clothing*	*200*	*2,000*
2.	*Restricted areas, protective clothing used only in restricted areas, skin*	*2,000*	*20,000*

APPENDIX D

Model Procedure for Leak-Testing Sealed Sources

Model Procedure

1. 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.

2. 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.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

    a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

    b. 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.

    c. If you are testing radium sources at the same time you are testing NRC-licensed sources, they should also be checked 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 described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:

    a. Select an instrument that is sufficiently sensitive to detect 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 crystal with a ratemeter or scaler or a GM survey meter 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 has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.

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

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

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

f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. The Division must be notified.

g. Sign and date the list of sources, data, and calculations.

APPENDIX E

Model Procedure for Waste Disposal

The following general guidance and procedure may be used for disposal of radioactive waste.

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 to in-house waste. Nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material.

General Guidance

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

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

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

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

1. **Regulations for disposal in the sanitary sewer appear in Section 462. Material must be readily water soluble or readily dispersible biological material in water. There are monthly 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.**

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Appendix B of Chapter 4. This limits apply at the boundary of the restricted 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.

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.

1. 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 departments may find it 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 the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date 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.

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

4. Prior to disposal as in-house waste, monitor each container as follows:

a. Check your radiation detection survey meter for proper operation;

b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

c. Remove any shielding from around the container;

d. Monitor all surfaces of each individual container;

e. 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 type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

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

5. 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 (preferable 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 0.06 mR/hr) area. Log 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 and some animal carcasses, 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 records 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. This permission does not relieve licensees from the requirement to comply with Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT Regulations, Paragraph 173.415(a) of 49 CFR Part 173).

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

3. Perform the dose rate and removable contamination measurements.

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

APPENDIX F

Model Procedure for Safely Opening Packages Containing Radioactive Material

Model Procedure

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits, as defined in Section 1503 and Appendix A of Chapter 15 of the Louisiana Radiation Regulations (e.g., more than 20 Curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 Curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 Ci of Ra-226). The licensee shall make arrangements to receive:

a. the package when the carrier offers it for delivery; or

b. the notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours. The Department must be notified if removable contamination exceed 0.01 microcurie (22,000 dpm)/100 cm_2.

2. For packages received under the specific license, the following procedure for opening each package will be followed:

a. Put on gloves to prevent hand contamination.

b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface; the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface.

d. Open the package with the following precautionary steps:

(1) Remove the packing slip.

(2) Open the outer package following the supplier's instructions, if provided.

(3) Open the inner package and verify that the contents agree with the packing slip.

(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

e. 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 (Tl) 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 sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement). Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in-house trash.

h. Make a record of the receipt.

APPENDIX G

Model Rules for Safe Use of Radiopharmaceuticals

Model Rules:

The following is an example of typical rules that could be specified for a laboratory using or preparing radioactive material. The applicant is encouraged to develop a set of rules specific to individual needs and the actual laboratory situation. Use of material which may become airborne (aerosols, Xenon-133, I-125/131) will necessitate additional rules, as will use of sealed sources. Rules should be written in the form of directions to be followed by employees.

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

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

3. Monitor your hands and clothing for contamination after each procedure and before leaving the area.

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

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

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

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

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

9. Never pipette by mouth.

10. Wipe-test radioactive material storage and preparation areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

11. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas at the end of each working day for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

12. Confine radioactive solutions in shielded containers that are plainly identified and labeled with the name of the compound, radionuclide, date, activity and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

14. Work over surfaces that are easily cleaned or covered with disposable absorbent coverings when handling open solutions of radioactive material. Work only in designated restricted use areas. Process volatile radioactive material under fume hoods or in glove boxes when possible.

APPENDIX H

Model Procedure for Calibrating Survey Instruments

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

Model Procedure

1. The source must be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 mCi of Cs-137 or 21 mCi of Co-60.

5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

6. A record must be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

8. Three kinds of scales are frequently used on survey meters:

    a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

    b. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

    c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be approximately 1/3 and 2/3 of the decade.

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:

    a. The owner or user of the instrument;

    b. A description of the instrument that includes manufacturer, model number, serial number and type of detector;

    c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;

    d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;

    e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);

    f. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);

    g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

    h. The apparent exposure rate from the check source; and

    i. The name of the person who performed the calibration and the date on which the calibration was performed.

APPENDIX I

Model Procedure for Calibrating Dose Calibrator

Model Procedure

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)

    a. Constancy at least once each day prior to assay of patient dosages (±5 percent).

    b. Linearity at installation and at least quarterly thereafter (±5 percent).

    c. Geometry dependence at installation (±5 percent).

    d. Accuracy at installation and at least annually thereafter (±5 percent).

2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a longer period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57, or Ra-226 using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

    a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

    b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

    c. 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.

    d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

e. 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 log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

4. 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.

5. 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 in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form. This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. On a 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.

e. 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.

f. If the worst deviation is more than ±0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.

b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through g above.

f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.

g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.

h. Continue for all sleeves.

i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

b. Steps c through e below must be completed within 6 minutes.

c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

e. Continue for all sleeves.

f. On a sheet of semilog graph, 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 model number and serial number of the dose calibrator.

g. Plot the data using the equivalent decay time associated with each sleeve.

h. 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.

i. If the worst deviation is more than ±0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

j. Put a sticker on the dose calibrator that says when the next linearity test is due.

6. 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 radiopharmaceuticals 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 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.

a. In a small beaker or vial, mix 2 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 nonradioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on a Dose Calibrator Geometry and Accuracy Form.

c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

d. Repeat the process until you have assayed a 2.0-cc volume.

e. 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. 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."

f. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, 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.

g. To test the geometry dependence for 3 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume the millicuries indicated.

i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical 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 horizonal 5 percent error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, 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.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value 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. At least two sources with different principal photon energies (such as Co-57, Co-60 or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries; other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on a Dose Calibrator Geometry and Accuracy Form. Repeat for a total of three determinations.

b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. 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.

e. 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 with the accuracy data.

f. Put a sticker on the dose calibrator that says when the next accuracy test is due.

8. The RSO will review and sign the records of all geometry, linearity and accuracy tests.

APPENDIX J

Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA

ALARA Program

(Licensee's Name)

(Date)

1. Management Commitment

a. We, the management of this (medical facility, hospital, etc.) are committed to the program described hereby 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. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. 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.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far 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.

2. Radiation Safety Officer

a. Annual and Quarterly Review

(1) <u>Annual review of the radiation safety program</u>. The RSO 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.

(2) <u>Quarterly review of occupational exposures.</u> The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) <u>Quarterly review of records of radiation surveys.</u> The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

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

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

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

4. Authorized Users:

Authorized User's Responsibility to Supervised Individuals

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

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

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

6. Signature of Certifying Official (The person who is authorized to make commitments for the facility).

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

_____

Signature

_____

Name and Title (print or type)