State of Georgia
Dept. Of Natural Resources
Environmental Protection Div.

Radioactive Materials Program
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APPENDICES & EXHIBITS

I. INTRODUCTION

1.1 Purpose of Guide

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

This guide is intended to provide 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 or an understanding of the rule and regulations.

After you are issued a license, you should conduct your program according to: (1) the statements, representations, and procedures contained in your application and in other correspondence with the Georgia Department of Natural Resources Radioactive Materials Program (RMP), (2) the terms and conditions of your license, and (3) the Department's Rules and Regulations (Chapter 391-3-17). Nothing in the Department's regulations or this guide relieves you from complying with applicable FDA, other State, and Federal 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 "nuclear pharmacy" prepares and distributes radioactive drugs, often labeled with radioactive material, to hospitals and to physicians for use in their private practice. The term "distribution" means the routine transfer of licensed material to others. In the case of nuclear pharmacies that are licensed according to 391-3-17-.02(11)(i), these transfers of radioactive drugs are to specific licensees according to the requirements in 391-3-17-.02(19). The term "distribution" may or may not involve a prescription for a specific patient.

A nuclear pharmacy's principal customers are medical use licensees. The phrase "medical use licensee" means a physician, podiatrist, dentist, or medical institution licensed under 391-3-17-.05 for "medical use," as defined in 391-3-17-.01(2) and .05(2).

> **Note: 391-3-17-.05 (8), (9), and (12) require the medical use licensee to use unsealed radioactive material for medical use that is either obtained from other licensees or prepared under the supervision of the medical use licensee's own workers. These other licensees are restricted to either manufacturers or preparers licensed pursuant to 391-3-17-.02(11)(i) or equivalent Federal Regulations or Agreement State* requirements. 391-3-17-.05(6)(m) requires medical use licensees to obtain sealed sources that have been manufactured, packaged, labeled, and distributed according to a specific license issued by either the NRC pursuant to 32.74 of 10 CFR Part 32, 391-3-17-.02(11)(k) or other 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.

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*An "Agreement State" is any State with which the NRC or, previously, the Atomic Energy Commission has entered into an effective agreement under Subsection 274b of the Atomic Energy Act of 1954, as amended.

1.2 Applicable Regulations

Department regulations applicable to nuclear pharmacy operations are:

391-3-17-.01	“General Provisons. Amended.”
391-3-17-.02	"Licensing of Radioactive Materials. Amended.”
391-3-17-.03	"Standards for Protection Against Radiation. Amended."
391-3-17-.05	“Use of Radionuclides in the Healing Arts. Amended.”
391-3-17-.06	“Transportation of Radioactive Material. Amended."
391-3-17-.07	"Notices, Instructions, and Reports to Workers; Inspections. Amended."

Unless otherwise stated, all regulations cited in this guide are in Chapter 391-3-17, “Rules and Regulations for Radioactive Materials”. You may request copies of the above documents from RMP's address: Atlanta Tradeport Suite 114, 4244 International Parkway, Atlanta, Georgia 30354.

Note: 391-3-17-.06 requires that licensees who transport licensed material or who offer such material to a carrier for transport must comply with the applicable requirements of the Department of Transportation (DOT) that are found in 49 CFR Parts 170 through 189.

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

This guide identifies the information needed to complete RMP Applications for Radioactive Materials License.

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

In 391-3-17-.03, RMP 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." .03(4)(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).” As an applicant, you must have an ALARA plan that embraces this philosophy when developing plans for working with radioactive materials.

The radiation safety program must be reviewed at least annually for the effectiveness of implementation. Licensees must maintain records of the provisions of their radiation protection program until the Department terminates the pertinent license. Licensee must maintain records of audits and other reviews of program content and implementation for 3 years after the record is made.

II. FILING AN APPLICATION

You, as the applicant for a radioactive materials license, should complete Georgia Department of Natural Resources Radioactive Materials Program “Application for Radioactive Materials License”. You should complete Items 1 thru 4 and Items 12 thru 13 on the form itself. For Items 5 thru 11 that require more space, 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 RMP to determine 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 prepare your application in duplicate. Submit the original copy to the RMP where it will become a part of the license if approved and retain a copy for your records. The license will require that you possess, use, and distribute licensed material according to the statements and representations in your application and in any supplements to it.

Licensees should remember that all documents submitted to the State of Georgia will be made available to the public.

The Department recommends that the licensee not include in any submittal trade secrets or personal information about your employees, unless the information is directly related to radiation safety or specifically required by the Department. For example (1) information submitted on training and experience of employees should be limited to training related to radiation safety; (2) home addresses and home telephone numbers should be submitted only if they are part of the emergency procedures; and (3) dates of birth, social security numbers, and radiation dose information should be submitted only if specifically required by the Department.

If you submit trade secrets, proprietary information, or personnel information that you want withheld from public disclosure, you must request withholding according to procedures specified in the Georgia Open Records Law*. Failure to follow this procedure may result in disclosure of the information to the public and/or substantial delays in processing your submittals. Using labels such as "confidential" or "restricted" will not guarantee that your documents will be withheld.

III. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on RMP Application for Radioactive Materials License. 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.

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

a) Item __: We, (name of commercial nuclear pharmacy), have established and agree to follow the procedures for _____ as described in Appendix ____ of Guide for Preparation of Nuclear Pharmacy Application; and

b) attach a copy of the appropriate Appendix ____ keyed to the item number on the application.

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*A copy of the Georgia Open Records Law is available from the Georgia Law Library, for a copy of the law the library may be contacted at (404) 656-3468.

If you refer in your application to a section or appendix of this guide or of any other 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 Georgia Radioactive Materials License Number.

Item 2a. Applicant's Name and Mailing Address

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

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used, as specified in Item 2b.

Item 2b. 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 3. Person To Be Contacted About Application

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

Item 4 Record Retention

Not Applicable

Item 5. and 6. Radioactive Materials, Uses

Note: You should use a separate sheet containing the required information for these items.

You should list the radioactive materials you wish to possess by (1) radionuclide, (2) chemical and physical form, (3) maximum amount you wish to possess at any one time, and (4) proposed use.

Exhibit A shows a sample nuclear pharmacy license. Items 6, 7, and 8 on the sample license constitute your possession authorizations. Item 9 constitutes the authorized uses for these materials. These four items are critical elements in determining the scope of your radiation safety program and the need for specific license

conditions found from Condition 10 to the end of the license.

If your nuclear pharmacy receives prepared radioactive drugs that were initially distributed by another nuclear pharmacy or radioactive drug manufacturer, you should use the format used in 6A, 7A, and 8A to list these materials.

Radioactive material received in any other form or source that will be used to prepare radioactive drugs should be listed using the appropriate format from 6, 7, 8 of Exhibit A.

The format of Items of 6, 7, and 8 in Exhibit A is used to designate whether radiation safety considerations are known or must be examined in more detail. The designation found in 6A, 7A, and 8A (i.e, "any radioactive material" or "any form" "initially distributed according to a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 [.02(11)(i) & (j)] or a specific license issued to the manufacturer by the NRC or another Agreement State pursuant to equivalent requirements") indicates the NRC or Agreement State has evaluated the radiation safety concerns associated with the preparation and distribution of these materials at the commercial manufacturer or nuclear pharmacy. This language will also be used to indicate the commercial nuclear pharmacy is receiving prepared radioactive drugs. Specifically, listing isotopes and the maximum quantities requested for each, as shown in 6F, 7F, and 8F in Exhibit A, will be used to identify when other radiation safety concerns must be evaluated before this authorization is given.

You must submit a license amendment and receive RMP authorization before you can make changes in types, forms, quantities, and uses of materials possessed (Items 6, 7, 8, and 9 on your license). You should follow the format in Items 6 through 9 of Exhibit A to provide the information needed by the RMP. Clearly identify which licensed materials you wish to possess only and which you wish to possess and distribute.

If you want to redistribute various items, see Section 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

Rule 391-3-17-.02(8)(a) specifies that before an application is approved, you must be qualified by training and experience to use the material for the purpose requested in such a manner as to protect health and minimize danger to life or property. Accordingly, you should describe the training and experience of your proposed authorized nuclear pharmacist (ANP) and proposed radiation safety officer (RSO).

7.2 Licensing Criteria

Only those individuals whose training and experience meet or exceed that described in Exhibit B of this guide can be authorized nuclear pharmacists or a radiation safety officer.

7.3 Response

7.3.1 Proposed Authorized Nuclear Pharmacists

According to 391-3-17-.02(11)(i) and (j), each nuclear pharmacy must have an authorized nuclear pharmacist to prepare radioactive drugs for medical use. A pharmacist may be listed as an authorized nuclear pharmacist if the individual is board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties or identified as a nuclear pharmacist on a NRC or Agreement State license. You may designate a pharmacist as an authorized nuclear pharmacist if the individual is identified as an "authorized nuclear pharmacist" on a nuclear pharmacy license issued by the RMP.

You will have to provide the RMP with a copy of each individual's certification by the Board of Pharmaceutical Specialties or the NRC or Agreement State license identifying the individual as an authorized nuclear pharmacist, and a copy of the state pharmacy license. This documentation must be submitted to the RMP and the license amended prior to the date the licensee allows the individual to work as an authorized nuclear pharmacist.

Specify the full name of each individual to be listed on your license as an authorized nuclear pharmacist.

Since the state Board of Pharmacy requires a pharmacist to be physically present at the facility during the preparation and dispensing of prescriptions, you should confirm that the pharmacist present during the use of licensed radioactive materials is an authorized nuclear pharmacist. Because nuclear pharmacy operations begin early in the morning and continue throughout the day, you should have sufficient authorized nuclear pharmacists to ensure that all shifts are covered and to allow for vacations, illness, etc.

For each individual you name, you should document training and experience that is at least equivalent to that described in Appendix C. You may find it convenient to present this documentation using a format similar to Exhibit B. Each hour of training may be listed only once, i.e., under the most applicable category.

> **Note: If you elect to list pharmacists on your license that are board certified or are listed as authorized users on a current nuclear pharmacy license, you will not have to provide training and experience documentation. In these cases, you need only submit documentation of their current status as "board certified" or the RMP license number listing the individual as an "authorized user" instead of the documentation requested above.**

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 D outlines the typical duties and responsibilities of an RSO in a nuclear pharmacy.

Specify whether your RSO will have responsibilities in other areas such as serving as general manager, preparing and dispensing radioactive drugs, calling on accounts, etc. If the nuclear pharmacy is located at a medical institution, the institutional RSO is responsible for the radiation safety program of the nuclear pharmacy. In either case, indicate the percentage of time that your RSO will be able to devote to the nuclear pharmacy radiation safety program.

391-3-17-.02(8)(a) requires that applicants be qualified by training and experience to use license 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 C. You may find it convenient to present this documentation using a format similar to Exhibit B.

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. Training and experience documentation is not needed for certain individuals who either have a specific board certification or were listed as RSO's on an equivalent NRC (or Agreement State) commercial nuclear pharmacy license. For these individuals you must: (1) submit documentation to show that either 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, or the American Board of Science in Nuclear Medicine; or (2) submit the RMP license number (and a copy of the other Agreement State License or NRC License) listing the individual as the RSO, or an authorized nuclear pharmacists.

Item 8 Training For Individuals Working In Or Frequenting Restricted Areas

8.1 Applicable Regulations

391-3-17-.07(3)
391-3-17-.05(6)(h)

8.2 Training

8.2.1 Training 391-3-17-.07(3)

You should establish and follow written procedures for instructing individuals working in or frequenting any portion of a restricted area as required by .07(3). As a minimum, these written procedures should include:

1. That workers be instructed in the subject matter specified in .07(3) at the time of their initial employment and at least annually thereafter.

2. That this instruction include all written procedures developed as a prerequisite for obtaining the RMP license and other terms of the license pertinent to radiation safety.

3. That other individuals whose duties may require them to work in the immediate vicinity of licensed material be informed about radiation safety hazards and appropriate precautions at the time of their initial employment and at least annually thereafter.

8.2.2 Training 391-3-17-.05(6)(h)

Any licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist shall, according to .05(6)(h), instruct the supervised individual in the preparation of radioactive material for medical use.

8.3 Response

8.3.1 Response .07(3)

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 .07(3).

2. State that you have adopted the training program described in Appendix E of Radioactive Materials Program Guide for Preparation of Application for Nuclear Pharmacy License. The personnel training program in Appendix E fulfills the criteria in Item 8.2. Include a copy of Appendix E.

8.3.2 Response .05(6)(h)

You should describe your training program to instruct supervised individuals in the preparation of radioactive material for medical use. This program should include the schedule for instruction and a description of the instruction. Also, you should describe how you will ensure that the supervising authorized nuclear pharmacist will periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

Item 9 Facilities and Equipment

Rule 391-3-17-.02(8)(b) states 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 RMP to evaluate the adequacy of your proposed facilities and equipment, you must provide a detailed description of the nuclear pharmacy's operations, 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 dimensions should be included on each diagram. The recommended scale is 1/4 inch = 1 foot.

9.1 Operations Description

The adequacy of your site, facilities, and equipment depends on the scope of your operations (e.g., the form of radioactive materials you possess, how you handle them, the types of radioactive emitters, etc.) Particular attention should be given to operations using large quantities of radioactive materials, preparation involving liquids, gases, and volatile radioactive materials, and the use of low energy photon- and low energy beta-emitters. When describing the elements of your operations, you must provide a radiation safety analysis for each. Specific site, facility, or equipment considerations may be addressed in the appropriate sections.

9.2 Site Description

9.2.1 Applicable Regulation

391-3-17-.02(8)(b)

9.2.2 Licensing Criteria

You should locate your facility only in an industrial park or similar out-of-the-way location. Residential areas and commercial areas with heavy public access (e.g., large shopping centers, office buildings) are not appropriate because there is a 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. 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, etc.

4. The location of fume hood stacks, their heights above roof level, and their relationship to the nearest windows, air intakes, etc.

5. Confirmation that operation of a nuclear pharmacy on the site does not conflict with local codes and zoning laws.

6. 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 informs it of 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.

7. If your requested possession limits involve 1 curie or more of iodine-131 or other potentially volatile radioisotopes, describe the fire protection method that you will use. Curie quantities of iodine-131 should be stored either in an area of the facility that is protected by a sprinkler system or in a fire-proof well or safe.

9.3 General Description of Facility

9.3.1 Applicable Regulations

391-3-17-.03(4)
391-3-17-.03(5)(a)
391-3-17-.03(5)(i)
391-3-17-.03(7)(a)
391-3-17-.03(9)(a)
391-3-17-.02(8)(b)

9.3.2 Licensing Criteria

Rule 391-3-17-.02(8)(b) states 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 adequate shielding 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 type, dimensions, position, and thickness of shielding that will be available for:

1. Use and storage of molybdenum-99/technetium-99m generators. The auxiliary shielding supplied by the manufacturer of the generator may be used. If generators are to be stored against a wall, however, additional shielding may be necessary depending on the activity of the generators, the type of auxiliary shielding provided, the construction of the wall, and the use of the area on the other side of the wall. The auxiliary shielding provided by some manufacturers shields only three sides of the generator.

2. Storage of radioactive drugs.

3. 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., the use of 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 kit radioactive drugs. When working with photon-emitting radionuclides it is acceptable for you to specify that you will use a lead/lead-glass L-block at each preparation station. For primarily beta-emitting radionuclides you will have to describe your shielding. For high energy beta-emitters discuss steps taken to minimize bremstrahlung radiation production. If you are not using reagent kits and are preparing radioactive materials for human use, you should describe the preparation steps, shielding needs for these steps, and efforts to reduce contamination when using unsealed materials.

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 and other non-employees should not have access to the main area where licensed material is stored.

Remember that radiation doses for individual members of the public may not exceed the dose limits specified in .03(5)(i) and that surveys are required by .03(7)(a).

9.3.4 Additional Response for 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/cooling system, e.g., via a common air space above tile ceilings. If so, 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 should be maintained under negative pressure with respect to the rest of the building. In order to do this, you should submit a facility diagram that indicates the location and the airflow ratings of the air supply and air exhaust vents.

Describe the equipment and the methods that were used to measure the airflow ratings. These airflow ratings may change with the seasons or as the equipment ages. Periodic measurements are necessary to ensure continued performance at the same ratings. At a minimum, airflow ratings should be measured and corrected, if necessary, at 6-month intervals. Describe the type and frequency of periodic measurements you will make to ensure that the airflow ratings of your ventilation system continue to meet the specifications submitted in your application.

9.4 Adequacy of Facility for Handling Volatile Materials that are Radioactive

9.4.1 Applicable Regulations

391-3-17-.03(5)(a)
391-3-17-.03(5)(i)
391-3-17-.03(5)(j)
391-3-17-.03(9)(a)
391-3-17-.03(9)(b)
391-3-17-.02(8)

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 .03(5)(j)1. In addition, you should show compliance with air emission criteria established in 40 CFR Part 61 under EPA's, Subpart I, "National Emission Standards for Nationwide Emissions from Facilities Licensed by the NRC." Records of the results of the measurements are required by .03(13)(c)2.(iv). The release of effluents from a fume hood to the atmosphere is considered to be a release to an unrestricted area.

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, use of radioactive gases, preparation from high activity bulk materials, boiling, ph adjustments, etc. 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 or 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, unit-dose vials), the form in which xenon-133 will be dispensed, and the manipulations involved between receipt and dispensing. This description should include an estimate of the fraction of xenon-133 lost during storage and manipulation.

It is assumed that you will receive xenon-133 in unit-dose vials and redistribute the product to your customers upon request. 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 RMP 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, .03(9)(a) 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, .03(5)(j) 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 .03(5)(j). 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 your 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.) 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. .03(5)(i) requires that:

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

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

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 µCi
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 Liquid Radioiodine

Your facility must be equipped to maintain effluent releases of radioactive iodine at ALARA levels according to .03(4)(b). As a guideline, the RMP staff uses 10% of the applicable limits specified in .03(5)(i)1.(i). Most applicants use a charcoal filtration system in conjunction with their fume hood in order to achieve this goal.

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 at ALARA levels. The general guideline is 10% of the limit specified in .03(5)(i)1.(i). 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.

3. You should include detailed procedures for changing charcoal filters associated with these fume hoods.

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. The RMP 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 in detail in Items 10.1 through 10.16.

10.1 Personnel Monitoring Program

10.1.1 Applicable Regulation

391-3-17-.03(7)(b)1.
391-3-17-.03(7)(a)2.
391-3-17-.03(7)(a)3.
391-3-17-.03(13)(c)1.

10.1.2 Licensing Criteria

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

1. That whole-body badges (i.e., film or thermoluminescent dosimeters, also called TLDs) be provided when required by .03(7)(b)1.(i)-(iii).

2. That whole-body badges and finger extremity monitors (i.e., film or TLD) be provided to personnel who elute, prepare, assay, or dispense millicurie quantities of radioactive material.

3. That whole-body and extremity badges be exchanged for processing at intervals not to exceed 1 month.

4. That whole-body and extremity badges be processed by a commercial personnel dosimetry service or a processor accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) as required by .03(7)(a)3.

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 .03(7)(a)2.); records of calibration and drift tests must be maintained as described in .03(13)(c)1.

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 as requirements the criteria in Item 10.1.2 of this Guide. 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

391-3-17-.03(7)(a)
391-3-17-.02(8)(b)

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 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, perform quality control tests, etc.

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

10.2.3 Response

Your response to Item 10.2 should be 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 and contamination control. Identify each instrument by type, sensitivity, and range for each type of radiation detected.

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 Georgia Radioactive Materials Program Guide for the Preparation of Applications for Nuclear Pharmacy Licenses, in your possession and available for use when you begin photon-emitting radionuclide operations.

Instruments used when handling millicurie quantities of liquid iodine, beta-emitters must be identified.

10.3 Calibration of Survey Instruments

10.3.1 Applicable Regulations

391-3-17-.03(7)(a)
391-3-17-.03(13)(c)1.
391-3-17-.02(8)(b)

Rule .03(7)(a)1. requires each licensee to make surveys that may be necessary to comply with the regulations in Rule .03. In order to perform appropriate surveys, the instruments used must be operable and calibrated (.03(7)(a)2.).

10.3.2 Licensing Criteria for Applicants That 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 the RMP, other Agreement State, or the NRC to perform calibrations for others.

2. Calibrate survey instruments at intervals not to exceed 1 year and after repair.

3. Maintain records of each calibration for at least 3 years after the calibration according to .03(13)(c)1. 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 That Will Not Calibrate Their Own Survey Instruments

If you will not calibrate your survey instruments, your response to Item 10.3 should be a statement that specifies (1) that your survey instruments will be returned to the manufacturer for calibration or provides the name, address, and RMP, another Agreement State, or the NRC license number of the organization that will provide the service, (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.

10.3.4 Licensing Criteria For Applicants That 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 include:

1. That survey instruments be calibrated at intervals not to exceed 1 year and after repair.

2. That calibration of dose rate instruments be performed with radionuclide sources at distances sufficient to approximate point sources.

3. That survey instruments be calibrated on every scale or range that the instrument offers, up to 1 rem per hour. (Note that calibration requires the following minimum activities of typical radionuclide sources: 85 millicuries of cesium-137, 21 millicuries of cobalt-60, or 30 millicuries of radium-226.)

4. That survey instruments 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. That a record of each instrument calibration showing the date and the results of the calibration 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 10.3.4.

2. A statement that you will calibrate your survey instruments in the manner described in Appendix F of Georgia Radioactive Materials Program Guide for the Preparation of Applications for Nuclear Pharmacy Licenses. Appendix F describes frequency, standards, and procedures for calibrating survey instruments that fulfill the licensing criteria in Item 10.3.4. Include a copy of Appendix F.

10.3.6 Licensing Criteria for Applicants That Will Calibrate Their Own Survey Instruments for Use With beta-emitting Radionuclides

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

10.3.7 Response

If you will calibrate your own survey instruments for use with beta-emitting radionuclides your response to 10.3 must describe the standards, frequency, and 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 Calibration of Instruments Used to Measure the Activity of Each Dosage of Photon- and Beta-emitting Radionuclides Prior to Medical Use

10.4.1 Applicable Regulation

391-3-17-.03(7)(a)2.
391-3-17-.02(6)(b)
391-3-17-.02(11)(i) and (j)

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

10.4.2 Licensing Criteria

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

10.4.2.1 Calibration of Dose Calibrators to Assay Photon-emitting Radionuclides

As a minimum, the written calibration procedures for the dose calibrators used to assay photon-emitting radionuclides should require:

1. That the reference sources in Table 1 be available for use in performing the constancy and accuracy tests described in 2 and 3 below:

Table 1
DOSE CALIBRATOR REFERENCE STANDARDS

Radionuclide	Activity	Calibration Accuracy
Cesium-137	100 microcuries or more	Within ±5%
Cobalt-57	1 millicurie or more	Within ±5%

2. That tests for constancy of operation be performed before each day's use of the instrument as follows:

   a. Assay at least one of the reference sources listed in Table 1 using the appropriate instrument setting (i.e., cesium-137 setting for cesium-137).

   b. Check to determine that the net activity is within +5% of the predicted activity after decay correction. (Net activity is calculated by subtracting the background radiation from the instrument reading.)

   c. Repeat this procedure using the same reference source on all commonly used radionuclide settings. (When using the same radionuclide source on other instrument settings, the predicted activity is calculated from a log of the results on previous days.)

   d. If variations of more than +5% are noted, either adjust the instrument or use an arithmetic correction factor to correct the dosage assays obtained at that instrument setting. If variations of more than ±10% are noted and the instrument cannot be properly adjusted, it must be taken out of service immediately and repaired or replaced.

3. That tests to ensure accurate response over the range of radionuclide energies to be assayed be performed at 1-year intervals as follows:

   a. Using the appropriate instrument setting, assay one of the reference sources listed in Table 1.

   b. Check to determine that the net activity is within ±5% of the certified activity of the reference source after decay correction.

c. Repeat this procedure using the other reference source listed in Table 1.

d. If variations of more than ±5% are noted, either adjust the instrument or have it repaired as soon as possible. If variations of more than ±10% are noted and the instrument cannot be properly adjusted, it must be taken out of service immediately and repaired or replaced.

4. That tests to ensure linearity of response over the range of activities assayed in daily operations be performed at 3-month intervals as follows:

a. Assay a vial of technetium-99m, the activity of which is equal to the highest activity assayed in daily operations. Subtract background.

b. Using the same vial of technetium-99m, repeat step "a" at known activity points over the full range of activities that are assayed in daily operations. (Known activity points may be obtained by diluting the source, allowing it to decay, or surrounding the source with lead sleeves from a commercially available linearity test kit.)

c. Check to determine that the instrument reading is within ±5% of the known activity at each point.

d. If variations of more than ±5% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.

5. That tests for the geometric dependence of the dose calibrator for commonly used volumes, vials, and syringes to be performed before initial use, periodically, and after repair as follows:

a. Using the appropriate instrument setting assay the activity in each commonly used vial and syringe while varying the volume and keeping the radioactivity constant.

b. Using one volume as the reference volume calculate the volume correction factor for each type of vial or syringe used.

c. Determine the volume correction factors to be used for routine assay procedures.

d. Similarly correction factors for vial to syringe measurements should be made.

e. If geometric variations are significant, i.e, greater than +2 percent, the appropriate correction factors should be used when performing routine assays.

6. That records of the calibration tests and checks specified in 2 through 5 above be maintained for RMP inspection for 3 years after each test or check.

7. That all appropriate tests (depending on the nature of the repair or adjustment) be repeated after each repair or adjustment of the dose calibrator.

10.4.2.2 Calibration of Dose Calibrators and Other Instruments for Measuring beta-Emitting Radionuclides

Your written calibration procedures for instruments used to measure the radioactivity of 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 calibrations need to be performed at least before initial use, after repair, and at a defined period. Calibration procedures need to include at least accuracy, linearity, and geometry dependence. If one of these basic calibration procedures is not appropriate for the instrument, this should be explained.

Note: If you are redistributing unit dosages of beta- radionuclides directly from the manufacturer to the customer (i.e, with no adjustment to the product) these instruments only need to meet accuracy tolerances that enable you to prevent misadministrations and detect gross errors by the manufacturer. However if you make adjustments to the manufacturer's product or prepare your own product, the measurement accuracy of the instruments must meet tighter tolerances of 10 percent.

10.4.3 Response

Your response to Item 10.4 should be the following:

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

2. When measuring only photon-emitting radionuclides, you could make a statement that you have adopted the dose calibrator calibration program described in Appendix G of this Guide. Include a copy of Appendix G.

The procedures in Appendix G for calibrating a dose calibrator fulfill the criteria in 10.4.2., when measuring the activity of photon-emitting radionuclides.

10.5 Procedures for Receiving Shipments Containing Radioactive Material

10.5.1 Applicable Regulations

391-3-17-.03(11)(f)

10.5.2 Licensing Criteria

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

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

2. That these written directions identify the area where deliveries are to be left during working

hours and during hours when the facility is closed.

3. That these written directions identify the names and telephone numbers of persons on your staff to contact in the event of a damaged package or other emergency.

4. That these written directions include instructions to secure the area after a delivery is made.

5. That a copy of these written directions 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 .03(11)(f). 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 H of Georgia Radioactive Materials Program Guide for Preparation of Application for Nuclear Pharmacy License, for ordering and receiving radioactive material. The procedures in Appendix H fulfill the criteria in Item 10.5.2. Include a copy of Appendix H.

10.6 Procedures for Safely Opening Packages Containing Radioactive Material

10.6.1 Applicable Regulation

391-3-17-.03(11)(f)
391-3-17-.03(13)(c)1.
391-3-17-.06(2)
391-3-17-.06(15)

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:

1. That each labeled package be monitored to determine that the surface dose rate is less than 200 millirems per hour.

2. That, if the surface dose rate exceeds 200 millirems per hour, the person opening the package must stop and notify the RSO immediately.

3. That the final source container shield be wipe-tested and that the wipe be checked with a calibrated low-level survey meter or other suitable instrument to detect the presence of unacceptable contamination levels.

4. That records of the surface dose rate and contamination survey measurements specified in items 2 and 4 will be maintained for RMP 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 I of Radioactive Materials Program Guide for Preparation of Applications for Nuclear Pharmacy Licenses. The procedures in Appendix I for opening packages fulfill the criteria in Item 10.6.2. Include a copy of Appendix I.

10.7 General Procedures for Safe Use of Radioactive Material

10.7.1 Applicable Regulations

391-3-17-.07(3)
391-3-17-.03(4)(a)
391-3-17-.02
391-3-17-.05(5)

10.7.2 Licensing Criteria

You must establish and follow written procedures for the safe use of radioactive material. As a minimum, these written procedures should require:

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

2. That waterproof gloves be used at all times when handling radioactive material.

3. That hands and clothing be monitored for appropriate photon- or beta- activity every time an individual exits an area where radioactive material is used or stored.

4. That appropriate syringe shields and vial shields be used during all activities involving millicurie quantities of radioactive material.

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

6. That individuals do not store food, drink, or personal effects in any area where radioactive material is used or stored.

7. That every vial, syringe, and capsule be assayed in a dose calibrator or other appropriate instrument before distribution for use in humans.

8. That each elution of technetium-99m from a molybdenum-99/technetium-99m generator 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 on 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 results shall be retained for 3 years.

9. That technetium-99m not be distributed for medical use if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m at the expiration date and time shown on the package label. The expiration date and time shown on the label must be such that the limits specified above are not exceeded for any single patient dose.

10. That each individual wear his or her assigned film or TLD 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 or low energy beta-emitting radioactive materials.

11. That each individual wear his or her assigned film or TLD finger badge at all times during activities that involve eluting, preparing, assaying, or dispensing millicurie quantities of radioactive material.

12. That individuals do not pipette radioactive solutions by mouth.

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 J of Radioactive Materials Program Guide for Preparation of Applications for Nuclear Pharmacy Licenses. The general rules in Appendix J fulfill the criteria in Item 10.7.2. Include a copy of Appendix J.

10.8 Emergency Procedures

10.8.1 Applicable Regulations

391-3-17-.07(3)
391-3-17-.03(4)(a)
391-3-17-.02(8)

10.8.2 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. That the written procedures be posted in each area of the facility where radioactive material is used or stored.

2. That equipment and material necessary for rapid response to spills or other radioactive contamination emergencies be maintained in the form of a "decontamination kit" in each restricted area.10.8.3 Response

Your response to Item 10.8 should be the following:

1. A copy of the procedures you have established and agree to follow for handling emergencies that involve radioactive contamination.

2. A statement that you have adopted the emergency procedures for spills involving photon- and high energy beta-emitting radionuclides described in Appendix K of Georgia Radioactive Materials Program Guide for Preparation of Application for Nuclear Pharmacy Licenses. The emergency procedures in Appendix K fulfill the criteria in Item 10.8.2, for photon- and high energy beta-emitting radionuclide spills. Include a copy of Appendix K.

3. A statement that you will adopt the emergency procedures described in Appendix K with a revision of the survey section naming the appropriate instrumentation and describing your procedures for detecting and monitoring fixed and removable 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 beta-emitting radionuclides. Include a copy of Appendix K.

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

391-3-17-.02
391-3-17-.06(5)

10.9.2 Licensing Criteria

1. Agree to retrieve only those items (e.g., syringes, vials) that contain or are contaminated with radioactive materials that you supplied.

2. Agree to provide detailed instructions to customers that will package radioactive waste for return to your facility. These instructions must clearly indicate that you will accept only items that contain or are contaminated with radioactive materials that you supplied. In addition, these

instructions must be adequate to ensure your customers comply with Department of Transportation (DOT) and RMP regulations for packaging and transport of licensed materials and for the radiation safety of drivers.

10.9.3 Response

You should submit a copy of your instructions to customers about the return of radioactive waste.

10.10 Precautionary Measures for Handling Millicurie Quantities of Liquid 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 liquid radioiodine need respond to Item 10.10.

10.10.1 Applicable Regulations

391-3-17-.03(4)
391-3-17-.03(5)(d)
391-3-17-.03(7)(b)
391-3-17-.02(8)

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 USNRC Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

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. Identify, by manufacturer's name and model number, the equipment you will use 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

391-3-17-.03(7)(a)

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 include:

1. That all areas used for eluting, preparing, assaying, or dispensing radioactive material be surveyed daily.

2. That all other areas where radioactive materials are used or stored be surveyed weekly.

3. That these surveys for external radiation from photon- and high energy beta-emitters be performed with 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, other appropriate instrumentation or monitoring techniques must be used.

4. That the instrumentation or measurement technique used to perform the daily and weekly surveys for or low energy beta-emitters is sufficiently sensitive to detect contamination.

5. That higher-than-normal readings for any area be investigated and corrected immediately.

6. That a series of wipe tests be performed at least weekly in order to detect surface contamination.

7. That the method for analyzing the wipe tests be sufficiently sensitive to detect 2000 disintegrations per minute (dpm) per 100 cm^2 for the contaminant involved.

8. That areas be either cleaned or posted and restricted from use if the contamination level exceeds 2000 dpm per 100 cm^2.

9. That areas be covered, cleaned, or identified to employees if the contamination level exceeds 2 times background but is less than 2000 dpm per 100 cm^2.

10. That records of the results of all surveys and wipe tests be maintained for RMP 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. A statement for photon- and high energy beta-emitters that you have adopted the area survey

procedures described in Appendix L of Radioactive Materials Program Guide for Preparation of Application for Nuclear Pharmacy Licenses. The area survey procedures in Appendix L fulfill the criteria in Item 10.11.2, for photon- and high energy beta- emitting radionuclides. Include a copy of Appendix L.

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

10.12 Distribution Operations

10.12.1 Applicable Regulation

391-3-17-.02(11)(i) & (j)

10.12.2 Licensing Criteria

You must provide assurance that the products to be distributed either are: (1) Initially distributed by a manufacturer licensed pursuant to .02(11)(i) & (j); (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 nuclear pharmacy license. The licensing criteria will be satisfied if the description of your distribution operations specifies the applicable statements listed below:

1. Your nuclear pharmacy is licensed by the Georgia State Board of Pharmacy, you should submit a copy of the permit or license;

2. The activities of your nuclear pharmacy are limited to the preparation of radiopharmaceuticals for delivery by prescription to physicians within a specified geographical area;

3. The activity of your nuclear pharmacy is limited to /includes repackaging prepared radioactive drugs initially distributed by a manufacturer licensed pursuant to .02(11)(i) & (j).

5. The activity of your nuclear pharmacy is limited to/includes the preparation of radioactive drugs by an authorized nuclear pharmacist or an individual under the supervision of the authorized nuclear pharmacist.

10.13 Product Labels

10.13.1 Applicable Regulations

391-3-17-.03(11)(d)
391-3-17-.03(11)(e)
391-3-17-.05(10)
391-3-17-.02(11)(i)& (j)
391-3-17-.05(5)
391-3-17-.05(8)

10.13.2 Licensing Criteria

Your product labels must fulfill the color, symbol, and wording requirements of .03(11)(d)and .02(11)(i) & (j) and must contain sufficient information to ensure that patients or human research subjects do not receive radioactive drugs labeled with technetium-99m that contain molybdenum-99 in excess of the regulatory limits specified in .05(10).

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 unit-dose syringe, on the container shield). The statement that you will use to comply with .02(11)(i) & (j) should specify that the particular section of Rule .05 (i.e., (8),(9), (10), (11), or (12)) that applies to the individual radioactive drugs will appear on the label for which it is intended. Describe the leaflets and brochures containing radiation safety information, that will accompany the product.

10.13.4 Discussion

You must label radioactive drug containers in compliance with the color, symbol, and wording requirements in .03(11)(d) and .02(11)(i) & (j). The label must include the name of the radioactivity or its abbreviation, quantity of radioactivity, and date and time of assay. The syringe or syringe radiation shield labels should also specify the clinical procedure to be performed or the name of the patient or human research subject in order to prevent errors that lead to misadministrations. Labels for containers of radioactive drugs tagged with technetium-99m should specify the total activity or concentration of molybdenum-99 and an expiration date and time such that no single patient dose at the time of administration will contain more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (See also number 9 of Item 10.7.2 in this guide.)

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

10.14 Product Shielding

10.14.1 Applicable Regulations

391-3-17-.02(11)(i) & (j)

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 physician offices and hospitals.

10.14.3 Response

For each radionuclide you intend to distribute you should:

1. State the maximum activity for each type of container (e.g., vial, syringe).

2. Describe the type and thickness of the shielding you will provide for each type of container.

3. Indicate the maximum radiation level to be expected at the surface of each type of shielded container when filled with the maximum activity.

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 shipping container, not the surface of the shielded syringe or vial. .02(11)(i) & (j) applies specifically to safe handling and storage of the final source container by medical use licensees.

10.15 Procedures for Packaging and Transporting Radioactive Drugs

10.15.1 Applicable Regulations

391-3-17.06(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 takes the responsibility of the shipper for returned materials, the pharmacy needs to ensure the customer 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 radiopharmaceuticals 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 previously 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 purpose of an independent audit of the radiation protection program content and implementation is to ensure compliance with all applicable regulations and with the terms and conditions of your RMP 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

391-3-17-.03(4)
391-3-17-.03(13)(b)
391-3-17-.02(13)

10.16.2 Licensing Criteria

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

*If a number of facilities are owned by the same parent company, this individual may be the corporate radiation safety officer. If the operation is conducted by a university, this individual may be the university radiation

responsibility for performing these audits. Use a format similar to that of Exhibit B of this Guide to document the training and experience of this individual. Specify the basis for this individual's authority to mandate changes as necessary for RMP compliance and good radiation health physics practice.

10.16.4 Discussion

RMP's experience in licensing and inspecting commercial nuclear pharmacies indicates that these operations need an independent audit program in order to ensure continued compliance with RMP regulations and the terms and conditions of the license. Frequently, a commercial nuclear pharmacy's day-to-day RSO devotes only part of his or her attention to compliance matters. This individual may also be the general manager and, as such, must juggle the time demands of a multitude of responsibilities. In an industry in which the emphasis is on production schedules with extremely tight deadlines, expansion of accounts, etc., compliance may take a back seat. A qualified individual who is not involved in day-to-day operations would be valuable in identifying lapses or weaknesses in a program.

Internal audits are usually conducted in a manner similar to RMP inspections. At the discretion of licensee management, the audits may also involve an examination of other aspects of the nuclear pharmacy's operations, e.g., compliance with State pharmacy rules or good pharmacy practices. 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 non-compliance are noted.

Item 11 Waste Management

11.1 Disposal by Transfer or Release into Sewer

11.1.1 Applicable Regulations

391-3-17-.03(12)(i)
391-3-17-.03(12)(c)

RMP licensees are authorized in .03(12)(i) to dispose of radioactive waste by transfer to an authorized recipient (i.e., a radioactive waste disposal service licensed by RMP, another Agreement State, or the NRC). .03(12)(c) establishes limits on the type and amount of material that may be disposed of into a sewer. .03(13)(i) requires that disposal records be maintained.

11.1.2 Response

If you will dispose of radioactive waste by transfer to an authorized recipient or by release into a sewer, it is acceptable to state in response to Item 11 that you will dispose of radioactive waste according to the requirements in .03(12)(c) and .03(12)(i).

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safety officer. Otherwise, this function may be performed by a consultant.

11.2 Disposal by Other Methods

.03(12)(e) permits disposal of certain specific wastes. Specific approval in the form of a licensing action is required according to .03(12)(b), for other disposal methods. You may request other disposal methods provided you submit the specific details in the form of an application. The "other disposal method" most frequently requested by nuclear pharmacy applicants is decay-in-storage.

11.2.1 Applicable Regulation

391-3-17-.03(12)(e)
391-3-17-.03(12)(b)
391-3-17-.03(12)(i)

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. 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.)

2. 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.)

3. That records of the results of the measurements required in 2 above be maintained for RMP inspection for 3 years.

4. 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.

2. The following statement:

   Item 11: We, (name of nuclear pharmacy), will dispose of radioactive waste according to the requirements in .03(12)(c), .03(12)(e), .03(12)(i) but also request authorization pursuant to .03(12)(b) to dispose of radioactive waste by decay-in-storage. We, (name of nuclear pharmacy), have established written procedures covering this disposal method and these procedures include as requirements the criteria in Item 11.2.2 of Georgia Radioactive Materials Program Guide for Preparation of Application for Nuclear Pharmacy Licenses.

Item 12 License Fees

The applicant should refer to the DNR Radioactive Materials License Fee Schedule (Appendix B) to determine the appropriate licensing fee and category. (Note that, in addition to licensing fees licensees are required to pay inspection fees and annual fees. No action will be taken on applications filed without the proper fee. Checks for the fees should be made payable to the **Department of Natural Resources, Radioactive Materials Program**, and mailed to the following address:

Radioactive Materials Fees
P.O. Box 101161
Atlanta, Georgia 30392

Note: Prior approval from the Department must be obtained before Small Entity classification can be used.

Mail license applications, amendment, renewal requests, and terminations of license to the following address:

Radioactive Materials Program
4244 International Parkway
Atlanta Tradeport, Suite 114
Atlanta, GA. 30354

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.

Item 14 Decommissioning

14.1 Applicable Regulations

391-3-17-.02(8)(g)

Rule .02(8)(g) requires that applicants for or holders of a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days, or large sealed source or plated foil users must provide financial assurance for decommissioning. Generally a nuclear pharmacy will not be affected by this regulation. You may state in your application that you will not exceed the possession limits for radioactive material which would require financial assurance for decommissioning.

14.2 Licensing Criteria

All applicants and licensees are responsible for decommissioning their facilities. Certain radioactive material applicants and licensees must provide up-front decommissioning financial assurance. Those applicants and licensees subject to financial assurance requirements (Rule .02(8)(g)1., 2., and 3.) must provide such assurance through either a rule specified amount (.02(8)(g)4.) or a cost estimate (.02(8)(g)6.) and a rule specified financial mechanism (.02(8)(g)6.)

14.3 Response

The applicant or licensee subject to financial assurance requirements must describe how the applicant or licensee will ensure that a rule required financial instrument is in place for a rule required decommissioning cost. Guidance for applying the decommissioning financial assurance for both cost estimating and development of 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".

IV. REQUESTS FOR AUTHORIZATION TO REDISTRIBUTE VARIOUS ITEMS

Some nuclear pharmacies have requested authorization to conduct activities other than those shown A and B of Item 9 in Exhibit A. For some of these activities, such as performing leak tests and instrument calibration for its customers, the nuclear pharmacy usually needs a separate license. Separate regulatory guides are being developed on these subjects.* Other activities that may be characterized as "redistribution" of various items can be authorized on the nuclear pharmacy license. "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 issued by RMP, by another Agreement State or the NRC pursuant to equivalent requirements) and selling it to the commercial nuclear pharmacy's customers with little or no change in the original packaging, shielding, etc. The information to be supplied for commonly requested redistribution practices is given below.

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.

However, if you wish to redistribute generators to medical use licensees, you should:

1. Specify that all generators to be redistributed will have been obtained from a manufacturer authorized to distribute the generators according to a specific license issued pursuant to .02(11)(j) or under equivalent requirements of another Agreement State, or the NRC.

2. The generators will be redistributed without opening or altering the manufacturer's packaging.

4.2 Redistribution of Sealed Sources--Calibration and Reference Source

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.

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

*Guidance is being developed on leak-testing services and calibration services.

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

   Note: **Although a 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 according to a specific license issued pursuant to .02(11)(j) or under equivalent requirements of another Agreement State or the NRC.

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 and distribute sealed sources for brachytheraphy or diagnosis as provided in .05(13) and (14)(or to be the initial distributor of such sources) to medical use licensees, you must file a separate application.

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 brachytheraphy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis according to a specific license issued pursuant to .02(11)(j)or under equivalent Agreement State or NRC 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 sample 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 color, symbol, and wording requirements of .03(11)(d) and .02(11)(j).

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 RMP 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.

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 according to a specific license issued pursuant to .02(11)(g) or under an equivalent license of another Agreement State, or the NRC.

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 units for in vitro tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

If you want to redistribute prepackaged units for in vitro tests to specific licensees (all medical use licensees by regulation 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 .02(6)(g).

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 RMP's regulations that authorize a general license (e.g., .02(6)(g)).

3. You will ensure that labeling on redistributed prepackaged units for in vitro tests conform to the requirements of .03(11)(d).

V. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program according to (1) the statements, representations, and procedures contained in your application and correspondence with RMP, (2) the terms and conditions of the license, and (3) RMP'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; RMP 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 **(Appendix A)** or in letter form and should be submitted to the address specified in Section 3 Item 12 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 nuclear pharmacist or to change the RSO. In these cases, specify not only the name but also

the training and experience of each new individual. See Section 2, Item 7, and Appendix C of this guide for additional guidance.

Note: Nothing in your radioactive materials license, this guide, or RMP regulations relieves you from complying with applicable FDA, other Federal, and other State requirements governing radioactive drugs or devices.

VI. 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 Section 3 Item12 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 according to 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, and so on. 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 RMP regulations to ensure that any changes in the regulations are appropriately covered in your program description.

4. After you have completed your review, submit a letter to the RMP 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 RMP takes final action on your renewal application. However, if you file an application less than 30 days before the expiration date and RMP cannot process it before that date, you could be without a valid license when your license expires.

If you do not wish to renew your license, you must dispose of all licensed radioactive material in a manner authorized by 391-3-17-.02(19). Complete RMP form , "Request to Terminate Radioactive Materials License" (Appendix M) and send it to the RMP 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 RMP's regulations that do not allow you to possess licensable material without a valid license.

VII. TERMINATION OF A LICENSE

You may request termination of your license at any time. This notification should include a request to terminate the license and must include a completed Department's form, "Request to Terminate Radioactive Materials License" (see Appendix M) , certifying that all sources have been disposed of properly. Note that a license is not terminated until the Department takes action to terminate the license. An application for license termination does not relieve the licensee from its obligations to comply with Department's regulations and the terms and conditions of the license.

APPENDIX A

Georgia Department of Natural Resources

Environmental Protection Division

Radioactive Materials Program

APPLICATION FOR RADIOACTIVE MATERIALS LICENSE

INSTRUCTIONS - Complete Items 1 through 13 if this is an initial application or renewal of a license. Use supplemental sheets where necessary. Item 13 on the application must be completed and signed. Retain one copy for your records. Submit original application to: Georgia Department of Natural Resources, Radioactive Materials Program, 4244 International Parkway, Suite 114, Atlanta, Georgia, 30354. Upon approval of this application, the applicant will receive a Georgia Radioactive Materials License. Georgia Radioactive Materials Licenses are issued according to the general requirements contained in the Georgia Department of Natural Resources Rules and Regulations, Chapter 391-3-17. **The Department can be reached via the Internet. The address is rad_materials @ mail.dnr.state.ga.us.**

1.This is an Application for: (Check appropriate item) A.☐ New License B. ☐ Amendment to License C. ☐ Renewal of License
If B or C , Please indicate GA. License Number _____

2.a. Name and Mailing Address of Applicant Name: Address: City, State, Zip Code: County: Telephone Number ( ) _____ -_____ Internet Address:	2.b. Address where licensed material will be stored and/or used (Street Address) A. Permanent B. Coordinates 1. Latitude: 2. Longitude: C. Temporary sites throughout Georgia? Yes _____ No_____
3. Person to Contact Regarding this Application Name: Title: Telephone Number ( ) _____ - _____	4. Locations where records will be kept:
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.	
5. RADIOACTIVE MATERIAL a. Element and mass number, b. Chemical and/or physical form; and c.. maxium amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7. INDIVIDUAL(S) RESONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSEE FEES (SEE DEPARTMENT'S FEE SCHEDULE) FEE CATEGORY : AMOUNT ENCLOSED $ CHECK MAILED ☐ PLEASE INVOICE ☐
MAKE CHECKS PAYABLE TO: DEPARTMENT OF NATURAL RESOURCES RADIOACTIVE MATERIALS PROGRAM	**MAIL FEES TO: RADIOACTIVE MATERIALS PROGRAM, P.O. BOX 101161 ATLANTA, GEORGIA 30392**

13. CERTIFICATION (Must be completed by the applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH GEORGIA DEPARTMENT OF NATURAL RESOURCES RULES AND REGULATIONS, DESIGNATED CHAPTER 391-3-17 AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

CERTIFYING OFFICER -- TYPED PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR DEPARTMENT USE ONLY

TYPE OF FEE	FEE CATEGORY	AMOUNT RECEIVED	INVOICE DATE	COMMENTS

APPROVED BY DATE:

DNR Radioactive Materials Licensee Fee Schedule Appendix B

License Category	Licensing Fees				Inspection Fees		Annual Fees		
	Code	Application	Renewal	Amendment	Routine	Non-Routine	Nominal	Small Entity	Lower Tier
Medical Teletherapy	A.1	3,400	790	430	1,200	1,900	3,200	600	135
Institutional Medical-Mult. Use	A.2	710	1,000	430	1,000	1,500	1,200	600	135
Institutional Medical-Single Use	A.3								
Private Practice	A.4								
In-Vitro Studies Only	A.5	500	500	380	1,200	1,200	500	500	135
In-Vitro General Licenses	A.6	0	0	0	0	0	100	100	100
Bone Mineral Analyzers	A.7	710	1,000	430	1,000	1,500	1,200	600	135
Medical Manufacturer for Distribution	A.8.a.	3,400	1,400	460	1,400	1,900	2,900	600	135
Medical Distribution or Redistribution Only	A.8.b.	1,100	500	310	800	1,200	900	600	135
Mobile Nuclear Medicine	A.9	710	1,000	430	1,000	1,500	1,200	600	135
Broad Medical	A.10	2,300	2,000	360	1,600	1,800	3,300	600	135
Eye Applicators	A.11	710	1,000	430	1,000	1,500	1,200	600	135
Depleted Uranium	A.12	110	110	110	290	350	130	130	130
Special Nuclear Material(sealed sources in devices)	B.1	500	500	380	460	1,300	400	400	135
Special Nuclear Material(other)	B.2	690	690	230	690	800	1,000	600	135
Industrial Mfg. for Distribution	C.1	1,300	2,300	550	1,000	2,000	1,500	600	135
In-house Industrial Radiography	C.2	3,000	1,800	490	1,200	2,500	2,600	600	135
Multiple Job-Site Industrial Radiography	C.3								
Gamma Irradiators (Self-Shielded)	C.4.a.	500	480	250	460	690	400	400	135
Gamma Irradiators (<10K Ci)	C.4.b.1.	1,000	750	250	500	1,000	1,000	600	135
Gamma Irradiators (>10K<100K Ci)	C.4.b.2.	5,000	3,750	1,250	1,200	2,400	5,000	600	135
Gamma Irradiators (>100K<1M Ci)	C.4.b.3.	10,000	7,500	2,500	2,500	5,000	10,000	600	135
Gamma Irradiators (>1M Ci)	C.4.b.4.	30,000	22,500	7,500	5,000	10,000	30,000	600	135
Broad Scope Distribution, Specific	C.5.a.	2,300	1,400	230	2,100	2,100	2,100	600	135
GL Distribution (source and/or device evaluation)	C.5.b.	2,500	580	390	690	690	1,700	600	135
GL Distribution (no source and/or device evaluation)	C.5.c.	1,900	940	290	690	690	1,400	600	135
NARM Exempt Distribution (device evaluation)	C.6.a.	2,100	1,100	250	690	690	1,500	600	135
NARM Exempt Distribution (no device evaluation)	C.6.b.	2,600	1,200	350	460	690	1,700	600	135
Well Logging/Tracers	C.7	3,400	2,000	540	800	800	2,300	600	135
Nuclear Laundries	C.8	1,400	1,400	350	1,200	1,900	1,600	600	135
Industrial Research & Development	C.9	1,100	1,100	630	800	930	1,300	600	135
Gas Chromatograph, Installed Gauges, etc.	C.10	500	500	380	1,200	1,200	500	500	135
Portable Moisture Density Gauges,Pb analyzers,etc.	C.11								
Calibration Sources	C.12								
Industrial (other)	C.13								
Broad Scope (Academic)	D.1	2,300	2,000	500	930	1,200	2,100	600	135
Broad Scope (Industrial R&D)	D.2								
Civil Defense	E.	580	400	310	690	690	500	500	135
Teletherapy Service Co.	F.	1,400	1,100	630	800	690	1,500	600	135
Consultants (Leak Testing Service)	G.	500	500	380	1,200	1,200	500	500	135
Storage Only	H.								
Academic (Non-Broad)	I.								
Device Evaluation	J.1	3,300	0	1,200	0	0	2,100	600	135
Source Evaluation	J.2	690	0	230	0	0	500	500	135
Reciprocity	K.	0	0	0	0	0	Appropriate License Renewal Fee		
Radioactive Waste Disposal-Burial	L.1	50,000	50,000	5,000	12,000	24,000	30,900	600	135
Radioactive Waste Disposal-Incineration	L.2								
Radiaoactive Waste-Storage,Packaging or Transfer	L.3	2,800	1,900	200	2,100	2,200	3,600	600	135
G L Devices(except tritium safety signs)	GL	0	0	0	0	0	100	100	100

APPENDIX C

TRAINING AND EXPERIENCE OF AUTHORIZED NUCLEAR PHARMACISTS AND RADIATION SAFETY OFFICERS

Rule 391-3-17-.02(8)(a) requires that applicants be qualified by training and experience to use licensed material for the purpose requested in the application. In the case of a nuclear pharmacy operation, the RMP 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 RMP finds acceptable for these individuals

Authorized Nuclear Pharmacist

An authorized nuclear pharmacist must be a nuclear pharmacist, i.e, an individual licensed by the State of Georgia, to practice pharmacy. This pharmacist must have 700 hours in a structured educational program constiting of training and experience in basic radioisotope handling and radiopharmacy techniques or is currently board certified as a Nuclear Pharmacist by the Board of Pharmaceutical Specialist.

The 700 hours must be in a structured educational program consisting of both:

(1) Didactic training in the following areas:
- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use; and
- Radiation biology; and

(2) Supervised experience in a nuclear pharmacy involving the following:
- 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 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 radioactive 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.

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 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 RMP 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 RMP 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. Experience in handling unsealed radioactive material under the supervision of an authorized user, physician authorized user, or authorized nuclear pharmacist (500 hours). This experience should cover the types and quantities of radioactive material requested in the application and should include:

   - Ordering, receiving, and unpackaging radioactive materials safely, including performing related radiation surveys;
   - Calibrating dose calibrators, scintillation detectors, and survey meters;
   - Calculating, preparing, and calibrating patient doses, including properly using radiation shields;
   - Following appropriate internal control procedures to prevent mislabeling errors;
   - Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests; and
   - Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing the eluate with reagent kits to prepare technetium-99m-labeled radioactive drugs.

You may use a format similar to that shown in Exhibit B for documenting hours of training in basic radioisotope handling techniques hours of experience using radioisotopes. The signed preceptor statement is not needed for individuals listed only as RSO's.

APPENDIX D

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

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

1. General surveillance over all activities involving radioactive material, including routine monitoring and special surveys.

2. Ensuring compliance with RMP rules and regulations as well as conditions of the RMP 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. Supervising and coordinating the receipt, opening, and delivery of all shipments of radioactive material arriving at the nuclear pharmacy.

6. Supervising and coordinating the preparation of all shipments of radioactive material leaving the nuclear pharmacy.

7. Supervising the distribution and processing of personnel monitoring equipment.

8. Conducting training programs in proper procedures for the use of radioactive material.

9. Supervising and coordinating the radioactive waste disposal program.

10. Supervising 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.

Note: In the absence of the RSO (e.g., in the early morning when only one authorized nuclear pharmacist is present, when the RSO is sick or on vacation), the authorized nuclear pharmacist should assume the duties of the RSO and ensure compliance with RMP's regulations and the terms and conditions of the RMP license.

APPENDIX E

PERSONNEL TRAINING PROGRAM

1. Schedule for Training

Training will be provided:

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

b. Annually as refresher training for all employees,

c. Whenever a significant change occurs in duties, regulations, or the terms of the RMP license.

2. Description of the Training Program

Training will be sufficient to ensure that:

a. Individuals who receive occupational dose are instructed in the subject matter specified in .07(3),

b. Individuals whose duties may require work in the immediate vicinity of radioactive materials are informed about radiation hazards and appropriate precautions.

3. Content of the Training Program

The training program will include the following topics:

a. Pertinent terms and conditions of the RMP license, including written procedures developed as a prerequisite for obtaining the license and commitments that have been incorporated into the license,

b. Areas where radioactive material is used or stored,

c. Potential hazards associated with radioactive material,

d. Radiological safety procedures appropriate to the duties of the employee,

e. Pertinent RMP regulations,

f. The employee's obligation to report unsafe conditions to the RSO

g. The appropriate response to emergencies or unsafe conditions,

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

i. The locations where the firm has posted or made available notices, copies of regulations, and copies of licenses and license conditions (including applications and

applicable correspondence) as required by 391-3-17-.07.

4. Records That Document Training

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

a. The name of the individual who conducted the training,

b. The names of the individuals who received the training,

c. The date of the training session, and

d. A list of the topics covered.

APPENDIX F

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

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

   a. The sources will be approximate point sources.

   b. The source used will be one of those listed in Table F-1.

Table F-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

   c. 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.

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

   e. Instruments will be calibrated on every scale or range of the instrument, up to 1 rem per hour.

   f. 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 this reference source should be taken:

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

   b. 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.b above will be maintained for at least 3 years after each calibration or check.

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

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

   a. 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.

      (1) The inverse square law may be used with any point source to calculate the exposure rate at other distances.

      (2) The radioactive decay law may be used to calculate the output at any time.

   b. 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, then:

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

      Note: R_a and R_b must be in the same units of dose rate (e.g., milli rem 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:

$$R_b = \frac{D^2}{D_b^2} \text{ a} \times R_a$$

c. Radioactive Decay Law

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

$$R_t = R_O \times e^{-(0.693 \times \frac{t}{T_{½}})}$$

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
- T½ is the radionuclide half-life

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 G

PROCEDURES FOR CALIBRATION OF DOSE CALIBRATORS* USED TO ASSAY PHOTON-EMITTING RADIONUCLIDES

1. Test for the following:

   a. Instrument constancy (each day of use)

   b. Instrument accuracy (at installation, after repair and 1-year intervals thereafter)

   c. Instrument linearity (at installation, after repair and 3-month intervals thereafter)

   d. Geometrical variation (at installation)

2. Maintain a record of the results of each test for RMP inspection for 3 years after each test.

3. After repair or adjustment of the dose calibrator, repeat all the appropriate tests depending on the nature of the repairs.

4. Test for Instrument Constancy.

   Instrument constancy means there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Before using the instrument each day, assay at least one of the reference sources listed in Table E-1 using reproducible geometry. Preferably, at least two reference sources (for example, 1 millicurie of cobalt-57 and 100 microcuries of cesium-137) should be alternated to test the instrument's performance over a range of photon energies and source activities.

   a. Assay each reference source using the appropriate instrument setting (i.e., cesium-137 setting for cesium-137).

   b. Measure the background level at the same instrument setting or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.

   c. Calculate the net activity of each source after subtracting the background level.

   d. Indicate the predicted activity of each source based on decay calculations and ±5% limits.

   e. For each source, list the net activity versus the predicted activity.

   f. Repeat the procedure using the same source on all commonly used radionuclide settings.

   g. If variations greater than +5% are noted, either adjust the instrument or use an arithmetic correction factor to correct the dosage assays obtained at that instrument setting. If variations greater than ±10% are noted and the instrument cannot be properly adjusted, it

*See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides." Copies may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

must be taken out of service immediately and repaired or replaced.

h. Investigate higher-than-normal background levels to determine their origin and to eliminate them, if possible, by decontamination, relocation, etc.

5. Test for Instrument Linearity.

The linearity of a dose calibrator must be ascertained over its entire range of activities. This test must use a vial of technetium-99m that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator).

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

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

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

d. 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 T½ = 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.

e. On semilog coordinate paper, plot the measured net activity and the calculated activity versus time.

f. On the graph, the measured net activity plotted should be within 10% of the calculated activity if the instrument is linear and functioning properly. If variations greater than 10% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.

g. 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 "e" to relate measured activities to calculated activities.

6. Test for Geometrical Variation.

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors should be computed if variations are significant, i.e., greater than ±2%. When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with a volume of liquid, a 30-cc vial containing 2 millicuries of cobalt-57 or other appropriate radionuclide in a volume of 1 ml can be used.

a. Assay the vial at the appropriate instrument setting and subtract background to obtain net activity.

b. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake the vial to mix the contents and assay as in step a. (Be sure to follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

c. Select one volume as a standard (such as the volume of the reference standard used in performing the test for instrument accuracy) and calculate the ratio of measured activity for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes, and 10 ml is the reference volume selected:

$$\text{4 ml volume CF} = \frac{2.00}{2.04} = 0.98$$

d. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

e. The true activity of a sample is calculated as follows:

True activity = Measured activity x Correction factor

where the correction factor used is for the same volume and geometrical configuration as for the measured sample.

f. Similarly, the same activity of cobalt-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.

7. Test for Instrument Accuracy.

Check the accuracy of the dose calibrator using each of the reference sources listed in Table E-1. The lower energy reference standard (cobalt-57) must be in a vial that has the same thickness of glass as the actual samples to be measured for best accuracy.

a. Assay each reference standard in the dose calibrator at the appropriate setting and subtract the background to obtain the net activity.

b. Repeat step "a" three times and average the three results.

c. The average activity determined in step "b" should agree with the certified activity of the reference source within ±5% after decay correction.

d. If variations greater than ±5% are noted, either adjust the instrument or have it repaired as soon as possible. If variations greater than ±10% are noted and the instrument cannot be properly adjusted, it must be taken out of service immediately and repaired or replaced.

Table G-1

DOSE CALIBRATOR REFERENCE STANDARDS

Radionuclide	Activity	Calibration
Cesium-137	100 microcuries or more	Within ±5%
Barium-133	100 microcuries or more	Within ±5%
Cobalt-57	1 millicurie or more	Within ±5%

APPENDIX H

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. Either an authorized nuclear pharmacist or the radiation safety officer will place 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 .03(5)(i)1.

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 receiving area of the nuclear pharmacy. If the carrier notices that the package is wet or appears to be damaged, he will be instructed to immediately contact the nuclear pharmacist on call who will then come to the authorized 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. 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 I
PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Determine the status of the shipment with respect to the requirements of 391-3-17-.03(11)(f). 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 must be carried out for all packages containing radioactive material:

   a. Put on waterproof gloves to prevent hand contamination.

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

   c. Measure the dose rate at 1 meter from the package surface and record it. If > 10 millirems per hour, stop and notify the RSO.

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

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

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

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

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

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

   f. Wipe the external surface of the final source container shield and 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.

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

      (1) If contaminated, treat as radioactive waste.

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

3. Records of exposure rate and contamination surveys in items 2.c, 2.d, and 2.f will be maintained for at least 3 years. Records of receipt of radioactive material will be

maintained according to the requirements of 391-3-17-.01(4).

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). 391-3-17-.03(11)(f)1. requires that the licensee make arrangements to receive or take possession of the package when the carrier offers it for delivery. These packages will be monitored 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 according to the requirements of .03(11)(f)2. & 3. All labeled shipments of liquids that exceed exempt quantities will be tested for leakage, and all damaged packages will be monitored for contamination. The RMP will be notified according to the regulations if removable contamination exceeds the limits in .06(15)(h) 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 .03(11)(f) will be maintained according to the requirements in .03(13)(c)1.

APPENDIX J

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 gloves when handling radioactive materials.

3. Monitor hands and clothing for appropriate photon or beta contamination after each procedure or before leaving the area.

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. Assay each vial, syringe, and capsule containing radioactive drugs in the dose calibrator or other appropriate instruments before distribution for medical use.

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

    a. Assay the eluate for technetium-99m in a dose calibrator; record the results and retain the record for 3 years after the assay.

    b. Test for total molybdenum-99 activity or test for molybdenum-99 concentration; record the results and retain the record for 3 years after the test (see 391-3-17-.05(10))

9. Do not distribute technetium-99m for medical use if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m or if it contains more than 0.15 microcuries of molybdenum-99 per dose of technetium-99m at the expiration time and date shown on the package label. The expiration date and time shown on the label must be such that the limits specified above are not exceeded for any single patient dose. Limits specified in .05(10) shall not be exceeded.

10. 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.

11. Always wear TLD (or film) finger badges when eluting the generator and preparing, assaying, or dispensing millicurie quantities of radioactive material.

12. Never pipette by mouth.

13. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

14. Survey the generator, kit preparation, and dose dispensing areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

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

16. Always transport radioactive material in appropriately shielded containers.

APPENDIX K

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 *_____. The contents of this kit include disposable waterproof gloves, remote handling tongs, absorbent paper, disposable pads, and plastic bags.

3. Minor Spills

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

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

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

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

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

4. Major Spills

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

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

   c. 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.

   d. CLOSE THE ROOM: Leave the room and lock the doors to prevent entry.

   e. CALL FOR HELP: Notify the RSO immediately.

   f. PERSONNEL DECONTAMINATION: Remove contaminated clothing and store for

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

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

RADIATION SAFETY OFFICER: *_____
OFFICE PHONE: *_____
HOME PHONE: *_____

NAMES AND TELEPHONE NUMBERS OF ALTERNATES DESIGNATED BY THE RSO:

*_____
_____
_____

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

APPENDIX L

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. Laboratory areas where only small quantities of radioactive material are used (less than 200 µCi) will be surveyed monthly.

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

4. The weekly and monthly surveys will consist of:

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

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 2000 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.

5. Records of all survey results,* including negative results, will be kept for 3 years after each survey. The record will include:

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

   b. Measured dose rates (in units of millirems per hour) keyed to locations on the drawing.

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

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

6. The area will be either cleaned or posted and restricted from use if the contamination level exceeds 2000 dpm per 100 cm^2.

7. The area will be covered, cleaned, or identified to all employees if the contamination level exceeds 2 times background but is less than 3000 dpm per 100 cm^2.

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*For daily surveys in which no abnormal exposures are found, only the date, the name of the person performing the survey, and the survey results will be recorded.

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM
REQUEST TO TERMINATE RADIOACTIVE MATERIAL LICENSE

1. Licensee Name _____ 2. License Number _____

3. Address _____
No. Street City, State Zip Code

4. Contact Person _____ 5. Telephone Number _____

6. Request is hereby made that the Radioactive Material License described above be terminated for the following reason:
_____

_____

7. Radioactive Material possessed under this license has been disposed of as indicated below:

☐ No materials have been possessed or procured by the licensee under this licensee.

☐ All material was used for the licensed purposes, none remains.

☐ All material was leased, and has been returned to lessor.

Name of lessor: _____ License No. _____

☐ Copy notice of receipt attached

☐ Material has been transferred to the following licensee:

Licensee Name _____ License No. _____

Address _____
No. Street City, State Zip Code

Date of transfer: _____

☐ Copy of receipt attached

☐ Material has been disposed of in the following manner:
_____

_____

☐ A radiation survey was conducted to confirm the absence of radioactive material and to determine whether any contamination remains at the facility covered by the license.

☐ Copy of survey results attached.

6. Management Official or Radiation Safety Officer

_____ _____
Signature of certifying officer Date

_____ _____
Print name Title

Keep one copy for your

records and send original to: GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM
4244 INTERNATIONAL PARKWAY, SUITE 114
ATLANTA, GEORGIA 30354

Georgia Department Of Natural Resources
Environmental Protection Division
Radioactive Materials Program

EXHIBIT A
PRECEPTOR STATEMENT

TRAINING AND EXPERIENCE
AUTHORIZED NUCLEAR PHARMACIST

1.a. APPLICANT NAME ADDRESS	**1.b. Authorized User at this Nuclear Pharmacy or at another Facility?**
FULL NAME:_____ ADDRESS: _____ CITY:_____ STATE:_____ ZIP:_____ DAYTIME TELEPHONE#_____	☐ Yes License #: _____ (Attach Copy of License) ☐ No **2.b. Georgia Licensed Nuclear Pharmacist?** ☐ Yes (Submit Copy of Current State of Georgia Nuclear Pharmacist License) ☐ No

2. CERTIFICATION
☐ Yes ☐ No (Complete Blocks 3 and 4)

Type of Certification [Attach Copy of Certification(s)to Application] Refer to Rule 391-3-17.05(16) to review "Specific Requirement for Training" **(List Certification(s) Below)**	**DATE CERTIFIED**

3. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (700 TOTAL 3 AND 4)

FIELD OF TRAINING	**LOCATION AND DATE(S) OF TRAINING**	**LECTURE/LABORATORY HOURS IN A STRUCTURED EDUCATIONAL PROGRAM**
RADIATION PHYSICS AND INSTRUMENTATION		
RADIATION PROTECTION		
MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY		
RADIATION BIOLOGY		
RADIOPHARMACEUTICAL CHEMISTRY		

4. EXPERIENCE FOR AUTHORIZED NUCLEAR PHARMACIST IDENTIFIED BELOW AND IN RULE 391-3-17-.05(16)

SUPERVISED WORK EXPERIENCE FOR AUTHORIZED NUCLEAR PHARMACIST (16) OF RULE 391-3-17-.05		
SPECIFIC TRAINING	**HR**	**DATE Completed**
1. Shipping, receiving, and performing related radiation surveys.		
2. Using and performing checks for proper operation of dose calibrators, survey meters, and if appropriate, instruments used to measure beta- emitting radionuclides.		
3. Calculating, assaying, and safely preparing dosages for patients or human research subjects.		
4. Using administrative controls to avoid mistakes in the administration of radioactive materials.		
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures		

5. CERTIFICATION

THIS SECTION TO BE COMPLETED ONLY IF BLOCKS 3 AND 4 WERE COMPLETED

THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. RSO SUPERVISOR NAME: SIGNATURE:

b. INSTITUTION'S NAME: LICENSE#:

c. MAILING ADDRESS:

d. CITY: STATE: ZIP: TELEPHONE#

6. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

SUPERVISOR'S NAME: _____

INSTITUTIONS'S NAME: _____

MAILING ADDRESS: _____

CITY: _____ STATE: _____ ZIP:_____

7. MATERIALS LICENSE NUMBER:

8. PRECEPTOR'S SIGNATURE:

9. PRECEPTOR'S NAME:

10. DATE:

EXHIBIT A