STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

REGULATORY GUIDE

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Revision 5

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GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL USE PROGRAMS

Regulatory Guides are issued to describe and make available to the public acceptable methods of implementing specific parts of STATE OF FLORIDA CONTROL OF RADIATION HAZARD REGULATIONS, to delineate techniques used by the staff in evaluating specific problems or postulating accidents, or to provide guidance to applicants or licensees. Regulatory Guides are not a substitute for regulations and compliance with them is not required unless specifically referenced in a Radioactive Materials License. Methods or solutions different from those set forth in the guides will be acceptable if they provide a basis for the Bureau of Radiation Control to make necessary determinations to issue, renew, amend, or terminate a license, or to establish standards of protection.

Guides are issued in the following six (6) broad categories.

1) License Application Guides
2) Inspection and Enforcement
3) General Health Physics
4.) Radioactive Waste
5) Transportation
6) General

Written comments and suggestions for improvements to these Regulatory Guides are encouraged at all times. Guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments, or requests for single copies or issued guides (which may be reproduced) should be sent to: Department of Health, Bureau of Radiation Control, Radioactive Materials Section, Bin C21, 4052 Bald Cypress Way, Bin C21, Tallahassee, FL 32399-1741.

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MEDICAL APPLICATION

Enclosure A

Fees*

The categories are:

Category	Description	Application Fee	Annual Fee	Reclamation Fee	Annual and Reclamation Fee
5A(I)	Teletherapy or gamma stereotactic radiosurgery including gamma knife devices	$1,838	$1,791	$89.55	$1,880.55
5A(II)	High dose rate remote afterloading devices	$1,697	$1,654	$82.70	$1,736.70
5A(III)	High dose rate remote afterloading devices and gamma stereotactic radiosurgery including gamma knife devices or teletherapy devices	$1,838	$1,791	$89.55	$1,880.55
5B	Medical Institutions, including hospitals, except categories 5A(I), 5A(II), 5A(III), 5E, 5F(I), and 5F(II)	$1,972	$2,290	$114.50	$2,404.50
5C	Private practice physicians except categories 5A(I), 5A(II), 5A(III), 5E, 5F(I), and 5F(II)	$1,421	$1,608	$80.40	$1,688.40
5D	Private practice physicians using only strontium 90 eye applications, materials authorized by 64E-5.631, F.A.C., and materials authorized by 64E-5.630, F.A.C.	$726	$898	$44.90	$942.90
5E	Nuclear powered pacemakers	$521	$319	$15.95	$334.95
5F(I)	Mobile Nuclear Medicine Services	$1,697	$1,950	$97.50	$2047.50
5F(II)	Mobile high dose rate remote afterloading therapy device when the treatment is only performed on the mobile vehicle	$2,970	$3,308	$165.40	$3473.40

*Fees are subject to change and may be found in section, 64E-5.204 F.A.C.

Effective August, 2007

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I. INTRODUCTION

The Department of Health (department), Bureau of Radiation Control, regulates the use of radioactive material administered to human beings. Medical use of radioactive materials requires a specific license. The regulations governing medical use are contained in Chapter 64E-5, Florida Administrative Code (F.A.C.), Part VI, "Use of Radionuclides in the Healing Arts."

The department issues a single radioactive material license to cover an entire radionuclides program except for teletherapy, high dose rate remote afterloaders, gammaknifes, nuclear-powered pacemakers, and irradiators. A license is issued to one facility, though the license may cover different departments within the hospital or different individuals employed or contracted with the hospital.

PURPOSE OF GUIDE

This guide is designed to describe the type and extent of information needed by the department to evaluate an application for a medical use license. This regulatory guide identifies the information needed to complete Department of Health, Form DH-1322 when applying for a license for a medical use program. This guide does not apply to generally licensed material or academic programs that do not use radioactive material for medical use.

TYPES OF LICENSES

The department issues three types of licenses for the use of radioactive material in the practice of medicine, as described below. This guide is only for persons who want to apply for a specific medical use license. However, persons who are applying for other types of licenses may find the information in this guide useful in designing their radiation safety program.

1. General License

Subsection 64E-5.206(8), F.A.C., "General Licenses for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing" establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use certain small quantities of radioactive material for in-vitro clinical or laboratory tests. This section explains the requirements for using these materials. If the general license alone meets the applicant's needs, only Department of Health, Form DH-360, " Certificate - In Vitro Testing With Radioactive Material Under General License," needs to be filed. Specific licensees do not need to file this form.

2. Specific License

Specific licenses issued to medical institutions authorize radioactive material for medical uses by physicians named on the license. The regulations require a medical institution licensee to have a radiation safety committee (RSC) to oversee the use of licensed material throughout the facility and to review the radiation safety program. The physicians named on the institution's license conduct their use of radioactive materials with the approval of the RSC. Specific licenses issued to outpatient facilities or individual physicians in private practice are commonly limited to physicians who are located in private offices. A radiation safety committee may be required. Methods of use that require hospitalization of the patient are not permitted for outpatient facilities or private offices.

3. Specific License of Broad Scope

Some medical institutions provide patient care and conduct research programs that use radionuclides for in-vitro, animal, and medical procedures. The department may issue a specific license of broad scope as discussed in section 64E-5.209, F.A.C., "Specific Requirements for a Specific License of Broad Scope." Specific licenses of broad scope for medical use may be issued to institutions that (1) have had previous experience operating under a specific institutional license of limited scope, and (2) are engaged in medical research as well as routine diagnosis and therapy using radionuclides. This type of license is not appropriate for most institutions performing routine procedures with radioactive materials.

APPENDICES, EXHIBITS AND SUPPLEMENTS

Applicants must acquire and maintain appropriate facilities and equipment, have appropriately trained workers, and implement procedures that ensure compliance with regulatory requirements. This guide provides a set of appendices, exhibits and supplements to assist in the development of a radiation protection program.

- **Appendices** are model procedures that may be used to address regulatory requirements.
- **Exhibits** are samples of the types of documents or forms that must be submitted as part of the application, and in some cases, are model forms that may be used to satisfy regulatory requirements.
- **Supplements** include resources for preparing the application and additional resources and reference material.

Model procedures and forms may be adopted by submitting them as part of the license application, or may be used as guides for developing equivalent procedures and forms. Carefully review the regulations, model procedures and forms before deciding if the models are appropriate for the activities being requested.

IMPORTANT NOTICE:

The information provided in a license application must demonstrate that proposed equipment, facilities, personnel and procedures are adequate to protect public health and property in accordance with regulatory requirements. Submission of incomplete or inadequate information will result in delays in the license approval process. Additional information will be requested when necessary to ensure that an adequate radiation protection program has been established. Such requests will delay completion of the application review, and may be minimized by a thorough study of the regulations and this guide prior to submitting the application.

While adoption of the attached model procedures and forms should provide for a radiation protection program that complies with regulatory requirements, applicants may need to consider additional equipment, procedures and training that may be appropriate for the scope of their operations.

APPLICABLE REGULATIONS

Florida is an Agreement State; it has an agreement with the U.S. Nuclear Regulatory Commission (NRC) to assume regulatory authority over most activities involving radioactive material within the state. With certain exceptions, the Department of Health (department), Bureau of Radiation Control (bureau) regulates the possession and use of radioactive material within Florida. Exceptions include nuclear power plants and federal agencies, and national security issues involving radioactive material, which remain under NRC jurisdiction.

Under authority of Chapter 404, Florida Statutes (the Florida Radiation Protection Act), the bureau issues licenses to users of radioactive material and performs inspections to ensure safe operations and compliance with Chapter 64E-5, Florida Administrative Code (F.A.C.), the department's radiation control regulations. Chapter 64E-5, F.A.C., is available on the Internet at http://www.floridahealth.gov/prevention-safety-and-wellness/radiation-control/radmat/index.html. The bureau amends these regulations periodically. Licensees are notified of changes as they occur. When applicable, licensees will need to revise their safety programs to address changes in regulatory requirements.

The following portions of the regulations are applicable to the use of radioactive material in the form of sealed sources in portable devices and should be used in conjunction with these instructions:

Part I "General Provisions"

Part II "Licensing of Radioactive Materials"

Part III "Standards for Protection Against Radiation"

Part IX "Notices, Instructions and Reports to Workers; Inspections"

Part XIII "Radiation Safety Requirements for Possession and Use of Sealed or Unsealed Sources of Radioactive Materials"

Part XV "Transportation of Radioactive Materials"

Licensees engaging in transportation of radioactive materials or related activities are also subject to U.S. Department of Transportation (DOT) regulations, which are found in Title 49, Code of Federal Regulations (49 CFR), and are incorporated into Chapter 64E-5 by reference. DOT regulations are available on the Internet at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1 and can be ordered from the U.S. Government Printing Office by calling (866) 512-1800 or writing P.O. Box 37954, Pittsburg, PA 15250-7954, Attn: Superintendent of Documents.

LICENSE REQUIREMENTS AND RESTRICTIONS

Licensees are required to confine use and possession of radioactive material to the locations and purposes authorized by the license. The license is divided into two sections: **Items** and **Conditions**, which are described on the following page. The first section of the license lists Items 1 - 9. The remainder of the document lists the license conditions, which may vary in number based on the authorizations provided by the license, but always begin with Condition 10.

License Items

Item No. and Title	Description
1. Name	Lists the legal name of the licensee (individual or business). If the license is issued to a business, Item 1 must list the company's name as it is registered with the Florida Department of State, Division of Corporations; 850-245-6052 or http://www.sunbiz.org. If a business operates under another name, Item 1 must list both the registered name and the fictitious name it is doing business as (d/b/a).
2. Address	Lists the mailing address, which may be different from the physical address where records and material are used and stored. If the two addresses are different, the physical address must be listed in Condition 10; if they are the same, Condition 10 will reference the address listed in Item 2.
3. License Number	Lists the number assigned to the license by the bureau. The number should be referenced in all license-related correspondence.
4. Expiration Date	Lists the date the license is due to expire. A radioactive materials license is valid for 5 years from the date issued. A renewal application must be received by the bureau at least 30 days prior to the expiration date to ensure that the license remains valid. The bureau sends out reminder notices as the license nears its expiration date.
5. Category	Lists the license category: e.g. 5A (II), 5B, 5C. Activities involving possession and use of radioactive materials are divided into license categories. Organizations seeking to conduct more than one category of licensed activity must obtain separate licenses for each category of use. Refer to section 64E-5.204, F.A.C., or Regulatory Guide 6.20, Revision 5, for a complete listing of license types and fees at http://www.floridahealth.gov/prevention-safety-and-wellness/radiation-control/radmat/matform.html.
6. Radioactive Material	Describes the type (element and mass number) of radioactive material the license authorizes for possession and use.
7. Form	Describes the form of radioactive material the license authorizes for possession and use.
8. Possession Limit	Lists the maximum possession limit for radioactive sources. In order to accommodate future business growth, a licensee may request authorization for a possession limit higher than the number of sources initially being obtained. Possession of more sources than authorized is a license violation and may result in enforcement actions.
9. Use	Describes the types of uses that are approved for the sources and devices listed in the previous items. Improper use of radioactive material is a license violation and may result in enforcement actions.

License conditions describe requirements and limitations applicable to the radioactive materials authorized by the license. Additional requirements and conditions may be incorporated as appropriate to protect public health and the environment. If a licensee seeks added authorizations, supplementary license conditions may be added.

II. FILING AN APPLICATION

Chapter 64E-5, F.A.C., this guide, forms, and other guidance documents are available on the bureau's website: http://www.floridahealth.gov/prevention-safety-and-wellness/radiation-control/index.html.

Applicants for a materials license must complete Items 1 through 35 of the department's form DH-1322, "Application for a Radioactive Materials License, Human Use." Use supplemental sheets as necessary. For Items 7 through 34, be sure to check the appropriate box for each item. 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 8.5 x 11 inch paper to facilitate handling and review.

All application items must be addressed in sufficient detail to demonstrate that equipment, facilities, personnel qualifications and procedures are adequate to protect public health and safety or property. Complete and submit the table provided as Supplement B to this guide to indicate whether model or equivalent procedures and forms have been included in the application.

Mail to:	If using an overnight delivery service, use:
Florida Department of Health Bureau of Radiation Control Radioactive Materials Program 4052 Bald Cypress Way, Bin C21 Tallahassee, FL 32399-1741	Florida Department of Health Bureau of Radiation Control Radioactive Materials Program 4042 Bald Cypress Way, Rm. 220.09 Tallahassee, FL 32399

With the exception of security-related information, all license applications and documents submitted to the bureau are available for review by the general public. Do not submit proprietary information unless it is absolutely necessary for evaluation of the application. Any request for withholding documents is subject to a determination by the department as to whether the document may actually be withheld in accordance with applicable laws and regulations.

Personal information about employees should not be submitted unless it is necessary. Home addresses, home telephone numbers, dates of birth, and social security numbers should not be submitted unless the bureau specifically requests it.

When issued, the license will require that radioactive material be possessed and used in accordance with statements, representations and procedures provided in the application and supporting documentation (which are incorporated by referenced into the license). Regulatory requirements specified in Chapter 64E-5, F.A.C., shall govern unless the statements, representations and procedures set forth in the license application and correspondence are more restrictive than the regulations.

LICENSE FEES

The following fees are assessed:

Application fee — A non-refundable fee for processing the license application. The amount is dependent on the category of license the applicant is seeking; refer to section 64E-5.204, F.A.C., or Regulatory Guide 6.20 for a description of application fees. Review of the application will not begin until the proper fee is received by the department. An application fee is also required to process an application for a new license replacing an existing license due to a change of ownership.

Annual fee — An annual fee covers department costs for administration of the materials licensing program. The amount is dependent on the license category. Refer to section 64E-5.204, F.A.C., or Regulatory Guide 6.20 for a description of annual fees. Annual fees are due within 60 days of issuance of the new license; an invoice for this fee is included with the cover letter accompanying a new license.

Reclamation fee — In addition to the application and annual fees, a reclamation fee will be assessed for the Radiation Protection Trust Fund, established to pay department costs associated with a licensee's abandonment of radioactive materials, default on lawful obligations, insolvency, or other inability to meet regulatory requirements, and to assure the protection of the public and environment. Reclamation fees are equal to 5% of the annual fee. Reclamation fees are due within 60 days of issuance of a new license; a fee invoice is included with the cover letter accompanying a new license.

Notes:

1. Annual and reclamation fees are assessed on the anniversary of the license issuance date. An invoice is sent to the licensee 60 days in advance of the due date.

2. Fees are not assessed for license renewals, amendment requests, licensing actions, inspections initiated by the department, license terminations, or requests for regulatory information (except for document copying costs).

III. CONTENTS OF AN APPLICATION

ITEM 1.a. NAME AND MAILING ADDRESS OF APPLICANT

Enter the legal name, mailing address, telephone number and fax number of the applicant for ownership of the license. An individual should be designated as the applicant only if they are acting in a private capacity and the use of the radioactive material is not connected with their employment with a corporation or other legal entity. Otherwise, the applicant should be the corporation or other legal entity applying for the license. The bureau verifies the legal status of corporations, partnerships and fictitious names with the Department of State, Division of Corporations. Their phone number is (850) 488-9000. Their web-site is www.sunbiz.org.

ITEM 1.b STREET ADDRESS WHERE RADIOACTIVE MATERIAL WILL BE USED.

List the address and location(s) where radioactive material will be used or stored if other than the address stated in Item 1.a. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use. Separate locations may require separate specific licenses.

ITEM 2.a. and b. LICENSE CATEGORY AND FEE

The application fee for a new license must be submitted with the application. Failure to submit the application fee will delay the review of the application. The annual and reclamation fees are due within 60 days after the license is issued. There is no fee required when applying for subsequent amendments, renewals or inspections concerning the license. The appropriate category and fees are listed in Enclosure A or may be found in section 64E-5.204, F.A.C. Make checks payable to the Bureau of Radiation Control.

ITEM 3 THIS IS AN APPLICATION FOR:

Identify if the application is for renewal or new license. Form DH-1322 may be submitted but is not required for an amendment request.

ITEM 4 INDIVIDUAL USERS (AUTHORIZED USERS)

Provide a separate attachment listing the full names of all physicians and authorized medical physicists who may receive, possess, prepare, use or transfer radioactive materials or directly supervise others in these activities. These are the physicians and authorized medical physicists who use radioactive material directly or who are direct supervisors of physicians in training, technologists or other ancillary personnel to whom specific activities are delegated. Physicians and authorized medical physicists must be professionally licensed by the department's Division of Medical Quality Assurance.

A medical licensee can provide a means of preceptoring physicians, not listed on a license, to obtain clinical training and experience that will qualify them as authorized users according to 64E-5.608, F.A.C.

If a physician or therapeutic radiological physicist has been specifically named as an authorized user for medical use and wants to use material permitted by the other license, submit the license number of the other license if issued by the department or a copy of the entire license if issued by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The physician or therapeutic radiological physicist must be identified on a license within the last 7 years or have completed appropriate documented continuing education.

If a physician is certified by an organization listed in the appropriate section of Part VI of Chapter 64E-5, F.A.C., submit a copy of the certification. If a physician seeks authorization other than what is defined by their certification then submit a preceptor/ applicant statement.

Physicians or authorized medical physicists not previously authorized by a radioactive materials license and not certified by a preceptor/applicant appropriate organization must submit a complete description of their training and experience. Regulatory Guide 3.50, Preceptor Attestation for Medical Authorized Users can be accessed at http://www.floridahealth.gov/prevention-safety-and-wellness/radiation-control/radmat/matform.html. The documentation will be evaluated for approval, if it demonstrates training and experience consistent with the requirements listed in Part VI of Chapter 64E-5, F.A.C. This training must have been received within the last seven years or the physician must have completed appropriate documented continuing education.

ITEM 5.a. RADIATION SAFETY OFFICER (RSO)

State the name and title of the person designated by, and responsible to, the applicant's management as the RSO. If the RSO is not one of the proposed authorized users or authorized medical physicists, submit a complete description of the individual's training and experience pursuant to 64E-5.648, F.A.C., using a preceptor/applicant statement.
The RSO must agree in writing to be the RSO.

In accordance with subsection 64E-5.213(7), F.A.C., our agency will be notified in writing within 30 days of a change of radiation safety officer (RSO). Such notifications should include documentation of the new RSO's qualifications for the position.

ITEM 5.b. ALTERNATE EMERGENCY CONTACT

During emergencies or after disasters such as hurricanes, the bureau contacts licensees to determine their status or convey important information. Sometimes the radiation safety officer is unavailable and the bureau needs to contact someone else who is familiar with the activities under the radioactive materials license. Therefore, the bureau requests the name and contact information of an individual, other than the RSO, who may be contacted for information. Because communications may be disrupted during or after an emergency, we are requesting several methods to communicate with this individual when possible.

ITEM 6.a RADIOACTIVE MATERIAL FOR MEDICAL USE

Check the items requested. Diagnostic procedures (64E-5.626 and 64E-5.627, F.A.C.) are separated according to written directive required or no written directive required. All therapy procedures (64E-5.630, 64E-5.632, and 64E-5.634, F.A.C.) require a written directive. Teletherapy, HDR, Gammaknife, and "Other Medical Uses Not Listed" require a separate license. Indicate only the types of use requested. For xenon 133 gas and technetium 99m aerosol, indicate the total amount of millicuries (mCi). If you will be using liquid radioiodine for therapy under 64E-5.630, F.A.C., include Appendix U (Bioassay Program).

ITEM 6.b RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a.

Each line entry must identify the radionuclide, the physical form, maximum amount possessed in mCi, and the purpose for which the material will be used. Additionally, make a separate line entry if selecting; a greater than 30 mCi calibration, reference or transmission source, and any other types of generators besides technetium 99m generators. For each eye applicator and sealed source for diagnosis, list each radionuclide, the physical form, maximum activity in mCi, the number of sources and the make and model number of the sealed source and device to be used.

ITEM 7 FACILITIES AND EQUIPMENT

Describe the available facilities and equipment (e.g., remote handling equipment, leaded glass L-block and shield, storage containers, shielding, and fume hoods) at each location where radioactive material will be used or stored. Include a description of the areas assigned for receipt, storage (including waste), preparation and measurement of radioactive material.
If utilizing a mobile coach, include a diagram of the coach in addition to the permanent facility.

Submit an annotated drawing of the rooms and adjacent areas where radioactive material will be used. See Exhibit 1 for an example. Indicate the following:

1. The direction of north;
2. Room numbers and principal use of each room or area;
3. Restricted and unrestricted areas;
4. Any shielding available; and
5. Additional safety equipment (e.g., fume hoods, L-block, or fixed area monitors).

If using xenon 133 gas, a licensee shall only administer radioactive gases in rooms that are at negative air pressure compared to surrounding rooms according to 64E-5.629 (3), F.A.C.
See the enclosed copy of Exhibit 2 for an example. Indicate the following:

6. The location and measured capacity of each air intake and exhaust opening;
7. The location of the radioactive gas storage and imaging room;
8. The dimensions of the rooms; and
9. The distances between the exhaust port and all air intakes, windows, doors or obstructions to air flow.

ITEMS 8 THROUGH 34 MODEL PROCEDURES

Submit a copy of each model procedure being adopted or submit an equivalent procedure. Complete the application by marking the appropriate box for each procedure.
NOTE: High Dose Rate (HDR) Remote Afterloaders, Gamma Stereotactic Radiosurgery (Gamma Knife), Sir-Spheres, and Theraspheres require additional model procedures not listed in this guide. You may access our web-site at http://www.floridahealth.gov/prevention-safety-and-wellness/radiation-control/radmat/matform.html for guidelines.

ITEM 35 CERTIFICATE

The application must be signed and dated by a certifying official. A certifying official is an individual authorized to make legally binding statements for the licensee such as the president, vice president, chief executive officer, or principal/owner. Any statement of commitment made in the application must be followed.

IV. LICENSE AMENDMENTS

Licensees are required to conduct operations in accordance with applicable regulations and the statements, representations and procedures contained in the license application and supporting documents. The license must be amended if any changes are planned. Submittal of an amendment request does not allow immediate implementation of proposed changes. Until the license has been amended to reflect approval of the change(s), the licensee must comply with the original terms and conditions of the license. Applications for license amendments may be filed in letter form or on Form DH-1322, "Application For Radioactive Materials License, Human Use." The request must be dated and signed by a certifying official to include the original and one copy, identify the license by name and number, clearly describe the nature of the changes, additions or deletions requested and be submitted to the address specified in Section II of this guide. Attach all supporting documentation, including facility diagrams, survey measurements, dosimetry data and calculations. References to previously submitted documents must be specific and identify the applicable information by date, page and paragraph. The licensee must maintain a copy of the submitted and referenced documentation on file for inspection.

V. LICENSE RENEWAL

Absent any actions by the department or the licensee, a license remains in effect for five years. An application for license renewal must be received by the department at least 30 days prior to the expiration date. Mail the original and one copy to the department. This filing will ensure that the license does not expire until final action on the application has been taken, as provided for by subsection 64E-5.207(3), F.A.C. If the application is received less than 30 days before the expiration date, the facility or individual may be without a valid license when the license expires. Renewal applications should be filed using Form DH 1322, "Application For Radioactive Materials License, Human Use." The renewal application should be completed as if it were an application for a new license, with complete and up-to-date information about the applicant's radiation protection program, demonstrating compliance with all licensing and regulatory requirements in effect at the time of renewal. Renewal applications should be submitted without reference to documentation and information submitted previously. Eligible participants in the department's program, which is described in Information Notice 2007-04, may submit a renewal attestation/application in lieu of the above.

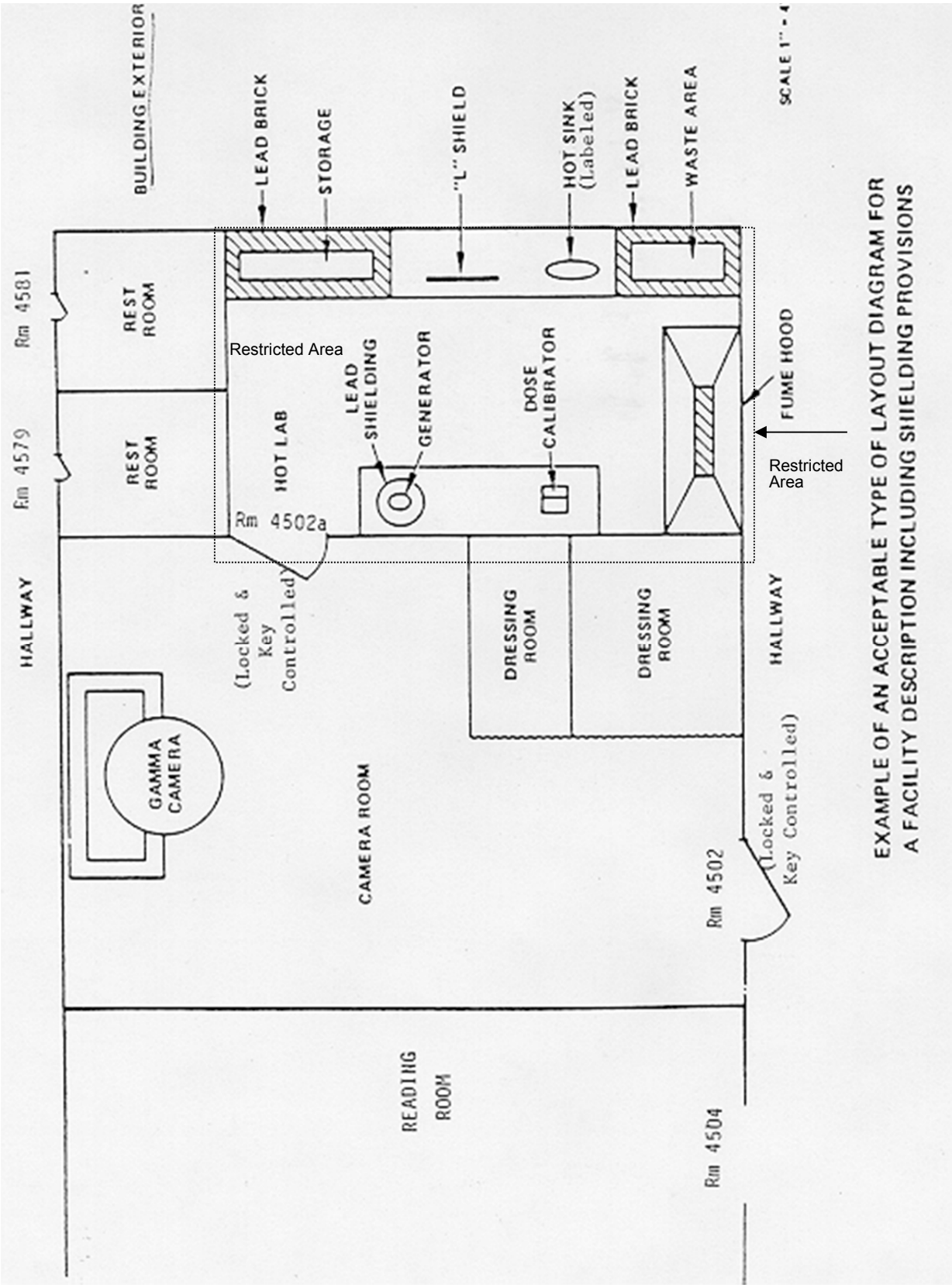
VI. LICENSE TERMINATION

Prior to license termination, the licensee must dispose of all licensed radioactive material possessed as required by 64E-5, F.A.C. and provide to this office the following:

A. Complete the department's Form DH-1059, "Certificate - Disposition of Radioactive Material" to satisfy the requirements of 64E-5.214, F.A.C., and submit it to the department before the expiration date of the license with a request that the license be terminated.

B. A close-out survey to release facilities for unrestricted use must be performed. The survey results should be keyed to a diagram showing the locations where the wipes were taken. Include the name of the person(s) who performed the survey and analyzed the results, and submit the manufacturer's name, model number, and detection range of the instrumentation used to perform the survey and analyze the wipes. Please refer to regulations 64E-5.214, 64E-5.314 and 64E-5.621, F.A.C., which provides instructions for performing the closeout survey. A confirmatory inspection may be performed by an area inspector if deemed necessary by this office.

Note: To prevent the potential for identity theft, never submit documentation that lists individuals' social security numbers or birth dates.



EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR A FACILITY DESCRIPTION INCLUDING SHIELDING PROVISIONS

↑ **NORTH**

Exhibit 1

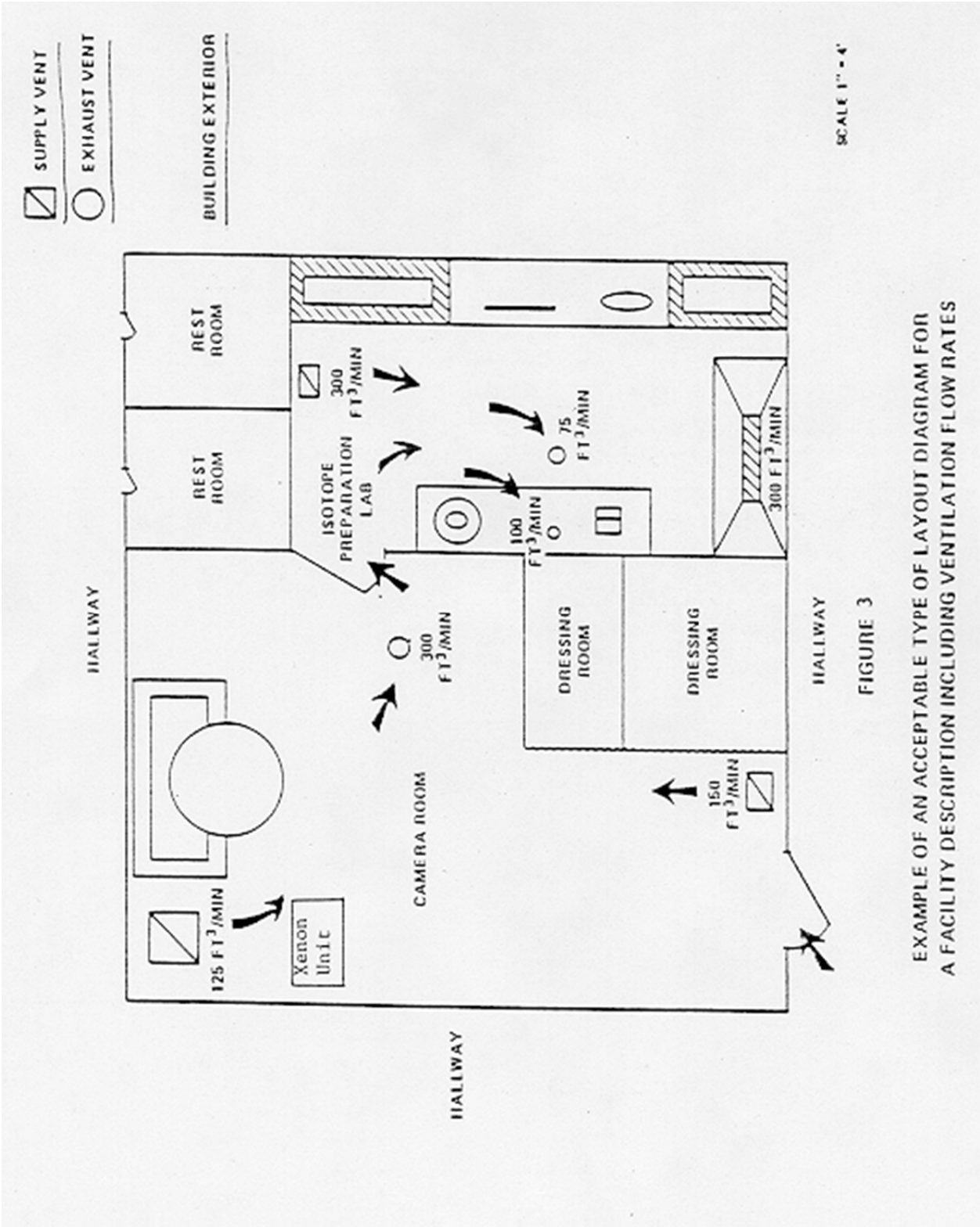


FIGURE 3

EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR A FACILITY DESCRIPTION INCLUDING VENTILATION FLOW RATES

↑ **NORTH**

Exhibit 2

REQUIRED By ALL Applicants

APPENDIX A	Radiation Safety Officer Responsibilities and Radiation Safety Committee Charter
APPENDIX B	Radiation Detection Instrumentation
APPENDIX E	Personnel External Exposure Monitoring Program
APPENDIX F	Training Program
APPENDIX G	Ordering and Receiving Radioactive Material
APPENDIX H	Opening Packages Containing Radioactive Material and Return of Radioactive Waste and Unused Dosages
APPENDIX K	Emergency Procedures
APPENDIX L	Procedures for Area Surveys
APPENDIX M	Procedures for Conducting a Member of the Public (MOP) Dose Study
APPENDIX R	ALARA Component of the Radiation Protection Program for including Radiation Safety Committees; OR Appendix S
APPENDIX S	ALARA Component of the Radiation Protection Program
APPENDIX T	Procedures for Leak-Testing Sealed Sources
APPENDIX V	Survey Meter Calibrations
APPENDIX W	Procedures for Waste Disposal
APPENDIX X	Inventory of Sealed Sources and Brachytherapy Sources

REQUIRED According To Medical Procedures Requested

Select from the following:

APPENDIX C	Quality Control of Diagnostic Instruments
APPENDIX D	Procedures for Calibrating a Dose Calibrator
APPENDIX I	Records of Radiopharmaceutical Use
APPENDIX J	Rules for Safe Use of Radiopharmaceuticals
APPENDIX N	Radiation Safety During Radiopharmaceutical Therapy
APPENDIX O	Implant Therapy
APPENDIX P	Monitoring, Calculating, and Controlling Air Concentrations When Using Noble Gases or Radioactive Aerosols
APPENDIX Q	Quality Management Program (QMP)
APPENDIX U	Iodine-131 In-Vivo Thyroid Bioassay Program
APPENDIX Y	Use of Diagnostic Radiopharmaceuticals
APPENDIX Z	Mobile Nuclear Medicine Service Procedures

NOTE: High Dose Rate (HDR) Remote Afterloaders, Gamma Stereotactic Radiosurgery (Gamma Knife), Sir-Spheres, and Theraspheres require additional model procedures not listed in this guide. You may access our web-site at http://www.floridahealth.gov/prevention-safety-and-wellness/radiation-control/radmat/matform.html for guidelines.

DELEGATION OF AUTHORITY TO MAKE LEGALLY BINDING STATEMENTS (OPTIONAL)

The Bureau of Radiation Control requires applications and amendment requests to be signed by the applicant, a certifying official or a person duly authorized to act for and on the licensee's behalf. If someone other than a corporate officer wants to correspond with the department as a certifying official, complete and attach a delegation of authority form.

Below is a sample copy of a delegation of authority to make legally binding statements.

Memo To: All Employees and the Bureau of Radiation Control

From: Chief Executive Officer

Subject: Delegation of Authority to Make Legally Binding Statements

_____ has been delegated the authority to make legally binding statements with regards to the radioactive materials license application, inspections, renewal, amendments and termination.

_____
License Certifying Official (signature)

_____
Name (typed or printed)

_____
Title

_____
Date

APPENDIX A

Radiation Safety Officer Responsibilities and Radiation Safety Committee Charter

RADIATION SAFETY OFFICER (RSO) RESPONSIBILITIES

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures.

2. Ensure that licensed material is used in compliance with department regulations and the license.

3. Ensure that the use of licensed material is consistent with the ALARA philosophy.

4. Identify program problems and solutions.

5. Review the training and experience of the proposed authorized users to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and in accordance with the regulations and the license.

6. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material under the license.

7. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

8. The RSO will review, sign and date at least every three months the radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the Investigational Levels established in appendix R or appendix S.

9. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter.

10. Establish a program to ensure that all persons who in the course of employment are likely to receive an occupational dose in excess of 100 millirem in a year (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required, to include the ALARA philosophy and radiation safety as described in the training program.

11. Review and document at least annually the radiation safety program's contents and implementation to determine that all activities are being conducted safely, in accordance with department regulations and the conditions of the license, and consistent with the ALARA philosophy. The review will include an examination of records, reports, results of department inspections, written safety procedures, and the adequacy of the management control system.

12. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

13. Ensure that the radioactive material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

14. The RSO shall promptly investigate and implement corrective actions as necessary; and provide management a written report of these investigations and the corrective actions taken for the following:

    1. Overexposures;
    2. Accidents;
    3. Spills;
    4. Losses;
    5. Thefts;
    6. Unauthorized receipts, uses, transfers and disposals;
    7. Other deviation from approved radiation practices.

RADIATION SAFETY OFFICER

I _____ am responsible for implementing the radiation safety program
Radiation Safety Officer's name (type/print)
along with ensuring that radiation safety activities are performed with approved procedures and regulatory requirements in the daily operation. **I have been delegated the authority to sign and make legally binding statements with regards to the radioactive materials license application, inspections, renewal, amendments and termination.**

_____
Radiation Safety Officer's (signature)

In accordance with subsection 64E-5.213(7), F.A.C., the agency will be notified in writing within 30 days of a change of radiation safety officer (RSO). Such notifications should include documentation of the new RSO's qualification for the position.

DELEGATION OF AUTHORITY FOR THE RADIATION SAFETY OFFICER

_____ has been appointed radiation safety officer (RSO), **has the**
Radiation Safety Officer's name (type/print)
authority to sign and make legally binding statements with regards to the radioactive materials license application, inspections, renewal, amendments and termination, and is responsible for ensuring the safe use of radiation. The RSO is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The RSO shall ensure that the license activities are performed using approved procedures and meeting the regulatory requirements in the daily operations of the radiation safety program. The RSO is hereby delegated the authority necessary to meet those responsibilities.

The RSO is also responsible for assisting the radiation safety committee in the performance of its duties.

_____
License Certifying Official (signature)

_____
Name (typed or printed)

_____
Title

_____
Date

RADIATION SAFETY COMMITTEE CHARTER- "if applicable"
64E-5.606, Florida Administrative Code

Applicants that fit one or more of the criteria listed below shall establish a Radiation Safety Committee to oversee the use of radioactive materials;

- Medical institutions as defined in Rule 64E-5.101, F.A.C.; or

Other licenses authorized for any of the following combination of medical uses:

- 64E-5.627(2), F.A.C., & any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.; or
- 64E-5.627(3), F.A.C., & any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.; or
- 64E-5.627(4), F.A.C., & any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.; or
- 64E-5.630, F.A.C., & any subsection of Rule 64E-5.632 or 64E-5.634 or
- 64E-5.634(1) & 64E-5.634(2), F.A.C.; or
- 64E-5.634(1) & 64E-5.634(3), F.A.C.; or
- 64E-5.634(2) & 64E-5.634(3), F.A.C.

Check appropriate box:

☐ This application does NOT require a Radiation Safety Committee.

☐ Your authorization requires the oversight of a Radiation Safety Committee and will abide by the following procedures. (Submit a list of your committee members and their titles 64E-5.606(2), F.A.C.)

Charge. The committee shall:

1. Ensure that licensed material is used safely. This includes review as necessary of training programs, equipment, facilities, supplies, procedures and reports;

2. Ensure that licensed material is used in compliance with department regulations and the institutional license;

3. Ensure that the use of licensed material is consistent with the ALARA philosophy outlined in appendix R of this guide;

4. Establish a table of investigational levels for individual occupational radiation exposures; and

5. Identify program problems and solutions.

Responsibilities. The committee shall:

1. Review the training and experience of the proposed authorized users, the radiation safety officer (RSO), and the authorized medical physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;
2. Review all requests for authorization to use radioactive material on the basis of safety, limitations of the regulations, the license, and the ALARA philosophy. The committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess, or use radioactive material under the supervision of an authorized user. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that the physician, dentist or podiatrist has received the training and experience required by sections 64E-5.649, 64E-5.650, 64E-5.651, 64E-5.652, 64E-5.653 or 64E-5.655, F.A.C.
3. Approve procedures and radiation safety program changes based on safety and the advice of the RSO and management representative prior to sending to the department for licensing action.
4. Review every six months the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;
5. Review at least every twelve months the entire radiation safety program to determine that all activities are being conducted safely. The review must include summaries of the types, amounts and purposes of radioactive materials used; occupational dose reports; and continuing education and training of all personnel who work with or in the vicinity of radioactive material;
6. Recommend remedial action to correct any deficiencies identified in the radiation safety program;
7. Maintain written minutes of all committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken;
8. Review and approve procedures and radiation safety changes based on safety; and

Administrative Information

1. The committee shall meet as often as necessary to conduct its business but shall meet at least every six months.
2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, a representative of management who is neither an authorized user nor a RSO, and a person experienced in the assay of radioactive material and protection against radiation, such as a authorized medical physicist or nuclear medicine technologist.
3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.
4. To the extent that they do not interfere with the mission of the committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

APPENDIX B

Radiation Detection Instrumentation

SURVEY INSTRUMENTS

Survey instruments are calibrated before first use, at least every 12 months thereafter, and after repair.

When the primary instrument is out of service for calibration or repair, a calibrated survey instrument and probe with detection range equivalent to our primary instrument is accessible.

Section 64E-5.615, F.A.C., specifies a range from 0.1 millirem (1.0 μSv) per hour to 1,000 millirem (10 mSv) per hour. In addition, if a survey instrument is used to analyze contamination wipe surveys, the probe must have a maximum window thickness of 2.0 mg/cm^2 and a minimum probe diameter of 1.5 inches. At least one survey instrument must meet these specifications, if applicable.

Check appropriate box:

☐ Calibrations are performed in-house according to procedures specified in attached Appendix V.

☐ Calibrations are performed, other than in-house, by individuals identified on a radioactive materials license, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform these services.

Quantity	Manufacturer	Survey Meter Model No.	Min. to Max. Range in mR/hr	Probe Model No.	Minimum Probe Sensitivity

OTHER RADIATION DETECTION INSTRUMENTS

(dose calibrator, well counter, gamma camera, thyroid uptake probe, xenon trap monitor, electrometer and ion chamber, etc.)

Type of Instrument	Manufacturer	Model Number	Serial Number

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APPENDIX C

Quality Control of Diagnostic Instruments

PROCEDURE

The licensee will perform quality control procedures for all diagnostic instruments (such as gamma camera systems, thyroid probes, gamma-detecting intra-operative probes used for lymphoscintigraphy, etc.) as recommended by the manufacturer. These procedures must be in writing and available for review by the department.

Examples of the types of quality control tests for gamma camera systems are as follows:

1. System Uniformity
2. Resolution/Linearity
3. Multiple Window Spatial Registration
4. Center of Rotation
5. Tomographic Resolution
6. Rotational Uniformity
7. Collimator Hole-Alignment
8. Gantry Alignment
9. Head Alignment
10. Fan-Beam Collimators

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APPENDIX D

Procedures for Calibrating a Dose Calibrator

1. Test for the following at the indicated frequency. Repair, replace, or correct mathematically if the dose calibrator falls outside the stated tolerances.
   - Constancy at least once each day prior to assay of patient dosages, during an assigned shift for facilities operating continuously, or after re-location of the dose calibrator. Repair or replace if outside plus or minus 10 percent.
   - Accuracy at installation and at least every 12 months thereafter. Repair or replace if outside plus or minus 10 percent.
   - Linearity at installation and at least every three months thereafter. Repair, replace or correct mathematically if outside plus or minus 10 percent.
   - Geometry dependence at installation. Repair, replace or correct mathematically if outside plus or minus 10 percent.
2. After repair or adjustment of the dose calibrator, repeat the above tests as appropriate.
3. Any of the above dose calibrator tests other than daily constancy tests may be performed by an individual licensed by the department, U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform these tests. Nationally recognized standards or the manufacturer's instructions may be used to calibrate instrumentation. The standards or instructions used must be available for inspection by the department.

Constancy Test Procedures

Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, or Co-57 using a reproducible geometry each day before using the calibrator. Use the following procedure:

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

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

C. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

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

E. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of a suspected malfunction of the calibrator. These action levels will be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

Accuracy Test Procedures

Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by the NIST. Certified sources are available from the NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) will be used. One source will have a principal photon energy between 100 keV and 500 keV. If a Ra-226 source is used, it will be at least 10 microcuries; other sources will be at least 50 microcuries. Use at least one reference source with an activity in the range of activities normally assayed.

A. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.

B. Average the three determinations. The average value should be within 10 percent of the certified activity of the reference source, mathematically corrected for decay.

C. Repeat the procedure for other calibrated reference sources.

D. If the average value does not agree, within 10 percent, with the certified value of the reference source, the dose calibrator must be repaired or replaced.

Linearity Test Procedures

Linearity means that the calibrator is able to indicate the correct activity over the entire range of use of that calibrator. This test will be done using a vial or syringe of Tc-99m or F-18 whose initial activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy dose, whichever is largest. The test shall continue until the activity contained in the vial or syringe is smaller than the smallest activity assayed, but greater than 10 microcuries.

Decay Method

A. Assay the Tc-99m or F-18, syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time, for example, 8:00 a.m.

B. If starting at 8:00 a.m., repeat the assay at 2:00 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity normally assayed. For dose calibrators with a range switch, select the range normally used for the measurement.

C. Convert the time and date information recorded for each assay to hours elapsed since the first assay.

D. On a sheet of semi-log graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.

E. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$\frac{\text{A observed - A line}}{\text{A line}} = \text{deviation}$$

F. If the worst deviation is more than plus or minus 0.10, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

G. Place a sticker on the dose calibrator or record in log book when next linearity test is due.

Shield Methods

For initial calibration or reinstallation of the dose calibrator the decay method will be used to determine linearity and to establish calibration factors for shield methods.

☐ A nationally recognized standard or the manufacturer's linearity test kit and instructions will be used for doing linearity tests of the dose calibrator. These standards or instructions must be available for review by the department for inspection. **Submittal of standards or manufacturer's instructions to the department is not required.**

☐ We will use a set of "sleeves" of various thicknesses' to test for linearity other than the manufacturer's test kit. The sleeves will be calibrated using the following procedure:

Calibration of the sleeves:

A. Begin the linearity test as described in the above decay method. After making the first assay, the sleeves will be calibrated as follows. Steps B - D below must be completed within six minutes.
B. Put the base and sleeve one in the dose calibrator with the vial. Record the sleeve number and indicated activity.
C. Remove sleeve one and put in sleeve two. Record the sleeve number and indicated activity.
D. Continue for all sleeves.
E. Complete the decay method linearity test steps B - G above.
F. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve one in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step B.
G. 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 C.
H. Continue for all sleeves.
I. 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.

Calibration of the dose calibrator:

A. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the new activity in millicuries. Record the net activity.
B. Steps C - E below must be completed within six minutes.
C. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
D. Remove sleeve one and put it in sleeve two. Record the sleeve number and indicated activity.
E. Continue for all sleeves.
F. On a sheet of semi-log graph paper, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.
G. Plot the data using the equivalent decay time associated with each sleeve.
H. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$\frac{\text{A observed - A line}}{\text{A-line}} = \text{deviation}$$

I. If the worst deviation is more than plus or minus 0.10, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow a conversion from activity indicated by the dose calibrator to "true activity."
J. Place a sticker on the dose calibrator or record in log book when next linearity test is due.

Geometry Test Procedures

Geometry dependence means that the indicated activity does not change with volume or configuration. This test will be done using a syringe that is normally used for injections. When using generators and radiopharmaceutical kits we will also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If volumes of syringes and vials differ from above, then the procedures will be changed so that syringes and vials are tested throughout the range of volumes commonly used.

A. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline or tap water.

B. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Document the volume, millicuries and record instrument setting.

C. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

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

E. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. The data will be graphed with horizontal 10 percent error lines drawn above and below the chosen "standard volume."

F. If any correction factors are greater than 1.10 or less than 0.90, or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity." If this is necessary, label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

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

H. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

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

J. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed and draw horizontal 10 percent error lines above and below the chosen "standard volume."

K. If any correction factors are greater than 1.10 or less than 0.90 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

APPENDIX E

Personnel External Exposure Monitoring Program

PROGRAM

1. The Radiation Safety Officer (RSO) will review, sign and date all exposure reports at least every three months to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated luminescent dosimeter (OSLD).
2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film, TLD, or OSLD whole body or extremity monitor which will be processed by a contract service on a quarterly or less frequency.
3. Individuals who are exposed to radiation on an occasional basis are not normally issued exposure monitors.
4. All personal dosimeters will be processed and evaluated by a dosimetry provider holding NVLAP accreditation.

RECORDS

1. For each individual who is likely to receive in a year an occupational dose requiring monitoring the facility will determine the occupational radiation dose received during the current year and attempt to obtain the records of lifetime cumulative occupational radiation dose.
2. We will prepare for employee requiring personnel monitoring a report of the radiation exposure data for each affected individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body by the individual. This report will include data and results obtained as required by section 64E-5.903.
3. We will provide to each employee requiring personnel monitoring an annual report of the workers exposure to radiation as required by the section 64E-5.903. Records will be maintained for 3 years that indicate these reports were furnished to each employee.
4. Upon termination of an employee requiring personnel monitoring, a written report of the worker's exposure to radiation at this facility will be mailed to the last known address of the employee. This report will be furnished to the former employee within 30 days of termination of the employee or within 30 days after the exposure of the individual has been determined by the facility, whichever is later. This report will cover each calendar quarter in which case the employee's working activities involved the exposure to sources of radiation and shall include dates and location of work under the license in which the worker participated. Records will be maintained for 3 years that indicate these reports were furnished to each employee.

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APPENDIX F

Training Program

General Radiation Training Program

All individuals who in the course of employment are likely to receive an occupational dose in excess of 100 millirem (1mSv) in a year will be:

- Informed about the storage, transfer, or use of sources of radiation in the facility;
- Instructed in the health protection problems associated with exposure to radiation and the precautions or procedures to minimize such exposures, and the purposes and functions of protective devices employed;
- Instructed in and observed to the extent applicable the provisions of these regulations and licenses for the protection of personnel from exposures to radiation;
- Instructed of their responsibility to report promptly to the radiation safety officer (RSO) any condition that may cause a violation of the facility's license or any unnecessary exposure to radiation;
- Instructed in the appropriate response in the event of any unusual occurrence that may involve exposure to radiation; and
- Advised of the radiation exposure reports that workers are furnished pursuant to section 64E-5.903, F.A.C.
- Provided annual refresher training

All authorized users, nuclear medicine technologists, authorized medical physicists, radiation therapists, dosimetrists and nursing personnel as applicable will receive the training as described above. In addition the following categories of personnel will be trained:

☐ Security ☐ Ancillary ☐ Housekeeping ☐ Others _____

The method of training will include the following:

☐ Lectures ☐ Videos ☐ Self-study ☐ Demonstrations ☐ Other _____

Therapeutic Radiopharmaceuticals, Brachytherapy, HDR and Teletherapy Training

As required in section 64E-5.625, F.A.C., all personnel caring for patients undergoing radiopharmaceutical therapy, brachytherapy and personnel who operate teletherapy equipment will receive the following training.

- ♦ Radiopharmaceutical therapy instructions include procedures for: patient care, visitor access, contamination control and waste disposal.
- ♦ Instructions for brachytherapy shall describe the following: size and appearance of the brachytherapy sources; safe handling and shielding instructions in case of a dislodged source; and procedures for patient and visitor control.
- ♦ Instructions for teletherapy will be physically located at the teletherapy console as required by 64E-5.636, F.A.C.
- ♦ Instructions for a Remote Afterloader will be physically located at the Remote Afterloader console as required by 64E-5.636, F.A.C.
- ♦ Records will be maintained for individuals receiving instructions, and these records will include the date of instruction and the name of the individual who gave the instructions. Records will be maintained for three years.

The method of training: ☐ Lectures ☐ Videos ☐ Self-study ☐ Demonstrations ☐ Other ___

Hazardous Material Training

All employees, whose duties require them to receive, handle or prepare hazardous radioactive material for transportation will receive training.

The training will include the following:

- **General awareness/familiarization training**, designed to provide familiarity with 49 CFR requirements and to enable the employee to recognize and identify hazardous materials;
- **Function-specific training**, concerning USDOT requirements which are specifically applicable to the functions the employee performs;
- **Safety training**, concerning emergency response information, measures to protect the employee from the hazards posed by materials, and methods and procedures for avoiding accidents.
- **Security awareness training**, concerning recognizing and responding to risks associated with hazardous materials transportation.

Training will be conducted prior to the employee performing transportation duties on hazardous material or within 90 days of employment provided they are directly supervised by a trained employee as required by 49CFR 172.700.

Training will be conducted every three years.

Training records will be maintained for the duration of employment, plus 90 days. Record of training must include the following information:

- The hazmat employee's name.
- The most recent training completion date.
- A description and copy, or the location of the training materials.
- The name and address of the person providing the training.
- Certification that the hazmat employee has been trained and tested as required.

The USDOT Transportation Safety Institute offers hazmat employee training classes and may be contacted through their website at http://www.tsi.dot.gov/.

The method of training will include the following:

☐ Lectures ☐ Videos ☐ Self-study ☐ Demonstrations ☐ Other _____

APPENDIX G

Ordering and Receiving Radioactive Material

Ordering Radioactive Materials

1. The radiation safety officer (RSO) or a designee will authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded. A designee will be someone who has the appropriate pharmacological training.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system will contain the following information:

   A. For routinely used diagnostic materials, records will be made that identify the authorized user, isotope, chemical form, activity, and suppliers.

   B. For occasionally used materials and therapeutic dosages, the authorized user performing the procedure will make a written request that indicates the radionuclide, activity, and radiopharmaceutical.

   C. For brachytherapy sources, the authorized user performing the procedure will make a written request that indicates the radionuclide and activity.

Receiving Radioactive Material (Check all that apply)

☐ Deliveries will be received during normal working hours; the RSO will instruct the carriers to deliver radioactive packages directly to the nuclear medicine department. The person receiving the material will check the physician's written request to confirm that the material is what was ordered.

☐ Deliveries may be received during off-duty hours. The nuclear pharmacy delivering the radioactive materials will place the goods in a locked box as described in the attached drawing. The nuclear pharmacy personnel have keys to lock and unlock the box.

☐ Deliveries may be received during off-duty hours. The nuclear pharmacy delivering the radioactive materials will place material in the nuclear medicine hot lab. The nuclear pharmacy personnel have keys to lock and unlock the hot lab.

☐ Deliveries may be received during off-duty hours; the RSO will instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with the procedure outlined below.

The security guard on duty or designated persons will accept delivery of packages containing radioactive material that arrive during off-duty hours. Packages will be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room _____.

Unlock the door, place the package in the room, and relock the door. If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the facility until it can be determined if the driver or the delivery vehicle is contaminated.

Name_____ Home Phone_____

Radiation Safety Officer: _____

Chief of Nuclear Medicine: _____

Chief Nuclear Medicine Tech: _____

Nuclear Medicine Tech on call

(Call page operator at extension _____): _____

Nuclear Medicine Physician on call: _____

APPENDIX H

Opening Packages Containing Radioactive Material and Return of Radioactive Waste and Unused Dosages

During normal working hours, packages containing radioactive materials will be monitored as soon as practicable after receipt (not to exceed 3 hours). Packages received after normal working hours will be monitored within 3 hours from the beginning of the next working day, as required by subsection 64E-5.327(3), Florida Administrative Code, (F.A.C.).

OPENING PACKAGES CONTAINING SPECIFICALLY LICENSED MATERIAL

1. Put on gloves to prevent hand contamination.
2. Check the survey meter for proper operation with a dedicated check source.
3. Measure the exposure rate of the package at one meter (3.3 feet) and then measure the exposure rate at the surface of the package. Record the survey results and compare to the limits on the below listed DOT Shipping Label Chart.

If survey measurements exceed the values listed on the chart, stop the procedure and immediately notify the radiation safety officer (RSO).

4. Visually inspect the package for any sign of damage (e.g., wet or crushed).
   If damage is noted, stop the procedure and notify the RSO.

DOT Shipping Label Chart

Label Category	Surface Level (mR/hr)	Transportation Index (TI) at 1 meter (mR/hr)
White I	0-0.5	background
Yellow II	0.5 - 50	0.1 - 1.0
Yellow III	50 - 200	1.0 - 10

5. Open the package with the following precautionary steps:
   A. Remove the packing slip.
   B. Open the outer package following the supplier's instructions when provided.
   C. Open the inner package and verify that the contents agree with the packing slip.
   D. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
   E. If anything is other than expected, *stop and notify the RSO.*
6. Wipe the external surface of the final source container and remove the wipe sample to a low background area. Survey the wipe with the G-M survey meter. If the meter indicates a reading above background, *stop the procedure and notify the RSO.*
7. Check the user request to ensure the material received is the material that was ordered.

8. Monitor the packing material and the empty packages for contamination with a G-M survey meter before discarding.

   A. If contaminated, treat this material as radioactive waste.

   B. If not contaminated, remove or obliterate the radiation labels before discarding in non-radioactive trash.

9. Records of package opening survey results are maintained for 3 years as specified in section 64E-5.336, F.A.C.

10. Section 64E-5.327, F.A.C., allows certain exemptions from package contamination surveys for radioactive material in the form of gas or special form.

    "Special form" means radioactive material that satisfies all of the following conditions:

    (a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

    (b) The piece or capsule has at least one dimension not less than 5 millimeters; and

    (c) It satisfies the test requirements of 49 CFR, section 173.469. Special Form encapsulations designed in accordance with the requirements of section 49 CFR section 173.389 in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. Special form encapsulations either designed or constructed after June 30, 1985, must meet the requirements of this part.

RETURN OF WASTE AND UNUSED DOSAGES-LIMITED QUANTITIES

Under the provision of 49 CFR section 173.421, packages of radioactive material returned to pharmacies are labeled as "Limited Quantity Shipments." Limited Quantity is defined as a "maximum amount of a hazardous material for which there is a specific labeling or packaging exception." 49 CFR section 173.421 states that if a package meets the following requirements it is exempted from the specifications of packaging, marking, and labeling.

1. The amount of radioactivity in the package does not exceed a specified amount. (A table is attached specifying the limit for each commonly used radiopharmaceutical.)

2. The radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour.

3. The non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed 6600 dpm/300 cm^2. (49 CFR section 173.443[A][2]).

LIMITED SHIPMENT QUANTITES FOR COMMONLY USED RADIOPHARMACEUTICALS AND SEALED SOURCES

Radionuclide	Liquids (mCi)	Sealed Sources (mCi)
Ba-133	-	81.0
Co-57	27.0	27.0
Co-60	-	11.0
Cr-51	81.0	-
Cs-137	-	54.0
F-18	1.6	-
Ga-67	8.1	-
Gd-153	-	270.0
Ge-68		14.0
I-123	8.1	81.0 (solid form)
I-125	8.1	540.0
I-131	1.9	-
In-111	8.1	-
Mo-99	1.6	-
P-32	1.4	-
Pd-103		1100.0
Sm-153	1.6	-
Sr-89	1.6	-
Se-75	8.1	-
Tc-99m	11.0	-
Tl-201	11.0	-
Xe-133 gas (uncompressed, $A_2 \times 10^{-3}$)	270.0	-
Y-90	0.81	-

The above values have been calculated using information from 49 CFR section 173.423, Table 7, and 49 CFR 173.435, Table of A_1 and A_2 Values for Radionuclides. When shipping more than one type of radioactive material in the same package, the limit on the radioactivity that may be shipped is determined by the lowest curie quantity assigned for items shipped.

Example: If Tc-99m and Se-75 were being shipped in same package, only 8.1 mCi of total activity could be shipped.

Procedures

1. Ensure that the radioactive waste being returned does not exceed the specified limits for "Limited Quantity Shipments."
2. Determine that the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr by surveying the package prior to shipment.
3. Determine that the non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR subsection 173.443(a), for example, 22 dpm/cm^2 when wiped over a 300 cm^2 area. A wipe of the package will be performed, analyzed and evaluated for activity. To convert activity in microcuries to disintegration per minute multiply microcuries by 2.22×10^6.
4. If the package does not exceed the limits in 1, 2 and 3, the package may be shipped as a limited quantity shipment. The outside of the inner package or, if there is no inner package, the outside of the packaging itself bears the marking "Radioactive."

5. Outside of limited quantity package must be marked with UN identification number preceded by the letters UN (i.e. UN2910).

6. If the package exceeds the limited shipment quantity, surface dose rate or removable contamination in excess of 2200 dpm/100cm^2 , the package may not be shipped as limited quantities and will be held at the facility.

RETURN OF WASTE AND UNUSED DOSAGES-OTHER THAN LIMITED QUANTITIES

Procedures

1. Ensure that the radioactive waste being returned does not exceed the specified A_1 for special form and A_2 for normal form material as described in Appendix A to Part 71, Florida Administrative Code (F.A.C.), for Type A packages.

2. The radioactive material will be placed into appropriate shielding.

3. The shielded radioactive material will be placed in a DOT Type A shipping container. The container will also include absorbent material sufficient to absorb the liquid contents of the container.

4. A copy of the Type A container testing methods and results for each Type A package in use will be on file, for at least one year after the latest shipment.

5. The appropriate label will be applied to the outside of the box. Determination of the transport index is accomplished by placing the package one meter from a calibrated instrument in mR/hr. Determination of the radioactive White I, Yellow II, or Yellow III, is accomplished by taking surface readings of the package as well as the T.I. The following criteria will used to determine the proper labeling:

DOT Shipping Label Chart

Label Category	**Surface Level (mR/hr)**	**Transportation Index (TI) at 1 meter (mR/hr)**
White I	0 - 0.5	background
Yellow II	0.5 - 50	0.1 - 1.0
Yellow III	50 - 200	1.0 - 10

6. A wipe test shall be performed over 300 cm^2 external package area to ascertain that the container has removable contamination less than 6600 dpm/300 cm^2.

7. The package will be marked on the outside “USDOT 7A Type A” and “Radioactive Material.” The package will be labeled on at least two sides of the package and near the proper shipping name marking.

8. The radioactive label will state the radionuclide or radionuclides, its chemical form, the quantity.

9. Each package will state the name and address of the pharmacy who will receive the package.

10. Shipping papers will be completed and the package will be transferred to the nuclear pharmacy.

APPENDIX I

Records of Radiopharmaceutical Use

RECORDS OF UNIT DOSAGE USE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Lot number or control number, if assigned;
5. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
6. Molybdenum-99 concentration (if applicable);
7. Date of administration or disposal;
8. If administered,
    - Prescribed dosage;
    - Measured activity in millicuries or microcuries and date and time of measurement;
    - Patient name and identification number if one has been assigned; and
    - Initials of the individual who assayed and administered the dose.
9. If discarded, the date and method of disposal; and
10. Initials of the individual who made the record.

RECORDS OF MULTIDOSE VIAL USE

For each multidose vial received from a supplier or prepared in-house, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt or preparation;
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);
5. Molybdenum-99 concentration (if applicable);

6. If administered,

   - Prescribed dosage;
   - Date and time dosage was drawn and measured;
   - Calculated volume that is needed for the prescribed dosage;
   - Measured activity in millicuries or microcuries; and
   - Patient name and identification number if one has been assigned.
   - Initials of the individual who assayed and administered the dose.

7. If discarded, the method of disposal and date; and

8. Initials of the individual who made the record.

RECORDS OF MOLYBDENUM-99 GENERATOR USE

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect that should be reported.

The procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." The dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons, but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

Each time a generator is eluted, make a record of the:

1. Date and time of elution;

2. Measured Mo-99 activity in microcuries;

3. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;

4. Measured Tc-99m activity in millicuries;

5. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. If it isn't, stop and notify the Radiation Safety Officer (RSO). The 0.07 action level allows for the quicker decay of the Tc-99m through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.

6. Initials of the person who made the record.

APPENDIX J

Rules for Safe Use of Radiopharmaceuticals

1. Wear disposable gloves at all times while handling radioactive materials.
2. Either after each procedure or before leaving the area of use, monitor your hands for contamination in a low background area with a survey meter or camera.
3. Areas where radioactive materials are prepared, administered or stored will be covered with impervious material.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve.)
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used, stored or disposed. Also do not store food, drink, or personal effects in these areas.
6. Wear personnel monitoring devices at all times while in areas where radioactive materials are stored, used or disposed. These devices should be worn as prescribed by the radiation safety officer. When not being used, personnel monitoring devices should be stored, in the work place, in a designated low-background area.
7. Wear an extremity exposure monitor with the film, TLD or OSLD on the palmer side of the hand during the elution of generators, during the preparation, assay, and injection of radiopharmaceuticals, and when holding patients during procedures.
8. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
9. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart, wheelchair, or other containers to move flood sources, waste, and other radioactive material.
10. Never pipette by mouth.
11. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multi-dose diagnostic vials and therapy vials shall be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation as required by 64E-5.325. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages must be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.
12. Always keep flood source, syringes, waste, and other radioactive material in shielded containers when not in use.
13. Ensure security of radioactive materials. Do not leave radioactive materials unattended in unsecured areas as required by 64E-5.320 and 64E-5.321.

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APPENDIX K

Emergency Procedures

STOLEN, LOST OR MISSING RADIOACTIVE MATERIAL

1. Immediately notify the Radiation Safety Officer (RSO).
2. RSO will notify management and appropriate local authorities.
3. Conduct a complete search of the area with an appropriate survey meter capable of detecting the radioactive material.
4. RSO will contact the Bureau of Radiation Control at (407) 297-2095.
5. Within 30 days after making the initial report, submit a written report to the bureau that that includes all of the information identified in subsection 64E-5.343(2), Florida Administrative Code (F.A.C.)
6. Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information as required by 64E-5.343(3), F.A.C.

SPILLS OF RADIOACTIVE LIQUIDS AND SOLIDS

MINOR SPILLS

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. Wearing disposable gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. With the clean side out, carefully fold the absorbent paper and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector survey meter sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
5. Report the incident to the radiation safety officer (RSO).
6. The RSO will follow-up on the cleanup of the spill and will complete a Radioactive Spill Contamination Survey as specified in subsection 64E-5.621(8), F.A.C.

MAJOR SPILLS

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. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can 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 contamination remains, induce perspiration by covering the area with plastic. Wash the affected area again to remove any contamination that was released by the perspiration.
7. The RSO will supervise the cleanup of the spill and will complete a Radioactive Spill Contamination Survey as specified in subsection 64E-5.621(8), F.A.C.

MAJOR SPILL OR MINOR SPILL

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spreading contamination, types of surfaces contaminated, and the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be to restricted access pending decay to background levels.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

RELATIVE HAZARDS OF COMMON RADIONUCLIDES

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Yb-169	10
Ga-67	10	Hg-197	10
Se-75	1	Au-198	10
Sr-85	10	Tl-201	100
Sr-89	10	Sm-153	10
F-18	100	Y-90	10

SPILL KIT

Assemble a spill kit that may contain the following items:

- Disposable gloves and housekeeping gloves;
- Disposable lab coats;
- Disposable head coverings;
- Disposable shoe covers;
- Roll of absorbent paper with plastic backing;
- Masking tape;
- Plastic trash bags with twist ties;
- “Radioactive Material” labeling tape;
- Marking pen;
- Pre-strung “Radioactive Material” labeling tags;
- Contamination wipes;
- Instructions for “Emergency Procedures”;
- Clipboard with copy of Radioactive Spill Report Form;
- Pencil; and
- Appropriate survey instruments, including batteries.

POSTING REQUIREMENTS

A. A copy of our emergency (spill) procedures (Appendix K), general laboratory safety procedures for working with radioactive materials (Appendix J), our emergency notification notice, and a Notice to Employees document 3/01 will be conspicuously posted at our facility as required by 64E-5.901, F.A.C. Current copies of Part III and Part IX, the license, conditions or documents incorporated into the license by reference and amendments thereto, and operating procedures applicable to activities under the license are not required to be posted provided that a notice is posted which describes the documents and states where they may be examined.

B. The radiation safety officer's name and phone number and our 24 hour emergency notification number are listed in our emergency procedures.

C. The location of use for radioactive material will be posted with the proper signage as described in 64E-5.323, Florida Administrative Code.

APPENDIX L

Procedures for Area Surveys

AMBIENT DOSE RATE SURVEYS

1. Survey at the end of each day of use, or during an assigned shift for facilities operating continuously, with a radiation detection survey meter in radiopharmaceutical elution, preparation, and administration areas. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
2. Survey weekly with a radiation detection survey meter in radiopharmaceutical storage and radiopharmaceutical waste storage areas,
3. Survey quarterly with a radiation measurement survey meter in sealed source and brachytherapy storage areas,
4. Immediately notify the radiation safety officer (RSO) if you find unexpectedly high or low levels.

Note: End of day use, weekly radiopharmaceutical storage, and radiopharmaceutical waste storage area ambient dose rate surveys need not be performed in areas where patients or human research subjects are currently confined when such patients or subjects cannot be released as referenced in Rule 64E-5.622, Florida Administrative Code.

REMOVABLE CONTAMINATION SURVEYS (WIPES)

1. Survey weekly for removable contamination in all radiopharmaceutical storage, elution, preparation, administration and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). Assay the wipe sample in a low background area with a radiation detection survey meter using a probe with a maximum window thickness of 2.0 mg/cm^2 and a minimum probe diameter of 1.5 inches.
3. If this method is used, any reading above background will be considered above established action levels and appropriate action will be taken.
4. Immediately notify the RSO if you find unexpectedly high levels.

RECORDS

Keep a record of dose rate and contamination survey results for 3 years.
Records must include the following information:

1. The date of the survey;
2. A diagram of each area surveyed;
3. Action levels established for each area;
4. Measured dose rate at several points in each area, expressed in millirems (microseiverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 cm^2, or counts per minute if performed with a radiation survey instrument as described in Appendix B;
5. The serial number and the model number of the instrument used to make the survey or analyze the samples; and
6. The name of the person who performed the survey.

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APPENDIX M

Procedures for Conducting a Member of the Public Dose Compliance Study

If licensed for, or seeking licensure for possession and use of radioactive material, in accordance with section 64E-5.313, Florida Administrative Code (F.A.C), the radiation hazard resulting from licensed operations must be evaluated to demonstrate compliance with the member of public (MOP) dose limits described in section 64E-5.312, F.A.C. The dose in any unrestricted area from external sources will be less than 2 mr/hr.

Use steps 1, 2 and 3 to calculate Total Effective Dose Equivalent (TEDE) and keep calculations on file for inspection purposes.

1. Deep Dose Equivalent (DDE): External Exposure from Sealed Sources

Calculate DDE value for dose from external whole body radiation exposure; **DDE = TEDE**

Note: To demonstrate compliance with the annual MOP dose limit specified in 64E-5.312(1)(a), the TEDE must be ≤ 100 mrem.

Select one of the following methods:

☐ **Occupational Worker Dosimetry Data**
(The highest individual cumulative external dose for the 12 month monitoring period.)

☐ **Dosimetry Data for the Maximally Exposed Individual MOP**
(The highest individual cumulative external dose for the 12 month monitoring period where the MOP's workstation is located.)

☐ **Environmental Monitoring Data**
(Enter the TLD highest cumulative dose for the 12 month monitoring period, based on continuous year-round occupancy,8766 hours, in unrestricted areas or workplace occupancy factors, 2000 hours, for a work year.)

☐ **Radiation Level Data**
(Use of radiation survey instrument measurements and the inverse square law or use of RAM package Transport Index (TI) values or RAM package surface radiation levels and the inverse square law to calculate DDE.)

2. Committed Effective Dose Equivalent (CEDE):
Internal Exposure from Unsealed RAM OR Unsealed RAM and Sealed Sources

Calculate CEDE value for dose from internal radiation exposures.

Select one of the following methods:

☐ Current or requested RAM use does not correspond to one of the options listed below, separate calculations of the CEDE dose contributions will be performed to include a description of each RAM type and quantity.

☐ To determine the annual CEDE MOP dose for iodine 131 used as liquid NaI in quantities > 10 mCi, or I-131 used in any other chemical, liquid, or capsule form (e.g., Hippuran, diagnostic or therapeutic capsules, etc.) in quantities greater than 1,000 mCi, follow the steps listed below:

1. Determine the total annual activity (in mCi) of liquid I-131 used in therapeutic and diagnostic procedures, excluding I-131 in capsule form or sealed sources.
2. Divide the number by 10 and round to the nearest whole number. This value is the calculated CEDE MOP dose (in mrem) resulting from this licensed activity.

☐ To determine the annual CEDE MOP dose resulting from use of any other chemical, liquid, or capsule form of I-131 (e.g., Hippuran, diagnostic or therapeutic capsules, etc.) for therapeutic and diagnostic procedures, follow the steps listed below:

1. Determine the annual use any other chemical, liquid, or capsule form of I-131 from therapeutic and diagnostic procedures (in mCi).
2. Divide this number by 1,000 and round to the nearest whole number. This value is the CEDE dose (in mrem).

☐ To determine the CEDE resulting from annual Sr-89 use > 2,000 mCi, follow the steps listed below:

1. Determine the annual use of Sr-89 (in mCi).
2. Divide this number by 2,000 and round to the nearest whole number. This is the CEDE dose (in mrem) received for the use of these materials.

3. Total Effective Dose Equivalent (TEDE)

The **DDE** is added to **CEDE** to produce the dose resulting from internal and external radiation exposures **(TEDE)**.

Note: To demonstrate compliance w/ 64E-5.312(1)(a), TEDE must be ≤ 100 mrem.
To demonstrate compliance w/ 64E-5.313(2)(b)2., DDE must be ≤ 50 mrem.

APPENDIX N

Radiation Safety During Radiopharmaceutical Therapy

PROCEDURES FOR ADMINISTERING THERAPEUTIC RADIOPHARMACEUTICALS

1. An authorized user will personally review the patient's case to assure that the therapeutic procedure is appropriate.
2. An authorized user will prepare a written directive for each therapy procedure.
3. An authorized user will use radioactive material or direct technologists in using radioactive material. At facilities authorized for physician training, an authorized user will use radioactive material or direct physicians in training in using radioactive material, with the approval of the radiation safety committee.
4. An authorized user will regularly review the progress of the patient receiving therapy and modify the originally prescribed dose if needed.
5. Check each patient's name and identification number (or other identifier as specified in the quality management program) and the prescribed radionuclide, chemical form, and dosage before administering.
6. Each therapeutic radiopharmaceutical dosage will be assayed in the dose calibrator before it is administered to a patient. Do not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent, except for prescribed dosages of less than 10 microcuries. (When measuring the dosage the radioactivity that adheres to the syringe wall or remains in the needle need not be considered.)
7. Each therapeutic radiopharmaceutical dose will be assayed within 30 minutes before it is administered to a patient. A record of the assay will be made in accordance with 64E-5.616(1), Florida Administrative Code.

SAFETY PROCEDURES FOR USE OF THERAPEUTIC RADIOPHARMACEUTICALS REQUIRING HOSPITALIZATION

1. The patient's room is as far away from the nursing station and heavily trafficked hallways as is consistent with good medical care. It is a non carpeted private room with a private sanitary facility or a room with another individual who is receiving unsealed radioactive materials who cannot be released under Rule 64E-5.622, F.A.C.

2. Room preparation

   A. Use leak-proof absorbent paper to cover large surfaces that are likely to be contaminated, such as the bed, chairs, and the floor around the toilet. Small items, such as the telephone, door knobs, the nurse call cord, the bed remote control, and the television control may be covered with absorbent paper or plastic bags.

   B. Prepare separate containers for linen, disposable waste, and nondisposable contaminated items. Place a single large reclosable plastic bag in each container, or supply several small plastic bags.

   C. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use by nursing, nuclear medicine, and radiation safety personnel.

2. D. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine is collected, prepare collection containers.
   - Urine collection containers are unbreakable and closable.
   - When no assay or volumetric determination is required and urine is decayed in storage, add an absorbent such as vermiculite to each container.
   - Place containers in a box or deep tray lined with a plastic bag and absorbent paper or vermiculite, to avoid room contamination in the case of a spill.
   - Supply a few half-value layers of shielding for each container. (One half-value layer of iodine-131 is approximately 3 mm of lead.)
   - Supply a wide-mouth anti-splash funnel.

3. Order disposable table service (i.e. paper or plastic plates, cups, and utensils) for the duration of the patient's stay.

4. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

5. Supply the nurses with film badges, TLDs, OSLDs or pocket ionization chambers.

6. Ensure that nurses have received current radiation safety training as specified by 64E-5.625(1) Florida Administrative Code, (F.A.C.), and the facility training program. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

7. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

8. Post the room with a "Caution - Radioactive Materials" or “Danger, Radioactive Materials” sign. In addition, if the survey results indicate 5 mrem per hour at 30 centimeters from the patient, a conspicuous sign or signs bearing the radiation symbol and stating “Caution, Radiation Area” will be used and if 100 mrem per hour at 30 centimeters from the patient then the area will need to be posted with a sign indicating “Caution, High Radiation Area” or, “Danger, High Radiation Area”.

9. Only individuals needed for medical, safety, or training purposes will be present during the administration.

10. After administering the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the likely point for the “visitors' safe line," and in the surrounding hallways and rooms. The dose to members of the public will not exceed 2 mrem in any one hour or 100 mrem per year as described in 64E-5.312, F.A.C. The radiation dose may exceed 0.1 rem (1 mSv) to permitted visitors to an individual who cannot be released under Rule 64E-5.622, F.A.C. provided the dose does not exceed 0.5 rem (5 mSv) and the authorized user has determined before the visit that it is appropriate according to 64E-5.312(5), F.A.C.

11. Mark the ”visitors' safe line" on the floor. Determine where the safe line should be based on the survey measurements.

12. Record survey results and any other necessary information on the nursing instructions form or the nurses' dosimeter sign-out form.

13. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area. Materials and items removed from the patient’s or human research subject’s room will be monitored to determine any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or these materials and items will be handled as radioactive waste according to Rule 64E-5.625(8)(a), F.A.C.

14. Do not release any patient until either the exposure rate from the patient is less than 5 mR/hour at 1 meter - *or* - the radioactivity retained in the patient is less than 30 millicuries. When using the exposure rate as the release criterion, measure it with a radiation survey meter at a distance of 1 meter from the umbilicus while the patient is standing, or if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

15. Provide the patient with written radiation safety instructions. These instructions will include steps the patient may take to lessen radiation exposure to family members or others in contact with the patient.

RELEASING A ROOM FOR UNRESTRICTED USE

1. Remove all absorbent paper, and place it in the appropriate radioactive waste container.
2. Transfer all containers to a decay-in-storage or decontamination area.
3. Use a radiation detection survey meter to check for room contamination.
4. Conduct wipe tests for removable contamination in the patient's room and private sanitary facilities.
5. Clean contaminated areas until removable contamination is at background levels when surveyed with a G-M survey meter, or less than 200 dpm/100 cm^2.
6. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

USE OF OTHER THERAPEUTIC RADIOPHARMACEUTICALS

Ensure that nurses have received current radiation safety training as specified by subsection 64E-5.625(1), F.A.C., and the facility training program. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

EARLY RELEASE OF PATIENTS CONTAINING THERAPEUTIC RADIOPHARMACEUTICALS

Licensees and license applicants whose proposed procedures to release individuals who have been administered radiopharmaceuticals containing radioactive material from the control of the licensee that differ from the specifications in number 14 above must submit their proposed procedures to the department for approval according to 64E-5.622(4), F.A.C. NUREG 1556, Volume 9 may be accessed at the NRC's web-site www.nrc.gov for guidance on procedures and calculations.

The procedures must:

1. Demonstrate that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (5 mSv);
2. Contain a copy of the instructions including written instructions to be given to the released individual, or the individual's parent or guardian, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to another individual is likely to exceed 100 millirem (1 mSv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1 mSv) if there were no interruption of breast-feeding, the instructions also shall include:
   (a) Guidance on the interruption or discontinuance of breast-feeding and
   (b) Information on the consequences of failing to follow the guidance.
3. Include a record of the basis for authorizing the release of an individual from control that has been administered radiopharmaceuticals for 3 years after the date of release.

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APPENDIX O

Implant Therapy

We will be performing:

☐ Temporary Implants using the following procedures.

☐ Permanent Implants using the following procedures.

TEMPORARY IMPLANT

1. Assign the patient a private room which should be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care.
2. Supply the nurses with film badges, TLDs, OSLD or dosimeters.
3. Brief the nurses on radiation safety precautions as described in Appendix F. Personnel will be instructed to ask questions at the conclusion of the training.
   Attached is the outline of the training for nursing personnel.
4. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside and in the surrounding hallways and rooms. Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter sign-out form. Post the room with a "Caution Radioactive Materials" and “Caution Radiation Area.” In addition, if the survey results indicate 100 mrem per hour at 30 centimeters from the source then the area will need to be posted with a sign indicating “Caution, High Radiation Area” or “Danger, High Radiation Area.”
5. Upon completion of the implant therapy, perform a radiation survey of the patient and count the implant sources, trains, or ribbons to confirm that all sources have been removed from the patient and are returned to inventory. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source inventory form.

PERMANENT IMPLANT

1. Patient will be provided a private room.
2. A notice to visitors will state that they need to check with the nurse’s station prior to visitation. Nursing personnel will instruct visitors if there are any restrictions to visitation.
3. Brief the nurses on radiation safety precautions as described in Appendix F. Personnel will be instructed to ask questions at the conclusion of the training.
   Attached is the outline of the training for nursing personnel.
4. Brief the patient on radiation safety procedures prior to discharge.
   Attached is an outline of patient instructions.
5. Do not release any patient from the hospital who has received a permanent implant until the exposure rate from the patient is less than 5 mR/hr at 1 meter. Measure this exposure rate with a radiation survey meter at a distance of 1 meter from the umbilicus with the patient standing or if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

Note: Calibration measurements of manual brachytherapy sources must be in accordance with 64E-5.6331 and/or 64E-5.6332, F.A.C.

TEMPORARY IMPLANTS

Patient Name:_____ Patient Number:_____

Authorized User:_____Phone:_____Pager:_____

Dose:_____mCi of _____as_____individual sources was loaded on ____-____-____

Sources will be removed at approximately _____:_____ AM/PM on _____-_____-_____

Radiation Exposure Rates

Date	Time	Bedside	3 ft/1 meter from the bed door
_____-____-_____	____:____	_____mR/hr	____mR/hr ____mR/hr

Release certification: Patient may not be released from the hospital until the following criteria have been met and the attending physician or radiation safety officer (RSO) have signed and dated this section.
I have removed and counted _____ individual sources from this patient. A low-range GM survey of the patient indicated that there are no sources remaining in the patient.

_____ _____
Authorized User or Radiation Safety Officer — Date

Nursing Instructions

VISITOR RESTRICTIONS:

☐ No visitors under 18 or pregnant ☐ _____minutes each day maximum for each visitor.

NURSING RESTRICTIONS:

☐ Patient is restricted to room ☐ Patient is restricted to bed
☐ Patient must not move ☐ No nurses who are pregnant may render care
☐ ____ minutes each day per nurse in the room.

PATIENT CARE:

☐ Wear your radiation monitor when caring for patient. Leave the monitor at the nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share your monitor. Call RSO for additional monitors if needed.
☐ If source appears dislodged, call the attending physician and RSO immediately.
☐ Omit bed bath
☐ No perineal care. Pad may be changed as necessary.
☐ Save surgical dressings for disposal by attending physician or RSO.
☐ See special oral hygiene care instructions.
☐ _____

Emergency Numbers

In case of an emergency, or if you have a questions, phone:
RSO: _____Work:_____ Home:_____ Cell:_____Pager_____
MD: _____Work:_____ Home:_____ Cell:_____Pager_____

RADIATION SAFETY CHECKLIST FOR TEMPORARY IMPLANT THERAPY

Patient:_____ Room:_____ Date:_____

PREPARATION

- ☐ Schedule a private room in a low traffic area.
- ☐ Mark a visitors' "safe line" on the floor of the patient's room.
- ☐ Brief the nursing staff on radiation safety measures.
- ☐ Supply the nursing staff with personnel monitoring devices.

IMPLANT

- ☐ Clear the room of unneeded personnel.
- ☐ Brief the patient on the clinical procedures.
- ☐ Insert the implant.
- ☐ Measure dose rates at the bedside, 1 meter from bedside, visitors' "safe line", entrance door to the patient's room and surrounding hallways and rooms. Move safeline as necessary.
- ☐ Post the room with a "Caution: Radioactive Material" sign.

FOLLOW-UP

- ☐ Perform a radiation survey of the patient to assure that all sources have been removed.
- ☐ Count the number of sources removed from the patient to assure that all sources have been removed.
- ☐ Remove the "Radioactive Materials" sign and release room for general purpose use. Release trash for general disposal.

Instructions to Nursing Personnel for Temporary Implant Patients

All new personnel working with radioactive material will receive detailed instructions in the handling and documentation of radioactive material use.

CESIUM 137 (Cs-137) OR IRIDIUM 192 (Ir-192)

- Cs-137 or Ir-192 will be ordered and stored until insertion. Upon removal, it will be returned to the supplier or inventory.
- Sealed Cs-137 or Ir-192 sources do not produce any contamination of the environment as long as the integrity of the encapsulation is maintained. They are very strong and are designed not to break. Sources may be accidentally broken by cutting them or by dropping a heavy object on them. If a source is broken, tiny particles of cesium can escape and cause contamination.
- Ir-192 can be ordered as seeds in a ribbon.

PROCEDURES FOR HANDLING TEMPORARY IMPLANTS

- Use long forceps or tongs to handle sources.
- Use lead shields when handling radioactive materials.
- Wear a dosimeter when handling radioactive materials.
- Use radiation detection instruments while checking, unpacking, and using radioactive material.
- Ir-192 ribbons can be altered. Use long scissors to cut the ribbon, being careful not to cut into a source. If a source is accidentally cut, carefully dispose of the seed in a lead container. Survey the scissors and area to assure that there is no contamination. Do not use the scissors until they are free of contamination.
- Survey the area thoroughly where the radioactive materials were used to make sure no radioactive materials remain.
- In case of a lost source, immediately contact the RSO.

CHECKLIST (CHECK ALL THAT ARE APPLICABLE)

☐ Special nursing procedures are required. Instructions will be provided by the authorized user or the RSO, prior to assuming duties with patients.

☐ Posting of Patients room should state “Caution, Radioactive Materials” and “Caution, Radiation Area,” “Do Not Enter.”

☐ Nursing personnel monitoring is required. Instructions will be given by the authorized user or the RSO, prior to assuming duties with patients.

☐ No pregnant nursing personnel will take care of patient.

☐ No visitors under the age of 18 years of age or pregnant.

☐ All visitors will be limited to a specific time and will need to be instructed on where they are allowed to stand or sit in the patient’s room.

DISCHARGE OF THE PATIENT

☐ A survey will be conducted by the attending physician or RSO to verify that all sources have been removed from the patient.

☐ The linens, trash and supplies will be surveyed for radioactive materials. If no radioactive materials are found then the items can be treated as normal hospital linens, trash and supplies and can be discarded or cleaned.

☐ The room will be surveyed by the RSO. If no radioactive materials are found, then the room can be released to be used by other patients

☐ Remove all radiation postings on the door.

RADIATION SAFETY CHECKLIST FOR PERMANENT IMPLANT THERAPY

Patient:_____ Room:_____ Date:_____

PREPARATION

- ☐ Schedule a private room
- ☐ Brief the nursing staff on radiation safety measures

IMPLANT

- ☐ Clear the room of unneeded personnel
- ☐ Brief the patient on the clinical procedures
- ☐ Insert the implant in surgery
- ☐ Survey the room, waste, linens, and equipment to make sure no radioactive material remains in the procedure room before transferring the patient to their room.
- ☐ Measure dose rates at the bedside and at 1 meter from the bedside.

FOLLOW UP

- ☐ Perform a radiation survey of the patient to assure that patient release criteria have been met. (less than 5 mR/hr at 1 meter)
- ☐ Perform a survey of the room to assure that no sources remain in the room.
- ☐ Release room for general purpose use. Release trash for disposal.

Instructions to Nursing Personnel for Permanent Implant Patients

IODINE 125 (I-125) AND PALLADIUM 103 (Pd-103) IMPLANTS

Seeds of I-125 and Pd-103 are permanently implanted in the prostate for cancer.

The radioactivity is very low and presents no danger to the patient, visitors, nurses, or other hospital staff.

Some of the seeds may pass through the Foley catheter into the bag of urine so it will need to be surveyed. If there is a large quantity of seeds, the patient may need additional implants inserted to maintain the required dosage for the treatment.

All implants of I-125 or Pd-103 seeds that are found in the patient's urine must be saved. These seeds will be put in a special container. Call the RSO for instructions.

If a permanent radioactive implant patient should die while in the hospital, notify the RSO and the nursing supervisor immediately. The body cannot be released until all the radioactive sources are removed.

CHECKLIST

- ☐ Brief the nurses on radiation safety precautions as described in Appendix F.
- ☐ Posting of patient's room should state "Restricted Area, see nursing personnel before entering".
- ☐ No nursing personnel monitoring is required.
- ☐ No pregnant nursing personnel will take care for patient.
- ☐ No visitors under the age of 18 years or pregnant.

DISCHARGE OF THE PATIENT

- ☐ If patient is catheterized, have the RSO survey the urine, bag and catheter prior to disposal and discharge of the patient.

Instructions to Patients Receiving Permanent Implant

Seeds of I-125 and Pd-103 are permanently implanted in the prostate for cancer.

The radioactivity is very low and presents no danger to the patient, visitors, or family member if these procedures are followed:

1. You will need to strain your urine for 7 days. If some of your seeds are released in your urine you will need to collect the seeds in the provided container. Use a pair of tongs to pick up the seed and place in the container provided to you by the hospital. At the conclusion of 7 days, contact the person below for instructions on returning the container and any seeds to the facility.
2. Please notify any other physician that may be used to manage your care of your implant.
3. If you have any problems, contact the individual below with your concern.

When a permanent radioactive implant patient die, the authorized user should be notified to determine if the body can be released or if extraction of the permanent implant should be performed.

Emergency Numbers

In case of an emergency, or if you have a questions, phone:
RSO: _____Work: _____ Home: _____ Cell_____Pager: _____

MD: _____Work: _____ Home: _____ Cell_____Pager: _____

To return container and any loose seeds, phone:

_____ Work: _____ Home: _____ Cell_____Pager: _____

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APPENDIX P

Monitoring, Calculating, and Controlling Air Concentrations When Using Noble Gases or Radioactive Aerosols

Radioactive aerosols or gases are only administered when airborne concentrations are within the limits prescribed by the ALIs, DACs, and effluent concentrations, July 1993, Table I and Table II and in accordance with 64E-5.629, Florida Administrative Code, (F.A.C.).

PROCEDURE FOR MONITORING OR COUNTING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or spoiled by improper use, humidity, chemicals, or inadequate maintenance.

Radioactive Aerosols Used: ☐ Tc 99m ☐ Other: _____

☐ Aerosols are directly vented to the atmosphere through an air exhaust.

☐ Aerosols are not directly vented to the atmosphere. Spent aerosols are collected in a shielded trap with an effluent air contamination monitor. The monitor manufacturer's instructions for checking its accuracy and constancy are followed and records of the checks are maintained.

☐ Spent aerosol is collected in a shielded single-use device. The trap effluent of single-use devices is not monitored.

Noble Gases Used: ☐ Xenon 133 ☐ Other: _____

☐ Spent gas is directly vented to the atmosphere through an air exhaust system.

☐ Spent gas is not directly vented to the atmosphere. It is recirculated within the facility's air handling system. Recirculated air meets the limits specified in 64E-5.312, F.A.C. and the limits stated in ALIs, DACs, and effluent concentrations for Xenon 133 or other noble gases, Table II, Col. 1.

☐ Spent gas is not directly vented to the atmosphere. Spent gas is collected in a shielded trap with an effluent air contamination monitor. The monitor manufacturer's instructions for checking accuracy and constancy are followed and a record of the checks is maintained.

☐ Spent gas is not directly vented to the atmosphere. Spent gas is collected in a shielded trap. The trap effluent is not monitored by a detector designed to monitor effluent gas. The activity in the trap is counted on receipt and once each month. Monthly, prior to use, during one patient study, effluent is collected from the trap in a plastic bag. The activity in the bag is counted by holding the bag against a gamma camera, with the camera adjusted to detect the noble gas. The counts per minute (cpm) of the bag are compared to background cpm with no other radioactivity in the area. A record is kept of the date, the background cpm, and the measured bag cpm.

☐ The radiation safety officer (RSO) establishes an action level based on bag cpm levels or a multiple of background cpm. A significant increase in the bag cpm indicates that the trap is breaking down and will be replaced.

☐ The trap manufacturer's instructions are followed for replacing the trap.

Attached Calculations

☐ 1. Occupational dose from airborne effluent

☐ 2. Public Dose from airborne effluent

☐ 3. Negative air pressure in work areas

☐ 4. Tabulation of all measured air exhaust rates

☐ 5. Tabulation of all measured air supply rates

☐ 6. Spilled gas clearance time calculations

☐ 7. Other-Facility diagram with supply and exhaust rates for each opening in the restricted area.

OCCUPATIONAL EXPOSURE CALCULATIONS FOR NOBLE GASES

☐ The total activity released to the restricted area (activity used each week multiplied by estimated fractional loss per study - 20%) divided by the total volume of air exhausted over the week (sum of all exhaust rates multiplied by the number of hours the exhaust system was "on" during the week) - is less than the applicable limit stated in the ALIs, DACs, and effluent concentrations, Table I, Occupational Values, Column 3 Inhalation DAC .

☐ Other method used to calculate exposure - see attachment.

If limits are exceeded, determine if the average number of studies actually performed agrees with the number used in the calculations. If necessary fewer studies will be scheduled.

_____ Estimated number of studies per week

_____ Activity to be administered per study

_____ Estimated activity lost to the work areas per study (assume 20% loss)

_____ Sum of all exhaust air rates in cfm [ft^3/min] in areas where xenon gas is administered

_____ Estimated number of minutes the exhaust system is on during a week (continuous = 10,080 minutes = 168 hours)

_____ Total volume of air exhausted over the week [1ft^3 = 28,317 ml - *or* - 28,317 ml/ft^3]

$$\frac{\text{Activity used per week x 20\%}}{\text{Total volume of air exhausted over the week}} \times 50 \text{ weeks} = \text{Average annual airborne concentration}$$

☐ Average annual airborne concentration < ALIs, DACs, and effluent concentrations, Table I, Occupational Values, Column 3 Inhalation DAC.

Documenting Negative Air Pressure in Areas Where Noble Gases are Used

Attached is a facility diagram of each room where noble gas is administered. The diagram indicates the location of each air vent in the area and identifies each vent as a supply air vent or an exhaust air vent. Measured airflow in cubic feet per minute (cfm) for each air vent is recorded on the diagram.

Sum the total airflow for the supply air and sum the total airflow for the exhaust vents. Compare the total supply to the total exhaust. If the rate of total supply airflow exceeds the total rate of exhaust air flow, adjustments to the air handling system are made. Total air exhaust rate must be greater than total supply airflow, where noble gas is administered.

☐ This facility has more than two rooms where xenon gas is administered. Negative pressure calculations for the additional rooms are attached.

Xenon Room

Location or room number: _____

_____ Sum of measured airflow of supply air vents in area where gases are administered (if seasonal airflow differences occur, the lesser airflow rate is used).

_____ Sum of measured airflow exhaust air vents in the imaging room.

_____ Measured airflow exhaust at the storage site (e.g., a fume hood if applicable).

☐ The total exhaust rate is larger than the total air supply rate, indicating that the room where xenon gas is administered is at negative pressure, in comparison to the surrounding areas. (If more than one room is used for xenon studies, a measurement of air flow will need to be made for each additional room.)

SPILLED NOBLE GAS - AREA CLEARANCE PROCEDURES

Calculations are provided to determine for how long a room should be cleared in case of a noble gas spill. The results of the calculations are posted in areas where noble gas is administered. The clearance time may also be posted outside the administration area for reference during a spill. Clearance times are recalculated when major changes to the air handling system occur.

_____ Minutes = Calculated Spilled Gas Clearance Time for _____

_____ Minutes = Calculated Spilled Gas Clearance Time for _____

☐ Clearance time(s) posted as required in subsection 64E-5.629(5), F.A.C.

☐ Spilled gas clearance times are calculated as described in this appendix.

OR

☐ Spilled gas clearance times are calculated *other* than as described in this appendix and are attached for review.

SPILLED NOBLE GAS CLEARANCE TIME CALCULATION

Occupational DAC-hour values are found in the ALIs, DACs, and effluent concentrations, Table I, Occupational Values, Col. 3

Use DAC values to determine when the NMT or authorized user may return to the spill area.

- The Xe 133 DAC-hour value is 1×10^{-4} uCi/ml in restricted areas.
- The Xe 127 DAC-hour value is 1×10^{-5} uCi/ml in restricted areas.

The non-occupational (MOP) values are found in the ALIs, DACs, and effluent concentrations, Table II, Effluent Concentrations, Col. 1.

Use the Effluent Concentrations levels to determine when a MOP may return to the spill area.

- The Xe-133 non-occupational or effluent concentration value is 5×10^{-7} uCi/ml.
- The Xe-127 non-occupational or effluent concentration value is 6×10^{-8} uCi/ml.

Determine "A" The highest activity in microcuries in a single container of noble gas.

Determine "Q" The total room air exhaust measured in milliliters per minute. Measure the airflow (cfm) of each exhaust vent in the room and find the sum. Exhaust may be either the normal air exhaust or a specially installed gas exhaust system.

Determine "C" The allowable air concentrations for occupational exposure in restricted areas (derived air concentration-hour or DAC-hour) - *or* - the air concentration (effluent concentration) limits for member of the public dose.

Determine "V" The volume of the room in milliliters, [$1 ft^3$ = 28,317 ml -*or* - 28,317ml/ft^3].

Determine "t" The calculated evacuation time.

"ln" Is the Natural log

$$t = \frac{-V}{Q} \times \ln (C \times V/A)$$

Sample Calculation

Evacuation time $t = \frac{-V}{Q} \times \ln (C \times V/A)$

Volume of room in milliliters $V = 12' \times 30' \times 8' = 2880\ ft^3 \times 28{,}317\ ml/ft^3 = 81{,}552{,}960$ ml

Room exhaust ml/minute $Q = 900\ cfm \times 28{,}317\ ml/ft^3 = 25{,}485{,}300$ ml/min

Effluent concentration limit $C = 5 \times 10^{-7}$ uCi/ml (Xe-133)

Activity in microcuries $A = 10$ mCi $= 10{,}000$ uCi

$$t = \frac{-81{,}552{,}960}{25{,}485{,}300} \times \ln (5 \times 10^{-7} \times 81{,}552{,}960 / 10{,}000)$$

$$t = -3.2 \times \ln (0.0040776)$$

$$t = -3.2 \times -5.50$$

t = 17.6 minutes

APPENDIX Q

Quality Management Program (QMP)

A written directive will be provided prior to administration of the procedures indicated below except where a delay would jeopardize the patient's health.

This facility will perform the following types of procedures:

- ☐ Diagnostic nuclear medicine procedures using greater than 30 μCi (1.11 megabecquerels) of iodine 131 as sodium iodide;
- ☐ Therapeutic radiopharmaceutical procedures;
- ☐ Brachytherapy procedures;
- ☐ High dose rate remote afterloader procedures;
- ☐ Gamma stereotactic radiosurgery procedures; and/or
- ☐ Teletherapy procedures.

An oral directive will be acceptable if a delay to write a directive would jeopardize the patient's health because of the emergent nature of the patient's condition. The information contained in the oral directive will be immediately documented in the patient's record and a written directive will be prepared and signed by the authorized user within 48 hours.

An oral revision to an existing written directive will be acceptable when a delay to provide a written revision to an existing directive would jeopardize the patient's health. The oral revision will be immediately documented in the patient's record and a revised written directive will be signed by the authorized user within 48 hours of the oral revision.

A written directive that changes an existing written directive can be made for any procedure if the revision is dated and signed by an authorized user prior to the administration of radioactive materials or radiation.

Patients will be identified by more than one method. Prior to the treatment, staff will determine the patient name, the patient date of birth or verify from the hospital identification bracelet the patient's identity.

Final plans of treatment and related calculations, manually or computer generated for brachytherapy, teletherapy, high dose rate remote afterloader and gamma stereotactic radiosurgery will be compared and verified that they agree with the written directive. Verify that any computer-generated calculations are correctly transferred into the consoles of therapeutic medical units. Verifications will be conducted by the therapist on the first day of treatment. The medical physicist will further verify the treatment plans and calculations within three patient treatment days.

If the treatment plan and calculations do not agree with the written directive, the patient will not be treated until the authorized user has been consulted for clarification. If required the written directive will be revised or the treatment plan and calculations will be modified.

Each administration agrees with the written directive.

Any unintended deviation from the written directive is identified, evaluated and appropriate action will be taken at time of discovery.

A review of the QMP will be conducted at intervals not to exceed 12 months. This review and evaluation will include a representative sample of all patient administrations within the review period, all recordable events during the review period and all medical events.

The number of patient cases to be sampled will be based on the principles of statistically accepted sampling and represent each treatment modality performed in the institutions. An error rate or lot tolerance percentage defective of 2%, 5% or 10% per modality will be used. The number of patient cases to be reviewed would follow this table:

Lot Tolerance Percent Defective (Percent Error)		
Lot Size	Sample Size	Acceptance Number
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2001 to 100,000	75	1

The review of the quality management program will be maintained for three years for department review.

Copies of the quality management program will be maintained for the duration of the license.

APPENDIX R

ALARA Component of the Radiation Protection Program including Radiation Safety Committees

ALARA is a philosophy of excellence used in one's day-to-day work with radioactive materials and radiation sources. It is when one strives to keep one's radiation exposure **A**s **L**ow **A**s **R**easonably **A**chievable.

Some changes in procedures can greatly reduce one's radiation exposure. The ALARA philosophy encourages one to actively seek out these methods of exposure reduction. Examples include the use of tongs to handle radioactive material vials containing large activities or high energy emitters. Carrying a vial of radioactive material in a secondary container to increase the source-to-hand distance is also a procedure that helps to keep radiation exposure ALARA.

1. Management Commitment

   A. We, the management of the facility, are committed to keep individual and collective doses as low as is reasonably achievable (ALARA) as described herein. In accord with this commitment, we hereby describe an administrative organization for radiation safety and have established the necessary written policies, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a radiation safety committee (RSC) and a radiation safety officer (RSO).

   B. We will be an active member of the RSC and will consider any modifications or changes as recommended by the RSO as a result of the annual review of the radiation safety program performed by the RSO.

   C. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   D. In addition to maintaining doses to individuals as low as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

2. Radiation Safety Committee

   A. Review of Proposed Authorized Users and Uses

      (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

      (2) When considering a new use of radioactive material, the RSC will review the procedures to maintain exposure ALARA.

      (3) The RSC will ensure that authorized users justify their procedures and that individual and collective doses will be ALARA.

B. Delegation of Authority

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the RSC meeting.

C. Review of the ALARA Component

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a review of occupational radiation exposure every six months with particular attention to instances in which the investigational levels are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program effectiveness and to decide if action is warranted when investigational levels are exceeded.

(3) The RSC will evaluate the annual review performed by the RSO regarding our institution's overall efforts for maintaining doses ALARA and will make any necessary recommendations. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer

A. Annual, Biannual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts and will prepare and present this review to the RSC. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Biannual review of occupational exposures and records of radiation surveys. Every six months the RSO will prepare a summary report for the RSC reviewing occupational exposures and survey results.

(3) Quarterly review of occupational exposures. The RSO will review and initial at least every three months the radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the Investigational Levels of this program.

(4) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter.

B. Education Responsibilities for ALARA Program

(1) The RSO will coordinate briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

3. C. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

D. Reviewing Instances of Deviation from Good ALARA Practices

(1) The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

(2). The RSO will be notified when there is a radioactive spill and will be responsible for decontamination of the area and any involved personnel. The RSO will be responsible for releasing the area to use when the area is at background levels of radiation.

4. Authorized Users

A. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before starting new radioactive material uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

B. Authorized User's Responsibility to Supervise Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

A. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

B. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

6. Investigational Levels to Monitor Individual Occupational Radiation Doses

This institution hereby establishes investigational levels for occupational radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or RSO. The investigational levels that we have adopted are listed in the following table. These levels apply to the exposure of individual workers.

Investigational Levels

The RSO will review and initial the results of personnel monitoring at least every three months. The following actions will be taken at the investigational levels as stated in the table of Investigational Levels.

A. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than values for the Investigational Level I.

B. Personnel dose equal to or greater than Investigational Level I but less than Investigation Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the committee. The committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the committee minutes.

C. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

D. Establishment of new investigational levels above those listed in the table.

In cases where a worker's or a group of worker's doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

	Bimonthly(mrem)		**Quarterly(mrem)**	
Total effective dose equivalent (sum of deep dose equivalent and committed effective dose equivalent)	**Level I** 84	**Level II** 250	**Level I** 125	**Level II** 375
Lens of the eye(eye dose equivalent)	250	750	375	1125
Skin or any extremity (shallow dose equivalent)	840	2500	1250	3750
Individual organ or tissue(sum of deep dose equivalent and committed dose equivalent)	840	2500	1250	3750

APPENDIX S

ALARA Component of the Radiation Protection Program

ALARA is a philosophy of excellence used in one's day-to-day work with radioactive materials and radiation sources. It is when one strives to keep one's radiation exposure **A**s **L**ow **A**s **R**easonably **A**chievable.

Some changes in procedures can greatly reduce one's radiation exposure. The ALARA philosophy encourages one to actively seek out these methods of exposure reduction. Examples include the use of tongs to handle radioactive material vials containing large activities or high energy emitters. Carrying a vial of radioactive material in a secondary container to increase the source-to-hand distance is also a procedure that helps to keep radiation exposure ALARA.

1. Management Commitment

   A. We, the management of the facility, are committed to keep individual and collective doses as low as is reasonably achievable (ALARA) as described herein. In accord with this commitment, we hereby describe an administrative organization for radiation safety and have established the necessary written policies, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a radiation safety officer (RSO).

   B. We will consider any modifications or changes as recommended by the RSO as a result of the annual review of the radiation safety program performed by the RSO.

   C. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   D. In addition to maintaining doses to individuals as low as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

2. Delegation of Authority

   (1) Management will delegate authority to the RSO for enforcement of the ALARA concept.

   (2) Management will support the RSO when it is necessary for the RSO to assert authority.

3. Authorized Users

   A. New Methods of Use Involving Potential Radiation Doses

   (1) The authorized user will consult with the RSO during the planning stage before using radioactive materials for new uses.

   (2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

3. B. Authorized User's Responsibility to Supervise Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

Investigational Levels

The RSO will review and initial the results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in the table of Investigational Levels.

A. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than values for the Investigational Level I.

B. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate. However, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and record this review.

C. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be recorded.

	Bimonthly(mrem)		**Quarterly(mrem)**	
Total effective dose equivalent (sum of deep dose equivalent and committed effective dose equivalent)	**Level I** 84	**Level II** 250	**Level I** 125	**Level II** 375
Lens of the eye(eye dose equivalent)	250	750	375	1125
Skin or any extremity (shallow dose equivalent)	840	2500	1250	3750
Individual organ or tissue(sum of deep dose equivalent and committed dose equivalent)	840	2500	1250	3750

APPENDIX T

Procedure for Leak-Testing Sealed Sources

☐ Leak testing and sample analysis of sealed sources will be performed by individuals licensed by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform leak testing analysis

RECORDS

Records of leak tests must be maintained for 3 years. The records must include the model number and serial number (if assigned of each source tested), the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), the date of the test, and the name of the individual who performed the test analysis.

Additional information regarding leak tests can be found in 64E-5.618, Florida Administrative Code.

LEAK TEST SAMPLES

1. If testing sources stronger than a few millicuries, a survey meter, preferably with a speaker, will be used to monitor exposure rates.

2. A separate wipe sample for each source is prepared. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

   A. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

   B. For larger sealed sources and devices (instrument calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

   C. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care not to touch the field light, mirror or cross hairs. Also wipe the primary and secondary collimators and trimmers.

   D. If you are testing radium sources at the same time, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak test period.

☐ Leak testing of sealed sources will be performed in house following the procedures listed below.

LEAK TEST ANALYSIS

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, use a proportional flow counter or liquid scintillation counter. For gamma sources, a NaI crystal with a scaler will be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

2. Sensitivity of Instrument

   Determine the minimum sample counting times needed to distinguish 0.005 microcurie from the background for each instrument. List instrumentation in Appendix B.

   Measure the background count rate (Rb) in counts per minute (cpm) and record.

   Measure the correction factor (CF) using a known National Institute of Standards and Technology (N.I.S.T.) source and record. Assay a certified check source that has the same isotope as the sealed source being tested. If a certified check source is not available, it will be necessary to use one with a different isotope that has a similar energy spectrum.

   $CF = \frac{Rst-Rb}{A(\mu Ci)}$ Rst = count rate of standard (cpm)

   Example: Background is 30 cpm and a 10 μCi source measures 40,030 cpm on the instrument.

   $CF = \frac{40{,}030-30}{10\ \mu Ci} = 4000$ cpm/μCi.

   Calculate minimum sample counting time (t_{ms}) in minutes for the instrument.

   $$\text{Lower Limit of Detection (LLD)} = \frac{4.66}{CF}\sqrt{\frac{Rb}{t_{ms}}}$$

   $$t_{ms} = \left(\frac{4.66}{CF(.005)}\right)^2 Rb$$

   $$t_{ms} = \frac{868{,}624}{CF \times CF} \times Rb \quad \text{(minutes)}$$

3. Results:

   Count each wipe at least t_{ms}.

   Determine count rate for each sample $Rs = \frac{Ns}{ts}$ (cpm)

   Ns = number of counts ts = sample counting time

   Determine activity as follows:

   $A(\mu Ci) = \frac{Rs-Rb}{CF}$ Record in units of microcuries

4. Continue the same analysis procedure for all wipe samples.

5. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or properly disposed. A report shall be filed within 5 days of the test with the department.

6. Sign and date the list of sources, data, and calculations.

<u>Example</u>

Background is 150 counts in 5 minutes or $\frac{150}{5}$ = 30 cpm

10 μCi cesium standard measures 40,030 cpm

$CF = \frac{40{,}030-30}{10\ \mu Ci} = 4000\ cpm/\mu Ci$

CF = 4000 cpm/μCi Rb = 30 cpm

$t_{ms} = \frac{868{,}624 \times 30}{(4000)(4000)} = 1.63$ minutes

Must count at least 1.63 minutes.

Have chosen to count each sample 5 minutes.

Wipe #1 159 counts in 5 minutes

$R_1 = \frac{159}{5} = 31.8$ cpm

$A_1 = \frac{31.8-30}{4000} = 0.00045\ \mu Ci$

Wipe #2 164 counts in 5 minutes.

$R_2 = \frac{164}{5} = 32.8$ cpm

$A_2 = \frac{32.8-30}{4000} = 0.0007\ \mu Ci$

Both are < 0.005 microcurie.

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APPENDIX U

Iodine-131 or I-125 In-Vivo Thyroid Bioassay Program

Facilities involved in operations which exceed 1 mCi of unsealed radioiodine, must establish a thyroid bioassay program. This program shall be in compliance with section 64E-5.1320, F.A.C.

SENSITIVITY

Determine the minimum sample counting time needed to distinguish 0.04 μCi of I-131 in the thyroid from the background for the instrument. List instrumentation in Appendix B.

Measure the background count rate (Rb) in counts per minute (cpm) and record.

Measure a correction factor (CF) using an I-131 standard and record.

$$CF = \frac{Rst - Rb}{A(\mu Ci)} \qquad Rst = \text{count rate of standard (cpm)}$$

Example: Background is 30 cpm and a 100 μCi standard measures 40,030 cpm on the instrument.

$$CF = \frac{40{,}030 - 30}{100\ \mu Ci} = 400\ cpm/\mu Ci$$

Calculate minimum sample counting time (t_{ms}) in minutes for the instrument.

$$\text{Lower Limit of Detection (LLD)} = \frac{4.66}{CF}\sqrt{\frac{Rb}{t_{ms}}}$$

$$t_{ms} = \left(\frac{4.66}{CF(.04)}\right)^2 Rb$$

$$t_{ms} = \frac{13{,}572}{CF \times CF} \times Rb \quad \text{(minutes)}$$

RESULTS

Count the thyroid for at least t_{ms}.

The quantity of radioactive material (Q) deposited in the thyroid is:

$$Q = \frac{\text{Net Thyroid cpm}}{CF} \quad \text{or} \quad \frac{(\text{neck cpm - bkg cpm})\ (\mu Ci\ \text{capsule})}{\text{capsule cpm - bkg cpm}}$$

Example

Background is 150 counts in 5 minutes or $\frac{150}{5} = 30$ cpm

100 μCi I-131 standard measures 40,030 cpm

$$CF = \frac{40{,}030-30}{100\ \mu Ci} = 400\ cpm/\mu Ci$$

CF = 400 cpm/μCi Rb = 30 cpm

$$t_{ms} = \frac{13{,}572 \times 30}{(400)(400)} = 2.54\ minutes$$

Must count at least 2.54 minutes.

Have chosen to count 5 minutes.

Thyroid Count Rate (Rt) - 175 counts in 5 minutes.

$$Rt = \frac{175}{5} = 35\ cpm$$

$$Q = \frac{35-30}{400} = 0.0125\ \mu Ci$$

Result is < 0.04 microcurie.

BIOASSAY FREQUENCY AND CORRESPONDING ACTIONS.

1. A baseline (pre-employment or pre-operational) bioassay will be performed.
2. A bioassay will be taken within 72 hours of initial use of radioiodine and every two weeks thereafter. When work with radioiodine is on an infrequent basis (less frequent than every two weeks), a bioassay will be taken within ten days of the last day of use.
3. The corresponding actions will be taken if the thyroid burden at the time of measurement exceeds 0.04 microcurie of I-131:
   - A. An investigation of the operations involved, including air and other facility surveys, shall be carried out to determine the causes of exposure and to evaluate the potential for further exposures.
   - B. If the investigation indicates that further work in the area might result in exposure of a worker to concentrations that would cause the limiting intakes established in 64E-5.304, 64E-5.310 or 64E-5.311, Florida Administrative Code, (F.A.C.), to be exceeded, the licensee shall restrict the worker from further exposure until the source of exposure is discovered and corrected.
   - C. Corrective actions that will eliminate or lower the potential for further exposures shall be implemented.
   - D. A repeat bioassay shall be taken within two weeks of the previous measurement and shall be evaluated within 24 hours after the measurement in order to confirm the presence of internal radioiodine and to obtain an estimate of its effective half-life for use in estimating dose commitment.
   - E. Notification reports must be provided as required by 64E-5.345 and 64E-5.347, or as required by conditions of the license and pursuant to subsection 64E-5.625(8), F.A.C.

4. If the thyroid burden at any time exceeds 0.14 microcurie of I-131, the following actions shall be taken:

   A. Carry out all steps as described in 3. a. - e. above.

   B. As soon as possible, refer the case to an appropriate medical consultant for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of radioactive iodine from the body.

   C. Carry out repeated measurements at approximately one week intervals at least until the thyroid burden is less than 0.04 microcurie of iodine 131.

5. Bioassays may be performed quarterly, if the following conditions are satisfied:

   A. The average thyroid burden for each individual working in a given area for which bioassays were performed pursuant to Item 2., above, was less than 0.04 microcurie of iodine 131.

   B. If measurements of the concentration of radioiodine in air are required as a condition of the license, the quarterly average concentration does not exceed 25 percent of the value for I-131 specified in Table I, Column I, of State of Florida Bureau of Radiation Control, ALIs, DACs, and Effluent Concentrations July 1993.

   C. The working conditions during the three month period with respect to the potential for exposure are representative of working conditions during the period in which the quarterly bioassay frequency is employed, and there is no reasonable expectation that the criteria given in 5. A. and B. will be exceeded.

   D. Bioassays shall be randomly distributed over the quarter and will be done within one week after a procedure involving the handling of I-131 to provide a representative assessment of exposure conditions.

6. If the thyroid burden performed during quarterly bioassays exceed 0.04 microcurie of I-131, the following actions shall be taken:

   A. Carry out all steps as described in Items 3 and 4 above.

   B. Reinstitute bioassays every two weeks for at least the next three months before reestablishing quarterly bioassays.

RECORDS

Records of thyroid bioassay measurements will be maintained until termination of the radioactive materials license. The records will contain the thyroid burden measurement, the date of the measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

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APPENDIX V

Survey Meter Calibrations

CHECK APPLICABLE ITEMS

☐ Survey meters will be calibrated by individuals licensed to perform this service by the Florida Bureau of Radiation Control, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

☐ This facility performs survey meter calibrations using the procedures described below.

RECORDS

The facility will assure that all survey instruments will be calibrated at least every 12 months and after repair. The calibration record shall include:

1. A description of the source used;
2. The certified dose rates from the source;
3. The rates indicated by the instrument being calibrated;
4. The correction factors deduced from the calibration data;
5. The name of the individual who performed the calibration; and
6. The date of the calibration.

This record will be maintained for 3 years for inspection.

PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

Attached is a facility diagram illustrating where survey meter calibrations are performed and how the source, shielding and survey meter is configured during calibration.

1. The source used is approximately a point source.
2. Either the apparent source activity - *or* - the exposure rate at a given distance is traceable by documented measurements, to a standard certified by the National Institute of Standards and Technology, within 5% accuracy.
3. A source having approximately the same photon energy as the environment in which the calibrated device is employed is used for the calibration.
4. The source is of sufficient strength to give an exposure rate of approximately 30 mR/hr at 100 cm. (Typical minimum activities are 85 mCi of Cs-137 and 21 mCi of Co-60).
5. The inverse square law and the radioactive decay law are used to correct for changes in distance or source decay.
6. A record is made of each survey meter calibration.
7. A single point on a survey meter scale is considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10%, - *or* - 20% if a correction chart or graph is attached conspicuously to the instrument.
8. Meters offering a linear scale are calibrated on at least two points on each scale. The points are at approximately 1/3 and 2/3 of full scale.

9. Meters offering a multi-decade logarithmic scale are calibrated at no less than one point on each decade - *and* - no less than two points on one of the decades. Those points are approximately 1/3 and 2/3 of the decade.

10. Meters offering an automatically ranging digital display for indicating rates are calibrated at no less than one point on each decade - *and* - at not less than two points on one of the decades. Those points are at approximately 1/3 and 2/3 of the decade.

11. Meter ranges above 1,000 mR/hr may not be calibrated, but are checked for operation and approximately correct responses.

12. Survey meter calibration reports indicate the procedure used and the data obtained. The reports include:

    A. The owner or user of the instrument;

    B. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;

    C. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;

    D. For each calibration point, the calculated exposure rate, the indicated exposure rate, the scale selected on the instrument, and the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate);

    E. The reading indicated with the instrument in the "battery check" mode (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" indicating 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; and

    H. The name of the person who performed the calibration and the date the calibration was performed.

13. This information is attached to the instrument as a calibration sticker or tag.

    A. The source that was used to calibrate the instrument.

    B. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument).

    C. For each scale or decade, one of the following as appropriate:

        (1) The average correction factor;

        (2) A graph or graphs from which the correction factor for each scale or decade may be deduced; *or*

        (3) An indication that the scale was checked for function but not calibrated, or an indication that the scale was inoperative.

    D. The angle between the radiation flux and the detector during the calibration.

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

APPENDIX W

Procedures for Waste Disposal

The following methods of waste disposal will be used: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or return to the manufacturer; and release to in-house waste. Records will be maintained of the disposal of licensed material, with the exceptions of patient excreta and generally licensed in-vitro kit exemptions.

DISPOSAL OF NON-RADIOACTIVE WASTE

1. All radiation labels are defaced or removed from containers and packages prior to disposal and removal from restricted areas. If waste is compacted, all labels that are visible in the compacted mass are defaced or removed.

2. Non-radioactive waste such as leftover reagents, boxes, and packing material is not mixed with radioactive waste.

DISPOSAL OF RADIOACTIVE LIQUIDS AND GASES

Liquids disposed by release to the sanitary sewer or evaporative release to the atmosphere are in accordance with 64E-5.330, Florida Administrative Code (F.A.C.).

1. Material discharged by release into the sanitary sewer system will be readily soluble or readily dispersible in the water. Radioactive material released into the sewer in 1 month divided by the average monthly volume of water released into the sewer will not exceed the concentration listed in Table III of the ALIs, DACs, and effluent concentrations. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations).

   Records will be maintained indicating the date, radionuclide, estimated activity of the release (in millicuries or microcuries), and the sink, toilet or drain where the material is released.

2. Dose limits from effluents to unrestricted areas to members of the public will be maintained as required by 64E-5.312, F.A.C., and Table II of the ALIs, DACs, and effluent concentrations. These limits apply at the boundary of the restricted area. Records will be maintained indicating the date, radionuclide, estimated activity released (in millicuries or microcuries), estimated concentration, and the vent site at which the material is released.

3. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3 or C-14 will be disposed of without regard to its radioactivity. Records will be maintained indicating the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material is disposed.

DISPOSAL BY DECAY-IN-STORAGE (DIS) T1/2 < 120 DAYS

1. Radioactive material with a physical half-life less than 120 days will be segregated according to half-life (short, medium, etc.) when disposed by DIS.

2. One container for all waste for DIS - *or* -separate containers for different types of waste for DIS (e.g., one container for needles and syringes, a second container for gauze, etc., and a third container for unused doses) will be used.

3. Waste will be surveyed with all shielding removed, including any shielding provided by the container.

4. When a waste container is full, it will be sealed with string or tape and an identification tag will be attached. The tag will include the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container will by transferred to a DIS area.

5. Radioactive waste will be held for decay for at least 10 half-lives.

6. Each DIS container will be monitored prior to disposal as in-house trash, according to the following procedure.

   A. Check the radiation detection survey meter for proper operation.

   B. Remove any shielding from around the container.

   C. Monitor DIS waste in a low-level (less than 0.05 millirem per hour) area.

   D. Monitor all surfaces of each individual container.

   E. Monitor waste such that the container does not provide any radiation shielding.

   F. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date that the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

   G. Containers that can be distinguished from background radiation levels are returned to the storage area for further decay or transferred for burial at a low level waste disposal facility.

7. Waste (waste elute, generator tubing, waste bottle components, etc.) from strontium/rubidium generators may be disposed of by DIS in accordance with the procedures above. When there is no evidence of breakthrough, the decay time of holding the waste is based on the half-life of rubidium 82. In situations when a breakthrough of the parent strontium 82 is demonstrated, the decay time of holding the waste is based on the half-life of strontium 82.

8. Mo-99/Tc-99m generators will be returned to the nuclear pharmacy or held 60 days for decay in storage before being dismantled. When dismantling generators, a survey meter (preferably with a speaker) will be kept in the work area. The oldest generator will be dismantled first, subsequent generators will be dismantled in chronological order. Each individual column will be held in contact with the survey meter, in a low-background area. The generator date and disposal date will be logged in the waste disposal records. The radiation labels on the generator shield will be removed or defaced.

9. A record of all decay in storage radioactive material will be retained for 3 years. This record will include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the radiation survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids will be transferred to a burial site. Follow the packaging instructions received from the transfer agent and the burial site operator. The consignment sheet supplied by the transfer agent will be maintained as the record of disposal. The procedures described in 64E-5.332 F.A.C. will be followed.

GENERALLY LICENSED IN VITRO KITS RELEASED TO IN-HOUSE WASTE

Waste from in-vitro kits that are generally licensed are exempt from waste disposal regulations. Radioactive labels will be defaced or removed. No record of release or radiation measurement will be maintained.

RETURNING RADIOACTIVE SOURCES TO THE MANUFACTURER

Packages will be prepared for shipment following the manufacturer's recommendations or as described in Appendix H.

RETURNING GENERATORS TO THE MANUFACTURER

Used Mo 99/Tc 99m generators not decayed in storage for 60 days and all strontium/rubidium generators will be returned to the nuclear pharmacy, following the specifications in Chapter 64E-5, F.A.C., Part XV and the U.S. Department of Transportation (D.O.T.) regulations.

1. Records demonstrating that the package qualifies as a D.O.T. Specification 7A container will be maintained.
2. Packages will be assembled in accordance with the manufacturer's instructions.
3. Dose rate and removable contamination measurements will be performed as required in 49 CFR Part 173, Subpart I, Class 7 (Radioactive) Materials.
4. Packages will be labeled and the shipping papers are completed in accordance with the manufacturer's instructions.

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APPENDIX X

Inventory of Sealed Sources and Brachytherapy Sources

Sealed Source Inventory Requirements

An inventory of sealed sources or brachytherapy sources, except gamma stereotactic radiosurgery sources, will be performed at intervals not to exceed six months and records will be maintained for three years for inspection as required by section 64E-5.618 (8), Florida Administrative Code, (F.A.C). The inventory record will contain the following information:

1. Model number of each sealed source;
2. Serial number of each sealed source if one has been assigned;
3. Identity of each sealed source radionuclide;
4. Estimated activity of each sealed source;
5. Location of each sealed source;
6. Date of the inventory; and
7. Name of the individual who performed the inventory.

Brachytherapy Sealed Source Inventory Requirements

An inventory will be performed as soon as possible each time manual brachytherapy sources are returned to an area of storage from an area of use and shall immediately count or otherwise verify the number returned to ensure all sources taken from the storage area have been returned as required by section 64E-5.633, F.A.C. The inventory for manual brachytherapy sources will contain the following information:

(a) For temporary implants;

1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage; and
2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage.

(b) For permanent implants;

1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage;
2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage; and
3. The number and activity of sources permanently implanted in the patient or human research subject.

***Sealed sources designated as radioactive waste and held for decay in storage as in Rule 64E-5.624, F.A.C., are not required to be inventoried.**

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APPENDIX Y

Use of Diagnostic Radiopharmaceuticals

1. AUTHORIZED USERS SHALL HAVE THE FOLLOWING SPECIAL RESPONSIBILITIES.
   A. Prepare a written directive **- *or* -** assure that the procedure is in accordance with a diagnostic clinical procedures manual, by approving each clinical procedure in the manual including the radiopharmaceutical, dosage and route of administration. The authorized users will document approval of the diagnostic clinical procedures manual by signing and dating a statement of approval, to be maintained with the manual. Prior to administration, the authorized user must document deviations from the diagnostic clinical procedures manual for each patient. Written directives are required for diagnostic procedures involving more than 30 microcuries (1.11 MBq) of I-131 as sodium iodide.
   B. Review personally patients' cases **- *or* -** develop and implement written appropriateness procedures for use with a diagnostic clinical procedures manual, to assure those administering the radiopharmaceutical that the procedure requested by the referring physician is appropriate.
   C. Use radioactive material or direct nuclear medicine technologists in using radioactive material.
   D. At facilities authorized for physician training, direct physicians in training in the use of radioactive material with the prior approval of the radiation safety committee or the licensees' management.
   E. Interpret results of diagnostic procedures.

2. PROCEDURES FOR ADMINISTERING DIAGNOSTIC RADIOPHARMACEUTICALS
   A. An authorized user will prepare a written directive for all diagnostic procedures involving more than 30 microcuries (1.11 MBq) of iodine 131 as sodium iodide.
   B. Administer the dose in accordance with the written directive.
   C. When an authorized user has not provided a written directive, ensure that the referring physician's request agrees with one or more of the appropriateness indicators for the requested procedure and ensure that the dose is administered in accordance with the diagnostic clinical procedures manual.
   D. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
   E. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it varies by more than 20 percent from the prescribed dosage or if the dosage does not fall within the prescribed dosage range, except for prescribed dosages of less than 10 microcuries. (When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.)
   F. An authorized user or a nuclear medicine technologist shall determine by assay or by direct measurement within 30 minutes before each radiopharmaceutical dosage and record the activity of each dosage before medical use. A record of the assay shall be made and will include the information required by 64E-5.616(1), F.A.C.

3. POSTING REQUIREMENTS
   A. A copy of our emergency (spill) procedures (Appendix K), general laboratory safety procedures for working with radioactive materials (Appendix J), our emergency notification notice, and a Notice to Employees document 3/01 will be conspicuously posted at our facility as required by 64E-5.901, F.A.C. Current copies of Part III and Part IX, the license, conditions or documents incorporated into the license by reference and amendments thereto, and operating procedures applicable to activities under the license are not required to be posted provided that a notice is posted which describes the documents and states where they may be examined.
   B. The radiation safety officer's name and phone number and our 24 hour emergency notification number are listed in our emergency procedures.
   C. The location of use for radioactive material will be posted with the proper signage as described in 64E-5.323, Florida Administrative Code.

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APPENDIX Z

Mobile Medicine Service Procedures
64E-5.610, F.A.C.

Vehicle Identification Number (VIN):_____

1. A letter of authorization is obtained from each client location, where mobile medicine services are provided. The letter is signed by the management of each client location and it authorizes the use of radioactive material at their location. Each letter will be retained for three years after the provision of services.

2. All radioactive material will be received at the permanent location or it will be delivered directly to an authorized individual, in the vehicle, at the client location. All individuals authorized to receive radioactive material will receive HAZMAT training.

3. Radioactive material is secured from unauthorized access or is kept under constant surveillance and under the immediate control of the nuclear medicine technologist, authorized medical physicist, or an authorized user, named on the license.

4. Constancy testing is conducted on instruments used to measure the activity of unsealed or sealed sources on each day of use, and before use at each new location. Also daily quality control tests are required on all equipment used to obtain images or information from radionuclide studies and shall be done before medical use at each location.

5. A physician shall be on site at each client's address at the time radioactive materials are administered. An authorized user shall be immediately available to communicate with the supervised individuals or individuals under their direction.

6. All radioactive waste generated shall be removed from the client’s location and stored on the vehicle for subsequent removal at the permanent location.

7. Prior to leaving the client location and at the end of each day of use the nuclear medicine technologist, authorized medical physicist, or the authorized user shall perform a detailed survey of all areas where radioactive materials were used with a radiation survey instrument.

8. Records of survey results are retained for 3 years. Each record includes the date of the survey, a simple diagram of each area surveyed, the measured dose rate in mR/hour at several points in each area of use, the model and serial number of the survey instrument used to conduct the survey, and the initials or name of the individual who performed the survey.

9. Vehicle restrooms shall not be routinely used by patients who have been administered radioactive material. If such a patient does use the restroom, the sewage holding tank of the vehicle shall be emptied and thoroughly rinsed into a sanitary sewer system at the permanent location.

10. Dose generators will not be stored, transported, or used on the vehicle. An amendment to the license will be obtained prior to the transport or storage of dose generators on the vehicle.

11. Radioactive gases or aerosols shall not be used by a mobile service license.

12. Optimum temperature and humidity of the vehicle will always be maintained to prevent damage to sensitive equipment on board the mobile vehicle.

13. All records specified in the radioactive materials license, and required by Chapter 64E-5, F.A.C., are maintained in the vehicle for at least 2 years for inspection, by the Florida, Bureau of Radiation Control. All records that exceed 2 years may be kept at the permanent facility for the duration specified in Chapter 64E-5, F.A.C.

Transportation
D.O.T. – RADIOACTIVE MATERIAL SHIPMENT
Compliance with 49 CFR 170 – 189 and 10 CFR 71

14. Shipping papers: Packages, including radioactive waste transported on the vehicle require a “Bill of Lading” and “Shippers Certificate”. The Bill of Lading notes the contents, activity and form of the material shipped. The certificate is a signed portion of the document attesting to compliance with the U.S. Department of Transportation requirements. These documents are important in case of accident, loss or theft. These documents must be kept within immediate reach of the driver, restrained by a lap belt.

15. All packages containing radioactive material, except exclusive gaseous and "Special Form" shipments must be wipe tested on the exterior of the package for contamination. The limit is 22 dpm/cm^2 over 300 cm^2 or 6600 dpm.

16. Package labels, signs and measurements will be as specified by the U.S. Department of Transportation. Normal Form packages must contain the exterior labeling “Radioactive Material N.O.S. UN2982” and Limited Quantity packages must be labeled “UN2910” as international accepted content designations. Package interior must contain a Radioactive Materials sign. This can be on a syringe or lead container. Yellow II and Yellow III packages require the notation of a “Transport Index” (TI) which is the rounded-up one meter exposure reading.

17. Emergency response information (ERI): it will be kept within reach of the seat-belted driver, whenever the vehicle is in transit or parked on Department of Transportation maintained roads. The ERI must contain the following:
    - Description and technical name of the hazardous material;
    - Immediate health hazards;
    - Risk of fire and explosion;
    - Immediate precautions;
    - Immediate method of handling fire;
    - Handling spills; and
    - First aid.

18. Packages/Containers: A Security Seal is required for all Normal Form packages. This seal must be able to show if the package integrity has been breached. Therefore, padlocks are not acceptable.

19. The driver authorized to ship radioactive materials will receive HAZMAT training.

20. Radioactive material will be blocked and braced and secured during transit.

RADIOACTIVE MATERIALS SECTION
APPLICATION FOR RADIOACTIVE MATERIALS LICENSE
HUMAN USE

INSTRUCTIONS - Complete Items 1 – 35 as applicable. Item 35 must be completed on all applications. Use supplemental sheets where necessary. **Mail the original and one copy to:** Department of Health, Bureau of Radiation Control, Radioactive Materials Section, 4052 Bald Cypress Way, Bin #C21, Tallahassee, FL 32399-1741. *Regulatory Guidance Documents are available from the Bureau of Radiation Control to assist in completing this application.*

1.a. LEGAL NAME, MAILING ADDRESS
(Include ZIP code), FEI #, Phone & Fax Numbers:

FEI #_____

Telephone # _____

Fax # _____

1.b. STREET ADDRESS WHERE RADIOACTIVE MATERIALS WILL BE USED OR STORED (Include ZIP Code)

☐ Same as 1.a.

2.a. LICENSE FEE CATEGORY
(See 64E-5.204, F.A.C., for license descriptions)

_____

b. LICENSE FEE ENCLOSED: $_____

3. THIS IS AN APPLICATION FOR:

☐ **a.** New License

☐ **b.** Amendment To License Number:_____

☐ **c.** Renewal Of License Number:_____

4. INDIVIDUAL USERS & REQUESTED USES
(Name all Authorized Users & Authorized Medical Physicists, who may receive, possess, prepare, use or transfer radioactive materials or directly supervise others in these activities.)

☐ SEE ATTACHED LIST

5.a. RADIATION SAFETY OFFICER (RSO):
(Name and Contact Information)

Name: _____

RSO Phone #:_____

RSO E-Mail: _____

5.b. ALTERNATE EMERGENCY CONTACT:

Name: _____

Contact Phone #: _____

Contact E-Mail: _____

6.a. Radioactive Materials For Medical Use By 64E-5, Florida Administrative Code	Y=☒	Possession Limits
Both: 64E-5.626(1) & (2) Uptake, Dilution, Excretion (Written Directive Required) (NaI-131 ≥ 30 µCi) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	0.5 curies or _____ curies
Only 64E-5.626(1) Uptake, Dilution or Excretions (No Written Directive Required) (NaI-131 < 30 µCi)	☐	0.5 curies or _____ curies
Only 64E-5.626(2) Uptake, Dilution or Excretions **(Written Directive Required)** (NaI-131 ≥ 30 µCi) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	0.5 curies or _____ curies
All: 64E-5.627(1), (2), & (3) Imaging & Localizations (Written Directive Required) (NaI-131 ≥ 30 µCi) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	2 curies or _____ curies
Only 64E-5.627(1) Imaging and Localizations (No Written Directive Required) (NaI-131 < 30 µCi)	☐	2 curies or _____ curies
Both 64E-5.627(2) & (3) Imaging & Localizations **(Written Directive Required)** (NaI-131 ≥ 30 µCi) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	2 curies or _____ curies
☐ 64E-5.627 (4) Xe-133 Gas ☐ Tc99m Aerosol	☐	_____ millicuries
64E-5.628(1) Mo99/Tc99m Generator	☐	5 curies
64E-5.628(2) or (3) Other Generators	☐	Complete Item 6.b.
64E-5.630 Radiopharmaceutical Therapy (Written Directive Required) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	2 curies or _____ curies
64E-5.632 Manual Brachytherapy	☐	2 curies or _____ curies
64E-5.632(2) Sr-90 Eye Applicator ONLY	☐	Complete Item 6.b.
64E-5.632(3)&(4) Pd-103 or I-125 for Permanent Implants ONLY	☐	2 curies or _____ curies
64E-5.634(1) Gamma Stereotactic Radiosurgery	☐	Complete Item 6.b.
64E-5.634(2) Remote Afterloaders	☐	Complete Item 6.b.
64E-5.634(3) Teletherapy	☐	Complete Item 6.b.
64E-5.664 Other Medical Uses Not Listed Above (Detailed Information Attached)	☐	Complete Item 6.b.
64E-5.617 Quantities Exceeded: Calibration, Reference, or Transmission Sources or Other Radioactive Materials in Quantities Greater than Allowed by 64E-5.617	☐	Complete Item 6.b.
64E-5.631 Sealed Sources for Diagnostic Uses	☐	Complete Item 6.b.

6.b. Radioactive Materials Details Not Provided In Item 6.a.

Isotope	Chemical or Physical Form	Maximum number of sources, activity (curies) for each source and total activity	Purpose for which radioactive materials will be used:
Ex. Co-60	Sealed source XYZ Corp. Model XYZ for use in XYZ Corp Model AAA therapy device	30 sources, 2 curies each for a total of 60 curies.	64E-634(1). 15 sources for possession for source exchanges. See attached for procedure details

Item	Appendix	Title	Model Procedure Attached Or NA	Equivalent Procedure Attached
7	None	Facility Diagram	☐ NA	☒
8	A	Radiation Safety Committee	☐	☐
9	B	Instrumentation	☐	☐
10	C	Quality Control	☐	☐
11	D	Dose Calibrator	☐	☐
12	E	Personnel Monitoring	☐	☐
13	F	Training Program	☐	☐
14	G	Ordering And Receiving	☐	☐
15	H	Opening Packages	☐	☐
16	I	Use Records	☐	☐
17	J	Rules Of Use	☐	☐
18	K	Emergency Procedures	☐	☐
19	L	Area Surveys	☐	☐
20	M	Members Of Public Dose Study	☐	☐
21	N	Radiopharmaceutical Therapy	☐	☐
22	O	Implant Therapy	☐	☐
23	P	Radioactive Gases & Aerosols	☐	☐
24	Q	Quality Management Program	☐	☐
25	R	ALARA Program (Radiation Safety Committee Required)	☐	☐
26	S	ALARA Program (No Radiation Safety Committee)	☐	☐
27	T	Leak Testing	☐	☐
28	U	Bioassay	☐	☐
29	V	Survey Meter Calibration	☐	☐
30	W	Waste	☐	☐
31	X	Inventory	☐	☐
32	Y	Diagnostic Radiopharmaceuticals	☐	☐
33	Z	Mobile Nuclear Medicine	☐	☐
34	Other		NA	☐

35. CERTIFICATE

The applicant and any official executing this certificate on behalf of the applicant named in Item 1, certify that this application has been prepared in accordance with Chapter 64E-5, Florida Administrative Code, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. *In addition, the applicant or executing official is acknowledging that they are aware that knowingly making false statements to a public servant is a violation of section 837.06, Florida Statutes, and is punishable by fine or imprisonment*

Certifying Official (Signature)

Name (typed or printed)

Title

Date