RADIOACTIVE MATERIALS PROGRAM

GUIDE FOR NUCLEAR PHARMACY, revision 3

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APPENDICES

PART I

1. 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 safe and secure possession, use, preparation, redistribution, 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. 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 Rule 391-3-17-.05 for "medical use," as defined in Rule 391-3-17-.05(2) .

1.2 Applicable Regulations

Department regulations that may be applicable to nuclear pharmacy operations are:

391-3-17-.01	"General Provisions"
391-3-17-.02	"Licensing of Radioactive Materials"
391-3-17-.03	"Standards for Protection Against Radiation"
391-3-17-.05	"Use of Radionuclides in the Healing Arts"
391-3-17-.06	"Transportation of Radioactive Material"
391-3-17-.07	"Notices, Instructions, and Reports to Workers; Inspections. "
391-3-17-.10	"Administration"
391-3-17-.11	"Enforcement"
391-3-17-.13	"Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials"

Unless otherwise stated, all regulations cited in this guide are in Chapter 391-3-17, "Rules and Regulations for Radioactive Materials," which can be found on the Georgia Secretary of State website at: http://rules.sos.ga.gov/gac/391-3-17.

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 establishes the information needed to complete an RMP Application for a Radioactive Material License.

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

The 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." Rule 391-3-17-.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. Licensees must maintain records of audits and other reviews of program content and implementation for 3 years after the record is made.

2. FILING AN APPLICATION

Applicants must complete the Radioactive Materials Program "Application for Radioactive Materials License," which can be found on the Air Protection Branch of the Georgia Environmental Protection Division Air Protection Branch website under the "Radiation" section. You should complete Items 1 through 4, Item 13, and the APPLICATION SUPPLEMENTAL SHEET and on the form itself. For Items 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.

The license will require that you possess, use, prepare, distribute, and/or redistribute 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 are 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.

If you submit trade secrets, proprietary information, or personnel information that you want withheld from public disclosure, The applicant must request withholding according to procedures specified in the Georgia Open Records Act., which can be found here: https://www.georgiaarchives.org/documents/Open_Records_Act_2018.pdf. Failure to follow this

procedure may result in disclosure of the information to the public and/or substantial delays in processing your submittals. Simply stamping documents with terms such as "confidential," “proprietary,” or "restricted" will not allow your documents to be withheld from public review.

3. AMENDMENTS TO A LICENSE

An amendment request to your license shall be submitted if you discover or anticipate information in your current license, license application, and/or any subsequent amendments thereto: 1) is inaccurate or incomplete; or 2) will no longer be accurate or complete because of modifications you intend to request.

It is your obligation to keep your license current. A request for an amendment to your license may be submitted using either the application form or as a letter (which is preferable). Supporting documentation should be submitted as enclosures or attachments. Amendment requests may be submitted to the RMP by email to Rad.Materials@dnr.ga.gov.

Your request for an amendment 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.

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

4. RENEWAL OF A LICENSE

Licenses are issued by the RMP for a period of 5 years. Send an application for renewal to the address specified on the current license application form. Retain a copy of the renewal because the license requires that you possess and use licensed material in accordance with the statements and representations in your renewal request and any supplements to it.

You should submit an application for renewal as if it were an application for a new license without referring to previously submitted information (although you may incorporate any previously submitted information that remains accurate and complete). Submitting an entirely new application allows you to reevaluate your program periodically and consolidate the description of your program. A new application ensures that your program contains all needed information as requested in current licensing guidance.

In accordance with Rule 391-3-17-.02(15), you should file your application for license renewal at least 30 days before the expiration date of your license. A timely filed application ensures your expiring license will 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 the RMP cannot process it before that date, you will be without a valid license when your license expires.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal. The renewal is necessary to avoid violating the RMP’s regulations that do not allow possession of licensed material without a valid license.

5. 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 "Request to Terminate Radioactive Materials License" form with supporting documentation as applicable. The licensee shall certify that all radioactive materials have been transferred or disposed of properly, and that areas where radioactive materials were possessed, stored, and/or used are free of contamination. 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.

PART 2

6. CONTENTS OF AN APPLICATION

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

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 Material License Number.

Item 2.a. Name and Mailing Address of Applicant

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

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used or the annual fee billing address as specified in Items 2.b. and 3.c., respectively.

Item 2.b. Address(es) where licensed material will be stored and/or used (Street Address)

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 is not acceptable.

Item 3.a. Person to Contact Regarding this Application

You should name the individual who knows your proposed radioactive materials program and can answer questions about your application. Please provide the telephone number and email address at which this individual may be contacted.

Item 3.b. Radiation Safety Officer

Please identify a Radiation Safety Officer and provide their telephone number and email address.

Item 4. Locations where records will be kept

Records should be accessible at all locations of use specified in this application.

Item 5. Radioactive Material

The applicant must list the following information in items a, b, c, and 6 of the APPLICATION SUPPLEMENTAL SHEET for each requested radionuclide: a. Element and mass number; b. Chemical and/or physical form; and c. Maximum amount which will be possessed at any one time; and 6. The purpose – for each listed element and mass number - for which it will be used.

Item 5.1 Radionuclide Specific Instructions

- Under Element and mass number, "Any radioactive material authorized by Rule 391-3-17-.05(32)(a)" should be listed for sealed sources that are to be used for calibration and that do not exceed 30 millicuries.

- Under Chemical and/or physical form, provide the manufacturer's or distributor's name and model number for each sealed source and device that is not to be used for calibration.

- Under Maximum amount which will be possessed at any one time for each Ra-226 sealed source and device and discrete source of Ra-226 requested, provide the activity per source and the maximum possession limit [e.g., 1 millicurie (mCi) per source with a maximum possession limit of 3 mCi]. If the commercial radiopharmacy possesses discrete sources of Ra-226, the discrete source should be described, because additional precautions may need to be taken if the source is compromised.

A safety evaluation of sealed sources and devices is performed by the NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) registration certificate. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that the RMP can verify that they have been evaluated in an SSD registration certificate or specifically approved on a license.

A commercial radiopharmacy possessing a sealed source containing radioactive material that does not have an SSD registration certificate must provide the information required under Rule 391-3-17-.02(7)(i). As noted earlier, some sealed sources that contain accelerator-produced radioactive materials or Ra-226 may not have existing safety evaluations. A commercial radiopharmacy that intends to manufacture, distribute, or redistribute such a source must request a safety evaluation by the NRC or an Agreement State.

Applicants should consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the sealed source and device designations registered with the NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective SSD registration certificates, without obtaining NRC's prior permission in a license amendment. To ensure that applicants use sources and devices according to the certificates, they should obtain copies of the certificates and review them or discuss them with the manufacturer.

To obtain copies of the SSD registration certificate, applicants should contact the manufacturer or distributor of the device. If the manufacturer or distributor are no longer in service, a copy of the SSD registration certificate may be requested from the NRC or the issuing Agreement State. For additional guidance relating to sealed sources and devices, see also NUREG–1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

- Applicants that produce radionuclides using an accelerator [e.g., Positron Emission Tomography (PET) cyclotron] should list only those radionuclides produced for use in the commercial radiopharmacy (e.g., fluorine-18). All other radionuclides associated with PET radionuclide production (e.g., activation products) should be provided with the application submitted in accordance with NUREG–1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator."

- The applicant must request authorization to possess depleted uranium (DU) if it will be used as shielding for molybdenum (Mo)-99/Tc-99m generators or as other shielding. DU is frequently used as shielding for generators when the Mo-99 activity is greater than 4 Curies. In accordance with Rule 391-3-17-.02(2)(c)6., DU is exempt from the requirements for a specific or general license to the extent that the material is used as a shipping container, such as when Mo-99/Tc-99m generators are in transit from their manufacturer to the pharmacy. However, a specific license or authorization from the RMP is needed to possess and use the DU as a shield during the time that the pharmacy uses or stores the generator at its facility. The applicant must specify the total amount of DU, in kilograms (kg), that will be needed. For DU, specify the total amount in kilograms.
- Applicants who plan to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of quantity limits specified in Rule 391-3-17-.02(21)(e), Schedule E - "QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE" must, in accordance with Rule 391-3-17-.02(7)(h), provide with the application either: (i) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed one rem (.01 Sv) effective dose equivalent or five rem (.05 Sv) to the thyroid; or (ii) an emergency plan for responding to a release in accordance with the criteria listed in Rule 391-3-17-.02(7)(h)3. Refer to Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," Revision 1, issued April 2011, for additional information on emergency plans. For radiopharmacies, I-131 is the radionuclide most likely to trigger the need for an emergency plan due to its Schedule E quantity of 10 Curies.

5.1.1 Financial Assurance for Decommissioning

If financial assurance (FA) is required, submit the documentation and one of the funding instruments required in accordance with Rule 391-3-17-.02(8)(g) as appropriate.

- A licensee authorized to possess licensed material in excess of the limits specified in Rule 391-3-17-.02(8)(g) must provide financial assurance using an appropriate mechanism, and where required, must also submit a decommissioning funding plan (DFP) or provide a certification of financial assurance for decommissioning.

The requirements for FA for decommissioning are specific to the types and quantities of radioactive material authorized on a license. Most commercial radiopharmacy applicants and licensees do not need to take any action to comply with the FA requirements, because the vast majority of radioactive materials they possess and redistribute do not have half-lives greater than 120 days and the total inventory of licensed materials with half-lives greater than 120 days does not exceed the thresholds in Schedule F – Quantities for Use With Decommissioning of Rule 391-3-17-.02(21).

Applicants requesting more than one radionuclide may determine whether FA for decommissioning is required by calculating, for each radionuclide with a half-life greater than 120 days possessed, the ratio between the activity possessed, in curies, and the radionuclide's threshold activity requiring FA, in curies. If the sum of such ratios for all of the radionuclides possessed exceeds "1" (i.e., "unity"), applicants must submit evidence of FA for decommissioning.

Financial Assurance (FA) and Decommissioning Funding Plan (DFP) for Possession of Germanium-68 (Ge-68)/Gallium-68 (Ga-68) Generators

- In accordance with Rule 391-3-17-.02(8)(g), "Financial assurance and record-keeping for decommissioning," applicants must have a DFP to obtain a license to possess Ge-68/Ga-68 generators. In a NRC Memorandum dated July 13, 2017, "Revision of Technical Basis for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators," (Agencywide Documents Access and Management Accession No. ML17075A487), the Director of the NRC Office of Nuclear Material Safety and Safeguards delegated to the NRC Regional Administrators the authority to grant an exemption to the DFP requirements in Rule 391-3-17-.02(8)(g)1.(i) for the possession and use of Ge-68/Ga-68 generators (unsealed radioactive material) when certain conditions are met. **If an applicant or licensee requests an exemption from the requirements in Rule 391-3-17-.02(8)(g)1.(i) for the possession and use of Ge-68/Ga-68 generators, the applicant or licensee would still need to provide FA. The total amount of FA would vary depending on the number of generators that the applicant is requesting be authorized or the licensee is authorized to possess.** Additionally, in order to be granted an exemption from Rule 391-3-17-.02(8)(g)1.(i) for the possession and use of Ge-68/Ga-68 generators, the applicant or licensee must have a legally binding agreement in place with the manufacturer or distributor of the generators that addresses the return of expired generators. Applicants and licensees that request and are granted the exemption will have a specific license condition placed on their license addressing the exemption. Applicants and licensees who wish to request such an exemption to the DFP requirements in 10 CFR 30.35(a)(1) for the possession and use of Ge-68/Ga-68 generators should refer to the July 13, 2017, Memorandum for additional information. For commercial radiopharmacy licensees whose contamination incidents did not involve radioactive materials

with half-lives exceeding 120 days and whose sealed sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where radioactive material was used or stored.

NUREG–1757, Volume 3," Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness" (NUREG–1757, Vol. 3), provides guidance acceptable to the RMP staff on the information to be provided for establishing FA for decommissioning and a standard format for presenting the information.

5.1.2 Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material – 10 CFR Part 37

Rule 391-3-17-.13 incorporates the regulations in 10 CFR Part 37 by reference. 10 CFR Part 37 applies to licensees that possess an aggregated "Category 1 quantity of radioactive material" or "Category 2 quantity of radioactive material." These terms are defined in 10 CFR 37.5. The list of these radionuclides and the threshold quantities can be found in Appendix A to 10 CFR Part 37.

5.2 Applicable Georgia Rules

Description of Commercial Radiopharmacy Activities and Potentially Applicable Requirements	
Activities	**Authorized By**
General Provisions	GA Rule 391-3-17-.01
Licensing of Radioactive Material	GA Rule 391-3-17-.02
Manufacture, Prepare, or Transfer for Commercial Distribution Carbon-14 Urea Capsules for *in vivo* Human Diagnostic Use to Persons Exempt from Licensing	GA Rule 391-3-17-02(3)(c)4. = NRC 10 CFR 32.21
General Requirements for Issuance of Specific Licenses	GA Rule 391-3-17-.02(8) = NRC 10 CFR 30.33
Financial assurance and record-keeping for decommissioning	GA Rule 391-3-17-.02(8)(g) = NRC 10 CFR 30.35
Distribute Radioactive Material for In Vitro Clinical or Laboratory Testing under a General License	GA Rule 391-3-17-.02(11)(g) = NRC 10 CFR 32.71
Manufacture, Prepare, and Transfer Radiopharmaceuticals to Medical Use Licensees	GA Rule 391-3-17-.02 (11)(i) = NRC 10 CFR 32.72
Distribute Sealed Sources or Devices to Medical Use Licensees	GA Rule 391-3-17-.02(11)(j) = NRC 10 CFR 32.74
Transfer of Radiopharmaceuticals to Veterinarians, Laboratories, and Other Radiopharmacies, and Transfer of Radiopharmaceuticals to Medical Use Licensees	GA Rule 391-3-17-.02(19) = NRC 10 CFR 30.41

Standards for Protection Against Radiation	GA Rule 391-3-17-.03 = NRC 10 CFR Part 20
Use of Radionuclides in the Healing Arts	GA Rule 391-3-17-.05 = NRC 10 CFR Part 35
Transportation of Radioactive Material	GA Rule 391-3-17-.06 = NRC 10 CFR Part 71
Notices, Instructions, and Reports To Workers: Inspections and Investigations	GA Rule 391-3-17-.07 = NRC 10 CFR Part 19
Administration	GA Rule 391-3-17-.10
Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials	GA Rule 391-3-17-.13 = NRC 10 CFR Part 37

Item 6. Purpose(s) for which licensed material will be used

For each radionuclide listed in the application, the applicant shall describe its intended use on the SUPPLEMENTAL SHEET to the application. In addition, the following information must be provided for any materials or processes that are applicable:

Item 6.1 Specific types of materials, processes, and activities

For unsealed materials:

For potentially volatile materials (e.g., I-123, I-131), specify whether the material will be manipulated at the commercial radiopharmacy in a volatile form (e.g., compounding of I-131 capsules) or received in the form in which it will be distributed (e.g., redistribution of sealed, unopened vials of I-131 capsules). Also specify where manipulation occurs (i.e., a hood or a hot cell).

For sealed sources and discrete sources of Ra-226:

Applicants requesting discrete sources of Ra-226 and authorization to manipulate volatile radioactive material must describe appropriate facilities and engineering controls.

For preparation of radiopharmaceuticals:

Indicate the types of radiopharmaceutical preparation activities the applicant intends to perform (e.g., compounding of I-131 capsules, radioiodination, chemical synthesis of PET radiopharmaceuticals, and Tc-99m kit preparation).

Confirm that radiopharmaceuticals will be prepared under the supervision of an authorized nuclear pharmacist (ANP) or will be obtained from a supplier authorized pursuant to Rule 391-3-17-.02(11)(i), or under equivalent NRC or Agreement State requirements.

For radiopharmaceutical distribution or redistribution:

Describe all licensed material to be distributed or redistributed and described the method or system that will be used to ensure the intended customer is licensed to receive the material.

For generators:

Confirm that the generators will be obtained from a manufacturer licensed pursuant to Rule 391-3-17-.02(11)(i), or under equivalent NRC or Agreement State requirements.

Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

For redistribution of used generators:

Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.

Confirm that the manufacturer's packaging and labeling will not be altered.

Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.

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

Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

Note: Although redistribution of used generators may be authorized by the RMP, RMP approval does not relieve the licensee from complying with applicable U.S. Food and Drug Administration (FDA) or other Federal and State requirements.

For redistribution of sealed sources for brachytherapy or diagnosis:

Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to Rule 391-3-17-.02(11)(j), or under equivalent Agreement State requirements.

Confirm that the manufacturer's packaging, labeling, and shielding will not be altered 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.

For redistribution of calibration and reference sealed sources:

Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to Rule 391-3-17-.02(11)(j) or under equivalent NRC or Agreement State requirements, to initially distribute such sources.

Confirm 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.

For redistribution of prepackaged units for in vitro tests to specific licensees:

Confirm that the prepackaged units for in vitro tests to be redistributed will be obtained from a manufacturer authorized to distribute the prepackaged units for in vitro tests in accordance with a specific license issued pursuant to Rule 391-3-17-.02(11)(g), or under an equivalent NRC or Agreement State license.

Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for in vitro tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., Rule 391-3-17-.02(6)).

Confirm that the labeling on redistributed prepackaged units for in vitro tests will conform to the requirements of Rule 391-3-17-.03(12) for "Caution signs" and "Labeling containers."

For redistribution of prepackaged units for in vitro tests to general licensees (Rule 391-3-17-.02(11)(g)):

Confirm that the manufacturer's packaging and labeling of the prepackaged units for in vitro tests will not be altered in any way.

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

For Service Activities:

Specify the customer radiation protection services involving licensed material that will be provided and include the information described in NUREG–1556, Volume 18 - Program-Specific Guidance About Service Provider Licenses, as applicable.

Note: Examples of customer radiation protection services that may be provided include sealed source leak testing, instrument calibration, or other specified services.

For radioactive materials in unsealed form, on foils or plated sources, or sealed in glass:

Evaluate whether possession limits in the application exceed quantity limits in Rule 391-3-17-.02(21)(e), Schedule E and if required, provide an emergency plan in accordance with the criteria listed in Rule 391-3-17-.02(7)(h)3.

For new applicants and licensees subject to financial assurance:

Specify whether you are subject to a Decommissioning Funding Plan (DFP) and if so, i) either submit the DFP in accordance with the requirements of subparagraphs (g)5. and (g)6. of Rule 391-3-17-.02(8) for review and approval by the RMP along with a signed original of the financial instrument in an amount that equals or exceeds the decommissioning cost estimate (DCE) in the DFP; or ii) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Rule 391-3-17-.02(8), subparagraph (g)4. using one of the methods described in Rule 391-3-17-.02(8), subparagraph (g)7 along with a signed original of the financial instrument.

If an applicant defers execution of the financial instrument until after a new license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of Rule 391-3-17-.02(8), subparagraph(g)7. must be submitted to the RMP before the receipt of licensed material.

Financial assurance must be provided using a financial instrument prescribed under Rule 391-3-17-.02(8), subparagraph (g)7., and must utilize language and account structures as prescribed in NUREG-1757, Volume 3, revision 1 (or if revision 1 has been superseded, the latest revision). NUREG-1757 financial instrument guidance language that references the Nuclear Regulatory Commission (NRC), Federal statutes and Federal regulations must be changed to the Department of Natural Resources, and the corresponding State of Georgia statutes and regulations, respectively prior to submittal. If in doubt about the language and/or financial account structure, the applicant should submit a draft of the financial instrument to the RMP for review prior to submitting the final, executed financial instrument.

Beginning in 2019 and in accordance with rule 391-3-17-.02(8), subparagraph (g)6,, new applicants and existing licensees subject to DFP requirements must submit a copy to the RMP for review and approval with the new application and with each renewal application, respectively. In addition, DFPs must be submitted to the RMP at intervals not to exceed 3 years, and the DFP must be updated with adjustments as necessary to account for changes in costs and the extent of contamination.

For applicants and licensees subject to 391-3-17-.13 - Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials (10 CFR Part 37):

Specify that you are subject to the applicable requirements of this rule and that you shall implement a program as required. **Please note that you must not submit any documentation associated with the implementation of this program**. Specify that all information and documentation related to this program will be made available to the RMP at the time of inspection or upon request.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

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

In order for an individual to be placed on a license as an authorized nuclear pharmacist (ANP) or a Radiation Safety Officer (RSO), the licensee must provide the RMP documentation that meets the requirements of the applicable rules.

7.1 Applicable Georgia Rules

391-3-17-.05(2)
391-3-17-.05(22)
391-3-17-.05(24)
391-3-17-.05(26)
391-3-17-.05(27)

7.2 Licensing Criteria

Only those individuals whose training and experience meet the applicable requirements of paragraphs (2), (24), (26), and/or (27) of Rule 391-3-17-.05 can be listed as authorized nuclear pharmacists. Only those individuals

whose training and experience meet the applicable requirements of paragraphs (2), (22), (26), and/or (27) of Rule 391-3-17-.05 can be listed as a radiation safety officer.

7.3 Applicant Response

For Proposed Authorized Nuclear Pharmacists

Specify the full name of each individual to be listed on your license as an authorized nuclear pharmacist (ANP). If you are requesting to add a new ANP to your license, then the applicant must select one of four (4) pathways and submit the requisite documentation as described below (or in accordance with any new or revised requirement(s) under Rule 391-3-17-.05 as applicable):

Pathway 1: Documentation that a prospective ANP meets the grandfathering requirements of Rule 391-3-17-.05(26); or

Pathway 2: Documentation in accordance with Rule 391-3-17-.05(24)(a) that a prospective ANP has obtained an NRC-recognized specialty board certification as described here: https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html; in accordance with Rule 391-3-17-.05(24)(b)2. a signed and dated preceptor statement or letter of attestation from an authorized user who is qualified for the modalities being requested; and documentation in accordance with Rule 391-3-17-.05(24)(c) that the individual is licensed as a Nuclear Pharmacist by the Georgia Board of Pharmacy; or

Pathway 3: Documentation in accordance with Rule 391-3-17-.05(24)(b) that a prospective ANP has training and experience as described therein, and a preceptor statement or letter of attestation from an authorized who is qualified for the modalities being requested; in accordance with Rule 391-3-17-.05(24)(b)2. a signed and dated preceptor statement or letter of attestation from an authorized user who is qualified for the modalities being requested; and documentation in accordance with Rule 391-3-17-.05(24)(c) that the individual is licensed as a Nuclear Pharmacist by the Georgia Board of Pharmacy; or

Pathway 4: Documentation in accordance with the definition of "authorized nuclear pharmacist" in Rule 391-3-17-.05(2) that shows a prospective ANP was or is an ANP on another Radioactive Material License.

When an attestation statement or letter is required, it must be signed and dated by a qualified preceptor and should state that an individual has satisfactorily completed the requirements under the applicable rule(s) and has achieved a level of competency sufficient to independently practice.

Qualifying documentation must also show that any certification, training and experience, or listing as an ANP on another license has occurred within the last 7 years as per the recentness of training requirements in Rule 391-3-17-.05(27).

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 Proposed Radiation Safety Officer (RSO)

Rule 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. Specify the full name of each individual to be listed on your license as the radiation safety officer (RSO). If you are requesting to add a new RSO to your license, then the applicant must select one of six (6) pathways and submit the requisite documentation as described below (or in accordance with any new or revised requirement(s) under Rule 391-3-17-.05 as applicable):

Pathway 1: Documentation that a prospective RSO meets the grandfathering requirements of Rule 391-3-17-.05(26); or

Pathway 2: Documentation in accordance with Rule 391-3-17-.05(22)(a) that a prospective RSO has obtained an NRC-recognized specialty board certification as described here: https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html; in accordance with Rule 391-3-17-.05(22)(d) a signed and dated preceptor statement or letter of attestation from an authorized user who is qualified for the modalities being requested; and documentation in accordance with Rule 391-3-17-.05(22)(e) that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval; or

Pathway 3: Documentation in accordance with Rule 391-3-17-.05(22)(b) that a prospective RSO has training and experience as described therein, and a preceptor statement or letter of attestation from an authorized who is qualified for the modalities being requested; in accordance with Rule 391-3-17-.05(22)(d) a signed and dated preceptor statement or letter of attestation from an authorized user who is qualified for the modalities being requested; and documentation in accordance with Rule 391-3-17-.05(22)(e) that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval; or

Pathway 4: Documentation in accordance with Rule 391-3-17-.05(22)(c)1. that shows a prospective RSO is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under Rule .05(23)(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer; in accordance with Rule 391-3-17-.05(22)(d) a signed and dated preceptor statement or letter of attestation from an authorized user who is qualified for the modalities being requested; and documentation in accordance with Rule 391-3-17-.05(22)(e) that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval; or

Pathway 5: Documentation in accordance with Rule 391-3-17-.05(22)(c)2. that shows a prospective RSO is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; in accordance with Rule 391-3-17-.05(22)(d) a signed and dated preceptor statement or letter of attestation from an authorized user who is qualified for the modalities being requested; and documentation in accordance with Rule 391-3-17-.05(22)(e) that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval; or

Pathway 6: Documentation in accordance with the definition of “radiation safety officer” in Rule 391-3-17-.05(2) that shows a prospective RSO was or is an RSO on another Radioactive Material License.

When an attestation statement or letter is required, it must be signed and dated by a qualified preceptor and should state that an individual has satisfactorily completed the requirements under the applicable rule(s) and has achieved a level of competency sufficient to independently practice.

Qualifying documentation must also show that any certification, training and experience, or listing as an RSO on another license has occurred within the last 7 years as per the recentness of training requirements in Rule 391-3-17-.05(27).

The RSO must agree in writing to be responsible for implementing the radiation protection program. Submit competed copies of the Radiation Safety Officer Delegation of Authority and the Radiation Safety Officer Certification in Appendix A of this guide.

Item 8 Instructions to Workers Working In Or Frequenting Restricted Areas

8.1 Applicable Georgia Rules

391-3-17-.07(3)

8.2 Training

You should establish and follow written procedures for instructing individuals working in or frequenting any portion of a restricted area who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be:.

1. Instructed in the subject matter specified in Rule 391-3-17-.07(3) at the time of their initial employment and as appropriate thereafter;

2. Kept informed of the storage, transfer, or use of sources of radiation in the licensee's facility;

3. Instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

4. Instructed in, and instructed and required to observe, to the extent within the workers' control, the applicable provisions of the Rules and the license for the protection of personnel from exposures to radiation or radioactive material;

5. Instructed of their responsibility to report promptly to the licensee any condition which may constitute, lead to, or cause a violation of the Act, the Rules, and the license or unnecessary exposure to radiation or radioactive material;

6. Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

7. Advised as to the radiation exposure reports which workers shall be furnished pursuant to Rule 391-3-17-.07(4).

In determining those individuals subject to these requirements, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material which can reasonably be expected to occur during the life of the facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

8.3 Applicant Response

No response is required. The applicant must maintain a written program and implement the program at its facility(ies).

Item 9 Facilities and Equipment

9.01 Applicable Georgia Rules

391-3-17-.02(8)(b)
391-3-17-.03(4)
391-3-17-.03(8)
391-3-17-.03(9)
391-3-17-.03(10)
391-3-17-.03(11)
391-3-17-.03(12)
391-3-17-.13

In order for the RMP to evaluate the adequacy of your proposed facilities and equipment, the applicant 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.

A new applicant must demonstrate that it is a pharmacy by submitting evidence of at least one of the following:

- Licensure as a pharmacy by a State Board of Pharmacy, or
- Operation as a nuclear pharmacy within a Federal medical institution

If the registration or license has not been issued by the State Board of Pharmacy at the time of application, the applicant may provide it at a later date, but before license issuance by the RMP.

9.02 Applicant Response

For a new applicant, provide a copy of their registration or license from a State Board of Pharmacy as a licensed pharmacy, or evidence that the facility is operating as a nuclear pharmacy within a Federal medical institution.

Note: If the applicant’s particular activities are not recognized as the practice of commercial radiopharmacy, the applicant must submit evidence that it is registered or licensed with the State or FDA as a drug manufacturer. Refer to NUREG–1556, Volume 12, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution” for guidance on drug manufacturer requirements.

If applicable, in accordance with Rule 391-3-17-.13, facilities and equipment must also provide enhanced physical protection of aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5. In addition, licensed materials must be secured from unauthorized access and removal.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other requirements:

- Implement the physical protection requirements in 10 CFR Part 37 for material in use and storage, at permanent jobsites; and

- In accordance with 10 CFR 37.49, be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones, including those surrounding mobile devices, and immediately detect any unauthorized removal of Category 1 quantities of radioactive material from the security zone. (Monitoring and detection systems may include, among other methods, monitored video surveillance systems and electronic devices for intrusion detection alarms.)

- For mobile devices containing Category 1 or Category 2 quantities of radioactive material, have two independent physical controls to secure the material from unauthorized removal when the device is not under direct control and constant surveillance in accordance with 10 CFR 37.53. "Mobile device" is defined in 10 CFR 37.5.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not to be submitted to the RMP, but are subject to review and inspection.

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. Specific site, facility, or equipment considerations may be addressed in the appropriate sections.

9.2 Site Description

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).

9.2.1 Applicant 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.

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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.

8. An Organization Chart that at a minimum: 1) shows the reporting lines between the Radiation Safety Officer and upper management, and 2) identifies those individuals.

9.3 General Description of Facility

Diagram(s) should be submitted showing the applicant's entire facility and identifying activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to a specified scale, or dimensions that are indicated.

Notes: Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved.

Mark drawings, diagrams, and descriptions that provide the exact location of materials or depict specific locations of security equipment as, "Security-Related Information—Withhold under 10 CFR 2.390" and DO NOT SUBMIT unless specifically requested by the RMP. These documents must be available at the time of inspection or if otherwise requested by the RMP. ***Please note that only Federal agencies such as the NRC have authority with regard to 10 CFR 2.390. However, the RMP will honor a valid claim made by an applicant if it conforms to NRC guidance.***

9.3.1 Licensing Criteria

The applicant 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.

9.3.2 Applicant 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 bremsstrahlung 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 Rule 391-3-17-.03(5)(i) and that surveys are required by Rule 391-3-17-.03(7)(a).

Posting of signage in appropriate areas, and labeling of containers and radiation machines in accordance with Rule 391-3-17-.03(12) are required.

9.3.3 Applicant Response for Nuclear Pharmacies in Multitenant 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., 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

Radioiodines such as iodine-131 are the primary volatile materials of concern.

9.4.1 Licensing Criteria

The applicant must have adequate equipment and operating controls to ensure that airborne radioactivity, associated surface contamination, and effluent releases, are maintained within regulatory limits in accordance with Rule 391-3-17-.03(5).

Appendix B to 10 CFR Part 20 establishes 'Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

In addition, subject to the requirements of subparagraph (i)3. of Rule 391-3-17-.03, a licensee subject to the provisions of the U.S. Environmental Protection Agency's (EPA) generally applicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards.

9.4.2 Applicant 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.

To demonstrate compliance with Radiation Dose Limits for Individual Members of the Public, an applicant who applies for RMP authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv) must submit the following documentation:

(i) Demonstration of the need for and the expected duration of operations in excess of the limit in subparagraph (5)(i)1. of Rule 391-3-17-.03;
(ii) The applicant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit;
(iii) The procedure to be followed to maintain the dose as low as is reasonably achievable (ALARA).(iv) As appropriate, survey results of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas; and
(v) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or
(vii) Demonstrating that:
(I) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B of 10 CFR 20; and

(II) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in one hour and 0.05 rem (0.50 mSv) in one year.

9.5 Facilities and Equipment for PET Radiopharmacies

PET radiopharmacies must demonstrate that they are registered with a State agency, are licensed as a pharmacy by the State's Board of Pharmacy, or operate as a nuclear pharmacy within a Federal medical institution. Facilities and equipment must be adequate to protect health and minimize danger to life or property, minimize the likelihood of contamination, and keep exposures to workers and the public ALARA.

In addition to the information required for a radiopharmacy, PET radiopharmacy applicants should describe the equipment and/or method and shielding used to physically transfer (e.g., transfer lines) PET radiochemicals to the chemical synthesis equipment for radiopharmaceutical manufacturing and then to the dispensing area. The description should also include shielding used for chemical synthesis and/or dispensing radiopharmaceuticals. Also, the type of remote handling equipment used for handling the PET radionuclides and drugs should be described.

PET radiopharmacies should implement proper engineering controls due to the potential for radioactive air effluents produced during the chemical synthesis process. Examples of some engineering controls that should be used include exhaust filtration (e.g., high efficiency particulate air and carbon filters) and/or containment systems for decay of effluents. In addition, a continuous "real-time" effluent (stack) monitor should be installed at the facility.

9.5.1 Applicant Response

- For a new applicant, provide a copy of their registration or license from a State Board of Pharmacy as a licensed pharmacy, or evidence that the facility is operating as a nuclear pharmacy within a Federal medical institution.

Note: If the applicant's particular activities are not recognized as the practice of commercial radiopharmacy, the applicant must submit evidence that it is registered or licensed with the State or FDA as a drug manufacturer. Refer to NUREG–1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution" for guidance on drug manufacturer requirements.

AND

- Provide a description of the facilities and equipment at each location where radioactive material will be used, which includes the method and shielding used to physically transfer licensed material (e.g., transfer lines) to the different processes (e.g., chemical synthesis, dispensing).

Note: A diagram should be submitted that shows the applicant's entire facility and identifies activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to a specified scale, or dimensions that are indicated. Diagrams should include locations of shielding, such as shielding for hot cells and transfer lines.

AND

- The diagram(s) should also include: (1) descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials and the location(s) for

radioactive waste storage; (2) locations of shielding, the shielding thickness, the materials used for shielding, and the locations of hot cells for positron emitting radionuclides; (3) the proximity of radiation sources to unrestricted areas and other items related to radiation safety such as remote handling equipment and area monitors (4) a general description of any ventilation system that is used when handling radionuclides, including representative equipment, such as glove boxes or fume hoods; (5) confirmation that such ventilation systems will be employed for the use or storage of radioactive material likely to become airborne; and (6) verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of Rule 391-3-17-.03(5), and are within the ALARA constraints for air emissions established under Rule 391-3-17-.03(4)(d).

Notes: Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved.

Mark drawings, diagrams, and descriptions that provide the exact location of materials or depict specific locations of security equipment as "Security-Related Information—Withhold under 10 CFR 2.390" and DO NOT SUBMIT! <u>In your application, reference Item 9.5, identify each document by name, and state that each will be made available at the time of inspection or when otherwise requested by the RMP.</u> ***Although requests made in accordance with 10 CFR 2.390 are subject only to the authority of Federal agencies such as the NRC, the RMP will honor a valid claim that meets both RMP and NRC guidance for Nuclear Pharmacies.***

<u>Item 10 Radiation Safety Program</u>

In accordance with Rule 391-3-17-.03(4), each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program should include procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to the public that are ALARA. The program must be sufficient to ensure compliance with the provisions of Rules 391-3-17-.03 and 391-3-17-.05(15). The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material.
Respond to the following sections of this document regarding Item 10.

10.01 <u>Applicable Georgia Rules</u>

391-3-17-.02(8)(b)
391-3-17-.02 (11)(g)
391-3-17-.02(11)(h)
391-3-17-.02 (11)(i)
391-3-17-.02 (11)(j)
391-3-17-.03(4)
391-3-17-.03(5)
391-3-17-.03(6)
391-3-17-.03(8)
391-3-17-.03(10)
391-3-17-.03(11)
391-3-17-.03(12)
391-3-17-.03(13)
391-3-17-.03(14)
391-3-17-.05(15)
391-3-17-.06(5)
391-3-17-.06(14)

391-3-17-.06(18)
391-3-17-.06(19)
391-3-17-.07(4)
391-3-17-.13/10 CFR Part 37

10.1 Personnel Monitoring Program

10.1.1 Occupational Dose

Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure.

The use of individual monitoring devices for external dose is required pursuant to Rule 391-3-17-.03(8)(b) based upon the Occupational Dose Limits and Dose Limits for Individual Members of the Public established in Rule 391-3-17-.03(5).

Licensees should design a monitoring program to ensure compliance with ALARA and Rule 391-3-17-.03(5). The extent and frequency of monitoring will depend upon each licensee's scope and extent of licensed activities.

During RMP inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from licensed operations does not exceed the annual limit and
the dose constraint.

10.1.2 Licensing Criteria

If an adult radiation worker is likely to receive in a year a dose greater than 10 percent of any applicable limit, monitoring for occupational exposure is required. Monitoring is required for minors and declared pregnant women as shown in the criteria section. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

Licensees should also perform prospective evaluations of the doses that may be received by occupationally exposed minors and declared pregnant women. As with individual adult workers, licensees must supply and require the use of individual monitoring devices to monitor external exposures and monitor the occupational intake of radioactive material when the results of prospective dose evaluations exceed the doses specified in Rule 391-3-17-.03(5).

If this prospective evaluation shows that an individual is not likely to exceed 10 percent of any applicable limit, there are no recordkeeping or reporting requirements in regard to the individual's exposure. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only the dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and associated recordkeeping and reporting. If it was determined that monitoring was not required and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

Licensees should use NRC Form 4, “Cumulative Occupational Dose History,” and NRC Form 5, “Occupational Dose Record for a Monitoring Period,” to record individual dose. If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter “N/A” for “not applicable” in the blocks on NRC Form 4, “Cumulative Occupational Dose History,” and NRC Form 5, “Occupational Dose Record for a Monitoring Period,” to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter “ND” for “not detectable.”

If the prospective evaluation shows that the individual adult is likely to exceed 10 percent of an applicable limit, then monitoring—regardless of the actual dose received—is required. If air sampling or bioassay is required, discussion of air sampling or bioassay should provide enough detail so that the NRC staff is assured that appropriate steps will be taken to manage and monitor such exposure. Licensees must provide individual radiation exposure data to each worker as required by Rule 391-3-17-.07(4).

When personnel dosimeters that require processing to determine the radiation dose are used to comply with the individual monitoring requirement for external doses in Rule 391-3-17-.03(5), dosimeters must be processed by a National Voluntary Laboratory Accreditation Program (NVLAP)-accredited processor [Rule 391-3-17-.03(8))]. The exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP-accredited processor for its recommendations for exchange frequency and proper use of the dosimeter.

NRC guidance regarding personnel monitoring and bioassay requirements related to specific radionuclides or specific circumstances can be found in the table below:

Guidance on Personnel Monitoring and Bioassay	
Regulatory Guide 8.7, Revision 4	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9, Revision 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20, Revision 2	Applications of Bioassay for Radioiodine
Regulatory Guide 8.21, Revision 1	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.32	Criteria for Establishing a Tritium Bioassay Program
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Radiation Doses
Regulatory Guide 8.35, Revision 1	Planned Special Exposures
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
ANSI N13.30-2011	Performance Criteria for Radiobioassay
Information Notice 2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits

10.1.3 Applicant Response

Provide one of the following statements:

"We will maintain, for inspection by the RMP, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in Rule 391-3-17-.03(5)."

OR

"We will monitor individuals in accordance with the guidance in the Occupational Dose section of the Nuclear Pharmacy Guide, revision 3."

OR IN LIEU OF THESE STATEMENTS:

Provide a description of an alternative method for demonstrating compliance with the referenced regulations.

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

1. That whole-body badges (e.g., film or thermoluminescent dosimeters, also called TLDs) be provided when required by Rule 391-3-17-.03(8)(b).

2. That whole-body badges and finger extremity monitors (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 for individuals who work in or frequent restricted access areas where radioactive materials are possessed or used.

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 Rule 391-3-17-.03(8)(a).

5. That any direct reading dosimeters or electronic devices used to measure exposure from licensed material be operable, calibrated, and tested at intervals not to exceed 1 year.

6. All records of monitoring, prior occupational exposures, special planned exposures, and equipment calibration must be maintained in accordance with the applicable requirements of Rule 391-3-17.-03(14).

7. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, when required by Rule 391-3-17-.03(8)(b), shall be reported in writing to the individual as specified in Rule 391-3-17-.07(4).

Reference: The National Institute of Standards and Technology (NIST) maintains a directory of laboratories that are NVLAP-accredited.

10.1.4 Public Dose

Licensees must do the following to prevent or minimize dose to members of the public:

- Ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv [100 mrem] TEDE in a year from licensed activities.

- Ensure that the radiation dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any 1 hour, from licensed activities.

- Ensure that air emissions of radioactive material to the environment, excluding radon-222 and its daughters, will not result in a TEDE in excess of 0.1 mSv [10 mrem] to individual members of the public in a year from those emissions.

- Prevent unauthorized access, removal, or use of licensed material.

10.1.5 Licensing Criteria

Licensees should design a monitoring program to ensure compliance with ALARA and Rule 391-3-17-.03(5). The extent and frequency of monitoring will depend upon each licensee's scope and extent of licensed activities.

During RMP inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from licensed operations does not exceed the annual limit and
the dose constraint.

10.1.5 Applicant Response

No response is required. The applicant must maintain a written program and implement the program at its facility(ies).

References:

Regulatory Guide 4.20, Rev. 1, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," April 2012

Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993

10.2 Instruments

Licensees must possess radiation monitoring instruments for the evaluation, detection, and measurement of possible radiation hazards that may be present. Instruments used for quantitative radiation measurements must be calibrated periodically (e.g., annually) for the radiation measured.

10.2.1 Licensing Criteria

Licensees must possess calibrated and operable radiation instruments to detect and measure radiation levels, radioactive contamination, and radioactivity, as applicable.
Appropriate instruments must be available for use at all times when byproduct material is in use. The licensee should possess radiation monitoring instruments sufficiently sensitive to measure the type and energy of radiation used. Radiation detection and measurement instruments should be used for radiation protection activities, including:

- Package preparation and receipt surveys;
- Personnel and facility contamination measurements;
- Sealed source leak tests;
- Air sampling measurements;
- Bioassay measurements;
- Effluent release measurements; and
- Dose rate surveys.

For the purposes of this guide, radiation monitoring instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some types of instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters;
- Portable or stationary dose rate or exposure rate meters;
- Area monitors;
- Liquid scintillation counter (LSC);
- Well-type scintillation counters;
- Stack monitors;
- Continuous air monitors; and
- Hand and foot contamination monitors.

The choice of instrument should be appropriate for the type of radiation to be measured and for the type of measurement to be taken (e.g., count rate, dose rate). Radiopharmacies typically use a broad energy range of gamma and beta radiation emitters and need to use radiation detectors appropriate for those energies. Additionally, some radiopharmacies may handle or distribute alpha-emitting radiopharmaceuticals. Applicants should discuss the types of instruments to be used for each type of survey or measurement to be performed and the availability of a sufficient quantity of these instruments at their facility.

Instrument calibrations may be performed by the commercial radiopharmacy or by another person specifically authorized by the RMP, NRC, or an Agreement State to perform that function. If the applicant wishes to calibrate its instruments, the applicant must develop, implement, and maintain written radiation survey meter calibration procedures to ensure that instruments are properly calibrated. If the applicant chooses to use the services of another person for instrument calibration, the applicant should ensure that person has been authorized by either the RMP, NRC, or an Agreement State to perform that activity. Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts an authorized firm to perform calibrations, the licensee must retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made, in accordance with Rule 391-3-17-.03(14). Appendix F of NUREG-1556, Volume 13, revision 2., “General Radiation Monitoring Instrument Selection Guidelines and Radiation Instrument Calibration Guidelines,” provides general instrument selection guidelines and instrument calibration guidelines.

10.2.1 Applicant Response

Provide the following:

A statement that, “We will use calibrated and operable equipment that is capable of detecting the type(s) of radiation being monitored (e.g., gamma, beta, alpha) and the energy or energy range of the radiation being measured.”

OR

A description of the calibrated and operable instrumentation that will be used to perform radiation monitoring (e.g., portable or stationary count rate meters, LSCs, well-type scintillation counters, air monitors).

AND

A statement that, “We reserve the right to upgrade our monitoring instrumentation as necessary, as long as the instruments are adequate to measure the type of radiation and energy range of the radiation for which they are used.”

AND

If calibration is performed by a person or firm outside the applicant’s organization, specify that the calibration will be performed by an NRC or Agreement State licensee specifically authorized to perform instrument calibration as a service to other licensees, and state the frequency of the calibrations.

OR

If the calibration is to be performed in-house, submit the instrument calibration procedure that will be used, and state the frequency of the calibrations. In addition, identify the qualifications of the individuals who will perform the calibrations.

Note: Instrument calibration guidelines are included in Appendix F of NUREG-1556, Volume 13, revision 2., and they may be used to assist with development of the instrument calibration procedure.

10.3 Dose Measurement Systems

Commercial radiopharmacy licensees must possess and use instrumentation capable of accurately measuring the radioactivity in radioactive drugs.

Because of the potential for commercial radiopharmacy errors to adversely affect their customers (medical facilities) and their customers’ patients, each dosage of a radioactive drug must be measured before transfer to provide high confidence that the correct amount of the radioactive drug is transferred, in accordance with the customer’s request.

The applicant must have procedures for the use of the instrumentation, including the measurement, by direct measurement or by a combination of measurement and calculation, of the amount of radioactivity in dosages of alpha-, beta-, gamma-, and photon-emitting radioactive drugs before their transfer for commercial distribution.

These procedures must ensure that the dose calibrator, or other dose measurement system, functions properly. This is accomplished by performing periodic checks and tests before first use, followed by checks at specified intervals, and following repairs that could affect system performance. Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured.

For most photon-emitters, activity measurement is a fairly straightforward determination; however, for low-energy photon emitters, beta-emitters, and alpha-emitters, a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of low-energy photon-, beta-, and alpha-correction factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a NIST traceable standard for all radionuclides currently in use. If radiopharmacies intend to initially distribute (i.e., measure, prepare, and label) low-energy photon-, beta-, and alpha-emitting radionuclides, the applicant must provide the calculation to demonstrate its ability to accurately dispense such materials. If the applicant intends to use low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor. If commercial radiopharmacy applicants intend to only redistribute low- energy photon-, beta-, and alpha-emitting radionuclides that have been previously prepared and distributed by other persons licensed pursuant to Rule 391-3-17-.02 (11)(i)6, then the correction factor calculation is not required. The inherent technical difficulties in measuring alpha-emitting radionuclides are even greater than those of measuring beta emissions. In the absence of an additional photon, gamma, or beta particle emission that can be measured with traditional instrumentation used in nuclear medicine (e.g., ion chambers) and quantified in relation to the alpha particle emissions, most alpha measuring instruments (e.g., gas proportional counters and liquid scintillation counters) will require preparation and measurement of an aliquot of the unsealed byproduct material. Measurement of aliquots introduces additional uncertainties associated with removing precise and reproducible volumes from homogeneous samples. For example, NRC issued Information Notice (IN) 2016-03, “Revision to the National Institute of Standards and Technology Standard for Radium-223 and Impact on Dose Calibration for the Medical Use of Radium-223 Dichloride,” January 12, 2016, to notify licensees of a new calibration standard in measuring radium-223, which is primarily an alpha-emitter.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, because of the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

For each dose measurement system, specific periodic tests must be performed, as appropriate to the system, to ensure correct operation. Typically, all systems must be checked each day of use for constancy to ensure continued proper operation of the system. As required by Rule 391-3-17-.02 (11)(i)6, tests for accuracy (for the activities across the range of energies measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and types of containers to be measured) must be done periodically; therefore, the applicant must include the frequency for conducting these tests in its written procedures for the performance of dose measurement system checks and tests.

The applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration.

10.3.1 Licensing Criteria

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

10.3.2 Applicant Response

The applicant must describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs.

AND

When measuring only photon-emitting radionuclides, you state that you have adopted the dose calibrator calibration program described in Appendix B of this guide. Note: The procedures in Appendix B for calibrating a dose calibrator fulfill these criteria when measuring the activity of photon-emitting radionuclides.

OR

For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, and photon-emitting radioactive drugs, state: “We have developed, and will implement and maintain, a written procedure for the performance of dose measurement system checks and tests that meets the requirements in Rule 391-3-17-.02 (11)(i)6.”

AND

If applicable, include a sample calculation for determining low-energy photon-, beta-, and alpha-correction factors for dose calibrators with ionization chambers.

AND

Provide the calculations to demonstrate the ability to accurately dispense low-energy photon-, beta-, and alpha-emitting radionuclides for radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) these materials.

Note: Correction factor calculations are not required if radiopharmacy applicants intend to only redistribute low-energy photon-, beta-, or alpha-emitting radionuclides that were previously prepared and distributed by others who are licensed pursuant to Rule 391-3-17-.02 (11)(i).

OR

If applicable, include a means for ensuring the accuracy of low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer or other entity.

AND

If applicable, include a description of the methodology and equipment to be used for the assay of alpha-emitting radionuclide.

10.4 Procedures for Receiving Shipments Containing Radioactive Material

Licensees must ensure the security and accountability of licensed material. Licensees must track licensed materials from receipt (from another licensee or from its own radionuclide production operations) to disposal in order to ensure accountability at all times; identify when licensed material could be lost, stolen, or misplaced; and ensure that possession limits listed on the license are not exceeded. Licensees exercise control over licensed material accountability by including the following items (as applicable) in their Radiation Protection Program:

- Conducting physical inventories at intervals not to exceed 6 months (or some other interval justified by the applicant and approved by the RMP) to account for all sealed sources, in accordance with license condition;
- Ordering and receiving licensed material;
- Opening packages;
- Maintaining material inventory within license possession limits;
- Transferring material, including distribution; and
- Disposing of material.

10.4.1 Licensing Criteria

The applicant 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.

The applicant must also:

6. Maintain records of receipt, transfer, and disposal of licensed material;
7. Update transactions in the National Source Tracking System (NSTS), including performing annual inventory reconciliation, if applicable;

8. Before transferring aggregated Category 1 or Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37, use NRC's license verification system to verify that the recipient licensee is authorized to possess the radioactive material; and

9. Preplan, coordinate, and provide advance notification of shipment of Category 1 quantities of radioactive material and coordinate shipment of Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37.

A model procedure for ordering and receiving radioactive material is included in Appendix D of this guide.

10.4.2 Applicant Response

No response is required. The applicant must maintain a written program and implement the program at its facility(ies).

10.5 Procedures for Safely Opening Packages Containing Radioactive Material

Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with Rule 391-3-17-.03(12)(f), "Procedures for receiving and opening packages." Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

RMP regulations in Rule 391-3-17-.03(12)(f) states the requirements for monitoring packages containing licensed material. These requirements are described in Table 10.5 below:

Table 10.5 Package Monitoring Requirements

Package	Contents	Survey Type	Survey Time*
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A	Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas or Special Form Greater Than Type A	Contamination and Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than Type A	None	None
Labeled (White I, Yellow II, Yellow III)	Not Gas or Special Form Less Than Type A	Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Not Labeled	Licensed Material	None	None
Damaged	Licensed Material	Contamination and Radiation Level	As soon as practicable, but not later than

*Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has 3 hours after the beginning of the next work day to perform the required surveys.

Under Rule 391-3-17-.03(12)(f), the licensee is required to immediately notify the final delivery carrier and the RMP when removable radioactive surface contamination exceeds the limit in Rule 391-3-17-.06(16)(i); or external radiation levels exceed the limit in Rule 391-3-17-.06(16)(j), "External radiation standards for all packages."

For aggregated Category 1 and Category 2 quantities of radioactive material, licensees must, according to 10 CFR 37.49(a)(1), continuously monitor and detect, without delay, all unauthorized entries into security zones. Additionally, for Category 1 quantities of radioactive material, 10 CFR 37.49(a)(3)(i) requires immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. For Category 2 quantities of radioactive material, 10 CFR 37.49(a)(3)(ii) requires weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

Licensees are required under Rule 391-3-17-.03(11) to secure radioactive materials from unauthorized removal or access while in storage in controlled or unrestricted areas and to control and maintain constant surveillance over licensed material that is in a controlled or unrestricted areas and is not in storage. Applicants should establish policies and procedures for ensuring accountability of licensed materials.

10.5.1 Licensing Criteria

The applicant 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 millirem per hour.

2. That, if the surface dose rate exceeds 200 millirem 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.

A model procedure for safely opening packages containing radioactive material is included in Appendix E of this guide.

10.5.2 Applicant Response

No response is required. The applicant must maintain a written program and implement the program at its facility(ies).

10.6 General Procedures for Safe Use of Radioactive Material

Licensees must do all of the following:

- Keep radiation doses to workers and members of the public ALARA.
- Ensure security of licensed material.
- Make the required notifications of incidents to the RMP.

Licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material, listed in Appendix A to 10 CFR Part 37, must also establish, implement, and maintain its access authorization program; coordinate, to the extent practicable, with local law enforcement authorities, for responding to threats to the

licensee's facility; and be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones.

Licensees are responsible for the security and safe use of all licensed material from the time it arrives or is produced at their facility until its use, transfer, or disposal. Licensees should develop written procedures to ensure safe use of licensed material. The procedures should also include operational and administrative guidelines, as well as procedures to ensure that reports of events are complete and made in a timely manner in accordance with reporting requirements. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers, members of the public, and the environment.

All licensed materials stored in controlled or unrestricted areas must be secured from unauthorized access or removal so that individuals who may not be knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and so that unauthorized individuals cannot access the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material and prevent unauthorized persons from removing the material from the area.

Licensees should develop procedures that clearly state acceptable methods to secure licensed material at a facility. Particular attention may be required at facilities that have unusual needs because of the activities performed, such as hot cells and waste processing facilities.

- General Safety Procedures

The written procedures should include the following elements:

- contamination controls
- waste disposal practices
- personnel and area monitoring (including limits)
- use of protective clothing and equipment
- safe handling of radioactive materials
- recording requirements
- reporting requirements
- responsibilities

These procedures should include policies for:

- frequency of personnel monitoring
- performing Mo-99 breakthrough measurements of each eluate of a Mo-99/Tc-99m
- generator reporting to the RMP and the distributor when there is more than 0.15 kilobecquerel of Mo-99 per megabecquerel of Tc-99m (0.15 microcurie of Mo-99 per millicurie of Tc-99m) in the eluate
- use of personal protective equipment, such as lab coats and frequent glove changes to minimize exposure to the individual and to avoid spread of contamination in the facility
- special procedures for higher risk activities, such as use of radioiodine and repair of chemistry synthesis equipment for PET radiopharmaceuticals
- use of appropriate shielding

- Use of Appropriate Shielding in a Fume Hood

Applicants should also develop radionuclide-specific procedures based on the respective hazards associated with the radionuclides.

Furthermore, applicants that produce radioactive materials using an accelerator should also refer to the safety procedures found in NUREG–1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator."

Licensees must comply with Rule 391-3-17-.03(12), "Precautionary Procedures," as applicable.

10.6.1 Licensing Criteria

The applicant must establish and follow written procedures for the safe use of radioactive material. At 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.

10.6.2 Applicant Response

No response is required. The applicant must maintain a written program and implement the program at its facility(ies). A model program can be found in Appendix F of this guide.

10.7 Spill Procedures

Accidents and emergencies can happen during any operation with radionuclides, including their receipt, transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material and fires involving radioactive material, can adversely affect the safety of personnel and members of the public.

Applicants should develop and implement procedures to minimize, to the extent practical, the potential impact of these incidents on personnel, members of the public, and the environment.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of staff and the RSO. In addition, the licensee should develop procedures for routine contacts with its local fire department officials to inform them of its operations and identify locations of radioactive materials and elevated radiation levels in the event of their response to a fire. Except for minor spills or releases of radioactivity that can be easily controlled and cleaned up by the user, licensee staff should have a clear understanding of their limitations in an emergency with step-by-step instructions and clear direction of whom to contact. The licensee should establish clear delineations between minor contamination events, minor spills, and major spills and events. An example of a minor spill is when low millicurie quantities of material with a short half-life in a nonvolatile liquid spills onto a nonabsorbent surface.

Emergency spill response materials should be strategically placed in well-marked locations for use by all trained staff. All equipment should be periodically inspected for proper operation and replenished as necessary.

10.7.1 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.

10.7.2 Applicant Response

No response is required. The applicant must maintain a written program and implement the program at its facility(ies). A model program can be found in Appendix H of this guide.

10.8 Procedures for Retrieving Radioactive Waste from Customers

Only applicants who will retrieve radioactive waste from their customers need respond to Item 10.8.

Commercial radiopharmacies may receive radioactive waste from customers. This radioactive waste is limited to items that originated at the commercial radiopharmacy and that contained (or contain) radioactive material delivered for customer use (e.g., commercial radiopharmacy-supplied syringes and vials and their contents). It is *not* acceptable for customers to return items originating at their facilities that are contaminated with radioactive material supplied by the commercial radiopharmacy (e.g., gloves, absorbent material, and IV tubing).

Radiopharmacy customers, who act as the shipper for returned materials, should be supplied with detailed written instructions on how to properly prepare and package radioactive waste for return to the radiopharmacy. These instructions should clearly indicate that only items that contained or contain radioactive materials supplied by the radiopharmacy may be returned. In addition, these instructions should be adequate to ensure that customers comply with RMP and DOT regulations for the packaging and transport of licensed materials and for the radiation safety of drivers and couriers. Since customers may return unused syringes and vials, which may contain significant quantities of licensed material, the radiopharmacy should also include in their instructions methods for determining that the activities of radionuclides returned to the pharmacy are "limited quantities." If the packages contain greater than “limited quantities” of radioactive material, the radiopharmacy should provide instructions to customers to prepare and offer packages for transport that meet the RMP and DOT regulations for these packages. The commercial radiopharmacy should also have written instructions for commercial radiopharmacy staff to address pick-up, receipt, and disposal of the returnable radioactive waste.

10.8.1 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.

10.8.2 Applicant Response

Submit the following statement: “We have developed, and will implement and maintain, written procedures for customer return of commercial radiopharmacy-supplied syringes and vials and their contents, to specify that:

Only commercial radiopharmacy-supplied syringes and vials and their contents may be returned to the commercial radiopharmacy.

Instructions will be provided to commercial radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the commercial radiopharmacy.

Instructions will be provided to commercial radiopharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste to ensure compliance with Rule 391-3-17-.03(13)(a) and Rule 391-3-17-.02(8), as applicable."

10.9 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 10.9.

10.9.1 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 NRC Regulatory Guide 8.20, " Applications of Bioassay for Radioiodine."

10.9.2 Applicant Response

In response to Item 10.9 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).

10.10 Area Survey Procedures

Licensees are required to make surveys of potential radiological hazards in their workplace. Records of survey results must be maintained.

Survey is defined as an evaluation of radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. These evaluations may be measurements (e.g., radiation levels measured with a survey instrument, wipe test removable contamination results), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. Licensees should also use surveys to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public. In

certain cases, environmental monitoring may be required to demonstrate compliance with Rule 391-3-17-.03. In order to meet regulatory requirements for surveying, measurements of radioactivity should be understood in terms of its properties (i.e., alpha, beta, and gamma) and compared to the appropriate limits.

Types of surveys

- Contamination
  - -Fixed
  - -Removable
- Air Effluent
- Water Effluent
- Leak Test
- Bioassays
- Air Sample
- General Area
  - -Restricted
  - -Unrestricted

10.10.1 Licensing Criteria

Rule 391-3-17-.03 specify dose limits for unrestricted areas (2 mrem in any 1 hour) and posting requirements (5 mrem in any 1 hour for "Radiation Areas"). Applicants should propose and justify their removable surface contamination and radiation level action levels that will require action to (i) reduce the contamination or radiation level, or (ii) institute additional restrictions on access to the area.

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.

10.10.2 Applicant Response

Submit the following statement: "We have developed and will implement and maintain written procedures for a survey program that includes: (1) performance of radiation and contamination level surveys in restricted and unrestricted areas; (2) personnel contamination monitoring; (3) action levels; (4) survey frequencies; and (5) maintenance of survey records that meet the requirements in Rules 391-3-17.01(6), 391-3-17-.03(8), and 391-3-17-.03(14)(c) as applicable." Additional guidance can be found in Appendix L.

10.11 Leak Tests

The RMP requires testing to determine whether there is any radioactive leakage from the sealed sources. Licensees must maintain records of leak test results in accordance with license conditions or, if applicable, RMP regulations.

10.11.1 Licensing Criteria

When issued, a license will require performance of leak tests of sealed sources at intervals approved by the RMP and as specified in the SSD registration certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 0.005 microcuries [85 Bq] of radioactivity. In accordance with Rule 391-3-17-.03(6), sealed sources that are exempt from leak testing include those that contain 100 μCi (3.7 MBq) or less of beta- or gamma-emitting material or ten μCi (370 kBq) or less of alpha-emitting material, hydrogen-3, and those containing material in gaseous form with a half-life of 30 days or less.

Manufacturers, distributors, consultants, and other organizations may be authorized by the RMP, NRC or another Agreement State to either perform the entire leak test sequence on behalf of licensees or provide leak test kits to licensees. In the latter case, the licensee takes the leak test sample according to the instructions from the manufacturer (or distributor) and the leak test kit supplier. The licensee returns the sample to the leak test service provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. The RMP, NRC or another Agreement State may, in a license condition, specifically authorize commercial radiopharmacy licensees to conduct the entire leak test sequence themselves.

10.11.2 Applicant Response

State either of the following:

"Leak test sample collection and analysis will be performed by an organization authorized by the RMP, NRC or another Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the applicant, using a leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the RMP, NRC or another Agreement State to provide leak testing services."

OR

“Leak test sample collection and analysis will be done by the applicant.” Provide the information noted in Appendix H of NUREG-1556, Volume 13, Revision 2 supporting a request to perform leak test sample collection and sample analysis and either state that, “The applicant will follow the model procedures in Appendix H of NUREG–1556, Volume 13, Revision 2, “Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Commercial Radiopharmacy Licenses”’ or submit alternative procedures.

Note: Requests for authorization to perform leak test sample collection and sample analysis will be reviewed on a case-by-case basis and, if approved, the RMP staff will authorize these activities via a license condition.

10.12 Product Labels

The licensee must label each “transport radiation shield” to show the radiation symbol as described in Rule 391-3-17-.03(12)(a). The label must also include the words “CAUTION, RADIOACTIVE MATERIAL,” or “DANGER, RADIOACTIVE MATERIAL,” the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The phrase “transport radiation shield” refers to the primary shield for the radioactive drug, which may include the syringe, vial, or syringe or vial shield. The “transport radiation shield” should be constructed of material appropriate for the isotope to be transferred for commercial distribution. The “transport radiation shield” does not refer to the outer suitcase, packaging, or other carrying device, even though that barrier may provide some radiation shielding.

The licensee must label each syringe, vial, or other container (e.g., generator or ampoule) used to hold radioactive drugs to be transferred for commercial distribution to show the radiation symbol, as described in Rule 391-3-17-.03(12)(a). The label must include the words “CAUTION, RADIOACTIVE MATERIAL,” or “DANGER, RADIOACTIVE MATERIAL,” and an identifier that ensures the syringe, vial, or other container can be correlated with the information on the “transport radiation shield” label. The identifier must provide a correlation between the syringe, vial, or other container and the information on the label of its “transport radiation shield.” Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

10.12.1 Licensing Criteria

Your product labels must fulfill the color, symbol, and wording requirements of Rule 391-3-17-.03(12)(d) and Rules 391-3-17-.02(11)(i) & (j).

10.12.2 Applicant Response

The applicant must:

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

AND

agree to affix the required labels to all “transport radiation shields” and to each container used to hold the radioactive drugs.

10.13 Product Shielding

The shielding provided for each radioactive drug to be distributed must be adequate for safe handling and storage by the commercial pharmacy’s customers to maintain occupational exposures ALARA.

The applicant must provide appropriate "transport radiation shields" for the primary container of each radioactive drug that it intends to distribute. The shielding must be adequate for the types and quantities of radioactive materials that the applicant intends to distribute. Typically, "transport radiation shields" used by radiopharmacies have included two-piece, shielded syringe, and vial containers (or "pigs"). Pharmacies have used lead and tungsten shields for gamma-emitting materials and Plexiglass inserts for beta-emitters.

"Transport radiation shields" for Tc-99m products generally ensure surface radiation levels of not more than 0.03 mSv/h [3 millirem per hour (mrem/h)], because of the ease of shielding the low-energy gamma emitted. For I-131, surface dose rates on "transport radiation shields" have been approved up to 0.5 mSv/h [50 mrem/h] for diagnostic dosages and up to 1.5 mSv/h
[150 mrem/h] for therapeutic dosages. The applicant should select appropriate shielding materials and dimensions to ensure not only that occupational doses are ALARA, but also that the "transport radiation shield" can be easily handled.

10.13.1 Licensing Criteria

The shielding you provide for each product you wish to distribute must be adequate for safe handling, safe transport, and safe receipt and storage of the product at licensed facilities.

10.13.2 Applicant 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 to state that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the "transport radiation shield."

10.14 Procedures for Packaging and Transporting Radioactive Drugs

Applicants who will prepare for shipment, ship, or transport radioactive materials, including radioactive waste, must develop, implement, and maintain safety programs for the transport of those materials to ensure compliance with RMP and DOT regulations.

In accordance with 10 CFR Part 37 (Subpart D), licensees subject to this regulation must also preplan, coordinate and provide advance notification of the shipment of Category 1 quantities of radioactive material and coordinate the shipment of Category 2 quantities of radioactive material.

10.14.1 Licensing Criteria

The applicant must establish and implement a program that (1) ensures compliance with Rule 391-3-17-.06, which references 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. A shipping document that includes

the information required in 49 CFR Part 172, subpart C must be kept in the passenger section of the vehicle during transport of radioactive material via public roads and highways, and transported materials must be properly packaged, marked, labeled, and secured in accordance with DOT requirements.

The types and quantities of radioactive materials shipped by a commercial radiopharmacy licensee will nearly always meet the criteria for shipment in a "Type A" package, as defined by DOT. The regulations for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation levels and contamination limits. For radiopharmacies that transport their own packages, the packages must be blocked and braced, and shipping papers must be used and located properly in the driver's compartment.

Packaging used by a commercial radiopharmacy typically includes nylon "briefcases" and cardboard/fiberboard boxes. These packages will normally meet the criteria for "Type A" quantities, which must meet specified performance standards to demonstrate that they will maintain the integrity of containment and shielding under normal conditions of transport. Such packages will normally withstand minor accident situations and rough handling conditions.

The testing criteria for Type A packages are listed in 49 CFR 173.465, "Type A packaging tests," and 49 CFR 173.466, "Additional tests for Type A packagings designed for liquids and gases." Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped. In addition, the shipper must maintain records to furnish evidence of the quality of packaging for 3 years after the life of the packaging to which they apply.

The DOT regulations also require that individuals who perform functions related to the packaging and shipment of radioactive material packages receive training specific to those functions. The training must include a general awareness of DOT regulations, function-specific training for the individuals' duties, safety training, and security-awareness training. The DOT regulations also specify the frequency of the training and a record retention requirement for training (49 CFR Part 172, subpart H).

Import and Export of Commercial Radiopharmaceuticals

If radiopharmaceuticals will be procured from a company outside of the U.S. and imported into the U.S., the shipment must be made in accordance with appropriate DOT transportation regulations. In addition, the RMP licensee must also comply with the Federal requirements applicable to importation of radioactive material containing byproduct material in 10 CFR Part 110, including the general license requirements in 10 CFR 110.27 and the advanced notification requirements for certain radioactive material imports in 10 CFR 110.50(c). Likewise, any exports of radiopharmaceuticals must be in compliance with the requirements pertaining to export of radioactive material containing byproduct material in 10 CFR Part 110, including general export license requirements in 10 CFR 110.23 and the advanced notification requirements for certain radioactive material exports in 10 CFR 110.50(c). Also be aware of the list of embargoed and restricted destinations, as stated in 10 CFR 110.28 and 110.29, and ensure that all exports are made under the appropriate general or specific license authority.

10.14.2 Applicant Response

No response is required. The licensee's program for transportation of radioactive materials will be reviewed during inspection.

10.15 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.

10.15.1 Licensing Criteria

Licensees must review the content and implementation of their Radiation Protection Programs annually to ensure the following:

- Compliance with RMP and DOT regulations (as applicable) and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA; and
- Records of audits and other reviews of program content are maintained for 3 years after the record is made.

Licensees that are subject to the requirements in 10 CFR Part 37 must annually review their access authorization program and security program.

10.15.2 Applicant Response

No response is required. The applicant must maintain a written program and implement the program at its facility(ies).

Item 11 Waste Management

11.1 Applicable Georgia Rules

Rule 391-3-17-.03(13)
Rule 391-3-17-.05(40)

Radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, or unusable items contaminated with radioactive material (e.g., absorbent paper, gloves). Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal, unless specifically authorized to do so by the RMP. Commercial radiopharmacies may request authorization to receive certain radioactive waste returned from their customers.

All radioactive waste must be stored in appropriate containers until its disposal, and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. In accordance Rule 391-3-17-.03(13) and Rule 391-3-17-.05(40), the RMP requires commercial radiopharmacy licensees to dispose of radioactive waste generated at their facilities by one or more of the following methods:

- decay-in-storage (DIS)
- transfer to an authorized recipient
- release into sanitary sewerage

11.1 Licensing Criteria

Licensees may choose any one or more of the following methods to dispose of their radioactive waste. An applicant's programs for management and disposal of radioactive waste should include procedures for handling, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Records must be maintained in accordance with the applicable parts of Rule 391-3-17-.03(13).

11.1.1 Decay-in-Storage (DIS)

Materials with half-lives of less than 120 days are appropriate for DIS. If you wish to dispose of radioactive waste by decay in storage, you should establish and follow written procedures for this disposal method. At 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 back¬ground 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.

11.1.2 Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. These are typically radioactive wastes with half-lives greater than or equal to 120 days.

11.1.3 Release Into Sanitary Sewerage

Licensees may dispose of radioactive waste by release into sanitary sewerage if each of the following conditions are met:

- Material is readily soluble (or is readily dispersible biological material) in water.
- Quantity of licensed material or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer does not exceed the concentration specified in 10 CFR Part 20, Appendix B, Table 3.
- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3, cannot exceed unity.
- Total quantity of licensed material and other radioactive material released into the sanitary sewerage system in a year does not exceed the limits specified in Rule 391-3-17-.03(13)(c).

Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are indeed readily dispersible in water. NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," dated January 1994, provides the criteria for evaluating solubility of liquid waste. Careful consideration should be given to the possibility of re-concentration of radionuclides that are released into the sewer. The NRC alerted licensees to the potentially significant problem of re-concentration of radionuclides released to sanitary sewage systems in IN 84-94, "Re-concentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted under 10 CFR 20.303 (now 10 CFR 20.2003)," dated December 1984.

The requirements of Rule 391-3-17-.03(13)(c) are not applicable to releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas subject to Rule 391-3-17-.03(5), "Dose limits for individual members of the public." However, if licensed material is released to a private sewage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludge may be required to be disposed of as radioactive waste, using one of the methods described in this guide.

Applicants should provide procedures that will ensure that all releases of radioactive waste into a public sanitary sewerage, if any, meet the criteria stated in Rule 391-3-17-.03(13)(c), "Disposal by release into sanitary sewerage." Licensees are required to maintain accurate records of all releases of licensed material into sanitary sewerage.

11.2 Applicant Response

Submit the following statement: "We have developed, and will implement and maintain, written procedures for waste management that meet the requirements of Rule 391-3-17-.03(13) as applicable."

AND

If needed, the applicant should request authorization for extended interim storage of waste. The applicant should use the references listed below for guidance and submit the required information with the application. Transfer of waste for offsite disposal must be conducted in accordance with Rule 391-3-17-.03(13(i)...

Item 12 License Fees

Please refer to Rule 391-3-17-.10 for the current fee schedule, fee payment instructions, and requirements for small entity and lower tier classification.

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.

APPENDIX A

RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY AND CERTIFICATION FORMS

MODEL DELEGATION OF AUTHORITY

M E M O R A N D U M

To: All Employees
From: Chief Executive Officer Subject: Delegation of Authority

_____ has been appointed Radiation Safety Officer (or "and _____ have been appointed as Radiation Safety Officers") and is(are) responsible for ensuring the safe use of radiation. The Radiation Safety Officer(s) is(are) responsible for managing the radiation protection program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer(s) is(are) hereby delegated the authority necessary to meet those responsibilities.

The Radiation Safety Officer(s) is(are) also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary.

RADIATION SAFETY OFFICER CERTIFICATION

We certify that the individual(s) to be named on this license to perform the function of Radiation Safety Officer (RSO) will be responsible for implementing the radiation protection program. This individual:

1. Has read and understands the Department regulations applicable to this license and the specific conditions in the license,

2. Has sufficient technical knowledge to perform duties of the RSO;

3. Has and will continue to have sufficient time to perform the duties of the RSO;

4. Has and will continue to get sufficient resources to accomplish the tasks of the RSO;

5. Is completely willing to perform the functions of the RSO; and

6. Has and will continue to receive the support of the management of this licensee in ensuring that all licensed activities will be conducted according to Department regulations and the specific terms of the license.

RADIATION SAFETY OFFICER APPLICANT_____

AREAS OF RESPONSIBILITY IF NOT ALL_____

SIGNATURE AND DATE SIGNED_____

RADIATION SAFETY OFFICER APPLICANT_____

AREAS OF RESPONSIBILITY IF NOT ALL_____

SIGNATURE AND DATE SIGNED_____

CORPORATE OFFICER/CERTIFYING OFFICIAL_____

SIGNATURE AND DATE SIGNED_____

APPENDIX B

MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

The dose calibrator must be checked for accurate operation at the time of installation and periodically after that. The manufacturer's recommendations and instructions or other nationally recognized standards will be followed. The dose calibrator will be tested for constancy, accuracy, linearity, and geometry dependence according to Rule 391-3-17-.05(29), titled "Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials." Reference and calibration sources used will be traceable to the National Institute of Standards and Technology (NIST) or recognized as NIST equivalent according to Rule 391-3-17-.05(29)(b). Record keeping requirements of these tests are described in Rule 391-3-17-.05(29)(d). As part of these requirements the Radiation Safety Officer will review and sign the records for the geometry dependence, linearity, and accuracy tests.

The following procedures will be used to test for constancy, linearity, accuracy and geometry dependence. The tests should be performed at the indicated frequency:

- constancy, at least once each day prior to assay of patient dosages (+/− 10%)
- linearity, at installation and at least annually thereafter (+/− 10%)
- geometry dependence, at installation (+/− 10%)
- accuracy, at installation and at least annually thereafter (+/− 10%)

The dose calibrator will be repaired, replaced, or corrected arithmetically if the dose calibrator falls outside the suggested tolerances. For example, a licensee shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent and shall mathematically correct dosage readings [for dosages greater than 1.11 megabecquerels (MBq) or 30 microcurie (μCi)] if the geometry or linearity error exceeds 10 percent. In addition, after repair, adjustment, or relocation to another building, the dose calibrator tests will be repeated before use.

Constancy means reproducibility in measuring a constant source over a long period of time. At least one relatively long-lived source, such as cesium-137 (Cs-137), cobalt-60, cobalt-57 (Co-57), or radium-226 will be assayed using reproducible geometry each day before using the calibrator. The source activity will normally be in the low millicurie to hundreds of microcuries range. Two sources with different photon energies and activities may also be used to ensure the photon energy range for radionuclides used is covered.

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

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

3. For each source used, record (e.g., plot, log) the activity measured, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the name of the individual who performed the test.

4. Using one of the sources, repeat the above procedure for all commonly used radionuclide settings. Record (e.g., plot, log) the results.

5. Notify the radiation safety officer (RSO) or the authorized user if the test results fall outside +/− 10% of the expected results. For instance, the Cs-137 value should be compared to the reference activity, corrected for decay. Other radionuclides (e.g., Tc-99m) should be compared to the value determined during the last accuracy test, corrected for the reference standard's decay.

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. The linearity of a dose calibrator will be ascertained over the range of its use between the maximum activity administered and 1.11 MBq [30 μCi]. This test will be performed using a vial or syringe of technetium-99m (Tc-99m) or other readily available radionuclide whose activity is at least as large as the maximum activity normally assayed for administration. Tc-99m is routinely used due to its ready availability and lower energy, and therefore lower exposure to licensee personnel, as compared to higher energy radionuclides like those used in Positron Emission Tomography and Iodine-131.

Time Decay Method

1. Assay the Tc-99m syringe or vial in the dose calibrator and subtract background to obtain the next activity in millicuries. Record the date, time to the nearest minute, and net activity on the dose calibrator linearity test form.

2. Repeat the assay at approximately 4-hour intervals during the workday. Continue on subsequent days until the assayed activity is less than 1.11 MBq [30 μCi]. For dose calibrators on which the range is selected with a switch, select the range that would normally be used for the measurement.

3. Convert the time and date information that was recorded to hours elapsed since the first assay.

4. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.

5. Notify the RSO, if the deviation is more than +/− 10%.

Shield Method

“Sleeves” of various thicknesses are used to test for linearity. However, they must first be calibrated. The applicant should review the procedure for calibrating sleeves against the manufacturer’s instructions. Some sleeve manufacturer’s procedures indicate that various sleeves should be stacked to achieve a desired attenuation. The following procedure should be modified to allow for stacking of sleeves:

1. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps 2 through 4 below must be completed within 6 minutes (i.e., approximately 1 percent of decay of Tc-99m).

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

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

4. Continue for all sleeves.

5. Complete the decay method linearity test Steps 2 through 5 above.

6. From the data recorded in step 4 of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the “equivalent decay time” for sleeve 1. Record that time with the data recorded in step 2.

7. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the “equivalent decay time” for sleeve 2. Record that time with the data recorded in step 3.

8. Continue for all sleeves.

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

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

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

2. Steps 3 through 5 below must be completed within 6 minutes.

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

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

5. Continue for all sleeves.

6. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.

7. Notify the RSO if the greatest deviation is more than +/− 10%.

Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence will be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections or administrations, and a vial similar in size, shape, and construction to the generator and radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3 cubic centimeter (cc) plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials and the predetermined safety margin is +/−10%. If 5 cc syringes, 10 cc glass vials, or any other geometric variations are used, the geometry testing will include these.

Note: If these volumes are not used, change the procedure so that the syringes and vials are tested throughout the range of volumes commonly used.

1. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 millicuries (mCi)/milliliter. Set out a second small beaker or vial with water.

2. To test the geometry dependence for a 3 cc syringe, draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and activity (e.g., mCi) indicated.

3. Remove the syringe from the calibrator, draw an additional 0.5 cc of water and assay again. Record the volume and activity indicated.

4. Repeat the process until a 2.0 cc volume has been assayed.

5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen “standard volume.”

6. Record the model number and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.

7. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/− 10% error lines.

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

9. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of water and assay again. Record the volume and activity indicated.

10. Repeat the process until a 19.0 cc volume has been assayed. The entire process must be completed within 10 minutes.

11. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen “standard volume.”

12. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.

13. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/- 10% error lines.

Accuracy means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST.

Certified sources are available from the NIST and from many radionuclide suppliers. At least one source with a principal photon energy between 100 kiloelectron-volts (keV) and 500 keV (e.g., Co-57 or barium-133) will be used. At least one reference source whose activity is within the range of activities normally assayed will be used.

1. Assay a calibrated reference source at the appropriate settings (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record the net activity.

2. The measurement should be within +/− 10% of the certified activity of the reference source, mathematically corrected for decay.

3. Repeat the procedure for any other calibrated reference sources possessed.

4. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the name of the individual who performed the test.

5. Notify the RSO if the test results do not agree, within +/− 10%, with the certified value of the reference source(s).

6. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radionuclide settings.

APPENDIX C

MODEL PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated before first use, annually, and following any repair that will affect the calibration.

1. The source must be approximately a point source.

2. Calibration sources shall be certified to within five percent accuracy by the National Institute of Standards and Technology (NIST).

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

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

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

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

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 20 percent.

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

    a. Meters with a linear scale must be calibrated at no less than two points on each scale. The points should be approximately 1/3 and 2/3 of full scale.
    b. Meters with a multi decade logarithmic scale must be calibrated at least one point at midrange of each decade and at two points on at least one of the decades. Those points should be approximately 1/3 and 2/3 of the decade.
    c. Meters with automatic range digital display device for indicating rates must be calibrated at three points between two and 1,000 mrem (0.02 mSv and 10 mSv.)

9. The apparent exposure rate from a built-in or manufacturer supplied check source must be determined and recorded at the time of calibration.

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

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

    a. The owner or user of the instrument;
    b. Instrument description which includes the manufacturer, model number, serial number and type of detector;

c. Calibration source description which includes the exposure rate at a specific distance on a specific date, and the calibration procedure;
d. The calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument for each calibration point.
e. The "battery check" reading indicated (if available on the instrument);
f. The angle between the radiation flux field and the detector (For external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular". This indicates photons traveling either parallel with or perpendicular to the central axis of the detector. For instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument.);
g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
h. The apparent exposure rate of the check source; and
i. The name of the person who performed the calibration and the date on which the calibration was performed.

12. The following information shall be maintained for each instrument calibrated:

a. A description of the source used and the certified dose rates from the source;
b. Rates indicated by the instrument being calibrated;
c. The correction factor deduced from the calibration data;
d. The signature of the individual who performed the calibration and the date of calibration.

13. One word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

14. The form on Page C-3 is an example of a form that can be used for the Survey Meter Calibration Form and Calibration Sticker.

SURVEY METER CALIBRATION REPORT

Facility

Owner/User:

Department:

Instrument

Manufacturer:

Type: O Ion Chamber O GM O NaI(Tl) O Other (Describe) _____.
Meter Model Number: _____ Serial Number: _____.
Probe Model Number: _____ Serial Number: _____.
Calibration Source: ___mCi of _____. ____mR/hr at___inches on_____, 20__.
Instrument Checks: Battery Check: ____mR/hr or _____.
Constancy Check: integral check source indicates _____ mR/hr.

_____ mCi of _____ indicates _____ mR/hr.

Calibration Geometry:

Window: O Open O Closed O Fixed

Calibration Data

DISTANCE (ft.)	SOURCE (mR/hr)	AS FOUND SCALE READING	SCALE READING	CORRECTION FACTOR

CALIBRATION STICKER

Cal. date _____, 20 _____

Scale Corr. Fac. Bat: _____ mR/hr
_____ _____ Chk: mR/hr
_____ _____
_____ _____

APPENDIX D

MODEL PROCEDURE 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 2 millirem/hour.

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.

APPENDIX E

MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity as defined in Rule 391-3-17-.06(3). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or not later than 3 hours from the beginning of the next working day if it is received after working hours according to Rule 391-3-17-.03(12)(f)3. The licensee shall immediately notify the final delivery carrier and the Department by email, telephone, or facsimile when the removable radioactive surface contamination exceeds the limits of Rule 391-3-17-.06(16)(i) or when the external radiation levels exceed the limits of Rule 391-3-17-.06(16)(j) as required by Rule 391-3-17-.03(12)(f)4.

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

    a. Put on gloves to prevent hand contamination.
    b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
    c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. The “transport index” noted on packages with “Yellow II” or “Yellow III” labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface. The surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with “White I” labels should be less than 0.5 millirem per hour at the package surface.
    d. Open the package with the following precautionary steps:

        (1) Remove the packing slip.
        (2) Open the outer package following the supplier’s instructions if provided.
        (3) Open the inner package and verify that the contents agree with the packing slip.
        (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
        (5) If anything is other than expected, stop and notify the RSO.

    e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. You should specify in the procedure manual which instruments should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. A dose calibrator is not sufficiently sensitive for this measurement. Take precautions against the potential spread of contamination.
    f. Check the user request to ensure that the material received is the material that was ordered.

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

(1) If contaminated, treat this material as radioactive waste.
(2) If not contaminated, remove or obliterate the radiation labels before discarding in- house trash.

h. Make a record of the receipt.

3. For packages received under the general license in Rule 391-3-17-.02(6)(g), the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage. If damage is noted, stop the procedure and notify the RSO.
b. Check to ensure the material received is the material that was ordered.

4. For “empty” transport radiation shields being returned from consortium members, implement the following procedure for opening each package:

a. Monitor the package for radioactive contamination.
b. Visually inspect the contents to ensure that the transport radiation shield is empty. Notify the RSO if the transport radiation shield is not empty.

APPENDIX F

MODEL PROCEDURE FOR SAFE USE OF RADIOPHARMACEUTICALS

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor hands for contamination in a low-background area using an appropriate survey instrument.
- Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
- Wear extremity dosimeters, if required, when handling radioactive material.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Wipe-test unsealed radioactive material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
- Survey with a radiation detection survey meter all areas of licensed material use.
- Store radioactive solutions in shielded containers that are clearly labeled.
- Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled.
- Syringes and unit dosages must be labeled. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in Appendix C to 10 CFR Part 20, the syringe or vial need only be labeled to identify the radioactive drug. To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.
- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the Georgia license (or such individual's designee)

APPENDIX G

MODEL PRODECURE FOR AREA SURVEYS

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys:

- Perform surveys of dose rates in locations where:
  - Workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits; or
  - An individual is working in an environment with a dose rate of 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).

- Section Rule .03(5)(i) requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any 1 hour. Appropriate surveys will be conducted to ensure that the requirements of Rule .03(5)(i) are met.

- Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour in the following areas, at the frequency specified:
  - Survey at the end of each day of use all radiopharmaceutical elution, preparation, and assay areas .
  - Survey weekly all radionuclide use, storage, and waste storage areas.
  - Survey quarterly all sealed-source and brachytherapy-source storage areas.

- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for restricted and unrestricted areas are presented in Table G.1.

Table G.1 Ambient Dose Rate Trigger Levels

Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

Contamination Surveys

Facilities and equipment for contamination surveys:

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Procedures for contamination surveys:

- Contamination surveys are performed in areas where unsealed forms of materials are used:To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- After any spill or contamination event;
- When procedures or processes have changed;
- To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly; and
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.
- Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in Tables G.2 for restricted areas and G.3 for unrestricted areas (e.g., 200 dpm/100 cm^2 for isotopes of iodine-131 in unrestricted areas). Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:
    - Removable contamination surveys weekly for radiopharmaceutical elution, preparation, and assay areas.
    - Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.
- A radioactive source with a known amount of activity should be used to convert sample measurements (usually in cpm) to dpm.
- The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for restricted areas are presented in Table G.2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

Table G.2 Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)

Area, clothing	alpha emitters	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted areas, protective clothing used only in restricted areas	200	2000	20000

Table G.3 Surface Contamination Levels in Unrestricted Areas (dpm/100 cm^2)			
Nuclide[1]	**Average[2, 3, 6]**	**Maximum[2, 4, 6]**	**Removable[2, 5, 6]**
I-125, I-126, I-131, I-133, Sr-90	1000	3000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5000	15000	1000
Ra-226	100	300	20

1 Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.

2 As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

3 Measurements of average contaminants should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

4 The maximum contamination level applies to an area of not more than 100 cm^2.

5 The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

6 The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 centimeter and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

Establishing Alternate Trigger Levels for Restricted Areas

The following guidance is provided for those applicants who plan to develop procedures for surveying and controlling contamination using action levels for controlling contamination that differ from those provided in Tables G.1 and G.2:

Alternate action levels for cleanup of contamination in restricted areas may be developed without prior NRC approval if:

- acceptable unrestricted area trigger levels are implemented (e.g., Tables G.1 and G.3);
- the action levels maintain occupational doses ALARA; and
- the action levels meet all other regulatory requirements (e.g., they should also be designed to minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste).

Alternate Survey Frequency

A sample alternate survey frequency is described below using Tables G.4, G.5, and G.6. The objective is to determine how often to survey the laboratory. To do this, multiply the activity range for the appropriate group under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency. For instance, if 30 millicuries of iodine-131 is used in the hot laboratory, the survey frequency for the hot laboratory would be daily; since the group for iodine-131 is Group 2, the survey frequency category for an activity of greater than 10 millicuries is high, and the modifying factor is 1.

Table G.4 Isotope Groups	
Group 1	Pb-210 Po-210 Ra-223 Ra-226 Ra-228 Ac-227 Th-230 Pa-231 Pu-238 Am-241 Am-243 Cm-242 Cm-243 Cm-244 Cm-245 Cm-246 Cf-249 Cf-250 Cf-252 Ra-226
Group 2	Na-22 Cl-36 Ca-45 Sc-46 Mn-54 Co-56 Co-60 Sr-89 Sr-90 Y-91 Zr-95 Ru-106 Ag-110m Cd-115m In-114m Sb-124 Sb-125 Te-127m Te-129m I-124 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Ba-140 Ce-144 Eu-152 (13 y) Eu-154 Tb-160 Tm-170 Hf-181 Ta-182 Ir-192 Tl-204 Bi-207 Bi-210 At-211 Pb-212 Ra-224 Ac-228 Pa-230
Group 3	Be-7 C-14 F-18 Na-24 C1-38 Si-31 P-32 S-35 Ar-41 K-42 K-43 Ca-47 Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55 Fe-59 Co-57 Co-58 Ni-63 Ni-65 Cu-64 Zn-65 Zn-69m Ga-72 As-73 As-74 As-76 As-77 Se-75 Br-82 Kr-85m Kr-87 Rb-86 Sr-85 Sr-91 Y-90 Y-92 Y-93 Zr-97 Nb-93m Nb-95 Mo-99 Tc-96 Tc-97m Tc-97 Tc-99 Ru-97 Ru-103 Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111 Cd-109 Cd-115 In-115m Sn-113 Sn-125 Sb-122 Te-125m Te-127 Te-129 Te-31m Te-132 I-130 I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-31 La-140 Ce-141 Ce-143 Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149 Sm-151 Sm-153 Eu-152 Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166 Er-169 Er-171 (9.2 hr) Tm-171 Yb-175 Lu-177 W-181 W-185 W-187 Re-183 Re-186 Re-188 Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-l91 Pt-193 Pt-197 Au-196 Au-198 Au-l99 Hg-197 Hg-197m Hg-203 Tl-200 Tl-201 Tl-202 Pb-203 Bi-206 Bi-212 Rn-220 Rn-222
Group 4	H-3 O-15 Ar-37 Co-58m Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87 Y-9lm Zr-93 Nb-97 Tc-96m Tc-99m Rh-103m In-113m I-129 Xe-131m Xe-133 Cs-134m Cs-135 Sm-147 Re-187 Os-191m Pt-193m Pt-197m

Table G.5 Classification of Laboratories for Alternate Survey Frequency			
	Survey Frequency Category		
Group	**Low**	**Medium**	**High**
1	<0.1 mCi	0.1 mCi to 1 mCi	>1 mCi
2	<1 mCi	1 mCi to 10 mCi	>10 mCi
3	<100 mCi	100 mCi to 1 Ci	>1 Ci
4	<10 Ci	10 Ci to 100 Ci	>100 Ci

Survey Frequency:

- Low – Not less than once a month;
- Medium – Not less than once per week;
- High – Not less than once per normal working day. Proportional fractions are to be used for more than one isotope.

Table G.6 Modifying Factors for Alternate Survey Frequency	
Modifying Factors	**Factors**
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of nonoccupational persons (including patients)	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

Contents of Survey Records

- A diagram of the area surveyed,
- A list of items and equipment surveyed,
- Specific locations on the survey diagram where wipe tests were taken,
- Ambient radiation levels with appropriate units,
- Contamination levels with appropriate units,
- Make and model number of instruments used,
- Background levels, and
- Name of the person making the evaluation and recording the results and date.

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. Include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

APPENDIX H

MODEL PROCEDURE FOR SPILL CONTROL

The decision to implement a major spill control procedure instead of a minor spill control procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill control procedure may be to restrict access pending complete decay. In the event all contamination has been removed except fixed contaminants, the area may be put back into use if the fixed contamination is less than 2 millirem/hour at the surface.

FORMS

You may want to use Radioactive Spill Report and Radioactive Spill Contamination Survey Forms on Pages H-4 and H-5 of this appendix.

SPILL KIT

You may also want to consider assembling a spill kit that contains:
6 pairs disposable gloves, 1 pair housekeeping gloves
2 disposable lab coats 2
paper hats
2 pairs shoe covers
1 roll absorbent paper with plastic backing 6
plastic trash bags with twist ties “Radioactive
Material” labeling tape
1 china pencil or marking pen
3 prestrung “Radioactive Material” labeling tags
Supplies for 10 contamination wipe samples
Instructions for “Emergency Procedures”
Clipboard with one copy of Radioactive Spill Report Form Pencil

MODEL PROCEDURES

MINOR SPILLS OF LIQUIDS AND SOLIDS:

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves, remote handling tongs, and absorbent paper. Carefully fold the absorbent paper and pad with the clean side out. Place into a plastic bag and dispose of in the radioactive waste container. Also put all other contaminated, disposable materials into the bag.
4. Survey the area with a low range radiation detection survey meter with a thin end window. Check the area around the spill, hands, clothing, and shoes for contamination.
5. Report the incident to the Radiation Safety Officer (RSO).
6. The RSO will follow up on the clean-up of the spill and will complete the Radioactive Spill Report (page **I**-4) and the Radioactive Spill Contamination Survey (Page **I**-5).

MAJOR SPILLS OF LIQUIDS AND SOLIDS:

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. Limit the movement of all personnel potentially contaminated to prevent the spread of contamination.
3. Shield the source if possible. This should be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contaminant remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

The decision to implement a major spill/contamination procedure instead of a minor spill/contamination procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated, and radiotoxicity of the spilled material.

RADIOACTIVE SPILL REPORT

The spill occurred at_____am/pm on_____in room _____
(time) (date) (location)

Instrument used to check for personnel contamination:

Meter Model:_____Meter S/N:_____Probe Model:_____Probe S/N: _____

PERSONNEL PRESENT	PERSONNEL CONTAMINATION RESULTS*

* On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a post cleaning contamination wipe test.

RADIOISOTOPES PRESENT OR SUSPECTED IN THE SPILL

Millicuries	Isotope	Form

GIVE A BRIEF DESCRIPTION OF THE ACCIDENT:

GIVE A BRIEF DESCRIPTION OF FOLLOW UP ACTIONS TAKEN TO PREVENT RECURRENCE:

NAME_____ DATE_____

RADIOACTIVE SPILL CONTAMINATION SURVEY

The spill occurred at_____ am/pm on____ in room_____.
(time) (date) (location)

Decontamination completed at_____ am/pm on_____.
(time) (date)

Location	Preclean	Post Clean		Location	Preclean	Post Clean	
	mR/hr	mR/hr	dpm/100cm^2		mR/hr	mR/hr	dpm/100cm^2

dpm = cpm/instrument efficiency

SKETCH OF CONTAMINATED AREA:

NAME:_____ DATE:_____