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DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-0006

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GUIDE FOR THE PREPARATION OF APPLICATIONS FOR COMMERCIAL NUCLEAR PHARMACY LICENSES

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules Review and Directives Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by **July 31, 1997.**

Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Office of Administration, Distribution and Mail Services Section.

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1. INTRODUCTION

1.1 Purpose of Guide

The purpose of this regulatory 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 byproduct material in commercial nuclear pharmacy operations.

This regulatory guide is intended to provide you, the applicant or licensee, with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to commercial nuclear pharmacies. The information in this guide is not a substitute for training in radiation safety.

After you are issued a license, you should conduct your program in accordance with (1) the statements, representations, and procedures contained in your application and in other correspondence with the Nuclear Regulatory Commission (NRC), (2) the terms and conditions of your license, and (3) the NRC's regulations. Nothing in the NRC regulations or this regulatory guide relieves you from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices. The information you provide in your application should be clear, specific, and accurate.

Several terms used in this guide should be explained. A "commercial nuclear pharmacy" prepares and distributes radioactive drugs, often labeled with byproduct material, to hospitals, as well as to physicians for use in their private practices. The phrase "byproduct material" means any reactor-produced radioisotope. The term "distribution" has the same meaning as in 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material," i.e., the routine transfer of licensed material to others. In the case of nuclear pharmacies that are licensed in accordance with 10 CFR 32.72, these transfers of radioactive drugs are to specific licensees in accordance with the requirements in 10 CFR 30.41. The term "distribution" may or may not involve a prescription for a specific patient.

A commercial nuclear pharmacy's principal customers are medical use licensees. The phrase "medical use licensee" means a physician, podiatrist, dentist, or medical institution licensed under 10 CFR Part 35 for "medical use," as defined in 10 CFR 35.2.

Note: Sections 35.100, 35.200, and 35.300 of 10 CFR Part 35 require the medical use licensee to use unsealed byproduct material for medical use that is either obtained from certain other licensees or prepared under the supervision of certain of the medical use licensee's own workers. These other licensees must be either manufacturers or preparers licensed pursuant to 10 CFR 32.72 or equivalent Agreement State* requirements. Medical use licensees are required by 10 CFR 35.49 to obtain sealed sources that have been manufactured, packaged, labeled, and distributed in accordance with a specific license issued by either the NRC pursuant to 10 CFR 32.74 or an Agreement State pursuant to equivalent State requirements.

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 commercial nuclear pharmacy's customers with little or no change in the original packaging, labeling, etc.

1.2 Applicable Regulations

NRC regulations applicable to commercial nuclear pharmacy operations are 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material"; 10 CFR Part 35, "Medical Use of Byproduct Material"; 10 CFR Part 71, "Packaging and Transportation of Radioactive Mate-rial"; and 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as

*An "Agreement State" is any State with which the NRC, or previously the Atomic Energy Commission, has entered into an effective agreement under Sub section 74b of the Atomic Energy Act of 1954, as amended. The current Agreement States are shown in Figure 2 of this guide or a current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from the Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or from NRC's Regional Offices whose addresses are listed in Figure 1 and in 10 CFR 30.6.

Figure 1 NRC Regional Offices

Figure 2 Agreement States

Amended"; and 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licensees and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC." Unless otherwise stated, all regulations cited in this guide are in Title 10, "Energy," of the Code of Federal Regulations.

You may request copies of the above documents from NRC's Regional Offices whose addresses are listed in Figure 1. You may also order the two-volume bound version of Title 10, Code of Federal Regulations, Parts 0-50 and 51-199, from the U.S. Government Printing Office (GPO), Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. GPO's order desk in Washington, DC, can be reached at (202)512-2249.

Note: Licensees who transport licensed material or who offer such material to a carrier for transport are required by 10 CFR Part 71 to comply with the applicable requirements of the Department of Transportation (DOT) that are found in 49 CFR Parts 170 through 189. Copies of DOT regulations can be ordered from GPO, whose address and telephone number are listed above.

It is your responsibility as an applicant and as a licensee to have copies of, to read, and to abide by each regulation. As a licensee, you are subject to all applicable provisions of the regulations as they pertain to nuclear pharmacy operations.

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in the early stages of developing the regulatory positions. Draft regulatory guides have not received complete staff review and do not represent official NRC staff positions.

This regulatory guide identifies the information needed to complete NRC Form 313 for applications for a license for a commercial nuclear pharmacy. The information collection requirements in NRC Form 313 have been cleared under OMB Clearance No. 3150-0120.

1.3 Maintaining Radiation Doses As Low As Reasonably Achievable (ALARA)

In 10 CFR Part 20, NRC requires the licensee not only to meet specific dose limits but also to operate in a manner that keeps doses "as low as reasonably achievable." On ALARA, 10 CFR 20.1101(b) states: "The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable,"* provides the NRC staff position on this important subject. As an applicant, you should consider the ALARA philosophy as described in Regulatory Guide 8.10 in developing your plans for work with licensed radioactive materials.

2. FILING AN APPLICATION

You, as the applicant for a materials license, should complete NRC Form 313 (see Exhibit A of this guide). You should complete Items 1 through 4 and 12 and 13 on the form itself. For Items 5 through 11, 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 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, they should be folded to 8-1/2 x 11 inches. You should complete all items in the application in sufficient detail for the NRC to determine

*Single copies of regulatory guides, both active and draft, may be obtained free of charge by writing the Office of Administration, Attn: Distribution and Services Section, USNRC, Washington, DC 20555, or by fax at (301)415- 2260. Copies are also available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR□s mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634- 3273; fax (202)634-3343.

that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

You should file your application in duplicate. Also, retain a 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 for review by the general public in the NRC Public Document Rooms. Do not submit proprietary information unless it is absolutely necessary. If submittal of such information is necessary, follow the procedure in 10 CFR 2.790. Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, Social Security numbers, and radiation dose information should be submitted only if specifically requested by NRC.

If you wish to possess or use licensed material on Federal property or in any State subject to NRC jurisdiction, you should file your application with the NRC Regional Office for the State in which the material will be possessed or used. (A list of NRC's Regional Offices and the States they cover is provided in Figure 1.) If you are a non-Federal organization that wishes to possess or use licensed material in one of the Agreement States, your application should be filed with the State's radiation control program and not with the NRC.

3. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on NRC Form 313. Typically, each item includes an "Applicable Regulations" section that identifies pertinent regulations, a "Licensing Criteria" section that describes criteria against which an applicant's response will be judged, and a "Response" section that describes acceptable responses from applicants.

This guide contains several appendices that contain examples of procedures or programs. You may wish to adopt one or more of these examples as part of your program. If so, you may adapt the following paragraph as a response to the appropriate item in your application:

> Item __: We, (name of commercial nuclear pharmacy), have established and agree to follow the procedures for _____ as described in Appendix ____ of Draft Regulatory Guide DG-0006.

Even though this Draft Regulatory Guide DG-0006 is not in final form and does not represent an official NRC staff position, applicants may find the examples of procedures or programs acceptable for their use. Applicants may adopt these examples or they may propose their own procedures or programs.

If you refer in your application to a section or appendix of this guide or of any regulatory 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 should keep a copy of the referenced guide on hand at all times so that you can review your commitments as necessary.

Item 1 License Information

For a new license, check Subitem A. For an amendment to an existing license, check subitem B. For a renewal of an existing license, check Subitem C. If you check Subitem B or C, be sure to enter your license number.

Item 2 Name and Mailing Address of Applicant

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 3.

Item 3 Locations of Use

You should specify each location of use by the street address, city, and State or other descriptive address (such as 5 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 4 Person To Be Contacted About This Application

You should name the individual who knows your proposed radioactive materials program and can answer questions about your application. Also state the telephone number at which the individual may be contacted. If the contact changes, notify the NRC. Notification of a contact change is for information only and would not be considered an application for a license amendment.

Item 5, Radioactive Materials, and Item 6, Purposes for which Licensed Material Will Be Used

For Item 5, you should list the radioactive materials you wish to possess by (1) radionuclide, (2) chemical and physical form, and (3) the maximum amount you wish to possess at any one time. For Item 6, you should state the proposed uses of the radioactive materials.

Exhibit B shows a sample commercial nuclear pharmacy license. Items 6, 7, and 8 describe the possession authorizations. Item 9 lists the authorized uses for these materials. Items 10 and beyond provide specific license conditions. (The information in Items 6 through 9 is critical in determining the scope of a licensee's operations and radiation safety program, as well as the need for specific license conditions.)

If your commercial nuclear pharmacy receives prepared radioactive drugs that were initially distributed by a radioactive drug manufacturer, you should provide the information in a format that conforms with the format used in 6A, 7A, and 8A of the sample license to list these materials. Note: NRC realizes that pharmacies may distribute drugs to other pharmacies occasionally.

Byproduct material that is received in any other form or from any other source and that will be used to prepare radioactive drugs should be listed using the 6B, 7B, and 8B format.

You must submit a license amendment and receive NRC authorization before you can make changes in the types, forms, quantities, and uses of materials possessed (listed in Items 6 through 9 on your license). You should adapt the format used in Items 6 through 9 of Exhibit B to provide the information needed by the NRC.

Clearly identify which licensed materials you wish to only possess and which you wish to possess and distribute.

If you want to redistribute various items, see Section 4 of this guide about information to be supplied.

Item 7 Training and Experience of Authorized Nuclear Pharmacists and Radiation Safety Officer

7.1 Applicable Regulations

The applicable regulations are 10 CFR 30.33(a)(3), 10 CFR 32.72(b), 10 CFR 35.2, 10 CFR 35.972, and 10 CFR 35.980.

7.2 Licensing Criteria

When applying for a new license or a license renewal, you should identify and describe the training and experience of individuals who will work as authorized nuclear pharmacists (ANPs) or radiation safety officers (RSOs). Criteria for training and experience for authorized nuclear pharmacists and radiation safety officers are described in Appendix A of this guide.

7.3 Response

7.3.1 Proposed Authorized Nuclear Pharmacists

The regulation in 10 CFR 32.72(b)(1) states that a commercial nuclear pharmacy may prepare radioactive drugs for medical use provided that the radioactive drug is prepared by either an authorized nuclear pharmacist or an individual under the supervision of an authorized nuclear pharmacist. This means each commercial nuclear pharmacy must have an authorized nuclear pharmacist to prepare or supervise the preparation of radioactive drugs for medical use.

If you are applying for a new license or renewal of an existing license, you must identify and describe the training and experience of your authorized nuclear pharmacist and your radiation safety officer. If you have a license, you will not have to amend your license to permit certain individual pharmacists to work as authorized nuclear pharmacists if these individuals are already authorized nuclear pharmacists or if you (the licensee) designate the pharmacist as an authorized nuclear pharmacist. A pharmacist is an authorized nuclear pharmacist if the individual is board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties or is identified as an authorized nuclear pharmacist on an NRC or Agreement State license or a permit issued by a holder of an NRC or Agreement State specific license of broad scope. The regulations in 10 CFR 32.72(b)(4) allow you to designate a pharmacist as an authorized nuclear pharmacist if the individual was identified as an "authorized user" on a nuclear pharmacy license issued by the NRC prior to December 2, 1994.

In accordance with 10 CFR 32.72(b), you may allow a pharmacist to work as an authorized nuclear pharmacist provided you send to the NRC a copy of the State pharmacy licensure or registration for the pharmacist and one of the following: (1) a copy of the individual's certification by the Board of Pharmaceutical Specialties, (2) the NRC commercial nuclear pharmacy license that identifies the individual as an "authorized user" prior to December 2, 1994, or the NRC or Agreement State license identifying the individual as an authorized nuclear pharmacist, or (3) the permit issued by a licensee of broad scope that identifies the individual as an authorized nuclear pharmacist. This documentation must be submitted to the NRC no later than 30 days from the date the licensee allows the individual to work as an authorized nuclear pharmacist.

Any pharmacist not meeting the above criteria must, in accordance with 10 CFR 32.72(b)(2)(ii), be listed on your license if you want that individual to work as an authorized nuclear pharmacist.

Any pharmacist who is not qualified to be an authorized nuclear pharmacist may work under the supervision of an authorized nuclear pharmacist.

For each individual you name, you should provide his or her full name and document his or her training and experience that is at least equivalent to that described in Appendix A. You may find it convenient to present this documentation using a format similar to Figures A-1 and A-2 in Appendix A. Each hour of training may be listed only once, i.e., under the most applicable category.

Note: When you list pharmacists on your license who are board certified or were listed prior to December 2, 1994, as authorized users on nuclear pharmacy licenses, you will not have to provide documentation of their training and experience. In these cases, you need only submit documentation of their current status as "board certified" or the NRC license number listing the individual as an "authorized user."

7.3.2 Proposed Radiation Safety Officer (RSO)

You should name the person who will direct your day-to-day radiation safety program. The RSO you designate should be present daily at the facility. In the absence of the RSO (e.g., in the early morning or when the RSO is sick or on vacation), an authorized nuclear pharmacist should assume the RSO's duties. Appendix B outlines the typical duties and responsibilities of an RSO in a commercial nuclear pharmacy.

Provide assurances that the RSO will be able to devote sufficient time to carry out the duties and responsibilities of the RSO.

Applicants are required by 10 CFR 30.33(a)(3) to be qualified by their training and experience to use licensed material for the purpose requested in the application in such manner as to protect health and minimize danger to life or property. To meet this requirement, you must document that the training and experience of the proposed RSO is at least equivalent to that described in Appendix A. You may find it convenient to present this documentation using a format similar to Figure A-3 in Appendix A.

Any individual who has sufficient training and experience to be named as an authorized nuclear pharmacist is also considered qualified to serve as the day-to-day RSO. Documentation of training and experience is not needed for certain individuals who either have a specific board certification or were listed as RSOs on an equivalent NRC (or Agreement State) commercial nuclear pharmacy license. For these individuals, you must (1) submit documentation to show that they are certified by the Board of Pharmaceutical Specialties in nuclear pharmacy, the American Board of Health Physics in comprehensive health physics, the American Board of Radiology, the American Board of Nuclear

Medicine, the American Board of Science in Nuclear Medicine, the Royal College of Physicians and Surgeons of Canada in nuclear medicine, the American Osteopathic Board of Radiology, or the American Osteopathic Board of Nuclear Medicine, or (2) submit the NRC license number (or a copy of the Agreement State license) that lists the individual as the RSO or an authorized nuclear pharmacist.

The criteria for the RSO evolved from NRC's requirements for RSOs in hospital nuclear medicine programs because the type of use and the degree of radiation hazard are quite similar.

Item 8 Training for Individuals Working In or Frequenting Restricted Areas

8.1 Applicable Regulations

The applicable regulations are 10 CFR 19.12 and 10 CFR 32.72(b)(1).

8.2 Training

8.2.1 Instruction Under 10 CFR 19.12

All individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv), must be instructed according to 10 CFR 19.12. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place. These instructions must include (1) the storage, transfer, or use of radiation and radioactive material, (2) health protection problems associated with exposure to radiation or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed, (3) applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation or radioactive material, (4) responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation or radioactive material, (5) appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material, and (6) the right to be informed on the radiation exposure reports that workers may request pursuant to 10 CFR 19.13.

Shippers and carriers of radioactive material must also receive appropriate training. If a person making deliveries of radioactive material at the licensee’s facility is likely to receive a dose in excess of 1

mSv (100 mrmem) in a year from the licensee's activities, the licensee is responsible for ensuring that the person has received the training specified in 10 CFR Part 19, regardless of whether that person is an employee of the licensee. If the training has been provided by someone else (such as the shipper or another licensee), the licensee does not have to provide training except for specific training for site-specific radiation hazards.

8.2.2 Instruction for Individuals Preparing Radioactive Drugs Under 10 CFR 32.72(b)(1)

Any licensee who permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist (as provided in 10 CFR 32.72(b)(1)) must, as specified in 10 CFR 35.25(b), instruct the supervised individual in the preparation of byproduct material for medical use and the principles of and procedures for radiation safety.

NOTE: An authorized nuclear pharmacist is considered to be supervising the use of radioactive materials when he or she directs personnel in the conduct of operations involving licensed materials. The authorized nuclear pharmacist need not be present at all times during the use of such materials. However, the authorized nuclear pharmacists' supervisor is responsible for ensuring that personnel under his or her supervision have been properly trained and instructed. The authorized nuclear pharmacists' supervisor is therefore responsible for the supervision of operations involving the use of radioactive materials whether he or she is present or not.

NRC regulations do not relieve the licensee from complying with applicable Department of Health and Human Services (Food and Drug Administration), other Federal, and State requirements governing radioactive drugs (10 CFR 32.72(d)). From an NRC perspective, if the supervision requirements are met, it is permissible for the licensee to allow the supervised individual to prepare radiopharmaceuticals without the presence of the authorized nuclear pharmacist, but the licensee may have to resolve with the State any State pharmacy issues raised by this practice.

8.3 Response

8.3.1 Response Under 10 CFR 19.12

Your response to Item 8 should be one of the following:

(1) Submit a description of the personnel training program that you have established and that you follow for instructing individuals as required under 10 CFR 19.12.
(2) State that you have adopted the training program described in Appendix C of this guide (Draft Regulatory Guide DG-0006). The personnel training program in Appendix C would fulfill the criteria in Item 8.2.

8.3.2 Response Under 10 CFR 32.72(b)(1) and 10 CFR 35.25(b)

You should describe your program to instruct and review the work of supervised individuals in the preparation of byproduct material for medical use. This instruction may be fulfilled by the day-to-day instruction and monitoring of the supervised individual if an authorized nuclear pharmacist is always physically present when radioactive drugs are prepared, or by a schedule for instruction and a description of the instruction if this is not the case. Also, you should

describe how you will ensure that the supervising authorized nuclear pharmacist will periodically review the work of the supervised individuals.

Item 9 Facilities and Equipment

It is stated in 10 CFR 30.33(a)(2) that an application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. In order for the NRC to evaluate the adequacy of your proposed facilities and equipment, provide a detailed description of the nuclear pharmacy's facilities and equipment.

This description should include the information discussed in detail in Items 9.1 through 9.5. All diagrams referred to in Items 9.2 through 9.5 should be drawn to an indicated scale or else dimensions should be included on each diagram.

9.1 Operations Description

Provide a description of the scope of your operations (e.g., the types and forms of radioactive materials you will possess and how you will handle them). State if you will use large quantities of radioactive materials, preparations involving or producing gases and volatile radioactive materials, alpha-emitters, or low-energy photon-emitters and beta-emitters.

9.2 Site Description

9.2.1 Applicable Regulation

The applicable regulation is 10 CFR 30.33(a)(2).

9.2.2 Licensing Criteria

You should locate your facility in an industrial park or other location where public access is minimal. Residential areas, large shopping centers, or office buildings may not be appropriate because of the potential for accidents involving the spread of radioactive contamination (e.g., loss, theft, fire, explosion).

9.2.3 Response

In response to Item 9.2, you should describe the location where the nuclear pharmacy will be established. This description should include:

1. The type of neighborhood (e.g., commercial, industrial), the type of building construction (e.g., concrete, brick), and the location of other building tenants (if any).
2. Diagrams that indicate the use of land along the perimeter of the facility and the use of other buildings and spaces in the neighborhood.
3. A description of your security measures to prevent unauthorized access when the facility is closed. Include the type of doors and locks, window barriers (if necessary), intrusion alarm systems, and other pertinent information.
4. The location of fume hood stacks, their heights above roof level, their relationship to the nearest windows, air intakes, etc.
5. If the facility is in a residential area, confirm that operation of a nuclear pharmacy on the site does not conflict with local codes and zoning laws.

9.3 General Description of Facility

9.3.1 Applicable Regulations

Applicable regulations are 10 CFR 20.1101, 10 CFR 20.1201, 10 CFR 20.1301, 10 CFR 20.1501, 10 CFR 20.1701, and 10 CFR 30.33(a)(2).

9.3.2 Licensing Criteria

It is stated in 10 CFR 30.33(a)(2) that an application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. You must equip your facility with shielding adequate for the materials and uses proposed in your application. The overall plan and design of the facility must ensure that radiation levels can be maintained within regulatory limits and that licensed materials, including deliveries, will be secured against unauthorized removal.

9.3.3 Response

In response to Item 9.3, submit a diagram of your facility that indicates the location and description of your radioactive materials use and storage areas, as well as the type, dimensions, position, and thickness of shielding that will be available for:

1. The use and storage of molybdenum-99/technetium-99m generators. The auxiliary shielding supplied by the manufacturer of the generator may be used. If generators are to be stored against a wall, additional shielding may be necessary depending on the activity of the generators, the type of auxiliary shielding provided, the construction of the wall, and the use of the area on the other side of the wall. (NOTE: The auxiliary shielding provided by some manufacturers shields only three sides of the generator.)
2. The storage of radioactive drugs.
3. The storage of radioactive waste, including decay-in-storage before disposal. You should consider both short-term storage at each preparation station as well as long-term storage for decay before disposal. Long-term storage should be designed to allow for segregation of wastes with different half-lives (e.g., include multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. If you are requesting permission to receive waste from customers, you should have sufficient capacity for this waste as well as the waste generated from your own operation.
4. Preparing and dispensing radioactive drugs. Address shielding that will be available for each type of radiation emitter (e.g., photon, beta) that you will be handling.

Be sure to indicate the intended use of each area shown on the diagram. Also, indicate on your diagram the area designated for the receipt of shipments containing radioactive materials during hours when the facility is not staffed. This area should be chosen (and shielded, if necessary) with regard to the potential for radiation levels in unrestricted areas. In addition, delivery persons, who are not the licensee's employees, should not have access to the main area in which licensed material is stored.

Remember that radiation doses for individual members of the public may not exceed the dose limits specified in 10 CFR 20.1301, and that surveys are required by 10 CFR 20.1501.

9.3.4 Additional Response for Commercial Nuclear Pharmacies in

Multi-tenant Buildings

If radioactive material will be received, stored, or used frequently near a common wall, you should outline the access agreement you have with other tenants to allow you to perform the required surveys, or you should describe an alternative monitoring procedure (e.g., attaching film badges at specified intervals on the common wall).

You should state whether air from your premises may be circulated to other areas of the building by the heating and cooling system. You should show the rooms where volatile isotopes (e.g., xenon-133, iodine-131) are used or stored and potentially volatile radioactive processes are performed. Areas where volatile or potentially volatile radioactive materials are located or processed should be maintained under negative pressure with respect to the rest of the building. In order to demonstrate this, you should submit a facility diagram that indicates the location and the expected airflow ratings of the air supply and air exhaust vents. If you have an existing facility, you should also submit the measured airflow rating.

Describe the equipment and the methods that will be used to measure the airflow ratings. These airflow ratings may change with the seasons or as the equipment ages. Periodic measurements are necessary to ensure continued performance at the same ratings. At a minimum, airflow ratings should be measured, and corrected if necessary, at 6-month intervals. Describe the type and frequency of periodic measurements you will make to ensure that the airflow ratings of your ventilation system continue to meet the specifications submitted in your application. Also, see Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities."* This frequency should include the measurement of the airflow ratings prior to initial use of volatile isotopes at the facility.

9.4 Adequacy of Facility for Handling Volatile Materials that Are Radioactive

9.4.1 Applicable Regulations

*Single copies of regulatory guides, both active and draft, may be obtained free of charge by writing the Office of Administration, Attn: Distribution and Services Section, USNRC, Washington, DC 20555, or by fax at (301)415-2260.

The applicable regulations are 10 CFR 20.1201, 10 CFR 20.1203, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1701, 10 CFR 20.1702, and 10 CFR 30.33.

9.4.2 Licensing Criteria

You must have adequate equipment and operating controls to ensure that airborne radioactivity, associated surface contamination, and effluent releases are maintained within regulatory limits.

Users of volatile licensed material must perform surveys required by 10 CFR 20.1302(a). In addition, you should establish a program to constrain doses from air emissions in accordance with 10 CFR 20.1101(d). Records of the results of the measurements are required by 10 CFR 20.2103(b)(4).

9.4.3 Response

In response to Item 9.4, describe the scope and extent of your operations that produce or have the potential for producing volatile materials containing radioactivity. These operations could include, but are not limited to, the use of radioactive gases, boiling, radiohalogenation procedures, or preparation of iodine-131 or iodine-125 sodium iodide capsules using high specific activity bulk materials. Describe your equipment and operating controls to ensure that airborne radioactivity and associated surface contamination are maintained within regulatory limits. Sample guidance is provided below for handling xenon and millicurie quantities of I-131.

9.4.4 Handling Xenon-133

Include the form in which xenon-133 will be received (e.g., ampules containing 1 curie or more of gas, or unit-dose vials of gas or xenon in solution), the form in which xenon-133 will be dispensed, and the manipulations involved between receipt and dispensing. This description should include an estimate of the fraction of xenon-133 lost during storage and manipulation.

It is assumed that you will receive xenon-133 in unit-dose vials and redistribute the product to your customers upon request. One manufacturer estimated a loss factor of 0.5% per day from its unit-dose vials. This value has been used by some applicants and the NRC staff has found this acceptable. If you will use a more complicated process than simply redistributing unit-dose vials, you should provide information about your methods for estimating the loss factor.

For restricted areas, 10 CFR 20.1701 requires the use, to the extent practicable, of process and other engineering controls to control the concentrations of radioactive material in the air. In order to demonstrate compliance with this regulation, you may state that xenon-133 will be stored in a fume hood with adequate airflow and that all manipulations involving xenon-133 will be conducted in that fume hood. If you do not so state, you should describe and justify your alternatives.

For unrestricted areas, 10 CFR 20.1302 describes how to demonstrate compliance with the dose limits for individual members of the public. Submit calculations to estimate the concentration of xenon-133 in effluents to unrestricted areas and to show compliance with 10 CFR 20.1302. These calculations may be performed as follows.

1. Estimate the maximum amount of xenon-133 to be released per year and call this value A. Your estimate should be based on the total quantity handled per year multiplied by your estimated loss factor.
2. Determine the airflow rate of the exhaust system and describe the methods and equipment used for measuring the airflow rates. (If you have provided this description in Section 9.3.4, so state. You do not need to repeat it here.) For proposed facilities, the manufacturer's rating can be used to determine the expected air flow rate. However, before use of Xe-133 for existing facilities, the airflow rate should be determined by actual measurement. It is not appropriate to rely on the manufacturer's rating because it will be affected by factors at the site such as height of the stack and the use of filters. The units of measurement are usually cubic feet per minute. Linear airflow (e.g., feet per minute) cannot be used directly in the calculations; it must be multiplied by the area of the fume hood opening (in square feet) to obtain the airflow rating in cubic feet per minute.

   As explained in Item 9.3.4, airflow ratings should be measured periodically to ensure continued compliance. Describe the type and frequency of periodic measurements you will make to ensure that the airflow ratings of your ventilation system continue to meet the specifications submitted in your application.
3. Calculate the total airflow per year and call this value V.
4. Calculate the average concentration for unrestricted areas. The licensee is required by 10 CFR 20.1302(b)(2) to demonstrate compliance with the annual average concentration. The following equation may be used to demonstrate this:

$$C = \frac{A}{V} \leq 5 \times 10^{-7} \text{ mCi/ml}$$

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

Table 1 Release of Xe-133

Exhaust Rate (ft^3/min)	Average Release of Xe-133 per Year (mci)
100	712
500	3560
1,000	7120
1,500	10,700

Some Useful Conversions

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

9.4.5 Special Equipment for Handling Millicurie Quantities of Radioiodine

Your facility must be equipped to maintain effluent releases of radioactive iodine at ALARA levels in accordance with 10 CFR 20.1101(b). (Note: Refer to Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," for additional guidance.)

1. Specify that this work will be performed in a fume hood with adequate airflow. (Note that the fume hood may have been described in your response to Item 9.3.4 or 9.4.3.)
2. Show how you will maintain releases to the environment ALARA. Most applicants use a charcoal filtration system (or equivalent system) in conjunction with the fume hood. If you use a charcoal filtration (or equivalent) system, you should describe the system and indicate the percentage of radioiodine that the system is expected to remove from the effluent. You should also estimate the concentrations of radioiodine in effluents released to the environment. Other precautionary measures, including bioassays, should be described in response to Item 10.10.

Item 10 Radiation Safety Program

You, as the licensee, are responsible for the conduct of your nuclear pharmacy program and for the actions of your employees. According to 10 CFR 30.34(e), the NRC may incorporate in licenses such additional requirements and conditions that it deems appropriate or necessary to protect health or to minimize danger to life or property. Accordingly, you should provide information about your radiation safety program, addressing the information discussed here in detail in Items 10.1 through 10.16.

10.1 Personnel Monitoring Program

10.1.1 Applicable Regulations

The applicable regulations are 10 CFR 20.1501(b), 10 CFR 20.1501(c), 10 CFR 20.1502(a), and 10 CFR 20.2103(a).

10.1.2 Licensing Criteria

You should establish and follow written procedures for personnel monitoring. As a minimum, these written procedures should include the following criteria.

1. That whole body badges (i.e., film or thermoluminescence dosimeters (TLDs)) be provided when required by 10 CFR 20.1502(a)(1)-(3).
2. That whole body badges and finger extremity monitors (film or TLD) be provided to personnel who elute, prepare, assay, or dispense millicurie quantities of photon- or high energy beta-emitting radioactive material.
3. That whole body film and extremity badges be exchanged for processing at intervals not to exceed 1 month. TLD whole body badges may have a longer exchange interval if justified.
4. That whole body and extremity badges be processed by a commercial personnel dosimetry service or a whole body badge processor accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) as required by 10 CFR 20.1501(c).

5. That any pocket dosimeters used to measure exposure from licensed material be operable, calibrated, and tested for drift at intervals not to exceed 1 year (see 10 CFR 20.1501(b)); records of calibration and drift tests must be maintained as described in 10 CFR 20.2103(a).

10.1.3 Response

Your response to Item 10.1 should be a statement that you have established and agree to follow written personnel monitoring procedures that include the items in Item 10.1.2 of this guide (Draft Regulatory Guide DG-0006). Any response will be evaluated against the criteria in Item 10.1.2. You do not need to name the commercial service company that will provide your personnel monitoring devices.

10.2 Instruments

10.2.1 Applicable Regulations

The applicable regulations are 10 CFR 20.1501, 10 CFR 30.33(a)(2), and 10 CFR 32.72(c).

10.2.2 Licensing Criteria

When working with photon-emitting radionuclides, you should agree to have in your possession and available for use the following radiation detection instruments:

1. A low-level survey meter with a thin window capable of detecting 0.1 millirem per hour for performing accurate contamination surveys.
2. A high-level survey meter, such as an ionization type, capable of reading up to 1 rem per hour in order to measure dose rates that may exist in the vicinity of, for example, molybdenum-99/technetium-99m generators.
3. Dose calibrators to assay photon-emitting radioactive drugs.
4. A sodium iodide well crystal and either a gamma spectrometer or a multichannel analyzer to analyze wipe tests.

When working with alpha- and beta-emitting radionuclides, you should describe your instrumentation device used to (1) assay alpha- and beta-emitting radioactive materials for medical use, (2) measure air concentrations, and (3) measure contamination (either removable or fixed).

10.2.3 Response

Your response to Item 10.2 should include the following:

1. Describe the radiation detection and measuring instruments you will use for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment, contamination control, and radioactive drug assay. Identify each instrument by type, sensitivity, and range for each type of radiation detected. The manufacturer and model number does not convey this information and therefore does not need to be provided.
2. For photon-emitting radionuclides, instead of listing specific instruments, you may make a statement that you will have the instruments specified in Item 10.2.2 of this guide (Draft Regulatory Guide DG-0006), in your possession and available for use when you begin photon-emitting radionuclide operations.

Instruments to be used when handling, monitoring, and assaying alpha-emitters and beta-emitters should be identified, but the manufacturer and model number do not need to be provided.

10.3 Calibration of Survey Instruments

10.3.1 Applicable Regulations

The applicable regulations are 10 CFR 20.1501, 10 CFR 20.2103(a), and 10 CFR 30.33(a)(2).

Licensees are required by 10 CFR 20.1501(a)(1) to make surveys that may be necessary to comply with the regulations in Part 20. In order to perform appropriate surveys, the instruments used must be operable and calibrated (10 CFR 20.1501(b)).

10.3.2 Licensing Criteria for Applicants Who Will Not Calibrate Their Own Survey Instruments

1. Return survey instruments to the manufacturer for calibration or have them calibrated by an organization that is licensed by NRC or an Agreement State to perform calibrations for others.
2. Calibrate survey instruments at intervals not to exceed 1 year and after repair. Licensees should submit justification for any calibration period longer than a year.
3. Maintain records of each calibration for at least 3 years after the calibration in accordance with 10 CFR 20.2103(a). These records should show the date and results of the calibration and the name of the organization that provided the service.

10.3.3 Response for Applicants Who Will Not Calibrate Their Own Survey Instruments

If you will not calibrate your own survey instruments, your response to Item 10.3 should be a statement that specifies (1) that your survey instruments will be calibrated by an organization that is licensed by the NRC or an Agreement State to provide instrument calibration services to other licensees or returned to the manufacturer for calibration, (2) the frequency of calibration, and (3) that you will maintain for at least 3 years after each calibration a record of the calibration showing the date and the results of the calibration and the name of the organization that provided the service. Licensees should verify that the organizations that will provide instrument calibration services are authorized to perform the services.

Note: An organization might not have a license if it is located in a non-Agreement State and uses radium, a radioactive material not regulated by the NRC. Also, an organization might have a license that does not specifically authorize performing instrument calibration services for other licensees. In such cases, you should also submit a description of the procedures and the radioactive source or sources used by the company for calibrating survey instruments.

10.3.4 Licensing Criteria for Applicants Who Will Calibrate Their Own Survey Instruments for Use with Photon-Emitting Radionuclides

You should establish and follow written procedures for calibrating survey instruments. As a minimum, these written procedures should specify that:

1. Survey instruments will be calibrated at intervals not to exceed 1 year and after repair.
2. Dose rate instruments will be calibrated with radionuclide sources at distances sufficient to approximate point sources.
3. Survey instruments will be calibrated on every scale or range that the instrument offers. For scales up to 1 rem per hour, a radiation source must be used for calibration because electronic calibration does not test the radiation response of the instrument. Each scale or range has to be calibrated at two points (i.e., the 1/3 and 2/3 points on each scale or decade). (Note that calibration requires minimum activities of typical radionuclide sources such as 85 millicuries of cesium-137, 21 millicuries of cobalt-60, or 30 millicuries of radium-226.)
4. Survey instruments will be adjusted to provide readings on all calibrated scales or ranges within ±10% of true value (or ±20%, provided a calibration chart or graph is prepared, attached to the instrument, and used to interpret readings).
5. A record of each instrument calibration showing the date and the results of the calibration will be maintained for at least 3 years after the calibration.

10.3.5 Response

If you will calibrate your own survey instruments for use with photon-emitting radionuclides, your response to Item 10.3 should be one of the following:

1. A description of the standards, frequency, and procedures used to calibrate your survey instruments. This description will be reviewed against the criteria in Item 10.3.4.
2. A statement that you will calibrate your own survey instruments in accordance with written procedures that include the criteria described in Item 10.3.4 of this guide (Draft Regulatory Guide DG-0006).
3. A statement that you will calibrate your survey instruments in the manner described in Appendix D to this guide (Draft Regulatory Guide DG-0006). Appendix D describes frequency, standards, and procedures for calibrating survey instruments that fulfill the licensing criteria in Item 10.3.4.

10.3.6 Licensing Criteria for Applicants Who Will Calibrate Their Own Survey Instruments for Use With Alpha- or Beta-Emitting Radionuclides

You must establish and follow written procedures for calibrating survey instruments when used with alpha- or beta-emitting radionuclides.

10.3.7 Response

If you will calibrate your own survey instruments for use with alpha- or beta-emitting radionuclides, your response to Item 10.3 should describe the standards, the frequency of calibrations, and the procedures used to calibrate your survey instruments.

For detailed information about survey instrument calibration, refer to ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration" (May 26, 1978).*

10.4 Tests of Instruments Used To Measure the Activity of Each Dosage of Photon-, Alpha-, and Beta-Emitting Radionuclides Prior to Medical Use

10.4.1 Applicable Regulations

The applicable regulations are 10 CFR 20.1501(b), 10 CFR 30.33(a)(2), and 10 CFR 32.72.

10.4.2 Licensing Criteria

You should establish and follow written procedures for testing instruments used to measure the activity of dosages of photon-, alpha-, or beta-emitting radionuclides.

10.4.2.1 Tests of Dose Calibrators Used To Assay Photon-Emitting Radionuclides. Licensees are required by 10 CFR 32.72(c) to perform tests, before the initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence as appropriate. Your written test procedures for dose calibrators used to assay photon-emitting radionuclides should contain the following.

Constancy - Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. The check should be done on a frequently used setting with a

*Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any other photon-emitting radionuclide.

Accuracy - Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5% of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 kev and 500 kev.

Linearity - Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the maximum radioactivity to be measured in a vial and 30 microcuries.

Geometry Dependence - Upon installation, test each dose calibrator for geometry dependence over the range of volumes and volume configurations for which it will be used.

In addition, licensees should mathematically correct dosage readings for any geometry or linearity error that exceeds 10% if the dosage is greater than 10 microcuries and should repair or replace the dose calibrator if the accuracy or constancy error exceeds 10%.

Also, the licensee should perform appropriate checks and tests following adjustment or repair of the dose calibrator.

10.4.2.2 Tests of Dose Calibrators and Other Instruments for Measuring Alpha- and Beta-Emitting Radionuclides. Your written test procedures for instruments used to measure the radioactivity of alpha- and beta-emitting radionuclides should include standards, frequencies, measurement techniques, examples of necessary calculations, and evaluation of the accuracy and errors associated with calibrating these instruments. The tests need to be performed before initial use, after repair as applicable, and routinely at a defined period. Test procedures should include at least constancy, accuracy, linearity, and geometry dependence. If one of these basic test procedures is not appropriate for the instrument, this should be explained.

Note: If you are redistributing unit dosages of beta- or alpha-emitting radionuclides directly from the manufacturer to the customer (i.e., with no manipulation of the product or change in product labeling), these instruments should meet accuracy tolerances that enable you to detect gross errors by the manufacturer. However, if you manipulate the manufacturer's product or prepare your own product, the measurement accuracy of the instruments must meet tighter tolerances of 10%.

10.4.3 Response

Your response to Item 10.4 should include the following:

1. A description of the frequency, reference sources, and procedures you will use to test your dose calibrator and other instruments used to measure photon-, alpha-, and beta-emitting radionuclides.

2. If you are measuring only photon-emitting radionuclides, you could state that you have adopted the dose calibrator test program described in Appendix E to this guide (Draft Regulatory Guide DG-0006) and state the safe margin below ±10% you will use for tolerances.

The procedures in Appendix E for testing a dose calibrator would fulfill the criteria in Section 10.4.2 for measuring the activity of photon-emitting radionuclides.

10.5 Procedures for Receiving Shipments Containing Radioactive Material

10.5.1 Applicable Regulations

The applicable regulation is 10 CFR 20.1906.

10.5.2 Licensing Criteria

You should establish and follow written procedures for the receipt of packages containing radioactive material, both when the facility is staffed and when the facility is closed. As a minimum, these written procedures should require that:

1. Written directions will be provided to all delivery firms from which you expect to receive radioactive shipments.

2. These written directions will identify the area where deliveries are to be brought during working hours and left during hours when the facility is closed.
3. These written directions will identify the names and telephone numbers of persons on your staff to contact in the event of a damaged package or other emergency.
4. These written directions will include instructions to secure the area after a delivery is made.
5. A copy of these written directions will be posted in the area designated for receipt of shipments during hours when the facility is closed.

Note: In addition to the procedures specified in your license application, you must comply with the provisions of 10 CFR 20.1906. These regulations require special package receipt procedures for certain kinds or classes of packages.

10.5.3 Response

Your response to Item 10.5 should be one of the following:

1. A copy of the procedures you have established and follow for the receipt of packages containing radioactive material.
2. A statement that you have adopted the procedures described in Appendix F to this guide (Draft Regulatory Guide DG-0006) for ordering and receiving radioactive material. The procedures in Appendix F fulfill the criteria in Item 10.5.2.

10.6 Procedures for Safely Opening Packages Containing Radioactive Material

10.6.1 Applicable Regulations

The applicable regulations are 10 CFR 20.1906, 10 CFR 20.2103(a), 10 CFR 71.4, 10 CFR 71.47, and 10 CFR 71.87.

10.6.2 Licensing Criteria

You must establish and follow written procedures for safely opening packages containing radioactive material. As a minimum, these written procedures should require that:

1. Each labeled package will be monitored to determine that the surface dose rate is less than 200 millirems per hour.
2. The person opening the package must stop and notify the RSO immediately if the surface dose rate exceeds 200 millirems per hour
3. The package will be wipe-tested and the wipe will be checked with a calibrated low-level survey meter or other suitable instrument to detect the presence of unacceptable contamination levels.
4. Records of the surface dose rate and contamination survey measurements specified in items 2 and 4 will be maintained for NRC inspection for 3 years after each measurement.

10.6.3 Response

Your response to Item 10.6 should be one of the following:

1. A copy of the procedures you have established and follow for safely opening packages containing radioactive material.

2. A statement that you have adopted the procedures for opening packages described in Appendix G to this guide (Draft Regulatory Guide DG-0006). The procedures in Appendix G for opening packages fulfill the criteria in Item 10.6.2.

10.7 General Procedures for Safe Use of Radioactive Material

10.7.1 Applicable Regulations

The applicable regulations are 10 CFR 19.12, 10 CFR 20.1101(a), 10 CFR 30.34(g), 10 CFR 32.72(c), and 10 CFR 35.204.

10.7.2 Licensing Criteria

You must establish and follow written procedures for the safe use of radioactive material. These written procedures should state that:

1. Laboratory coats or equivalent protective clothing will be used at all times in areas where radioactive materials are being handled.

2. Disposable waterproof gloves will be used at all times when handling radioactive material.
3. Hands and clothing will be monitored for contamination (i.e., the appropriate photon, alpha, or beta activity) every time an individual exits an area where unsealed radioactive material is used or stored.
4. Appropriate syringe shields and vial shields will be used during all activities involving millicurie quantities of radioactive material.
5. Individuals do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.
6. Individuals do not store food, drink, or personal effects in any area where radioactive material is used or stored.
7. Every vial, syringe, ampule, or capsule of a photon-emitting radioactive drug will be assayed in a dose calibrator before distribution for use in humans.
8. Alpha- or beta-emitting radioactive drugs will be measured (either by direct measurement or a combination of measurements and calculations) before distribution for use in humans.
9. Each elution of technetium-99m from a molybdenum-99/technetium-99m generator will be (1) assayed for technetium-99m in a dose calibrator and (2) tested for molybdenum-99 concentration. The record of the results must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials of the individual who made the measurement. The record of each measurement will be retained for 3 years.
10. Technetium-99m will not be distributed for medical use if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

Note: According to 10 CFR 35.204(a), medical use licensees may not administer more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m. Therefore, commercial nuclear pharmacies should provide medical use licensees with information on the molybdenum-99 concentration in technetium-99m labeled radioactive drugs. One way to do this would be to label containers of radioactive drugs tagged with technetium-99m to specify the total molybdenum-99 activity or microcuries of molybdenum-99 per millicurie of technetium-99m and the date and time of assay. The medical use licensee can then determine whether the patient dose at the time of administration would contain more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m. Another way

would be to set the expiration time of the technetium-99m labeled drug to ensure that the molybdenum-99 concentration would not exceed 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m; with this method, the licensees must be informed that, to be in compliance with 35.204(a), the radioactive drug must be used before the expiration time. This notification process may be a generic statement to the medical use licensees that they will be in compliance with 10 CFR 35.204(a) if the radioactive drug is used before the expiration time.

11. Each individual will wear his or her assigned whole body monitoring badge at all times in areas where photon- and high-energy beta-emitting radioactive material is used or stored. Whole body monitoring badges are not needed when working exclusively with alpha- or low-energy beta-emitting radioactive materials.
12. Each individual will wear his or her assigned finger badge at all times during activities that involve eluting, preparing, assaying, or dispensing millicurie quantities of photon- and high-energy beta-emitting radioactive material. (The finger badge must only be worn for low-energy photon- or low-energy beta-emitting radioactive materials if the photons and beta particles can be detected by the badge.)
13. Individuals do not pipette radioactive solutions by mouth.
14. Disposal of radioactive waste will only be in specially designated and properly shielded receptacles.
15. Generator, kit preparation, and dose dispensing areas will be surveyed for contamination after each procedure or at the end of the day and will be decontaminated if necessary.
16. Radioactive solutions will be confined in covered containers that are clearly identified and labeled with the name of the compound, radionuclide, date, and activity.
17. Transport of radioactive material will always be in appropriately shielded containers.

10.7.3 Response

Your response to Item 10.7 should be one of the following:

1. A copy of the procedures you have established and follow for the safe use of radioactive material.
2. A statement that you have adopted the general rules for safe use of radioactive material described in Appendix H to this guide (Draft Regulatory Guide DG-0006). The general rules in Appendix H fulfill the criteria in Item 10.7.2.

10.8 Emergency Procedures

10.8.1 Spills and Contamination

10.8.1.1 Applicable Regulations. The applicable regulations are 10 CFR 19.12, 10 CFR 20.1101(a), and 10 CFR 30.33.

10.8.1.2 Licensing Criteria. You should establish written procedures for handling emergencies that involve radioactive contamination and should post these written procedures in the restricted area. As a minimum, these written procedures should include:

1. A statement that the written procedures will be posted in each area of the facility where radioactive material is used or stored.
2. A statement that equipment and material necessary for rapid response to spills or other radioactive contamination emergencies will be maintained in the form of a "decontamination kit" in each restricted area.

10.8.1.3 Response. Your response to Item 10.8 should be one of the following:

1. A copy of the procedures you have established and agree to follow for handling emergencies that involve radioactive contamination, or
2. A statement that you have adopted the emergency procedures for spills involving photon- and high-energy beta-emitting radionuclides described in Appendix I to this guide (Draft Regulatory Guide DG-0006). The emergency procedures in Appendix I fulfill the criteria in Item 10.8.2 for photon- and high-energy beta-emitting radionuclide spills.

Note: If you are also using alpha- or low-energy beta-emitting radio-nuclides, you should modify the survey section of Appendix I to name the appropriate instrumentation and describe your procedures for detecting and monitoring fixed and removable alpha- and low-energy beta-emitting radionuclide contamination. The instrumentation and procedures for detecting and monitoring fixed and removable contamination will be evaluated to determine whether they fulfill the criteria in Item 10.8.2 for alpha- and beta-emitting radionuclides.

10.8.2 Fire Protection

10.8.2.1 Applicable Regulations. The applicable regulation is 10 CFR 30.33(a)(2).

10.8.2.2 Licensing Criteria. Your facilities and equipment must be adequate to protect health and minimize danger to life or property. Therefore, arrangements should be made with local fire departments to respond to fires or explosions involving your facility.

10.8.2.3 Response. Describe the arrangements you have made with the local fire department to inform them of your operation and to instruct them in appropriate emergency procedures.

Note: Most applicants provide a written notice to the fire department that describes the applicant's location and scope of operation, invites fire department personnel to visit the facility, and provides appropriate instructions about handling emergencies at the applicant's facility. Most applicants also agree to send similar reminder notices to the fire department at least annually.

10.8.3 Emergency Plan

10.8.3.1 Applicable Regulations. The applicable regulation is 10 CFR 30.32(i).

10.8.3.2 Licensing Criteria. Each applicant or licensee reviews its operations to determine whether it needs to establish and implement an emergency plan as required by 10 CFR 30.32(i).

10.8.3.3 Response. If your program requires an emergency plan, as required by 10 CFR 30.32(i), submit your plan.

10.9 Procedures for Retrieving Radioactive Waste from Customers

Only applicants who will retrieve radioactive waste from their customers need respond to Item 10.9.

10.9.1 Applicable Regulations

The applicable regulations are 10 CFR 20.2001, 20.2002, 30.33, and 71.5.

10.9.2 Licensing Criteria

Licensees who will retrieve radioactive waste from customers should:

1. Request and receive approval to receive waste containing licensed materials from your customers.
2. Agree to retrieve only those items (e.g., syringes, vials) that contain or are contaminated with radioactive materials that you supplied.
3. Agree to provide detailed instructions to customers who will package radioactive waste for return to your facility. These instructions must clearly indicate that you will accept only items that contain or are contaminated with radioactive materials that you supplied. In addition, these instructions must be adequate to ensure that your customers comply with Department of Transportation (DOT) and NRC regulations for packaging and transport of licensed materials and for the radiation safety of drivers. As a minimum, these instructions are to:

   · Establish the user's responsibility and liability as the shipper,
   · Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process, and
   · Discuss all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189.

Note: If the pharmacy chooses to take the responsibility of the shipper for returned materials, the pharmacy needs to ensure that the customer acting as its agent follows DOT rules in the return process. This includes the customer having the proper documentation to demonstrate that the shipping containers meet the DOT regulations.

If you wish to operate a waste disposal service on a broader scale than this authorization allows, you may apply for a separate license under the general provisions of 10 CFR 30.33, and the license would only be issued pursuant to Part 30.

10.9.3 Response

You should submit a copy of your instructions to customers about the return of radioactive waste. Submit actual samples of all forms, labels, and instructions you will provide to customers for shipping radioactive waste back to your facility. Be sure your instructions include the points in Item 2 above. The discussion of the customer's responsibilities should include (but is not limited to):

- The requirements for surveying and wipe-testing the packages,
- The distance at which to survey packages,
- The action levels for the package wipe-test results,
- The dose rate limitations on the particular shipping label that you provide, and
- The need for sealing tape or another mechanism to fulfill the security seal requirement.

10.10 Precautionary Measures for Handling Millicurie Quantities of Radioiodine

Only applicants with operations that will involve performing radioiodinations, preparing radioiodine capsules from liquid solutions, and opening and dispensing from vials containing millicurie quantities of radioiodine need respond to Item 10.10.

10.10.1 Applicable Regulations

The applicable regulations are 10 CFR 20.1101, 10 CFR 20.1204, 10 CFR 20.1502, and 10 CFR 30.33.

10.10.2 Licensing Criteria

You should establish and agree to implement (1) precautionary measures to minimize exposure of workers to radiation and (2) an iodine bioassay program at least equivalent to that specified in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."*

*Single copies of regulatory guides, both issued and in draft, may be obtained free of charge by writing the Office of Administration, Attn: Distribution and Services Section, USNRC, Washington, DC 20555, or by fax at (301)415-2260.

10.10.3 Response

In response to Item 10.10, describe:

1. The precautionary measures you will require personnel to follow during iodination, capsule preparation, and opening and dispensing procedures (e.g., use of a fume hood, gloves).

2. Your procedures for performing thyroid uptake bioassay measurements. Your bioassay interval schedule, action levels, and the actions to be taken at those levels should be at least equivalent to those specified in Regulatory Guide 8.20. Demonstrate that you will have adequate equipment to perform bioassay measurements. Describe your procedure for calibrating this equipment before performing bioassays. State how you will derive the conversion factors necessary to convert counts per minute into microcurie units. Your bioassay procedures should address the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by tissue in the employee's neck).

10.11 Area Survey Procedures

10.11.1 Applicable Regulations

The applicable regulations are 10 CFR 20.1101(b) and 10 CFR 20.1501.

10.11.2 Licensing Criteria

You should establish and implement written procedures for performing periodic radiation surveys and contamination monitoring. As a minimum, these procedures should provide that:

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

appropriate instrumentation or monitoring techniques are used to detect the type of radiation used.

4. The instrumentation or measurement technique used to perform the daily and weekly surveys for alpha- or low-energy beta-emitters is sufficiently sensitive to detect contamination.
5. Higher than normal readings for any area will be investigated and corrected immediately.
6. A series of wipe tests will be performed at least weekly in order to detect surface contamination.
7. The method for analyzing the wipe tests will be sufficiently sensitive to detect 220 disintegrations per minute (dpm) per 100 cm^2 for the contaminant involved.
8. Areas will be either cleaned or posted and restricted from use if the contamination level exceeds 2,200 dpm per 100 cm^2.
9. Areas will be covered, cleaned, or identified to employees if the contamination level exceeds 220 dpm per 100 cm^2 but is less than 2,200 dpm per 100 cm^2.
10. Records of the results of all surveys and wipe tests will be maintained for NRC inspection for a period of 3 years.

10.11.3 Response

Your response to Item 10.11 should be the following:

1. A description of the intervals and the procedures you have established and follow for performing routine radiation surveys and contamination monitoring.
2. For photon- and high-energy beta-emitters, you may either provide the information requested in Item 1 above or state that you have adopted the area survey procedures described in Appendix J to this guide (Draft Regulatory Guide DG-0006). The area survey procedures in Appendix J fulfill the criteria in Item 10.11.2 for photon- and high-energy beta-emitting radionucludes.

Note: For radiation emissions that cannot be detected and measured with a low-range survey meter, the general guidelines in Appendix J can be used provided the appropriate instrumentation and measurement techniques and detection levels are described.

10.12 Distribution Operations

10.12.1 Applicable Regulation

The applicable regulation is 10 CFR 32.72.

10.12.2 Licensing Criteria

You should provide assurance that the products to be distributed are either (1) initially distributed by a manufacturer licensed pursuant to 10 CFR 32.72 or (2) prepared by either an authorized nuclear pharmacist or an individual under the supervision of an authorized nuclear pharmacist.

10.12.3 Response

In response to Item 10.12, submit a description of the distribution operations you plan to conduct under your commercial nuclear pharmacy license. The licensing criteria will be satisfied if the description of your distribution operations states one of the following as applicable to your operations.

1. Your commercial nuclear pharmacy is licensed by the State Board of Pharmacy in the State in which the facility is located (you should submit a copy of the permit or license), or
2. Your commercial nuclear pharmacy is within a Federal medical institution.

The activity of your commercial nuclear pharmacy is expected to include the preparation of radioactive drugs by an authorized nuclear pharmacist or an individual under the supervision of the authorized nuclear pharmacist. Indicate whether the activities of your commercial nuclear pharmacy include:

- Activities (specify) other than the preparation of radiopharmaceuticals for distribution to medical use licensees (e.g., in vitro test kits, sealed sources), or
- Repackaging prepared radioactive drugs initially distributed by a manufacturer licensed pursuant to 10 CFR 32.72.

10.13 Product Labels

10.13.1 Applicable Regulations

The applicable regulations are 10 CFR 20.1901, 10 CFR 20.1904, 10 CFR 20.1905, 10 CFR 30.34(g), and 10 CFR 32.72(a)(4).

10.13.2 Licensing Criteria

Your product labels must fulfill the color, symbol, and wording requirements of 10 CFR 20.1901 and 20.1904 and 10 CFR 32.72(a)(4).

10.13.3 Response

In response to Item 10.13, describe all labels, indicating the colors to be used, that will accompany your products and describe where each label is placed (e.g., on the radiation transport shield or the container used to hold the radioactive drug).

10.13.4 Discussion

In order to meet the requirements in 10 CFR 32.72(a)(4)(i), you must agree to label each transport radiation shield to show the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The "transport radiation shield" could be constructed of lead glass, plastic, or other material, as appropriate for the isotope to be transferred for commercial distribution. The phrase "transport radiation shield" does not refer to the outer suitcase, package, packing, or other carrying device, even though that barrier may provide some radiation shielding. Also, the radioactive symbol on the label must be as described in 10 CFR 20.1901.

In order to meet the requirements in 10 CFR 32.72(a)(4)(ii), you must agree to label each syringe, vial, or other container (e.g., generator or ampule) used to hold radioactive drugs to be transferred for commercial distribution to show the radiation symbol, the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL," and an identifier that ensures the syringe, vial, or other container can be correlated with the information on the transport radiation shield label. The radiation symbol must be the same as described in 10 CFR 20.1901. The identifier must

provide a correlation between the syringe, vial, or other container and the information on the label of its transport radiation shield. Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

10.14 Product Shielding

10.14.1 Applicable Regulations

The applicable regulation is 10 CFR 32.72(a)(3).

10.14.2 Licensing Criteria

The shielding you provide for each product you wish to distribute must be adequate for safe handling and storage of the product at hospitals, physicians' offices, and other medical use sites.

10.14.3 Response

For each radionuclide you intend to distribute (except for products you redistribute without manipulation and in the manufacturer's original shipping package), you should:

1. Specify the radionuclide and its chemical and physical form.
2. State the maximum activity for each type of container (e.g., vial, syringe).
3. Describe the type and thickness of the shielding you will provide for each type of container.
4. Indicate the maximum radiation level to be expected at the surface of each transport radiation shield when the radioactive drug container is filled with the maximum activity.

Note: It is not acceptable for you to state that you will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the shielded syringe or vial; 10 CFR 32.72(a)(3) applies specifically to safe handling and storage of the radioactive drug by medical use licensees.

10.15 Procedures for Packaging and Transporting Radioactive Drugs

10.15.1 Applicable Regulations

The applicable regulation is 10 CFR 71.5.

10.15.2 Licensing Criteria

You should establish and implement written procedures that (1) ensure compliance with the DOT regulations set forth in 49 CFR Parts 170 through 189 and (2) ensure that radioactive material is secured at all times against unauthorized removal. You should keep adequate information available in the delivery vehicle for drivers, police, or civil authorities in case of traffic accidents, etc.

Note: If the pharmacy chooses to take the responsibility of the shipper for returned materials, the pharmacy needs to ensure that the customer acting as its agent follows DOT rules in the return process. This includes the customer having the proper documentation to demonstrate that the shipping containers meet the DOT regulations.

10.15.3 Response

In response to Item 10.15, you should submit:

1. Your step-by-step procedures for packaging and transporting radioactive drugs to customers.
2. A description or copy of the written instructions you will provide to drivers about radiation safety and delivery procedures. Your instructions should include directions to lock the vehicle whenever it is left unattended and to leave deliveries only in secured places that have been designated by your customers.
3. A description or copy of the written instructions you will keep conspicuously available in your delivery vehicles for drivers, police, or civil authorities in case of traffic accidents, etc. These instructions should describe in general terms the contents of the vehicle, provide telephone numbers of responsible nuclear pharmacy employees who can assist at the scene, and give general "common sense" instructions for the interim until an employee can reach the scene.
4. A description or copy of your written instructions to the customer for repackaging used or unused materials and containers for transport back to the commercial nuclear pharmacy.

10.16 Independent Audit

The purposes of an independent audit of the content and implementation of the radiation protection program are to provide an objective review of the program and to ensure compliance with all applicable regulations and with the terms and conditions of your NRC license and to assure that occupational doses and doses to members of the public are as low as is reasonably achievable.

10.16.1 Applicable Regulations

The applicable regulations are 10 CFR 20.1101 and 10 CFR 20.2102.

10.16.2 Licensing Criteria

You should establish and implement a radiation protection audit program, preferably conducted by an individual or group who is not connected with your day-to-day operations. The audit program must be adequate for management to assess compliance with all regulatory requirements, including the terms and conditions of your NRC license.

10.16.3 Response

In response to Item 10.16, you should describe the type, extent, and frequency of independent radiation protection audits to be performed. Describe how the audit program will ensure compliance with all the regulatory requirements. Submit the name and qualifications of the individual* who will assume primary responsibility for performing these audits. Use a format similar to that of Figure A-3 of Appendix A to document the training and experience of this individual. Specify the basis for this individual's authority to mandate changes as necessary for NRC compliance and good radiation health physics practice.

*If a number of facilities are owned by the same parent company, this individual may be the corporate Radiation Safety Officer provided this individual is not listed on the individual licenses as the RSO. If the operation is conducted by a university, this individual may be the university Radiation Safety Officer. Otherwise, this function may be performed by a consultant.

10.16.4 Discussion

The NRC's experience in licensing and inspecting commercial nuclear pharmacies indicates that these operations benefit from an independent audit program, which helps to ensure continued compliance with NRC regulations and the terms and conditions of the license. A qualified individual who is not involved in day-to-day operations would be valuable in identifying lapses or weaknesses in a program. The frequency of audits is usually quarterly for a new facility and might decrease to annually after the facility has been in operation for some time and no items of noncompliance are noted.

Item 11 Waste Management

11.1 Disposal by Transfer or Release into Sewer or Disposal of Specific Waste

NRC licensees are authorized in 10 CFR 20.2001, 10 CFR 20.2006, and Appendix F to 10 CFR Part 20 to dispose of radioactive waste by transfer to an authorized recipient (i.e., a radioactive-waste disposal service licensed by NRC or an Agreement State). Limits on the type and amount of material that may be disposed of into a sewer are established in 10 CFR 20.2003. Also, NRC licensees are authorized in 10 CFR 20.2005 to dispose of 0.05 microcuries (1.85 Kbq) or less of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting as if it were not radioactive. The disposal records that must be maintained are stated in 10 CFR 20.2108.

11.1.1 Applicable Regulations

The applicable regulations are 10 CFR 20.2001, 10 CFR 20.2003, 10 CFR 20.2005, 10 CFR 20.2006, and 10 CFR 20.2108.

11.1.2 Response

If you will dispose of radioactive waste by transfer to an authorized recipient (10 CFR 20.2006), by release into a sewer (10 CFR 20.2003), or by disposal of specific waste (10 CFR 20.2005), it is acceptable to state in response to Item 11 that you will dispose of radioactive waste in accordance with the appropriate requirements.

11.2 Disposal by Decay-in-Storage

11.2.1 Applicable Regulations

The applicable regulations are 10 CFR 20.2001 and 10 CFR 30.51.

11.2.2 Licensing Criteria for Decay-in-Storage

If you wish to dispose of radioactive waste by decay-in-storage, you should establish and follow written procedures for this disposal method. As a minimum, these written procedures should include:

1. The maximum physical half-life of the radioactive material to be held for decay-in-storage.
2. That radioactive waste be held a minimum of 10 half-lives before disposal as normal trash. (Radioactive waste should be segregated according to half-life in order to facilitate this step.)
3. That radioactive waste intended for disposal as normal trash be held until radiation levels (as measured with an appropriate low-level survey meter in a low-background area with all shielding removed) are indistinguishable from background levels. (Because molybdenum-99/technetium-99m generator columns may contain long-lived radioisotopic contaminants, these columns should be segregated from other waste and monitored separately to ensure decay to background levels before disposal.)
4. That records of the results of the measurements described in 3 above be maintained for NRC inspection for 3 years.
5. That radiation labels be removed or obliterated before disposal as normal trash.

11.2.3 Response

Your response to Item 11.2 should be one of the following:

1. A description of your procedures for disposal of radioactive waste by decay in storage, or
2. The following statement (if you will dispose of radioactive materials that have a physical half-life of less than 65 days by decay-in- storage):

Item 11: We, (name of nuclear pharmacy), will dispose of radioactive waste in accordance with the requirements in 10 CFR 20.2003, 20.2005, and 20.2006. We have established written procedures covering decay in storage, which include the criteria in Item 11.2.2 of this guide (Draft Regulatory Guide DG-0006).

11.3 Decommissioning

11.3.1 Applicable Regulations

The applicable regulation is 10 CFR 30.35.

Applicants for or holders of a specific license authorizing the possession and use of unsealed byproduct material with a half-life greater than 120 days, or users of a large sealed source or plated foil, must provide financial assurance for decommissioning according to 10 CFR 30.35.

11.3.2 Licensing Criteria

All applicants and licensees are responsible for decommissioning their facilities. Certain byproduct material applicants and licensees must provide up-front decommissioning financial assurance. Applicants and licensees should review the requirements in 10 CFR 30.35(a), (b), and (c) to determine whether they are subject to these financial assurance requirements. If so, you must provide such assurance through either a rule-specified amount (10 CFR 30.35(d)) or a cost estimate (10 CFR 30.35(e)) and a rule-specified financial mechanism (10 CFR 30.35(f)).

11.3.3 Response

If subject to financial assurance requirements, the applicant or licensee must describe the arrangements to ensure that a rule-required financial instrument is in place to cover the costs of decommissioning. Guidance on financial assurance for decommissioning, for both cost estimating and developing acceptable financial instruments, is provided in Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72."* If you do not possess and use unsealed byproduct material with a half-life greater than 120 days, or large sealed sources or plated foil, you should state that these parts do not apply.

*Single copies of regulatory guides, both issued and in draft, may be obtained free of charge by writing the Office of Administration, Attn: Distribution and Mail Services

Item 12 License Fees

As stated in 10 CFR 170.12, each application for which a fee is required, including applications for license amendments and renewals, must be accompanied by the appropriate fee. Refer to 10 CFR 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections, and Import and Export Licenses," to determine the amount of the fee that must accompany your application. The NRC will not issue the new license, amendment, or renewal prior to receipt of the appropriate fee. All application fees will be charged regardless of the NRC's disposition of your application or your withdrawal of the application.

Note that, in addition to the licensing fees described in 10 CFR 170.31, most NRC licensees are also subject to annual fees (see 10 CFR 171.16). Section 171.11 provides additional information on exemptions from annual fees, while 10 CFR 171.16(c) permits reduced annual fees for licensees qualifying as "small entities" under NRC size standards (10 CFR 2.810).

All questions about NRC's fees should be directed to the Office of the Controller (OC) at NRC headquarters' office in Rockville, Maryland. OC's telephone number is (301)415-7554.

Item 13 Certification

If you are an individual, date and sign the form yourself. Otherwise, have the application dated and signed by a representative of the corporation or legal entity authorized to sign official documents and to certify that it contains information that is true and correct to the best of your knowledge and belief. Unsigned applications will be returned for proper signature.

4. REQUESTS FOR AUTHORIZATION TO REDISTRIBUTE VARIOUS ITEMS

Section, USNRC, Washington, DC 20555, or by fax at (301)415-2260.

Some commercial nuclear pharmacies have requested authorization to conduct activities other than those shown in A and B of Item 9 in Exhibit B. For some of these activities, such as performing leak tests and calibrating instruments for its customers, the commercial nuclear pharmacy needs a separate license. Guidance is being developed on these subjects.* Other activities that may be characterized as "redistribution" of various items can be authorized in the nuclear pharmacy license (i.e., C, D, and E of Item 9 in Exhibit B). "Redistribution" usually involves obtaining an item from an approved supplier (i.e., an organization that has an approval to distribute the item to medical use licensees of the NRC or an Agreement State pursuant to equivalent State requirements) and selling it to the commercial nuclear pharmacy's customers with little or no change in the original packaging, shielding, etc. Applicants should supply information on the following commonly requested redistribution practices as applicable.

4.1 Redistribution of Generators

If you want to *manufacture* and *distribute* generators (or to be the initial distributor of generators) to medical use licensees, you must file a separate application (see Draft Regulatory Guide DG-0007 for proposed guidance).

However, if you wish to *redistribute* unused generators to medical use licensees, you should state that all generators to be redistributed will have been obtained from a manufacturer authorized to distribute the generators in accordance with a specific license issued pursuant to 10 CFR 32.72 or under equivalent requirements of an Agreement State. If you wish to *redistribute* opened generators to medical use licensees, you should (1) describe the procedures and instructions for safely repackaging the generators and (2) specify that the manufacturer's packaging and labeling will not be altered and that the

*Guidance has been proposed on leak-testing services and calibration services, and draft guides have been issued for public comment on these subjects. They are Draft Regulatory Guides FC 412-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Leak-Testing Services," and FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments."

redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

4.2 Redistribution of Sealed Sources -- Calibration and Reference Sources

If you wish to *manufacture* and *distribute* sealed calibration or reference sources (or to be the initial distributor of such sources) to medical use licensees, you must file a separate application (see Draft Regulatory Guide
DG-0007, "Guide for the Preparation of Applications for Licenses To Authorize Distribution of Various Items to Commercial Nuclear Pharmacies and Medical Use Licensees," for proposed guidance).

However, if you want to *redistribute* sealed calibration or reference sources to medical use licensees, you should:

1. Specify the categories of licensees (e.g., medical use licensees, other licensees specifically authorized to receive the sources) to which you wish to redistribute the sources.

   Note: Although a commercial nuclear pharmacy's customers for the sources are primarily medical use licensees, many commercial nuclear pharmacies also request authorization to redistribute the calibration or reference sources to other specific licensees.

2. Specify that the calibration or reference sources to be redistributed will have been obtained from a manufacturer authorized to distribute the sources in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent requirements of an Agreement State.
3. Specify that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

4.3 Redistribution of Sealed Sources -- for Brachytherapy or Diagnosis

If you want to *manufacture* or be the *initial distributor* to medical use licensees of sealed sources for brachytherapy or diagnosis as provided in 10 CFR 35.400 and 35.500, you must file a separate application (see Draft Regulatory Guide DG-0007 for proposed guidance).

However, if you want to *redistribute* sealed sources for brachytherapy or diagnosis to medical use licensees, you should:

1. Specify that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements.
2. Specify that the manufacturer's packaging, labeling, and shielding will not be altered (except as indicated in 3 below) and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.
3. Submit samples of the labels and indicate the colors on the labels you will affix to the sources or to the shield or other device containing the source. Note: Labels must fulfill the symbol and wording requirements of 10 CFR 20.1901 and 20.1904 and 10 CFR 32.74.

4.4 Redistribution of Prepackaged Units for In Vitro Tests

If you want to *manufacture* and *distribute* prepackaged units for in vitro tests to general licensees or to persons exempt from licensing, you should contact the NRC licensing staff for further information.

Many nuclear pharmacies have requested authorization to *redistribute* prepackaged units for in vitro tests to general licensees and to specific licensees. Guidance on obtaining these authorizations is given below.

4.4.1 Redistribution to General Licensees

If you want to redistribute prepackaged units for in vitro tests to *general* licensees, specify that:

1. The prepackaged units for in vitro tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for in vitro tests in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State.

2. The manufacturer's packaging and labeling of the prepackaged units for in vitro tests will not be altered in any way.
3. Each redistributed prepackaged unit for in vitro tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

4.4.2 Redistribution to Specific Licensees

If you want to redistribute prepackaged units for in vitro tests to *specific* licensees (all medical use licensees, in accordance with 10 CFR 31.11(a), automatically have a general license to receive prepackaged units for in vitro tests and do not fall in this category of licensees), specify that:

1. You will obtain prepackaged units for in vitro tests (10 CFR 31.11(a)) for redistribution to specific licensees.
2. You will ensure that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for in vitro tests do NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11).
3. You will ensure that labeling on redistributed prepackaged units for in vitro tests conforms to the requirements of 10 CFR 20.1901 and 20.1904.

5. AMENDMENTS TO A LICENSE

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 correspondence with NRC, (2) the terms and conditions of the license, and (3) NRC'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 or other correspondence is to be modified or changed, you should submit an application for an amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended; NRC 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 (NRC Form 313, Exhibit A) or in letter form and should be submitted in duplicate to the appropriate address from Figure 1 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.

In the past, the most frequently requested amendment to commercial nuclear pharmacy licenses was to add a new "authorized user." However, with the implementation of the notification procedures (10 CFR 32.72(b)(5)), few amendments are expected for this purpose. If an amendment for a new authorized nuclear pharmacist is needed, specify not only the name of the individual but also his or her training and experience. See Section 2, Item 7, and Appendix A of this guide for additional guidance. Amendment requests in the future are expected to be to change the RSO or for changes in the facility, shielding, or equipment, as necessary, to safely prepare and dispense radioactive drugs (authorizations similar to 6B, 7B, and 8B in Exhibit B).

You must send the appropriate fee for a license amendment with your application. The NRC will not issue an amendment to the license before the proper fee is paid in accordance with 10 CFR 170.12.

Note: Nothing in your NRC license, this draft regulatory guide, or NRC regulations relieves you from complying with applicable Food and Drug Administration (FDA), other Federal, and State requirements governing radioactive drugs or devices.

6. RENEWAL OF A LICENSE

Licenses are issued for a period of up to 5 years. You must send an application for renewal to the address specified in Figure 1 of this guide. If your original application predates this guide, submit an entirely new application for renewal as if it were an application for a new license without referring to previously submitted information (except for the qualifications of previously approved users).

If your original application was prepared in accordance with this guide, the following alternative is also acceptable.

1. Review your current license to determine whether the information about radioactive materials to be possessed or distributed, the location of use, authorized nuclear pharmacists, etc., accurately

represents your current and anticipated program. Identify any necessary additions, deletions, or other changes and then prepare information appropriate for the requested additions or changes.

2. Review the documents you submitted in the past to determine whether they are up to date and accurately represent your operations, facilities, equipment, personnel, radiation safety procedures, locations of use, etc. The documents you consider to represent your current program should also be identified by date. Any out-of-date and superseded documents should be identified and changes should be made in the documents as necessary to reflect your current program.
3. Review NRC regulations to ensure that any changes in the regulations are appropriately reflected in your program description.
4. After you have completed your review, submit a letter to the NRC in duplicate, with the proper fee, requesting renewal of your license and providing the information specified in the above items 1, 2, and 3, as necessary.
5. Include the name and telephone number of the person who may be contacted about your renewal application and include your current mailing address if it is not indicated correctly on your license.

If you file your application for license renewal at least 30 days before the expiration date of your license and include the appropriate fee for license renewal, your present license will automatically remain in effect until the NRC takes final action on your renewal application. However, if you file an application less than 30 days before the expiration date and NRC cannot process it before that date, you could be without a valid license when your license expires.

It is important that the appropriate fee accompany your application for license renewal. In accordance with 10 CFR 170.12, the NRC will not renew the license before the proper fee is paid.

If you do not wish to renew your license, you must dispose of all licensed radioactive material in a manner authorized by 10 CFR Part 20. Complete NRC Form 314, "Certificate of Disposition of Materials," and send it to the NRC before the expiration date of your license with a request that your license be terminated.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for “storage only” of the radioactive material. The renewal is necessary to avoid violating NRC's regulations that do not allow you to possess licensable material without a valid license.

7. IMPLEMENTATION

The purpose of this section is to provide information to you about the NRC staff's plans for using this regulatory guide and how these plans affect you. This draft guide has been distributed for comment to encourage public participation in its development. It represents the current position of the NRC staff, which is subject to change after the review of public comments. Comments received during the public comment period on this draft guide will be considered in developing the final guide, i.e., the guide that will represent an official NRC staff position.

Until the final guide is published, this draft document represents the best available guidance, and you may use it when preparing requests for licensing actions. After the final guide is published, the NRC staff will use the final guide in its review of requests for licensing actions.

The draft and final guides may differ. If your license was issued or amended based on recommendations in the draft guide that are more restrictive than those in the final guide, you may choose to request an amendment to your license to incorporate the less restrictive guidance. If the final guide is more restrictive than the draft guide, this will not affect licensing actions already completed since all required regulatory findings will have been made.

APPENDIX A

TRAINING AND EXPERIENCE OF AUTHORIZED NUCLEAR PHARMACISTS AND RADIATION SAFETY OFFICERS

According to 10 CFR 30.33(a)(3), applicants must be qualified by training and experience to use licensed material for the purpose requested in the application. For nuclear pharmacy operation, the NRC reviews the training and experience of the individuals who are to be listed as authorized nuclear pharmacists and radiation safety officers to determine whether they meet this requirement. This appendix lists the training and experience that the NRC finds acceptable for these individuals.

AUTHORIZED NUCLEAR PHARMACIST

An authorized nuclear pharmacist must be a pharmacist, i.e., an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy. This pharmacist must have 700 hours of training and experience in basic radioisotope handling and radiopharmacy techniques.

The 700 hours must be in a structured educational program consisting of both didactic training and supervised experience.

Didactic training must include training in:

- Radiation physics and instrumentation,
- Radiation protection,
- Mathematics pertaining to the use and measurement of radioactivity,
- Chemistry of byproduct material for medical use, and
- Radiation biology.

Supervised experience in a nuclear pharmacy must involve:

- Shipping, receiving, and performing related radiation surveys;
- Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
- Calculating, assaying, and safely preparing dosages for patients or human research subjects;

- Using administrative controls to avoid mistakes in the administration of byproduct material; and
- Using procedures to prevent or minimize contamination and using proper decontamination procedures.

The pharmacist must have a written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy. You may use a format similar to Figures A-1 and A-2 for documenting hours of training and hours of experience using radioisotopes.

RADIATION SAFETY OFFICER

A Radiation Safety Officer should have the following.

1. Training in basic radioisotope handling techniques specifically applicable to the use of unsealed sources (200 hours). This training should consist of lectures and laboratory sessions in the following areas:

- Radiation physics and instrumentation
- Radiation protection
- Mathematics pertaining to the use of radioactive material and measurement of radioactivity
- Radiation biology
- Radiopharmaceutical chemistry

This training should emphasize radiation physics, instrumentation, and radiation protection, with no less than 130 of the 200 hours total devoted to these subject areas.

On-the-job training may not count toward the hours listed above unless it was obtained as part of a formal training course. A "formal" training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the NRC upon request.
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to NRC upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile.
- A permanent record that the student successfully completed the course is kept at the institution.

2. One year, full-time, of experience monitoring radiation safety at a nuclear pharmacy or medical institution under the supervision of the individual identified as the Radiation Safety Officer on either a commercial nuclear pharmacy license or a Commission or Agreement State license that authorizes the medical use of byproduct material.

You may use a format similar to that shown in Figure A-3 for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes. Submit a statement providing the location, dates, and times of the individual’s one year of full-time experience in monitoring radiation safety at a nuclear pharmacy or medical institution.

APPENDIX B

TYPICAL DUTIES AND RESPONSIBILITIES OF A RADIATION SAFETY OFFICER FOR A COMMERCIAL NUCLEAR PHARMACY

In a nuclear pharmacy, the Radiation Safety Officer's (RSO's) day-to-day duties and responsibilities should include:

1. General surveillance over all activities involving radioactive material, including routine monitoring, special surveys, and responding to events.
2. Ensuring compliance with NRC rules and regulations as well as conditions of the NRC license.
3. Monitoring the performance of fume hoods that are associated with isotope work.
4. Serving as the primary source of radiation protection information for personnel at all levels of responsibility.
5. Overseeing and coordinating the receipt, opening, and delivery of all shipments of radioactive material arriving at the nuclear pharmacy.
6. Overseeing and coordinating the preparation of all shipments of radioactive material leaving the nuclear pharmacy.
7. Overseeing the distribution and processing of personnel monitoring equipment.
8. Conducting training programs in proper procedures for the use of radioactive material.
9. Overseeing and coordinating the radioactive waste disposal program.
10. Overseeing the safe storage of all radioactive materials not in current use.
11. Ensuring that sealed sources are leak-tested at proper intervals.
12. Maintaining an inventory of all radioactive materials and limiting the quantity of radionuclides at the facility to the amounts authorized by the license.
13. Reviewing the licensee’s procedures and controls, based upon sound radiation protection principles, to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA).

Note: In the absence of the RSO the authorized nuclear pharmacist should assume the duties of the RSO.

APPENDIX C

PERSONNEL TRAINING PROGRAM

1. Schedule for Training

Training will be provided:

1.1 Before an employee assumes duties with or in the immediate vicinity of radioactive materials,

1.2 Annually as refresher training for all employees,

1.3 Whenever a significant change occurs in duties, regulations, or the terms of the NRC license.

2. Description of the Training Program

Training will be sufficient to ensure that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) will be instructed according to the requirements in 10 CFR 19.12. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place.

3. Content of the Training Program

The training program will include the following topics:

3.1 The storage, transfer, or use of radiation or radioactive material,

3.2 Health protection problems associated with exposure to radiation or radioactive material, in precautions or procedures and functions of protective devices employed,

3.3 Applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation or radioactive material,

3.4 Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation or radioactive material,

3.5 Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material, and

3.6 The right to be informed of the radiation exposure reports that workers may request pursuant 10 CFR 19.13.

4. Records That Document Training

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

4.1 The name of the individual who conducted the training,

4.2 The names of the individuals who received the training,

4.3 The date of the training session, and

4.4 A list of the topics covered.

APPENDIX D

PROCEDURES FOR CALIBRATION OF SURVEY INSTRUMENTS USED TO MEASURE PHOTON-EMITTING RADIONUCLIDES

1. Calibration of survey meters will be performed with radionuclide sources.

1.1 The sources will be approximate point sources.

1.2 The source used will be one of those listed in Table D-1.

The use of the small check source contained in some survey meters is not appropriate or acceptable for calibration purposes.

Table D-1

SOURCES USED FOR SURVEY INSTRUMENT CALIBRATION

Radionuclide	Minimum Activity (To give at least 700 millirem per hour at 20 cm)
Cesium-137	85 millicuries
Cobalt-60	21 millicuries
Radium-226	34 millicuries

1.3 The source activities or dose rates at given distances will be traceable by documented measurements to a standard source certified within 5% accuracy to the National Institute of Standards and Technology (NIST) calibration sources.

1.4 Calibration will be performed at intervals not to exceed 12 months and after servicing.

1.5 Instruments will be calibrated on every scale or range of the instrument. A radiation source must be used on all scales up to 1 rem per hour. Three kinds of scales are frequently used on survey meters:

- 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.

- 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.
- 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.

1.6 The dose rate measured by the instrument will differ from the true exposure rate by less than ±10% at the calibration points (read the appropriate section of the instrument manual to determine how to make necessary adjustments to bring the instrument into calibration). Readings within ±20% will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings.

2. A reference source (check source) that has a long half-life, e.g., cesium-137 or radium D and E, will also be read at the time of the calibration. The readings will be taken with the reference source placed in specific geometry relative to the detector. A reading of the reference source should be taken:

2.1 Before each use and after each survey to ensure that the instrument was operational during the survey and

2.2 After each maintenance or battery change.

If any reading with the same geometry is not within ±20% of the reading measured immediately after calibration, the instrument will be recalibrated.

3. Records of Items 1 and 2.2 above will be maintained for at least 3 years after each calibration or check.

4. The inverse square law and radioactive decay law may be used for calibration.

4.1 A calibrated source will have a calibration certificate giving its output at a given distance or its activity measured on a specified date by the manufacturer.

- The inverse square law may be used with any point source to calculate the exposure rate at other distances.
- The radioactive decay law may be used to calculate the output at any time.

4.2 Inverse Square Law

If R_a is the dose rate at a distance D_a from a point source and R_b is the dose rate at a distance D_b from the same point source,

$$R_a D_a^2 = R_b D_b^2$$

Note: R_a and R_b must be in the same units of dose rate (e.g., millirem per hour, rem per hour) and D_a and D_b must be in same units of distance (e.g., centimeters, meters).

If R_a, D_a, and D_b are known, R_b can be calculated from:

$$R_b = \frac{D_a^2}{D_b^2} \times R_a$$

4.3 Radioactive Decay Law

The dose rate of a standard source at a time t after a specified calibration date is given by:

$$R_t = R_O \times e^{-(0.693 \times \frac{t}{T_{1/2}})}$$

$$= R_O \times (1/2)^n$$

where

R_t is the dose rate at a time t after the source calibration date
R_O is the dose rate on the day the standard source was calibrated
t is the time elapsed since the calibration date
$T_{1/2}$ is the radionuclide half-life

n is the number of half-lives through which the radioactive source has decayed and is equivalent to the quantity of $t/T_{½}$

Note: R_t and R_O must be in the same units of dose rate (e.g., millirem per hour, rem per hour), and t and $T_{½}$ must be in the same units of time (e.g., seconds, days, years).

APPENDIX E

MODEL PROCEDURES FOR TESTING DOSE CALIBRATORS USED TO MEASURE PHOTON-EMITTING RADIONUCLIDES

You may use the following model procedures for checking and testing dose calibrators.

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.

    1.1 Constancy, at least once each day prior to assay of patient dosages (a safe margin below ±10%).

    1.2 Linearity, at installation and at least quarterly thereafter (a safe margin below ±10%).

    1.3 Geometry dependence, at installation (a safe margin below ±10%).

    1.4 Accuracy, at installation and at least annually thereafter (a safe margin below ±10%).

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

3. Constancy means reproducibility in measuring a constant source over a long 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:

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

*Co-57 and Ra-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine its requirements for possessing this material.

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

3.3 For each source used, either plot or log (i.e., record in the dose calibrator log book) the background level for each setting checked and the net activity of each constancy source.

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

3.5 Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the authorized nuclear pharmacist or the radiation safety officer of a suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The dose calibrator should be repaired or replaced if the error exceeds 10%.

4. The linearity of a dose calibrator should be ascertained over the range of its use between the maximum activity in a vial and 30 microcuries. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This example uses a vial of technetium-99m that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator) and assumes your predetermined safety margin is ±5%.

4.1 Time Decay Method

4.1.1 Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

4.1.2 Assay the technetium-99m vial in the dose calibrator and subtract background to obtain net activity in millicuries.

4.1.3 Repeat step 4.1.2 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

4.1.4 Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time* (hours)	Correction Factor
0	31.6
6	15.8
24	2.00
30	1.00
48	0.126

*Assay times should be measured in whole hours and correction factors should be used to three significant figures as indicated. The half-life of $T_{½}$ = 6.02 hours has been used in calculating these correction factors.

Example: If the net activity measured at 30 hours was 15.6 mCi, the calculated activities for 6 and 48 hours would be 15.6 mCi x 15.9 = 248 mCi and 15.6 mCi x 0.126 = 1.97 mCi, respectively.

4.1.5 Plot both the measured net activity and the calculated activity versus time.

4.1.6 On the graph, the measured net activity plotted should be within ±5% of the calculated activity if the instrument is linear and functioning properly. If variations greater than 5% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.

4.1.7 If instrument linearity cannot be corrected, for routine assays it will be necessary to use either an aliquot of the eluate that can be accurately measured or the graph constructed in step 4.1.5 to relate measured activities to calculated activities.

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

4.2 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.

4.2.1 Begin the linearity test by assaying 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. This first assay should be done in the morning at a regular time. After making the first assay, the sleeves can be calibrated as follows. Steps 4.2.2 through 4.2.4 must be completed within 6 minutes.

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

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

4.2.4 Continue for all sleeves.

4.2.5 Complete the following decay method linearity test steps:

4.2.5.1 Repeat the assay at about noon, and again at about 4:00 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.

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

4.2.5.3 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.

4.2.5.4 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

4.2.5.5 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."

4.2.6 From the graph made in step 4.2.5.3, 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 4.2.2.

4.2.7 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 4.2.3.

4.2.8 Continue for all sleeves.

4.2.9 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.

4.2.10 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.

4.2.11 Steps 4.2.12 through 4.2.14 below must be completed within 6 minutes.

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

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

4.2.14 Continue for all sleeves.

4.2.15 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 model number and serial number of the dose calibrator.

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

4.2.17 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.

4.2.18 If the worst deviation is more than $\pm$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."

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

5. Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence should be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following example assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials and your predetermined safety margin is ±5%.

5.1 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.

5.2 Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries.

5.3 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.

5.4 Repeat the process until you have assayed a 2.0-cc volume. The entire possess must be completed within 10 minutes.

5.5 Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal error lines above and below the chosen "standard volume."

5.6 If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 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.

5.7 To test the geometry dependence for a 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.

5.8 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 and millicuries indicated.

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

5.10 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 horizontal 5% error lines above and below the chosen "standard volume."

5.11 If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5% 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.

6. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined 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. Certified sources are available from NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, Cs-137) should be used. One source should have a principal photon energy between 100 keV and 500 keV. If a Ra-226 source is used, it should be at least 10 microcuries; other sources should be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

6.1 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. Repeat for a total of three determinations.

6.2 Average the three determinations. The average value should be within your predetermined safety margin, which in this example is 5% of the certified activity of the reference source, mathematically corrected for decay.

6.3 Repeat the procedure for other calibrated reference sources.

6.4 If the average value does not agree, within 5%, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The dose calibrator should be repaired or replaced if the error exceeds 10%.

6.5 At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

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

7. The individual performing the tests will sign or initial the records of all geometry, linearity, and accuracy tests.

APPENDIX F

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. Either an authorized nuclear pharmacist or the radiation safety officer will approve all orders for radioactive material and 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 10 CFR 20.1301(a)(2).

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

4. When the commercial nuclear pharmacy is closed, delivery firms will have written instructions to place packages in the designated receiving area of the nuclear pharmacy. The carrier will be instructed that, if he notices the package is wet or appears to be damaged, he will 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 that neither he nor the delivery vehicle is contaminated.

5. 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 commercial nuclear pharmacy)*

FROM: (name of radiation safety officer)*

RE: Delivery of packages containing radioactive material

Any packages containing radioactive material that are to be delivered to our commercial 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 authorized nuclear pharmacist on call by calling our answering service at *_____. Remain at the nuclear pharmacy until it can be determined that neither you nor the delivery vehicle is contaminated.

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

APPENDIX G

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Determine the status of the shipment with respect to the requirements of 10 CFR 20.1906. Implement any special procedures for package receipt as required by these regulations. (A chart showing routinely expected shipments and their status with respect to these regulations may be prepared in advance to facilitate this step.)

2. The following procedures should be carried out for all packages containing radioactive material:

2.1 Put on waterproof gloves to prevent hand contamination.

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

2.3 Measure the dose rate at 1 meter from the package surface and record it. If it is greater than 10 millirems per hour, stop and notify the RSO.

2.4 Measure the surface dose rate and record it. If it is greater than 200 millirems per hour, stop and notify the RSO.

2.5 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. Compare the requisition, packing slip, and label on the container.

(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.

2.6 Wipe the external surface of the final source container shield and remove the wipe to a low-background area. Check wipe with a thin-end-window G-M survey meter or other

appropriate instrument and take precautions against the spread of contamination as necessary. Record results.

2.7 Monitor the packing material and packages for contamination with appropriate instrumentation 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 2.3, 2.4, and 2.6 will be maintained for at least 3 years. Records of receipt of byproduct material will be maintained in accordance with the requirements of
10 CFR 30.51.

4. Special procedures will be followed for receiving packages containing quantities of radioactive material in excess of the Type A quantity limits specified in Appendix A of Part 71 (e.g., more than 20 curies for molybdenum-99 and 10 curies of iodine). According to 10 CFR 20.1906(a), the licensee must make arrangements to receive or take possession of the package when the carrier offers it for delivery. These packages will be monitored, with appropriate instrumentation, for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 3 hours of the beginning of the next working day if received after working hours in accordance with the requirements of 10 CFR 20.1906(b) and (c). All labeled shipments of liquids that exceed exempt quantities will be tested for leakage, and all damaged packages will be monitored for contamination. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds the limits in 10 CFR 71.87(i) or if external radiation dose rates exceed 200 millirems per hour at the package surface or 10 millirems per hour at 1 meter. Records of the results of monitoring required by 10 CFR 20.1906 will be maintained in accordance with the requirements in 10 CFR 20.2103(a).

APPENDIX H

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Always wear laboratory coats or other protective clothing in areas where radioactive materials are used.
2. Always wear disposable waterproof gloves when handling radioactive materials.
3. Monitor hands and clothing as appropriate for photon, alpha, or beta contamination after each use or before leaving the area with unsealed radioactive materials.
4. Always use syringe shields and vial shields for preparing and dispensing radioactive drugs.
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. Every vial, syringe, or capsule of a photon-emitting radioactive drug will be assayed before distribution for use in humans.
8. Alpha- or beta-emitting radioactive drugs will be measured (either by direct measurement or a combination of measurements and calculations) before distribution for use in humans.
9. Each elution of technetium-99m from a molybdenum-99/technetium-99m generator will be (1) assayed for technetium-99m in a dose calibrator and (2) tested for molybdenum-99 concentration. The record of the results must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials of the individual who made the measurement. The record of each measurement will be retained for 3 years.
10. Technetium-99m will not be distributed for medical use if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

    Note: According to 10 CFR 35.204(a), medical use licensees may not administer more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m. Therefore, commercial nuclear pharmacies should provide medical use licensees with information on the molybdenum-99 concentration in technetium-99m labeled radioactive drugs. One way to do this would be to label containers of radioactive drugs tagged with technetium-99m to specify the total molybdenum-99

activity or microcuries of molybdenum-99 per millicurie of technetium-99m and the date and time of assay. The medical use licensee can then determine whether the patient dose at the time of administration would contain more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m. Another way would be to set the expiration time of the technetium-99m labeled drug to ensure that the molybdenum-99 concentration would not exceed 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m; this method should include an explanation to licensees that when the radioactive drug is used before the expiration time, Part 35 licensees will be in compliance with 35.204(a).

11. Always wear personnel monitoring devices (film badge or TLD) in areas where photon- and high-energy beta-emitting radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices, when not being worn to monitor occupational exposures, should be stored in the designated low-background area.
12. Always wear TLD (or film) finger badges when eluting the generator and preparing, assaying, or dispensing millicurie quantities of photon-or high energy beta-emitting radioactive material.
13. Never pipette by mouth.
14. Dispose of radioactive waste only in specially designated and properly shielded receptacles.
15. Survey the generator, kit preparation, and dose dispensing areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.
16. Confine radioactive solutions in covered containers that are clearly identified and labeled with the name of the compound, radionuclide, date, and activity.
17. Always transport radioactive material in appropriately shielded containers.

APPENDIX I

EMERGENCY PROCEDURES FOR SPILLS INVOLVING PHOTON- AND HIGH-ENERGY BETA-EMITTING RADIONUCLIDES

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 *_____. This kit includes disposable waterproof gloves, remote handling tongs, absorbent paper, disposable pads, and plastic bags.
3. Minor Spills
   - 3.1 NOTIFY: Notify persons in the area that the spill has occurred.
   - 3.2 PREVENT THE SPREAD: Cover the spill with absorbent paper.
   - 3.3 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.
   - 3.4 SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.
   - 3.5 REPORT: Report the incident to the Radiation Safety Officer (RSO).
4. Major Spills
   - 4.1 CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
   - 4.2 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.
   - 4.3 SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
   - 4.4 CLOSE THE ROOM: Leave the room and lock the doors to prevent entry.
   - 4.5 CALL FOR HELP. Notify the RSO immediately.

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

4.6 PERSONNEL DECONTAMINATION: Remove contaminated clothing and store for 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 NUMBERS OF ALTERNATES DESIGNATED BY THE RSO:

*_____

_____

_____

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

APPENDIX J

AREA SURVEY PROCEDURES FOR PHOTON- AND HIGH-ENERGY BETA-EMITTERS

1. All elution, preparation, assay, and dispensing areas for photon- and high-energy beta-emitters 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:
   - 3.1 A measurement of radiation dose rates with a survey meter sufficiently sensitive to detect 0.1 milliroentgen per hour.
   - 3.2 A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 220 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other high-background areas will be removed to a low-background area for measurement.

4. The daily surveys will consist of a measurement of radiation dose rates with a survey meter sufficiently sensitive to detect 0.1 milliroentgen per hour.

5. Records of all survey results, including negative results, will be kept for 3 years after each survey. The record will include:
   - 5.1 A drawing of the area surveyed identifying relevant features such as radioactive drug preparation and dispensing areas (including radionuclide binding area and capsule preparation area), active storage areas, and active waste areas.
   - 5.2 Measured dose rates (in units of millirems per hour) keyed to locations on the drawing.
   - 5.3 Detected contamination levels (in units of dpm or microcuries) keyed to locations on the drawing.
   - 5.4 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.
   - 5.5 The date of the survey.
   - 5.6 The name of the person performing the survey.

6. The area will be either cleaned or posted and restricted from use if the contamination level exceeds 2,200 dpm per 100 cm^2.
7. The area will be covered, cleaned, or identified to employees if the contamination level exceeds 220 dpm per 100 cm^2 but is less than 2,200 dpm per 100 cm^2.

EXHIBITS

Exhibit A

Exhibit B

DRAFT VALUE/IMPACT STATEMENT

1. BACKGROUND

Among the licenses issued by the Nuclear Regulatory Commission (NRC) are those for possession and use of byproduct material in commercial nuclear pharmacy operations and for distribution of certain materials, primarily radioactive drugs, to NRC's medical use licensees. The phrase "medical use licensees" means a physician, podiatrist, dentist, or medical use institution licensed under 10 CFR Part 35 for medical use as defined in 10 CFR 35.2. It was decided that a new regulatory guide dealing exclusively with nuclear pharmacy operations and conforming to NRC Form 313 should be issued. NRC issued Draft Regulatory Guide FC 410-4 in February 1985 for preparing applications for nuclear pharmacy licensees, which were filed on NRC Form 313. This guidance was never finalized and the NRC significantly changed 10 CFR 32.72 and deleted 10 CFR 32.73 in 1995. Radionuclide generators are now included as a radioactive drug in 10 CFR 32.72, and reagent kits are no longer regulated because they do not contain byproduct material. Therefore, the NRC staff has decided to issue a new regulatory guide to provide current, appropriate guidance to applicants and licensees on the preparation of license applications for commercial nuclear pharmacies.

2. PROPOSED ACTION

2.1 Description

An applicant for a license to use byproduct material in commercial nuclear pharmacy operations must develop a program that complies with NRC regulations and must describe this program in the license application. The proposed action is to issue a new regulatory guide that provides guidance on the requirements for nuclear pharmacies and provides guidance on preparing applications for licenses for commercial nuclear pharmacies.

2.2 Need

The regulatory changes to 10 CFR 32.72 and the deletion of Section 32.73 necessitate new guidance for the applicant to complete NRC Form 313.

2.3 Value/Impact

2.3.1 NRC

The review and approval of applications for the use of byproduct material in commercial nuclear pharmacy operations would be facilitated by the instructions and guidance provided in the new regulatory guide. The proposed action would clearly list the regulations to be followed and the information required for licensing and implementing an acceptable program for the operation of a nuclear pharmacy. Staff review time would be shortened because less correspondence would be needed to compensate for a lack of sufficient detail in license applications.

2.3.2 Other Government Agencies

Other government agencies would not be affected.

2.3.3 Industry

The proposed action would contribute to a reduction in the total amount of time applicants and licensees spend attempting to understand NRC's regulations and guidelines. Applicants would spend less time trying to interpret NRC regulations and requirements for submission of information. Accordingly, their applications should be complete and they should not have to spend time preparing answers to NRC's inquiries. More importantly, the proposed action would help provide information to applicants for designing and implementing a more effective radiation safety program that would minimize workers' exposure to radiation.

2.3.4 Public

No impact on the public is foreseen.

2.3.5 Worker

The worker would benefit from the proposed action through reduced radiation exposure discussed in Item 2.3.3.

2.4 Decision On Proposed Action

A new regulatory guide should be prepared to provide guidance to applicants for preparing applications for commercial nuclear pharmacy licenses.

3. TECHNICAL APPROACH

Not applicable.

4. PROCEDURAL APPROACH

4.1 Alternatives

The alternative is to provide no specific guidance to applicants and to write individual letters to applicants.

4.2 Discussion

A regulatory guide is the most effective way to transmit information about regulations and licensing requirements. A regulatory guide ensures uniform transmission of information to applicants. Individual letters would be inefficient and, depending on the reviewing official, may not uniformly convey the same information to each applicant. Issuance of a new regulatory guide is the most effective alternative.

5. STATUTORY CONSIDERATIONS

5.1 NRC Authority

Authority for the proposed action is derived from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, and implemented through the Commission's regulations cited in this guide.

5.2 Need for NEPA Assessment

Issuance or amendment of guides for the implementation of regulations in Title 10, Chapter I, of the Code of Federal Regulations is a categorical exclusion under 10 CFR 51.22(c)(16). Thus, an environmental impact statement or assessment is not required for this action.

6. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

No conflicts or overlaps appear to exist.

7. SUMMARY AND CONCLUSIONS

The regulatory guide, when disseminated, will assist the NRC in its review of applications for the use of byproduct material in nuclear pharmacy operations and will provide applicants with guidance on submitting applications in conformance with the revised NRC Form 313. The proposed regulatory guide should be issued.