**NEW YORK STATE DEPARTMENT OF HEALTH**
**BUREAU OF ENVIRONMENTAL RADIATION PROTECTION**

**Radiation Guide 10.16**

# GUIDE FOR THE PREPARATION OF APPLICATIONS FOR NUCLEAR PHARMACIES

## I. INTRODUCTION

### A. PURPOSE OF GUIDE

The purpose of this licensing guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments, and license renewals for the possession, use, and distribution of radioactive material in nuclear pharmacy operations.

This regulatory guide is intended to provide you with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to nuclear pharmacies.

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application and in other correspondence with the Department; (2) the terms and conditions of your license; and (3) State Sanitary Code Part 16. The information you provide in your application should be clear, specific and accurate.

A "nuclear pharmacy", as the term is used in this guide, prepares and distributes radioactive drugs to hospitals and to physicians for use in their private practice. The term "distribution" implies routine transfer of licensed material to others and may or may not involve a prescription for a specific patient. The services you may provide will depend on how your facility will be registered with the New York State Board of Pharmacy and you should contact the Board directly.

Section 4 of this guide discusses requests to redistribute various items. "Redistribution" usually involves obtaining the item to be redistributed from an authorized manufacturer and selling the item to the nuclear pharmacy's customers with little or no change in the original packaging, labeling, etc.

### B. APPLICABLE REGULATIONS

Licensees of the New York State Department of Health must comply with the provisions of State Sanitary Code Part 16. It is your responsibility as an applicant and as a licensee to have copies of, to read, and to abide by these regulations. As a licensee, you are subject to all provisions of the regulations as they pertain to nuclear pharmacy operations.

## II. FILING AN APPLICATION

As the applicant for a materials license, you must complete form DOH-370. You should complete items 1 through 4 and item 26 on the form itself. For Items 5 through 25 submit the information on supplementary pages. Each separate sheet or document submitted with the application should be identified and keyed to the item number on the application to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8½ X 11 inch paper to facilitate handling and review. If larger drawings are necessary are necessary, they should be folded to 8½ X 11 inches. You should complete all items in the application in sufficient detail for this office to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and safety and minimize danger to life and property.

The application should be filed in duplicate. Retain one copy for yourself, because the license will require that you possess, use, and distribute licensed material in accordance with the statements and representations in your application and in any supplements to it. Please note that license applications are available under Freedom of Information. Do not submit proprietary information unless it is absolutely necessary.

## III. CONTENTS OF AN APPLICATION

This guide contains appendices that present model procedures or programs acceptable to the Department. If you refer in your application to a section or appendix of this guide, that section or appendix will be incorporated as a part of the terms and conditions of your license. You will be inspected against the commitments contained in the referenced section, appendix, or document, just as you will be inspected against your more detailed responses. Accordingly, you must keep a copy of the referenced guide on hand at all times so that you can review your commitments as necessary.

### Item 1.a. APPLICANT'S NAME AND MAILING ADDRESS

If you are an individual, you may be the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment with a corporation or other legal entity. Otherwise, you, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used, as specified in Item 1.b.

### Item 1.b. LOCATIONS OF USE

You should specify each location of use by the street address, city, and State or other descriptive address (such as five miles east on Highway 10, Anytown, State) to allow us to easily locate each of your facilities. A post office box address is not acceptable.

Item 2. CONTACT PERSON

Enter the name and telephone number (including area code) of an individual who knows your program and can answer questions about the application. This should be a staff member and not a consultant.

Item 3. TYPE OF ACTION

Indicate whether this is an application for a new license, an amendment, or a renewal; and enter the license number.

Item 4. RADIATION SAFETY OFFICER

Submit the name and qualifications of the person who will provide day-to-day oversight of your radiation protection program, and the percentage of this person's time to be given to such duties. Please note that paragraph 16.2(a)(99) and section 16.5 of the State Sanitary Code Part 16 describe requirements for Radiation Safety Officers.

Item 5. INDIVIDUAL USERS

List the name(s) of the Nuclear Pharmacist(s) who will supervise pharmacy activities at this facility and submit documentation of their certification by the State Board of Pharmacy. List the names of all persons who will use, supervise, or direct the use of radioactive material.

Items 6. & 7. RADIOACTIVE MATERIALS, USES

You should list the radioactive materials you wish to possess, and the maximum activity for each. Clearly identify which licensed materials you wish to possess only, and which you wish to possess and distribute.

If you want to redistribute various items, see Section IV of this guide about information to be supplied.

Be sure to include any calibration or check sources (for your own instruments) in this listing if they require a license. Indicate the purpose of each source and the activity desired.

Item 8. a. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Please review the model procedure for typical duties of the Radiation Safety Officer described in Appendix A, and confirm you will adopt the model procedures or submit your changes in red ink.

You should also describe how the RSO will delegate functions to ensure that

supervision of the radiation protection program will be adequate during all times when the facility is operating.

Item 8. b. RADIATION PROTECTION PROGRAM

You are required by section 16.5 of State Sanitary Code Part 16 to develop, document and implement a radiation protection program commensurate with the scope and extent of the radioactive materials use authorized by the license. Responses to the following sections will be evaluated to determine if your program is adequate to protect health and safety.

Submit a commitment to conduct, or have conducted, an annual review of the radiation protection program content and implementation, and of the performance of your Radiation Safety Officer. You should include the qualifications of the person or persons who will conduct the audit and what will be covered. The latter can be satisfied by submitting a copy of the form to be used.

Item 9. TRAINING

You should state that if persons will perform the duties of Nuclear Pharmacists at this facility, they will be certified as such by the New York State Board of Pharmacy, and that all pharmacy activities will be conducted in accordance with the Board's policies and regulations.

A. All persons who will perform duties under a radioactive materials license within a restricted area must be adequately trained before assuming duties, and must receive appropriate refresher training at least annually.

Appendix B, Part 1, contains a personnel training program acceptable to the Department. Please confirm that your program will meet these criteria, and submit the information requested in the Appendix. Please also submit curriculum vitae for all professional personnel.

B. Anyone who will be permitted to enter areas posted for radiation protection, or which are potentially contaminated or contain potentially contaminated items, must be instructed and supervised. This includes visitors and repair, or service, personnel of any kind.

Appendix B, Part 2, addresses this need. Please review the appendix and submit the requested information.

Item 10. INSTRUMENTATION AND CALIBRATION

A. Survey Instruments.

You must provide appropriate survey instruments for contamination surveys, measuring exposure rates in work and storage areas, on incoming and outgoing packages, and for personnel frisking.

These should include meters with thin window pancake probes and audible signals for surface contamination surveys, a high range ion chamber that will measure up to 1 R/hr and microrem meters for frisking personnel and "cold" waste.

Please list the instruments that will be provided by make, model, type, range and quantity.

All survey instruments must also be calibrated at least annually by a person or company licensed to perform such services. Please confirm that these instruments will be calibrated at 12-month intervals by a properly licensed person or company (you need not name the person or company, but you must maintain their license on file).

B. Dose Calibrators.

Please list the make, model and number of dose calibrators to be provided. Indicate whether any will be used for special purposes (such as calibrating strontium 89 dosages), and whether they were designed for those purposes.

All dose calibrators must be maintained and tested in accordance with accepted standards for accuracy and reproducibility. Appendix C specifies the necessary tests and checks and the type of sources to be used. Submit the procedures and sources you will use for tests and checks to be performed as Quality Control on your dose calibrators. Include in these procedures the minimum activity at which calibration and check sources will be replaced.

If any dose calibrators are to be used for special purposes (such as calibration of beta emitters), you must also describe calibration procedures that will ensure traceability of all dosages to an accepted standard for each nuclide.

C. Analytical Equipment.

You must have a well counter for analysis of wipe tests, and a thyroid uptake system if you will handle millicurie quantities of iodine 131. The uptake system must provide a reproducible geometry and have sufficient sensitivity to detect 0.04 microcurie of iodine 131 in the thyroid.

List the make, model and type of each analytical instrument and the lower limit of detection for nuclides of interest. For uptake systems, this must be calculated for the minimum activity detectable in a neck phantom.

Also submit procedures for annual calibration of equipment, and for QC on days of use. For uptake systems, this must include use of a neck phantom for reference measurements.

Item 11. FACILITIES AND EQUIPMENT

You must provide a detailed description of the facilities at which you propose to conduct your program, and the equipment you will have available for shielding, handling, storage and processing of radioactive materials.

A. Facility layout should be shown on scaled drawings, clearly showing the overall layout and use of all areas within, and contiguous to, your facility. Drawings of each use and storage area should also be submitted, and should clearly show the location of all equipment. The drawings should also indicate areas for receipt of radioactive materials both during and after hours, and how security will be maintained.

B. Provisions for security, fire detection and fire suppression should also be described. This should include the type of doors and locks, any window barriers, sprinkler systems, alarms, etc.

C. The location of the facility and the uses of surrounding buildings should also be described. Areas with heavy public traffic such as office buildings or large shopping centers are not appropriate due to the potential for an accident involving a large airborne release, or the spread of radioactive contamination in significant quantities.

D. The ventilation system for your facility must be designed by a qualified individual, experienced in the design of ventilation systems for facilities using large quantities of radioactive materials, and must be tested in-place prior to the start of licensed operations. Areas where volatile or gaseous materials are used or stored, or where radiopharmaceutical preparations are heated, should be at negative pressure and equipped with fume hoods.

In a multi-tenant building, you must also provide assurance that air from your premises will not be circulated to other areas of the building.

Submit a diagram of your ventilation system showing measured air supply and exhaust data and exhaust points (you may submit calculated or design values if the system is not yet completed, and submit actual measurements before operations begin). You should also submit a commitment to repeat such measurements at six- month intervals and make any necessary repairs or adjustments to maintain the airflow as designed.

E. Shielding must be provided to maintain staff exposures ALARA below regulatory limits. Describe the shielding you will provide for:

— Generator storage and elution areas

— Storage of other radioactive materials including calibration and check sources

— Radioactive materials handling areas

— Radioactive waste storage, both in use areas and storage rooms. Waste containers should also have shielded covers to reduce workers exposure.

Item 12. PROCEDURES FOR ORDERING AND RECEIVING SHIPMENTS OF RADIOACTIVE MATERIAL

Appendix D contains a set of procedures acceptable to the Department. You may respond to this section by stating that you adopt and will implement the procedures in Appendix D of NYSDOH Radiation Guide 10.16.

A. Procedures for Receiving Back Radioactive Materials From Customers.

If you will receive back radioactive materials not used by customers, or empty vials or syringes contaminated with those materials you must submit your procedures, and directions to customers on the preparation, packaging and paperwork for such returns.

B. Handling of Returned Radioactive Materials.

You should submit your procedures for handling return packages of radioactive materials and contaminated items. Include information on how they will be picked up, who will deliver them to your facility, where they will be delivered and processed, who will open the packages and how the contents will be handled and stored.

Item 13. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS

Appendix E contains a set of procedures acceptable to the Department. You may respond to this section by stating that you adopt and will implement the procedures in Appendix E of NYSDOH Radiation Guide 10.16.

Item 14. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIALS

Appendix F contains a set of general rules acceptable to the Department. You may respond to this section by stating that you adopt and will implement the procedures in Appendix F of NYSDOH Radiation Guide 10.16.

Item 15. SPILL PROCEDURES

Appendix G contains spill procedures acceptable to the Department. You may respond to this section by stating that you will adopt, post and implement the procedures in Appendix G of the NYSDOH Radiation Guide 10.16.

Item 16. AREA SURVEY PROCEDURES

You must adopt and implement procedures for radiation surveys and contamination monitoring.

Appendix H to this guide describes initial surveys to be performed before routine operations, and on an ongoing basis. You may respond to this section by stating that you adopt and implement the procedures in Appendix H of the NYSDOH Radiation Guide 10.16. You must also commit to initial and ongoing monitoring to be performed in areas above, below, or contiguous to your facility and submit this as part of the application.

Item 17. WASTE DISPOSAL

Appendix I of this guide contains information regarding management of radioactive waste. Parts of the appendix require a response, therefore you should review the appendix and provide information as appropriate to describe your waste management and minimization program.

Appendix I-1 contains a model low-level radioactive waste (LLRW) minimization plan. You should review this plan and confirm you will adopt it, or provide a copy of your own plan.

Appendix I-2 describes the information needed by the Department to authorize decay-in-storage of short-lived radioactive materials.

Appendix I-3 describes procedures for handling Mo-99/Tc-99m generators. Please review that material and confirm generators will be managed in accordance with Appendix I-3, or submit your methods of handling the used generators.

Items 18-21. Not applicable.

Item 22. OTHER PROCEDURES AND PRECAUTIONS

A. Radioiodine Handling Procedures.

In addition to the general rules for safe handling of radioactive materials you should submit your procedures and precautions for the handling of millicurie quantities of radioiodine.
These should include use of a fume hood, gloves and protective clothing and all monitoring to be performed during opening and handling of such material

(including any breathing zone monitoring).

You should also describe exactly what processing will be performed with radioiodine, and how you have taken ALARA requirements into account for such handling.

B. Labeling and Shielding of Products.

All products which you distribute for human use must be labeled in accordance with the regulations of the USFDA and the New York State Board of Pharmacy.

In addition the shielded container label must contain the name of the radiopharmaceutical or its abbreviation, the quantity of radioactivity and the date and time of assay (or the date and time for which the activity is specified). If the product is dispensed for a specific patient, a patient identifier must also be indicated on the inner container label or on the outer container, with means to correlate the two, should they become separated. All labels must meet the requirements of section 16.12 of State Sanitary Code Part 16.

Radiopharmaceuticals tagged with technetium-99m should specify the concentration of molybdenum-99 at the time of expiration (see also Appendix F).

Please submit samples of labels.

Shielding provided for products must be reasonable for safe handling and storage.

For each radionuclide you will distribute:

— State the maximum activity for each container to be used.

— Describe the type and thickness of shielding.

— Indicate the maximum radiation level at the surface when filled with the maximum activity.

— Confirm that this information will be provided to customers.

C. Procedures for Packaging and Transport of Radiopharmaceuticals.

You must adopt and implement procedures to ensure that radiopharmaceuticals are packaged, labeled and transported in accordance with all requirements.

You should submit your step-by-step procedures for packaging, labeling and

transporting; including the staff who will perform all functions.
You should submit written instructions to be given to delivery personnel concerning radiation safety and delivery procedures. These should include keeping the vehicle locked when not occupied; limits on leaving the vehicle unoccupied; secure areas for parking which are arranged with your customers; and steps to take in the event of an accident or incident. You should also state that these instructions for responding to accidents or incidents will be conspicuously available in all vehicles, and will contain emergency contacts and phone numbers, generally describe the contents of the vehicle and prescribe reasonable measures for an accident responder to take. The phone numbers must include the Department's daytime (518/458-6485) number, and the after-hours phone number for the NYS Warning Point (518/457-2200).

Item 23. PERSONNEL MONITORING AND BIOASSAYS

You must establish and implement procedures for a personnel monitoring and bioassay program. At a minimum these procedures must include the following requirements:

1. Whole body badges will be provided to all staff who handle radioactive materials on a regular basis. They will be exchanged for processing on a monthly basis, by a processor accredited by NVLAP.

2. Finger badges will be provided to all staff who handle radioactive materials on a regular basis.

3. Finger badges issued to Nuclear Pharmacists will be exchanged for processing on a weekly basis, as will finger badges for any other staff who elute generators.

4. Finger badges issued to other staff will be exchanged for processing on a monthly basis.

5. A bioassay program will be conducted for any staff who handle millicurie quantities of iodine 131. Thyroid uptakes will be measured on a weekly basis, or 24 to 48 hours after handling occurs if it is infrequent, using the uptake system described in response to Items 12 and 13. The monitoring program will be conducted in accordance with NRC Regulatory Guide 8.20, which is included as Appendix D to this guide.

Item 24. Not applicable.

Item 25. ALARA PROGRAM

ALARA (As Low As is Reasonably Achievable) in medical institutions. Each institutional medical licensee must have a formal ALARA program. 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. A Radiation Safety Committee composed of individuals who have special expertise in the safe use of radioactive material is required to review each proposed method of use for safety and ALARA considerations.

The Committee, the Radiation Safety Officer, and management should audit the radioactive material program to ensure the continued safe use of radioactive material. In addition to being a member of the Committee, the Radiation Safety Officer serves as a technical consultant to the Committee and is also responsible for the day-to-day operation of the radiation safety program.

Submit your program for maintaining radiation exposures and releases of radioactive material ALARA.

Item 26. CERTIFICATE

The application should be signed by the President or CEO of the company or senior administrator of the facility. Identify the titles of the signators.

## IV. REQUESTS FOR AUTHORIZATION TO REDISTRIBUTE VARIOUS ITEMS

Redistribution of items obtained from approved suppliers (who hold Agreement State, State or U.S. Nuclear Regulatory Commission licenses authorizing distribution of the items in question), and sale to your customer's with little or no change in packaging, shielding, etc. will be authorized in a separate license.

If you wish to have such authorization, please submit the following information.

1. Generators.

   Specify that all generators will be obtained from a manufacturer authorized under a current valid license to distribute them; and that they will be redistributed without opening or altering the manufacturer's packaging. Also specify that generators will only be redistributed to facilities holding current valid licenses to receive them.

2. Sealed Calibration and Reference Sources.

   Specify that all sources will be obtained from a manufacturer authorized under a current valid license to distribute them, that packaging and labeling won't be altered and that the manufacturer's calibration certificate, handling procedures and any other documentation intended for the end user will be supplied to customers. Also specify that sources will only be redistributed to facilities holding current valid licenses to receive them.

3. In-Vitro Kits.

   Specify that all in-vitro kits will be obtained from a manufacturer authorized under a current valid license to distribute such kits to general licensees, that the packaging and labeling will not be altered in any way and that documentation intended for the end user will be supplied to customers.

## V. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with (1) the statements, representation, and procedures contained in your application; (2) the terms and conditions of the license; and (3) the Department's regulations.

It is your obligation to keep your license current. You should anticipate the need for a license amendment insofar as possible. If any of the information provided in your application is to be modified or changed, submit an application for a license amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended; Department regulations do not allow you to implement changes on the basis of a submission requesting an amendment to your license.

An application for a license amendment may be prepared either on the application form (DOH-370) or in letter form and should be submitted in duplicate to the address specified in Section II of this guide. Your application should identify your license by number and should clearly describe the exact nature of the changes, additions or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page and paragraph. For example, if you wish to change the RSO, your application for a license amendment should specify the new individual's name, training and experience. The qualifications of the new RSO should be equivalent to those specified in Item 4 of this guide.

# APPENDIX A

## MODEL PROCEDURE FOR DESCRIPTION OF DUTIES OF THE RADIATION SAFETY OFFICER

A. The responsibilities of the Radiation Safety Officer have been recognized, and the appointed Radiation Safety Officer has been delegated the authority to meet these responsibilities. Although certain tasks may be delegated to trained and qualified staff, the responsibility for seeing that those tasks are satisfactorily completed remains with the Radiation Safety Officer.

B. The Radiation Safety Officer is responsible for:

1. providing classroom instruction to non-professional personnel who will perform work under the license;

2. reviewing personnel monitoring reports and recommending methods to reduce exposures exceeding ALARA levels;

3. reviewing survey records and making confirmatory measurements;

4. reviewing air monitoring and emission levels and ensuring compliance with limits;

5. assisting in thyroid bioassays and reviewing absorbed dose calculations;

6. observing operations and making recommendations for improvements;

7. assisting in response to, and evaluation of, root causes of incidents and accidents in order to minimize their impact and prevent their recurrence.

8. ensuring compliance with regulations; and

9. assisting the Radiation Safety Committee in the performance of its duties.

## APPENDIX B, PART 1

## PERSONNEL TRAINING PROGRAM

A. Authorized Nuclear Pharmacists

1. All persons who will perform the duties of Nuclear Pharmacists at this facility will be certified as such by the New York State Board of Pharmacy, and will act in accordance with all Board requirements, rules and regulations.

2. Nuclear Pharmacists will also be trained in the policies, procedures and license requirements of this facility, and the provisions of State Sanitary Code Part 16, before assuming duties under this license.

3. Nuclear Pharmacists will also receive annual refresher training appropriate to their duties. This will include any changes/improvements in dosage preparation, and any other changes in facility policies and procedures or in the license, which have occurred during the year.

B. Other Professional Personnel

1. All professional personnel other than Nuclear Pharmacists (such as nuclear medicine technologists or health physics staff) will have received formal training in nuclear medicine technology and/or health physics, and be experienced in the use and handling of the types and quantities of radioactive materials to be used under the license. The duties of all professional personnel are specified in job descriptions and have been submitted to the Department as part of this application.

2. Such staff will also be trained in the policies, procedures and license requirements of this facility, and the provisions of State Sanitary Code Part 16, before assuming duties under the license.

3. Such staff will also receive annual refresher training appropriate to their duties. This will include any changes in facility policies and procedures, or in the license, which have occurred during this year.

C. Other Personnel Performing Work Under the License

1. Minimum hiring qualifications and job descriptions specifying tasks to be performed, have been developed for all other personnel who will perform work under the license and have been submitted to the Department as part of this application, along with a detailed training program for each job description and the tests to be given as a part of the program. This training will be given in a classroom setting in the presence of a qualified instructor, to all personnel who will handle radioactive materials or perform tasks essential to compliance with regulations, and will include at least forty hours of classroom instruction. The training will be given before personnel assume duties

under the license, and after successful completion of a test or tests demonstrating understanding of the instruction given.

2. All ancillary staff will also be trained in the policies, procedures and license requirements of this facility, and the provisions of State Sanitary Code Part 16, before beginning work.

3. All such staff will also receive annual refresher training appropriate to their duties.

D. All Personnel

1. All personnel who handle radioactive materials will participate in annual retraining in emergency procedures, which will include "dry runs."

2. All personnel who are involved in incidents or accidents (such as dosage errors, personal contamination, delivery or pickup errors, exposures exceeding ALARA levels, etc.) will receive individual retraining designed to prevent a recurrence.

3. Records of all training, identifying the individuals who conducted the training, the personnel trained, dates of training and the content covered will be maintained.

## APPENDIX B, PART 2

## INSTRUCTIONS TO VISITORS, AND SUPERVISION

Anyone other than your personnel who will be permitted to enter posted areas, or work on potentially contaminated items or equipment must first receive appropriate instruction.

Please describe policies and procedures that will ensure that appropriate instruction in possible radiation hazards, and precautions to be taken, will be given before you permit any persons to enter posted areas or work on potentially contaminated items or equipment.

Please also describe how such persons will be supervised so that observance of appropriate precautions will be ensured.

# APPENDIX C

## QUALITY CONTROL OF DOSE CALIBRATIONS

1. Constancy Checks

   Constancy will be checked by measuring the activity of a known source over a long period of time. Dose Calibrators will be checked for constancy with at least one dedicated check source at the beginning of each day of use. This includes weekends and holidays, if doses are prepared.

   The reference source, or sources, used for the constancy check will be assayed at a frequently used setting. Dose calibrators having both pre-adjusted controls (i.e., push buttons) and variable potentiometers will be tested on both the variable potentiometer technetium-99m (or other frequently used isotope) setting and the pre-adjusted control. Discrepancies or fluctuations between the two controls, when tested for constancy with the same check source, will be considered indicative of equipment malfunction. We will compare the measured activity of each source to the calculated activity, based on decay of the dedicated check source. If the error between the two values exceeds 10 percent, the dose calibrator will be repaired or replaced.

2. Accuracy Test

   Accuracy tests will be performed to ensure that the measured activity is within five percent of a given calibrated reference source whose activity has been determined by the manufacturer to be within five percent of the activity stated by the National Institute of Standards and Technology (NIST), or by the supplier who has compared that source to a source that was calibrated by NIST. At least two sealed sources with different principal photon energies, one of which has a principal energy between 100 keV and 500 keV, will be used to determine accuracy upon installation, and at least annually thereafter. The activity will be at least 10 µCi for Ra-226 and 50 µCi for any other photon-emitting radionuclide. The lower energy reference standard will be in vials of similar thickness to those for actual samples. If measurement error exceeds five percent, the dose calibrator will be repaired or replaced.

3. Linearity Tests

   Linearity tests will be performed to ensure that dose calibrators indicate the correct activity over the range of use between the highest dose that will be calibrated and 10 microcuries. Dose calibrators will be tested for linearity upon installation and at least quarterly thereafter. If the percent deviation exceeds five percent, dosage readings will be mathematically corrected.

4. Geometry Dependence

Tests will be performed to ensure that the indicated activity does not change with volume or configuration of the dosage. This test will be performed on each dose calibrator upon installation, over the range of volumes and volume configurations for which it will be used. The test should be done using the vials and syringes normally used; and should also be done for iodine capsule volumes and configurations. Geometry testing performed by the manufacturer may be acceptable, provided that the manufacturer has included all volumes and volume configurations for which the dose calibrator will be used at the licensee's facility and the licensee keeps a record of this test.

Licensees must also perform appropriate checks and tests following adjustment (e.g., a constancy check after battery replacement) or repair of the dose calibrator. It is also appropriate to recheck the geometry if repairs are done that might affect the response of the chamber, and to conduct linearity and accuracy tests following any repairs to the dose calibrator.

## APPENDIX D

## PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS FROM SUPPLIERS

1. An authorized user will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. The receiving area will be located so that the radiation levels in unrestricted areas do not exceed the limits specified in State Sanitary Code Part 16.

3. When the nuclear pharmacy is open, carriers will be instructed to deliver radioactive packages directly to the receiving area of the nuclear pharmacy.

4. When the nuclear pharmacy is closed, delivery firms will have written instructions to place packages in the receiving area of the nuclear pharmacy and to note the condition of the delivered package. If a package is or appears to be damaged, the carrier will be instructed to immediately contact the nuclear pharmacist on call who will then come to the nuclear pharmacy to inspect the package. The carrier will be asked to remain at the nuclear pharmacy until it can be determined whether he/she or the delivery vehicle is contaminated. The following letter will be posted in the receiving area and will be given to each carrier service.

   TO: Any courier service delivering radioactive materials to (name of nuclear pharmacy)*

   FROM: (name of radiation safety officer)*

   SUBJECT: Delivery of packages containing radioactive material

   Any packages containing radioactive material that are to be delivered to our nuclear pharmacy after normal hours of operation are to be placed in the designated "receiving area." Be sure to lock the door upon leaving.

   If the package is wet or appears damaged, immediately contact the nuclear pharmacist on call by calling our answering service at *_____. Remain at the nuclear pharmacy until you and your delivery vehicle are surveyed for contamination, and decontaminated if necessary.

* This information will be filled in and updated as necessary.

## APPENDIX E

## PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Some packages of radioactive materials require special handling procedures (see paragraph 4 below). A chart showing routinely expected shipments and their status with respect to these requirements may be prepared in advance to assist your staff in compliance.

2. The following procedures must be carried out for all packages containing radioactive materials:

   a. Put on waterproof gloves to prevent hand contamination.

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

   c. Measure the exposure rate at three feet (or one meter) from the package surface and record it. If >10 milliroentgens per hour, stop and notify the RSO.

   d. Measure the surface exposure rate and record it. If >200 milliroentgens per hour, stop and notify the RSO.

   e. Open the package with the following precautionary steps and record receipt of the radioactive material.

      1. Open the outer package (following manufacturer's directions, if supplied), and remove the packing slip.

      2. Open the inner package and verify that the contents agree with those on the packing slip, and label on the bottle.

      3. Check the integrity of the final source container (i.e., inspect for broken seals or vials, loss of liquid, and discoloration of packaging material).

      4. Check also that the shipment does not exceed possession limits.

   f. Wipe the external surface of the final source container shield and count the wipe. If there is removable contamination on the wipe, secure the container and notify the

* If this is noted while the carrier is still on-site, detain the carrier until the RSO responds so that the driver and vehicle can be surveyed for contamination.

RSO.

g. If removable contamination exceeds 200 dpm per $cm^2$, the final source container shield is not to be opened, and will be returned to the supplier by the RSO.

h. Monitor the packing material and packages for contamination before discarding.

    1. If contaminated, treat as radioactive waste.

    2. If not contaminated, obliterate the radiation labels before discarding in the nonradioactive trash.

3. Records of exposure rate and contamination surveys in items 2.c, 2.d, and 2.f will be maintained for at least two years. Records of receipt of radioactive material will be maintained in accordance with the requirements of section 16.14 of State Sanitary Code Part 16.

4. Special procedures will be followed for receiving packages containing quantities of radioactive material in excess of Type A quantity limits (e.g., more than 20 curies for molybdenum-99 and technetium-99m). These packages will be monitored for surface contamination and external radiation levels within three hours after receipt if received during working hours or within three hours from the beginning of the next work day if received after working hours. The New York State Department of Health will be notified in accordance with the regulations if removable contamination exceeds 2200 dpm per 100 $cm^2$ or if external radiation levels exceed 200 milliroentgens per hour at the package surface or 10 milliroentgens per hours at three feet (or one meter). Records of the results of package monitoring will be maintained for inspection for a period of three years.

## APPENDIX F

## GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Always wear laboratory coats or other protective clothing in areas where radioactive materials are used or stored (e.g., processing, packaging, and waste areas).

2. Always wear disposable gloves when handling radioactive materials, or articles that may be contaminated with radioactive materials (such as empty containers), or surfaces where radioactive materials have been used.

3. Monitor hands and clothing for contamination after each handling procedure or when leaving an area where radioactive materials are used or stored.

4. Always use syringe shields, vial shields and tongs for preparing, dispensing and assaying radiopharmaceuticals.

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

6. Do not store food, drink, or personal effects with radioactive material.

7. Assay each vial, syringe, and capsule containing more than 10 microcuries of a beta or gamma-emitting radiopharmaceutical in the correct dose calibrator before distribution for use in humans.

8. For each elution of technetium-99m from a molybdenum-99/technetium-99m generator:

    a. Assay the eluate for technetium-99m in a dose calibrator; record the results and retain the record for three years after the assay.

    b. Test for molybdenum-99 concentration; record the results and retain the record for three years after the test.

9. Do not distribute technetium-99m for human use if the technetium-99m does or will contain more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m at the expiration time and date shown on the package label. The expiration date and time shown on the label must be adjusted so that the limit specified above is not exceeded for any patient doses.

10. Always wear your personal monitoring badges 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, badges should be stored in the designated low-background area.

11. Always wear finger badges when eluting the generator and handling millicurie quantities of radioactive material. Finger badges must also be worn when removing the contents of returned radiopharmaceutical cases.

12. Never pipette by mouth.

13. Waste from use and storage areas must be surveyed with a microrem meter to determine whether it is radioactively contaminated before disposal. Dispose of radioactive waste only in specifically designated and properly shielded receptacles.

14. Survey the generator, kit preparation, and dose dispensing areas for contamination after each procedure or at the end of the day. Decontaminate if radiation levels exceed the action limits for area surveys.

15. Confine radioactive solutions in covered containers that are clearly identified and labeled with the name of the compound, radionuclide, date and activity.

16. Always transport radioactive material in appropriately shielded containers.

## APPENDIX G

## SPILL PROCEDURES

1. A copy of these procedures will be posted in each area where radioactive material is used or stored.

2. A decontamination kit is located _____[*]. The contents of this kit include disposable waterproof gloves, remote handling tongs, absorbent paper, disposable pads, and plastic bags.

3. Minor Spills (A single patient dose, other than radioiodine)

   a. NOTIFY: Notify persons in the area that the spill has occurred.

   b. PREVENT THE SPREAD: Cover the spill with absorbent paper.

   c. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper. Insert into a plastic bag. Also insert into the plastic bag all other contaminated materials such as disposable gloves. Put the plastic bag into the radioactive waste container.

   d. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

   e. REPORT: Report the incident to the Radiation Safety Officer (RSO).

4. Major Spills (multidose vial, eluate, any radioiodine spill)

   a. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

   b. PREVENT THE SPREAD: Cover the spill with absorbent paper or pads, but do not attempt to clean it up. Confine the movement of all potentially contaminated personnel to prevent the spread.

   c. RESTRICT THE AREA: Leave the room and take steps to prevent entry. Do not leave the area unless a survey of your hands, shoes and clothing shows no contamination.

   d. CALL FOR HELP: Notify the RSO, or have another person do so immediately.

   e. PERSONNEL DECONTAMINATION: Remove contaminated clothing and store for

[*] This information will be filled in and updated as necessary.

further evaluation by the RSO.  If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: [*] _____

OFFICE PHONE: [*] _____

HOME PHONE: [*] _____

NAMES AND TELEPHONE NUMBER OF ALTERNATES DESIGNATED BY THE RSO:

[*]

_____

_____

_____

[*] This information will be filled in and updated as necessary.

# APPENDIX H

## AREA SURVEY PROCEDURES

1. All elution, preparation, assay, and dispensing areas will be surveyed daily with a low-range survey meter and decontaminated if necessary.*

2. Waste storage areas and all other laboratory areas will be surveyed weekly.

3. The weekly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 milliroentgen per hour.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 2,000 dpm per 100 $cm^2$ , and 200 dpm per 100 $cm^2$ for radioiodine. Wipes of elution and preparation areas or other high-background areas will be removed to a low-background area for measurement.

4. Other surveys

   Radiation levels in any unrestricted area, such as areas above, below or adjacent to your facility, must also be evaluated to demonstrate that no member of the public could receive a dose greater than 2 millirem in any one hour, or 100 millirem in a year. Exposures must also be maintained ALARA below these limits.

   This can be done on an ongoing basis through use of area monitoring badges on your side of a common wall; or placed in occupied areas above or below your premises, or on the other side of a common wall. Such badges must be exchanged on a monthly basis unless a longer interval is specifically approved by the Department.

   However, an initial survey of such areas must be performed after radioactive materials are first received and reported to the Department.

5. Records of all survey results*, including negative results, will be kept for one year after each survey. The record will include:

   a. A drawing of the area surveyed identifying relevant features such as active storage areas, active waste areas, etc.

   b. Measured exposure rates (in units of milliroentgen per hour) keyed to locations on

* Daily surveys need not be recorded.

the drawing.

c. Detected contamination levels (in units of dpm or microcuries) keyed to locations on the drawing.

d. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. The area will be cleaned if the removable contamination level exceeds 1,000 dpm per 100 $cm^2$ or 200 dpm per 100 $cm^2$ for radioiodine.

# APPENDIX I

## WASTE DISPOSAL

In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, New York State Department of Health is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with 6 NYCRR Part 380.

### 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 packing material should not be mixed with radioactive waste.

3. Periodically 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).

5. In New York State the Department of Environmental Conservation regulates releases to the environment and has enacted regulations on the transport of low-level radioactive waste in New York State (6 NYCRR Part 381). These regulations require that a properly executed manifest and a valid transport permit issued by Department of Environmental Conservation accompany all waste shipments. For further information contact:

   New York State Department of Environmental Conservation
   Division of Hazardous Substance Regulation
   Bureau of Radiation
   50 Wolf Road
   Albany, New York 12233-0001

## APPENDIX I-1

## MODEL LOW-LEVEL RADIOACTIVE WASTE MINIMIZATION PLAN

1. All sealed sources which are expected to be routinely exchanged will only be obtained from providers which guarantee to receive them back.

2. No non-"disposable"* radioactive materials will be acquired under our radioactive materials license unless it can be demonstrated that a non-radioactive or "disposable" radioactive alternative is not reasonably available.

3. Any non-"disposable" radioactive materials that are permitted to be acquired will be limited to the minimum amount needed.

4. All uses of non-"disposable" radioactive materials will be conducted so as to minimize waste production.

5. All persons engaged in work under the radioactive materials license will receive initial training and annual refresher training in policies and procedures to minimize production of non-"disposable" LLRW.

* For purposes of this guide, "disposable" radioactive waste is waste that can be managed under the license by some available means other than disposal to a LLRW waste site. This includes decay-in-storage, use of sanitary sewer allowances, exemptions such as certain levels of H-3 or C-14 in scintillation cocktail, etc.

## APPENDIX I-2

## DECAY-IN-STORAGE PROGRAM FOR LOW-LEVEL RADIOACTIVE WASTE

Submit your management program for radioactive waste that is to be decayed-in-storage. Include a description of:

1. any waste processing that will be done.

2. the facility or area used for storage (e.g. an 8 x 10 foot concrete block room without windows that is climate-controlled and sprinklered).

3. the waste packages to be used; if packages are stored for more than a year they should be sturdy enough for the purpose (e.g. commercially available waste boxes 11" square x 22" high constructed of heavy cardboard and lined with heavy gauge plastic).

4. security; state how access to the room or area will be controlled.

5. operations; describe your system for managing the decay-in-storage program. The following model may be used:

    i. Each box or bag will be assigned an I.D. number.

    ii. A written log will be kept where we will enter the box I.D. number, initial start date for empty box, date and survey reading at box surface when it is full and goes into storage, contents of the box and projected date of removal from storage (after at least ten half-lives).

    iii. The log information will also be written on each box and a radiation label will be applied.

    iv. Monthly inspections of packages in storage will be done along with wipe surveys of the storage area. Procedures will specify actions to be taken by staff if packaging appears to be degrading.

    v. At disposal the box will be surveyed in a low background area to ensure that radiation levels do not exceed background; the reading, date and initials of the surveyor will be recorded in the log, radiation labels will be defaced and the waste disposed of.

## APPENDIX I-3

## MODEL PROCEDURE FOR MANAGING GENERATORS

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 required by paragraph 173-475(i) of 49 CFR Part 173.

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

For decay-in-storage, 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 0.05 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.