

NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION

RADIATION GUIDE 10.11

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR THE USE OF
SEALED SOURCES FOR DIAGNOSIS

INTRODUCTION

A. Purpose of Guide

This guide describes the type and extent of information needed by the New York State Department of Health staff to evaluate an application for a specific license to possess and use radioactive material in the form of sealed devices for diagnosis in humans. This type of license is provided for under Sections 16.120 and 16.121 of 16 NYCRR 16, "Ionizing Radiation."

The New York State Department of Health will issue a single radioactive materials license to cover an institution's entire radioisotope program, other than teletherapy. Separate licenses are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the institution. The license will be issued in the institution's name in all cases, except for private practices located outside an institution's premises.

The applicant should carefully study the regulations and this guide, and should submit all information requested. The Department will request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

B. Applicable Regulations

All regulations pertaining to this type of license are found in Title 10, Chapter 1, Part 16 of the New York Code of Rules and Regulations (10 NYCRR 16). Chapter 1 is entitled "State Sanitary Code" and Part 16 is entitled "Ionizing Radiation." The statutory authority for the rules and regulations is found in the New York State Public Health Law, Section 225.

C. As Low As is Reasonably Achievable (ALARA)

Item (a) of 10 NYCRR 16.5 requires that persons who operate or permit the operation of radiation installations shall make every effort to maintain radiation exposures and releases of radioactive material as far below the limits of Part 16 as is reasonably achievable.

1. General ALARA Considerations

Each individual who is authorized to use radioactive material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material, and should ensure that the facility and equipment are adequate for safe use. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Officer (RSO).

FILING AN APPLICATION

A license application for specific licenses for human use should be submitted on Form GEN 307B "Application for Radioactive Materials License" and appropriate attachments. The applicant should complete all items on the application form in sufficient detail for the review staff to determine that the applicant's equipment, facilities, personnel training and qualifications, and radiation protection program are adequate to protect health and minimize danger to life and property.

For Items 5 through 25, submit the required information on supplementary pages. You should identify and key each separate sheet or document submitted with the application to the item number on the application to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

One copy of the application, with all attachments, should be retained by the applicant, since the license will require as a condition that the licensee follow the statements and representations set forth in the application and any supplement to it. The original and one copy should be mailed to the Bureau of Environmental Radiation Protection, New York State Health Department, 2 University Plaza, Albany, New York 12237.

CONTENTS OF AN APPLICATION

The following paragraphs explain the information requested on Form GEN 307B. The item numbers correspond to the appropriate section of the form.

- 1a. Enter the name, mailing address and telephone number of the applicant. If the request is for a private license, enter the name of the physician or partnership. It is particularly important that the mailing address be sufficiently complete so that all correspondence to the licensee will reach persons responsible for the radiation safety program.
- 1b. List the addresses and locations where radioactive material will be used or stored if other than the address stated in Item 1a. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use. The actual locations of use should be listed, whether or not they are the same as the mailing address in Item 1a; i.e., a post office box may be most suitable for Item 1a. in some cases, but this address does not adequately describe the location of use.
2. Enter the name and telephone number (including area code) of the individual to be contacted.
3. Indicate whether this is an application for a new license, an amendment, or a renewal.
4. State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program. If the radiation safety officer is assisted by a consultant or part-time employee, state the consultant's name and describe his/her duties, responsibilities and the amount of time to be devoted to the radiation safety program.
5. List the names of all persons who will use, supervise, or direct the use of radioactive material. These authorized users must be physicians, dentists, or podiatrists licensed and registered in New York State.

Physicians, dentists, and podiatrists authorized to use radioactive material have the following responsibilities:

- a. The approval of procedures involving the use of sealed sources for diagnosis in humans.
- b. The interpretation of the results of such procedures.

5. (Continued)

Properly trained technicians, technologists or other paramedical personnel under an authorized user's direction may be delegated the following activities:

- a. Quality control testing of sources of radiation.
- b. Operation of devices containing sealed sources for bone mineral analysis.

6.1 List the manufacturer's name, model number, and activity (in millicuries) for each sealed source. List the total amount of material to be possessed at any one time. Applicants usually request a total possession limit that is twice the amount of the source to be used. This permits possession of a second source stored temporarily at the facility at the time of source exchange.

6.2 Specify the manufacturer's name and the model name and number of the device in which the source will be used.

7. Describe the intended use for each radionuclide and form listed in Item 6.

8. Radiation Safety Officer - The radiation safety officer will generally be an authorized user on this type of license. If this is not the case, submit the candidate's curriculum vitae.

9. Training and Experience

a. Authorized users(s). If the physician, dentist, or podiatrist has been previously authorized to use the radioactive material requested in this application, it is necessary to submit only the previous license number if issued by the New York State Health Department, or a copy of the complete license if issued by another licensing agency.

b. Persons not previously authorized to use the radioactive material requested. The authorized user of a sealed source in a device for diagnosis must be a physician, dentist or podiatrist who:

(i) is certified in

1) Radiology, Diagnostic Radiology, or Therapeutic Radiology by the American Board of Radiology;

2) Nuclear Medicine by the American Board of Nuclear Medicine;
or

9. b. (i) 3) Diagnostic Radiology or Radiology by the American Osteopathic Board of Radiology; or
- (ii) Has had 8 hours of classroom training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:
- 1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
 - 2) Radiation biology;
 - 3) Radiation protection; and
 - 4) Training in the use of the device for the uses requested.

Submit documentation of (i) or (ii).

- c. Personnel Training Program. Describe your training program for individuals who work with or in the vicinity of radioactive materials; particularly those who will operate devices containing radioactive materials and process any data generated.

10 a. Instrumentation

- (i) Survey instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation survey meter. Identify the meter you will use. The meter shall be calibrated annually and following repair at two points on each scale. A calibration report must be available for review and shall contain:

- 1) A description of the calibration procedure; and
- 2) The date of calibration, a description of the source used and the certified exposure rates from the source; and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature and license number of the individual who performed the calibration.

Confirm that the most recent calibration report will be available and will contain this information.

- b. Diagnostic devices. Describe the quality control procedures you will follow. As a minimum these must include the manufacturers recommended procedures.

11. Facilities and equipment. Submit a detailed diagram of the facility showing the area where diagnostic devices and sources will be used or stored. Indicate the security measures to be employed to prevent unauthorized access to the devices and sources.
12. Procedures for ordering and receiving radioactive material. Describe how packages will be received; e.g. always during business hours or will special arrangements be made for deliveries at times when your facility is not staffed?
13. Procedures for package opening. Submit a copy of your procedures for opening packages that contain radioactive materials. See Appendix A.
14. General rules for the safe use of radioactive material. Licensees shall use sealed sources in accordance with the manufacturer's radiation safety and handling instructions. These instructions must be available in your facility and included in your personnel training program. Confirm that this will be done.
15. NA
16. NA
17. Waste disposal. Confirm that sealed sources will be returned to the manufacturer when they are no longer useful to you.
18. NA
19. NA
20. NA
21. NA
22. a. Source change procedures. Only trained personnel should perform a source change. Confirm that sources will be removed and installed only by trained personnel using the manufacturer's detailed operating procedures.
- b. Leak testing of sealed sources. The leak-test service may be done in-house or performed as a contract service. Leak-test wipes cannot be measured in a dose calibrator, and a GM survey meter may not be sensitive enough to detect contamination on a wipe sample. Usually a well-type NaI (Tl) crystal with a ratemeter is necessary to assay gamma-emitter leak-test wipes. To determine the efficiency of detection, a sealed source with the same radioisotope as the source being tested is used, and the source should have an activity between 0.1 and 10 microcuries. This activity will be certified by the manufacturer to an accuracy within a few percent.

If you will do your own leak-testing, describe the instrument and calibration source you will use and provide an example of a calculation for converting leak-test sample counting results to microcuries.



22. (Continued)

Iodine sources must also be tested for leakage of iodine vapor, which will not be detected by a wipe survey. Describe your method of testing iodine sources for vapor leakage if you do your own leak testing.

c. General Rules for the Safe Use of Radioactive Materials in Leak-Testing:

Each individual who will perform leak-tests on sealed sources or sources in devices should have a set of operating and emergency procedures. You should state in your application that personnel will be provided with operating and emergency procedures. Submit an outline of the basic elements of these procedures to be provided to personnel. The following elements should be included in your operating and emergency procedures, if applicable:

- (i) Instructions for performing the wipe tests, including materials to use and methods of handling samples to prevent or minimize exposure to personnel.
- (ii) Surveys to be performed, such as those around the housing to be sure the device is in the "safe," "store," or "off" position before wipe samples are taken from designated areas of the device.
- (iii) Surveys to be performed on wipe- or leak-test samples to check for gross contamination.
- (iv) Any specific instructions provided by source and device manufacturers on recommended methods and areas to be wiped.
- (v) Instructions on what to do in case of emergencies; for example, if sources or devices are found to be leaking or excessive radiation levels are found around devices. These instructions should include procedures for means of preventing and controlling the spread of contamination, and means of obtaining professional assistance, if needed.

23. Personnel monitoring program. Operators of devices containing gadolinium-153 should wear extremity monitors. These may be discontinued after one calendar quarter if the dose received is less than the dose described in 10 NYCRR 16.11.

24. NA

25. NA

26. Certificate. If an application is for a private practice, it should be signed by a senior partner or the president. If the application is for an institution, hospital, or medical center, it must be signed by its director or chief executive officer. Identify the title of the office held by the individual who signs the application.

AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, authorized users or radiation safety officer, or radioactive material to be used.

Applications for license amendments may be filed either on the application form or in letter form. The application should identify the 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.

Amendment applications must be signed as described in Item 26 and dated. An original and two copies of the application for amendment should be prepared, and the original and one copy should be submitted, as in the cases for new or renewal applications.

RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the New York State Health Department as provided for in Section 16.105 of 10 NYCRR 16.

Renewal applications should be filed on Form GEN 307B appropriately supplemented, should contain complete and up-to-date information about the applicant's current program, should meet all licensing and regulatory requirements in effect at the time of renewal, and must be signed as described in Item 26 and dated. Renewal applications should also include the physician-user's training and experience or make a clear and specific reference to previous applications on which individual users received approval.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information (except for previously approved users). If such references cannot be avoided, they are acceptable provided:

- a. The reference is made in response to a particular item of required information (i.e. bioassay procedures).

- b. The reference is clear and specific (i.e. title of document, date of submission, page and paragraph); and
- c. The referenced document contains all information required for a particular item at the time of renewal.

Prepare an original and two copies of the application. Retain one copy of the application, with all attachments, because the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplement to it. Mail the original and one copy to the Bureau of Environmental Radiation Protection, New York State Health Department, Empire State Plaza, 421 Corning Tower, Albany, New York 12237.

LICENSE TERMINATION REQUESTS

Submit a signed Form GEN 322 indicating the disposition of the radioactive material. Form GEN 322 is available from the Bureau of Environmental Radiation Protection, New York State Health Department.

Submit survey results showing that all previously occupied areas are free of contamination and all sources of radioactive material have been removed in accordance with Section 16.10 of 10 NYCRR 16. A decontamination guide is available from the Bureau of Environmental Radiation Protection, New York State Health Department.

Such submissions must be made at least 30 days prior to relinquishing possession or control of premises where radioactive material is or has been stored or used.

APPENDIX A

MODEL PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

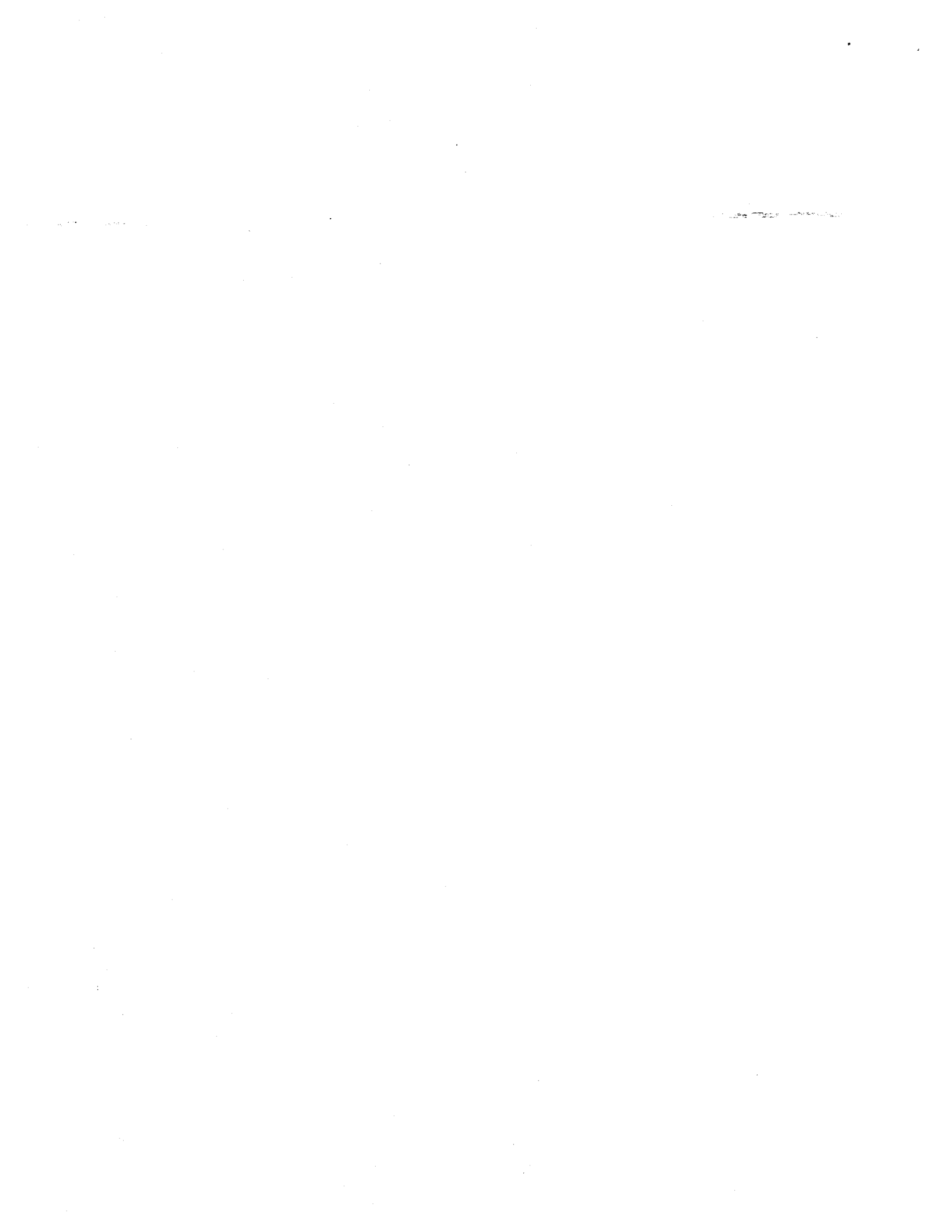
You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix A to Radiation Guide 10.11."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended," and append your package opening procedure.

Model Procedure

For all packages, the following procedures for opening packages will be carried out:

- a. Put on gloves to prevent hand contamination.
- b. Visually inspect package for any sign of damage (i.e. torn, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
- c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If it is higher than usual, stop and notify the Radiation Safety Officer.
- d. Open the package with the following precautionary steps:
 - 1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.
 - 2) Open inner package and verify that contents agree with those on packing slip.
 - 3) Check integrity of final source container.



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- e. If there is any reason to suspect contamination, wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (i.e. dpm/100 cm², etc.). Check wipes with a thin-end window GM survey meter, and take precautions against the spread of contamination as necessary.
- f. Monitor the packing material and packages for contamination before discarding.
 - 1) If contaminated, treat as radioactive waste.
 - 2) If not contaminated, obliterate radiation labels before discarding in regular trash.
- g. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

Radioactive Shipment Receipt Report

1. P.O. No. _____ Survey Date _____ Time _____
Surveyor _____

2. Condition of the Package:
_____ OK _____ Punctured _____ Stains _____ Wet _____ Crushed
_____ Other

3. Radiation Units of Label: _____ units (mR/hr)

4. Measured Radiation Levels:
a. Package Surface _____ mR/hr
b. 3 feet or 1 meter from Surface _____ mR/hr

5. Do Packing Slip and Contents Agree?
a. Radionuclide _____ Yes _____ No Difference _____
b. Amount _____ Yes _____ No Difference _____
c. Chemical Form _____ Yes _____ No Difference _____

6. Wipe Results From:
a. Outer _____ CPM ÷ _____ (efficiency) = _____ DPM
b. Final Source Container _____ CPM ÷ _____ (efficiency) = _____ DPM

7. Survey Results of Packing Material and Cartons _____ mR/hr, CPM

8. Disposition of Package After Inspection _____

9. If NRC/Carrier Notification Required, Give Time, Date, and Persons
Notified

Signature Date