STATE OF FLORIDA

DEPARTMENT OF HEALTH

BUREAU OF RADIATION CONTROL

REGULATORY GUIDE

Regulatory Guide 1.50

Revised: July 2013
Revision 1

Instructions for Preparing Applications for Radioactive Materials Licenses Authorizing

UNSEALED AND/OR SEALED SOURCES

(FOR IN-VITRO/CLINICAL LABORATORIES, ACADEMIC, RESEARCH, NUCLEAR SERVICE AND OTHER MISCELLANEOUS USES SUBJECT TO PART XIII OF CHAPTER 64E-5, FLORIA ADMINISTRATIVE CODE)

Regulatory guides are issued to describe and make available to the public acceptable methods of implementing specific parts of Chapter 64E-5, Florida Administrative Code ("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 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 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 Program, 4052 Bald Cypress Way, Bin C21, Tallahassee, FL 32399-1741.

TABLE OF CONTENTS

TABLE OF CONTENTS

I. INTRODUCTION

A. PURPOSE OF GUIDE

This guide provides instructions for preparing an application for a state of Florida radioactive materials license authorizing possession and use of unsealed and/or sealed sources in varying settings ranging from in-vitro, clinical and environmental laboratories, academic, research and development, nuclear service and other miscellaneous uses subject to Part XIII of Chapter 64E-5, F.A.C. Due to the varying nature and scope of licensed operations for which this regulatory guide was developed, the applicability of the procedures contained in this guide will vary for each applicant. In turn, additional information or procedures may be requested when necessary to ensure that an adequate radiation protection program has been established or to address unique aspects of the proposed use of radioactive materials.

License Type: General and Specific

There are two license types: general license and specific license. Certain concentrations, quantities, and items are exempt from the regulatory requirements and may be received without a general or specific license. For additional information concerning exempt concentrations, quantities, and items, review section 64E-5.303, F.A.C.

A general license does not require the filing of applications with the department or the issuance of licensing documents, although the filing of a certificate with the department is required of certain users as specified in subsections 64E-5.206(7) and (8), F.A.C. The license becomes effective upon receipt of the radioactive material. The supplier is required to notify Florida whenever radioactive material has been delivered to a Florida customer. While general licenses offer ease of acquisition, minimal documentation requirements and lower fees, they are subject to certain conditions, requirements, limitations and restrictions. For additional information concerning issuance of a general license or the varying types of general licenses, review section 64E-5.204, F.A.C., and section 64E-5.206, F.A.C.

Radioactive materials whose nuclear properties, chemical and physical form, and activity present a greater health and safety hazard or are not otherwise permitted under a general license require issuance of a specific license. The specific license is a document issued to an applicant, authorizing a particular use of radioactive material. The license identifies the radioactive material, chemical and physical form, maximum activity and the purposes for which it may be used. Applicants must demonstrate that they have appropriately trained and qualified personnel, appropriate facilities, equipment and procedures to ensure safe operations. The fees for a specific license are significantly higher than a general license. The specific license application process is detailed, requiring establishment and implementation of a detailed radiation protection program.

Florida allows authorization for a general license to be included under a specific license. Applicants seeking to include authorization for generally licensed radioactive materials as part of their specific license must include a written request for general license authorization as part of their application; see section III.7. of this introduction for additional guidance. Once approved, authorization for generally licensed radioactive materials will be included as part of Items 6, 7, 8 and 9 of the license, and a general license condition describing requirements associated with generally licensed radioactive materials will be included in the license.

This guide provides instructions for applicants seeking a specific license. Unless otherwise noted, when used in this guide, the term “license” refers to a specific license.

Appendices, Exhibits and Supplements

Applicants must acquire equipment, train 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** are documents used for preparation and submittal of an application. Supplement A is Form DH-1054, which must be completed for each application. Supplement B is a table of attachments that should also be completed and submitted with each application. Supplement C is a checklist that should be used to ensure completeness of an application.

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 safety 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 the 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.

B. 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 (BRC) 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 BRC 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.doh.state.fl.us/environment/radiation. The BRC 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 parts of the regulations applicable to unsealed and/or sealed sources for use in in-vitro and clinical laboratory, academic, research and development, nuclear service and other miscellaneous uses subject to Part XIII are listed below, and should be used in conjunction with this guide. Chapter 64E-5, F.A.C., Part XIII, Subparts A and D include rules that specifically apply to the use of unsealed and/or sealed sources.

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.

C. 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 below. 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; (800) 755-5111 or http://www.sunbiz.org/corpweb/inquiry/search.html. 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 radioactive materials are used/stored. If the two addresses are different, the physical address must be listed in License Condition 10; if they are the same, Condition 10 references the address listed in License Item 2.
3. License Number	Lists the number assigned to the license by the BRC. The number should be referenced in all correspondence with the BRC.
4. Expiration Date	Lists the date the license will expire. A radioactive materials license is valid for 5 years from the date of issuance.
5. Category	Activities involving possession and use of radioactive materials are divided into license categories. Section 64E-5.204, F.A.C., lists license categories and fees. Conducting more than one category of licensed activity requires a separate license for each category of use.

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 (e.g., liquid, sealed source, manufacturer/distributor and model number).
8.	**Possession Limit**	Lists the maximum possession limit and if applicable, it identifies the quantity of sealed sources that the licensee may possess. Possession of quantities greater than are permitted by the license is a 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. Unauthorized use of radioactive material is a violation and may result in enforcement actions.

License Conditions

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. The following conditions may be applicable to unsealed and/or sealed sources for use in in-vitro and clinical laboratory, academic, research and development, nuclear service and other miscellaneous uses subject to Part XIII of Chapter 64E-5, F.A.C.

- Authorized location of use and storage
- Enforcement provisions
- Authorized User (AU) and RSO designations
- Radioactive material transfer limitations
- Radioactive material transportation requirements
- Enforcement provisions
- Part III and IX provisions
- Bioassay requirements
- Leak testing requirements
- Inventory requirements
- Contamination control program
- Exemptions as applicable
- Other restrictions or limitations
- Licensee commitments

II. FILING AN APPLICATION

A. GENERAL

Chapter 64E-5, F.A.C., this guide, forms, and other guidance documents are available on the BRC website: http://www.doh.state.fl.us/environment/radiation.

An application for a specific licenses authorizing unsealed and/or sealed sources for use in in-vitro and clinical laboratory, academic, research and development, nuclear service and other miscellaneous uses of radioactive material subject to Part XIII, must be submitted on Form DH-1054, "Application For Radioactive Materials License, Non-Human Use." The form is included as Supplement A of this guide, and is also available on the BRC website. Space provided on the application form is limited, so 8.5” x 11” paper should be used to append additional pages. Each page submitted with the application should be identified and keyed to the item number on Form DH-1054 to which it applies. Three copies of the application and all attachments must be submitted (original and two copies), with another copy retained by the applicant. 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:
Department of Health Bureau of Radiation Control Radioactive Materials Program 4052 Bald Cypress Way, Bin C21 Tallahassee, FL 32399-1741	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 BRC 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 BRC 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.

B. 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 30 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

This section provides instructions on completing each item listed in Form DH-1054.

1.a. NAME AND MAILING ADDRESS

List the name and mailing address of the individual or company to whom the license will be issued. An applicant corporation or other legal entity must be listed by the legal name registered with the Department of State, Division of Corporations. If a fictitious name is to be included, it will be identified as the name the applicant is doing business as (d/b/a) and must also be registered with the Division of Corporations. For example, "ABC Corporation d/b/a ABC Enterprises of Florida." Business registration may be verified by contacting the Division of Corporations at (800) 755-5111 or on the Internet at: http://www.sunbiz.org/corpweb/inquiry/search.html.

To assist in identifying the proper legal entity, applicants should also list their business' Federal Employer Identification (FEI) or Document Number if known or applicable; the FEI or Document Number is available on the Division of Corporations website.

If the mailing address is different from where radioactive material will be used and/or stored and where license-related records will be maintained, list that address in Item 1.b.

1.b. STREET ADDRESS AT WHICH RADIOACTIVE MATERIAL WILL BE USED AND/OR STORED, IF DIFFERENT FROM 1.a.

Identify by street address the location where radioactive material will be used and/or stored and where license-related records will be maintained, if different that the address listed in Item 1.a. Non-contiguous locations of use and storage may require a separate license; refer to section 64E-5.213, F.A.C.

2.a. LICENSE FEE CATEGORY

Indicate the appropriate license fee category, as follows: For in-vitro and clinical laboratory, list category 3L(II); for academic, list category 3L(III); for industrial or medical research and development, list category 3K; for nuclear service, list category 3P; for gas chromatography devices, list category 3N; for reference or calibration sources equal to or less than one millicurie total, list category 3O; for all other specific license except otherwise noted, list category 3L(V). Refer to section 64E-5.204, F.A.C., or to Regulatory Guide 6.20 for a listing of fees.

2.b. LICENSE FEE ENCLOSED

Indicate the amount of the enclosed license application fee in the space that is provided. Refer to section II.B., of this guide, for a description of licensing fees.

3. THIS IS AN APPLICATION FOR:

Mark the appropriate choice; if submitting an amendment request or a renewal application, indicate the applicable radioactive materials license number in the space provided.

4. INDIVIDUAL USERS

List each individual to be designated as an authorized user (AU) of radioactive material. Specify the radioactive material that each individual is qualified to use, (i.e., sealed and/or unsealed sources) and describe the extent to which each individual is authorized to use each source type or device. Condition 12 of the license will either list each individual with their corresponding authorizations or it may state that "licensed materials shall be used by, or under the supervision and in the physical presence of, individuals who have successfully completed the licensee's training program for authorized users described in their license application. . . " Maintaining documentation of training is required to demonstrate that personnel are adequately trained.

The training program (submitted as part of the radiation protection program under III.13.) must provide a commitment that all AUs will complete either:

- An approved radiation safety course provided by a third party (manufacturer/distributor or another approved training provider), that may be supplemented with supervised experience using the licensed radioactive material and instruction in the licensee's operating and emergency (O&E) procedures; or
- An approved in-house training program meeting the requirement of section 64E-5.1307, F.A.C. If this option is chosen, a detailed description of the in-house training program must be submitted.

5. RADIATION SAFETY OFFICER (RSO)

Provide the name of the individual assigned the position of RSO. This person is designated by and responsible to management for implementation of the radiation safety program and for ensuring compliance with the applicable regulations and license provisions. As a minimum, the RSO must have sufficient training and experience to be an authorized user of the requested radioactive materials. Additional training in administration of a radiation protection program is recommended for the RSO position.

6. TRAINING AND EXPERIENCE IN RADIATION SAFETY

a. FORMAL TRAINING IN RADIATION SAFETY

Submit documentation of radiation safety training for each individual listed in Items 4 and 5 of the application. Restrict training documentation to relevant information (i.e., Information demonstrating that the individual has the radiation safety training and experience specific to the requested activities to be conducted). Appropriate training certificates such as those provided by the manufacturer/distributor or other approved third parties are acceptable. Such certificates may need to be supplemented with documentation of training in the applicant's operating and emergency (O&E) procedures to satisfy Chapter 64E-5, F.A.C., Part XIII training requirements, because third party trainers may not provide such training.

b. EXPERIENCE

Describe any additional relevant work experience with radiation and where and under whose supervision the experience was obtained. Identify the radioactive material, chemical and physical form, maximum activity, and the tests, procedures or research conducted using the material. A curriculum vitae may also be included as supporting documentation, but please do not include the individuals' birth dates or social security numbers.

7. RADIOACTIVE MATERIAL

a. ELEMENT AND MASS NUMBER

List each type of radioactive material requested; refer to the example provided below.

b. CHEMICAL AND/OR PHYSICAL FORM

Complete for each type of radioactive material requested. Identify if the radioactive material, is a solid, liquid, aerosol or gas. Or you may request authorization for any form, or any form except gas. Describe the chemical form (e.g., inorganic or organic). For sealed sources, state the name of the source, manufacturer and the source model number; refer to the example provided below.

c. MAXIMUM AMOUNT TO BE POSSESSED AT ANY ONE TIME

Complete for each radioactive material requested. List the maximum activity of radioactive material that may be possessed. For sealed sources, indicate the total number of sources and maximum activity per source.

Example:

(a)	ELEMENT AND MASS NUMBER	(b)	CHEMICAL AND/OR PHYSICAL FORM	(c)	MAXIMUM AMOUNT TO BE POSSESSED AT ANY ONE TIME
1.	Cesium 137		Sealed source (A.B.C. and Associates Model Model 58-2)		1 source; not to exceed 330 millicuries
2.	Iodine 125		Liquid humic acid in a phosphate buffered solution		200 millicuries
3.	Thorium 230		Any form, except gas		0.1 microcurie
4.	Nickel 63		Foil source (Alpha Beta Chi Corporation Model XYZ-123 or Delta Kappa Rho Company Model 987)		2 sources; not to exceed 15 millicuries each
5.	Sulfur 35		Any form, except gas		10 millicuries

If authorization for generally licensed (GL) sources or devices is sought, include a request for GL sources and devices.

Example:

(a)	ELEMENT AND MASS NUMBER	(b)	CHEMICAL AND/OR PHYSICAL FORM	(c)	MAXIMUM AMOUNT TO BE POSSESSED AT ANY ONE TIME
6.	Radioactive material distributed to a general licensee per 64E-5.206(1) & (4), F.A.C.		Sealed or contained source		No single source to exceed that quantity authorized for the general license

Note: Applicants seeking authorization for GL sources and devices must comply with section 64E-5.1308, F.A.C., which describes requirements for GL devices possessed under a specific license. Annual inspections/inventories must include the GL sources, and the sources must be leak tested at the interval specified by the manufacturer.

8. PURPOSE FOR WHICH RADIOACTIVE MATERIALS WILL BE USED

Complete for each radioactive material requested. Include the name of the manufacturer and model of the device or source holder in which each source is used or stored.

Example:

1. To be used in a low dose irradiator for the calibration of radiation detection instruments.
2. To be used for the measurement of the uptake of humic acids by phytoplankton.
3. To be used as reference, calibration and/or sample spike sources for analysis of environmental samples.
4. To be used in Psi-Epsilon Model 900-0822 electron capture detector (ECD) cells in Psi-Epsilon Model 1230C gas chromatographs (GCs) for sample analysis.
5. To be used for in vitro testing.

If authorization for GL material, sources, or devices is requested, describe the intended use of the GL material, sources or devices.

Example:

6. To be used in devices approved for receipt under general license provisions.

CURRENT INVENTORY

Applicants for renewal of an existing license must include an inventory of all sealed sources and devices currently possessed. List all generally licensed and specifically licensed sources and devices, and indicate the licensing designations for each (i.e., general or specific). If in possession of any exempt sources (e.g., check sources), it is recommended that they be included in the inventory in order to avoid any confusion over their licensing status. If exempt sources are included, identify their exempt status on the inventory form.

9. RADIATION DETECTION INSTRUMENTS

List and describe all radiation detection instruments used for contamination control and other required surveys, analytical analysis or research, including those used for analysis of leak tests and iv-vivo or in-vitro bioassays. An instrument shall be available for detection of radioactive materials authorized by the licensee. Provide all requested information for each instrument as specified and as required by section 64E-5.1318, F.A.C. Attachments may be included as necessary.

10. CALIBRATION OF INSTRUMENTS

If radiation detection instruments will be used, mark the appropriate box to indicate who will perform calibrations. Indicate the calibration frequency for all radiation detection instruments. Note that radiation detection instruments and equipment used for quantitative measurements must be calibrated at least annually.

a. CALIBRATED BY SERVICE COMPANY

If a service company will be used, list the vendor(s) name, address, license number and the government agency that issued the company's license (i.e., NRC or a state agency). Survey instruments must be calibrated at least annually per subsection 64E-5.314(2), F.A.C.

b. CALIBRATED BY APPLICANT

If seeking approval to calibrate instruments in-house, submit detailed information describing the facilities, equipment, personnel, and procedures to be used to perform the calibrations. Contact the BRC for additional guidance on equipment calibration requirements. Note: in-house calibration requires use of reference sources; list each requested calibration/reference source in Item 7.

11. PERSONNEL MONITORING DEVICES

Common personnel monitoring badges include film badges, thermoluminescent dosimeters (TLDs) and optically stimulated luminescent dosimeters (OSLDs), which are described below. Personnel monitoring badges must be capable of detecting the type of radiation (e.g., beta, gamma, neutron) emitted by the radioactive material authorized by the license.

Badge processors must hold accreditation form the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology. A list of NVLAP-accredited badge vendors is available at http://ts.nist.gov/Standards/scopes/dosim.htm. A list of commercial personnel monitoring badge vendors is available from the BRC upon request.

Each order of badges includes a control badge for measuring the amount of background radiation the badges receive each monitoring period. This enables background radiation to be subtracted from the total reading to provide an accurate record of each worker's occupational exposure. When not in use, personnel monitoring badges should be stored with the control badge in an environment protected from radiation, chemicals, excessive heat, light, moisture, etc. to ensure accurate dose records. The control badge must be returned with the other personnel monitoring badges each monitoring period.

Film badges are small pieces of x-ray film contained in a plastic holder. The film darkens in proportion to the amount of radiation it has been exposed to, so the film's optical density provides a measurement of the wearer's radiation exposure. Film badges must be exchanged monthly.

TLDs are personnel monitoring badges that contain small crystals capable of storing some of the energy from radiation. Heating the crystals releases the stored energy as light. The amount of light released is proportional to the amount of radiation the TLD badge received, which is measured to determine the badge wearer's dose. TLDs must be exchanged at least every three months.

OSLDs measure radiation using a thin layer of aluminum oxide. A laser light stimulates the aluminum oxide after use, causing it to become luminescent in proportion to the amount of radiation exposure. OSLDs must be exchanged at least every three months.

in accordance with section 64E-5.315, F.A.C., and subsection 64E-5.1310(4), F.A.C., a whole body film badge, optically stimulated luminescent dosimeter (OSLD), or thermo luminescent dosimeter (TLD) personnel monitoring device shall be supplied and required to be worn by:

- Any individual likely to receive a radiation dose exceeding 500 millirem in any one year; or
- Any individual using or assisting in the use of unsealed sources of radioactive materials of any gamma-emitting isotope with a gamma ray energy greater than 50 kiloelectron volts or the use of any beta-emitting isotope with a maximum beta energy of 300 kiloelectron volts or more.

In accordance with subsection 64E-5.1310(5), F.A.C., an extremity film badge, OSLD, or TLD, monitoring device shall be worn by:

- Any individual using or assisting in the use of unsealed sources of radioactive materials of 1,000 microcuries or more of beta-emitting isotopes with a maximum beta energy of 1,000 kiloelectron volts or more in any month; or
- Any individual using or assisting in the use of unsealed sources who receives a dose of 40 millirem or more on a whole body film badge, OSLD, or TLD, for 2 consecutive months.

12. FACILITIES AND EQUIPMENT

Facilities and equipment must be adequate to protect health and minimize danger to life and property.

Facility Diagram

Submit an annotated diagram of the facility identifying all areas where radioactive materials are received, stored (including waste), prepared, measured and used. Depict the countertops, glove boxes, fume hoods, sinks, cabinets, refrigerators, freezers and other areas where radioactive materials are used, disposed or stored. Identify all adjacent areas and occupied workstations.

Security

Radioactive materials must be secured to prevent unauthorized access or removal. Describe the security measures in place to prevent unauthorized access or removal of radioactive materials.

Fume Hoods and Glove Boxes

Specify the withdrawal rate for fume hoods (an average linear face velocity of 150 feet per minute with a minimum of 125 feet per minute is recommended) and indicate the appropriate window sash height required to maintain this withdrawal rate. If more than one fume hood is available, depict their proximity to each other and indicate if they are used in tandem. A charcoal or high efficiency particulate air (HEPA) filter may be installed in the fume hood or glove box to maintain effluent releases within allowable limits. If a filtration device is used, indicate the frequency at which is monitored and exchanged. Submit applicable procedures.

Ventilation Diagrams

If using radioactive gases outside of a properly functioning fume hood or glove box, submit additional details relating to room ventilation indicating the locations of each supply, return and exhaust vents and the withdrawal rate in cubic feet/minute. As applicable, submit calculations demonstrating compliance with the permissible annual limit on intake, derived air concentrations and effluent concentrations.

Safety Equipment

Submit a list of available safety equipment (e.g., remote handling equipment, personnel respiratory protection equipment, shielded containers, spill kits and fixed area monitors), available shielding and describe the methods used for minimizing the spread of contamination from unsealed sources (e.g., installing vinyl flooring in lieu of carpet and using plastic backed absorbent paper on countertops).

Instrument Calibration Shielding, Equipment and Configuration

If performing calibrations of portable radiation detection instruments, describe the related shielding, equipment (e.g., shielded box, irradiator chamber, remote viewing and handling equipment) and facilities utilized.

13. RADIATION PROTECTION PROGRAM

Submit a detailed description of the proposed radiation protection program, which must include the following components. The appendices and exhibits included with this guide are model procedures and forms that may be adopted by including them as part of the submitted radiation protection program, or used as guides for developing equivalent procedures and forms.

> Reminder: Complete Tables 1 – 3 of Supplement B of this guide to indicate whether model or equivalent procedures and forms have been submitted, and attach a copy to Form DH-1054.

Member of the Public (MOP) Dose Limit Compliance Study **Appendix A**

Applicants for a new license must submit proposed procedures for demonstrating compliance with the public dose limits specified in section 64E-5.313, F.A.C. (2 millirem in any one hour and 100 millirem per year). Applicants for renewal of an existing license must submit a completed study demonstrating compliance with the limits. Appendix A is a model study.

ALARA Policy **Appendix B**

Applicants must submit a policy describing management's commitment to the ALARA philosophy of maintaining doses as low as reasonably achievable, and a description of the commitments of management and workers for implementing the policy. Appendix B is a model ALARA policy.

Duties and Responsibilities of the Radiation Safety Officer (RSO) **Appendix C**

Applicants must submit a description of the RSO's duties and responsibilities that includes the duties listed in section 64E-5.1305, F.A.C. Appendix C is a model procedure.

Radiation Safety Training Program **Appendix D**

Multiple training requirements are applicable to unsealed and/or sealed sources used in-vitro and clinical laboratory, academic, research and development, nuclear service and other miscellaneous uses subject to Part XIII of Chapter 64E-5, F.A.C.

- **Radiation awareness training** ("Instructions to Workers") must be provided to personnel engaged in licensed activities (AUs and workers under their supervision). This training is also recommended for individuals that work in the vicinity of radioactive materials. Section 64E-5.902, F.A.C., specifies radiation awareness training requirements. The rule does not specify the minimum duration for this training, because the amount of training needed will vary depending on the scope of the radiological hazards present in the applicant's workplace.
- **Hazmat employee training** must be provided to any worker with job functions associated with radioactive materials. Hazmat employee training is specified in 49 CFR Part 172, Subpart H. U.S. DOT regulations are incorporated by reference in Chapter 64E-5, F.A.C. The rule does not specify the minimum duration for this training.
- **Authorized User (AU) training** must be provided to workers independently working with radioactive materials or supervising such activities by other workers. AU training requirements are specified in subsection 64E-5.1307, F.A.C.

The training program must describe how the above training requirements will be addressed. Because the topics that must be addressed to satisfy radiation awareness and hazmat employee training overlap with the topics that must be covered during AU training, these training requirements may be addressed concurrently. Training can be provided by qualified third parties, in-house, or by using a combination of the two. Appendix D is a model radiation safety training program aimed at licensees using an approved third party training course, supplemented by in-house training in the licensee's O&E procedures.

Applicants seeking to conduct in-house training must address the requirements specified in subsection 64E-5.1307(2), F.A.C., by submitting a detailed description of the training program for review and approval, including a description of training reference materials, instructor qualifications, and a sample exam.

Personnel Monitoring Procedure **Appendix E**

If PM is conducted, a procedure is required to provide instructions on proper use, exchanges, use of spare badges, lost or damaged badges, and PM record-keeping requirements. Appendix E is a model PM procedure. Exhibits E, F and G are model forms for addressing declared pregnant female requirements.

Operating and Emergency Procedures

Sections 64E-5.208 and 64E-5.1302, F.A.C., require establishment and implementation of O&E procedures that provide instructions adequate to ensure safety to workers, the public and to property. As a minimum, O&E procedures must include the procedures described below.

- **Operating Procedure** **Appendix F**

Due to the varying nature and scope of licensed operations for which this regulatory guide was developed, it is not feasible to provide a model operating procedure that addresses all uses of unsealed and/or sealed sources in in-vitro and clinical laboratory, academic, research and development, nuclear service and other miscellaneous uses subject to Part XIII of Chapter 64E-5, F.A.C. Applicants must consider their own unique licensed operations and use of unsealed and/or sealed sources to ensure that all necessary instructions are included. Therefore, we suggest that you supplement our model procedure with other applicable procedures that relate to your own unique operations.

Appendix F provides generic instructions on availability of procedures, general rules of use/ ALARA principles, radiation surveys, security and routine maintenance. Operating procedures must include instructions on those topics; additional guidance is provided below.

Training

Proper training is the most important factor contributing to safe handling, transport and use of radioactive materials. Individuals shall complete applicable training prior to handling or using radioactive materials.

Availability of Procedures

Operating procedures must include a commitment that AUs will have access to the licensee's O&E procedures, as well as the manufacturer operation/maintenance manual for each type of licensed device or instrument possessed.

Personnel Monitoring Instructions to Workers

Individuals supplied whole body and/or extremity personnel monitoring devices must be provided instructions about when and how the device should be worn, stored and exchanged.

General Rules of Use/ALARA Principles

Instructions should be provided on techniques for minimizing dose, general precautions and the performance of radiation surveys if damage to a radioactive source or device is suspected. The instructions may be supplemented by any specific instructions provided by the manufacturer or distributor of the radioactive source or device.

Security

Radioactive materials must be stored and used in a manner that secures them from unauthorized access or removal. Additional controls (e.g., building locks, monitored security systems, fences, guards, etc.) should be utilized as appropriate to enhance security.

Routine Maintenance

Radioactive sources and devices may require periodic maintenance. Maintenance must be performed in accordance the manufacturer's procedures and recommendations. Typically, the manufacturer's procedures allow for the performance of routine maintenance by authorized users. The performance of non-routine maintenance may be restricted to those acting as the manufacturer's representative.

Posting Requirements

Areas where radioactive materials are used and stored must be posted with appropriate radiation warning as described in 64E-5.323, F.A.C. This procedure also addresses the posting of required documents as specified in section 64E-5.901, F.A.C.

- **Procedures for Ordering, Receiving, Opening and Shipping Packages Containing Radioactive Material** **Appendix G**

Procedures must address preparation and handling of incoming and outgoing shipments of radioactive material transported by common carriers, and if applicable, for radioactive materials transported as private use shipments. The instructions must conform to current U.S. DOT regulations. Sample shipping papers and emergency response information must be provided. Appendix G is a model procedure, Exhibit C is a sample shipping paper for private use shipments, and Exhibit D is a model emergency response information sheet.

- **Rules of Use of Unsealed Sources** **Appendix H**

If using unsealed radioactive materials, the procedures must provide instructions to personnel addressing the safe use and handling of unsealed sources of radioactive material. Appendix G is a model laboratory rules of use procedure.

- **Contamination Control** **Appendix I**

If using unsealed radioactive materials, the procedures must provide instructions to personnel addressing the control of the spread of contamination. Appendix H is a model contamination control procedure.

- **In-Vivo Thyroid Bioassay** **Appendix J**

If using unsealed radioiodine, the procedures must address in-vivo thyroid bioassay monitoring to assess the internal exposure resulting from the use of unsealed radioisotopes. Table 1 of the U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.20, “Applications of Bioassay for I-125 and I-131,” specifies the criteria for the establishment of a bioassay monitoring program.

- **In-Vitro Urinalysis Bioassay** **Appendix K**

If using hyrdorgen-3 (H-3) in tritiated compounds, including HTO, the procedures must address in-vitro urinalysis bioassay monitoring to assess the internal exposure resulting from the use of unsealed radioisotopes. Establishment of a bioassay monitoring program must be in accordance with Table 1 of the U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.32, “Criteria for Establishing a Tritium Bioassay Program.”

- **Emergency Procedures** **Appendix L**

The procedures must provide instructions for responding to accidents, unusual events and the loss or theft of radioactive material and must include emergency notification numbers for the RSO and BRC. If using unsealed sources, the procedures must also address the incidental release or spills of radioactive aerosols, gases, fine particulates, liquids and solids and must include emergency notification numbers for the RSO and BRC. Appendix J is a model emergency procedure.

Leak Testing Procedures

Sealed sources must be tested at regular intervals to ensure that the radioactive material is not leaking contamination. Leak test requirements are specified in section 64E-5.1303, F.A.C.

- **Leak Test Frequency, Collection and Records** **Appendix M**

Sealed sources must be tested at regular intervals to ensure that the radioactive material is not leaking contamination. Leak test requirements are specified in section 64E-5.1303, F.A.C. If a leak test kit is used, indicate the manufacturer and model number. The procedure must specify the leak test interval and include instructions on collecting leak test samples. This information may be obtained from the manufacturer. The procedures must identify the vendors who will be contracted to conduct leak test analysis or include a commitment to have analysis performed by licensed vendors. The procedures must provide instructions for retention of leak test records. Appendix M is a model leak test procedure.

- **Leak Test Analysis** **Appendix N**

If authorization to perform in-house leak test analysis is sought, additional procedures addressing sample analysis must be submitted. The procedure must describe the instrumentation used to perform the analysis and include step-by-step instructions for calculating instrument efficiency and performing sample counts. Appendix N is a model leak test analysis procedure.

Inventory Procedure **Appendix O**

The procedure must provide instructions for performing annual physical inventories and inspections of all generally and specifically licensed sealed source or devices. Inspections must evaluate the physical condition of the sealed source or device and the associated labels. A sample inventory form is also required. Appendix O is a model inventory procedure; Exhibit A is a model inventory form.

Record Retention Procedure **Appendix P**

Certain records must be retained for specified periods of time for compliance purposes. These intervals have been established for BRC inspection staff and other authorized entities (e.g., U.S. DOT) to have access to the documents as required by the regulations. Appendix N provides a model procedure addressing record retention requirements.

Notification and Reporting Procedure **Appendix Q**

Notification and reporting requirements are specified in Parts II and III of Chapter 64E-5, F.A.C. Appendix Q provides a model procedure summarizing notification and reporting requirements.

Radiation Detection Instrumentation Calibration Procedure **Appendix R**

Radiation detection instruments used for quantitative analysis (e.g., dose rate and effluent monitoring) must be calibrated annually for each type of radiation measured. Sections 64E-5.314 and 1318, Florida Administrative Code (F.A.C.), provide additional information regarding radiation detection instrument specifications and calibration. Appendix R is a model radiation detection instrument calibration procedure.

14. WASTE DISPOSAL **Appendix S**

Submit a procedure describing how radioactive materials will be disposed. The procedure must include a commitment that sealed sources will be disposed of either by returning it to the manufacturer or by transferring it to a specifically licensed recipient. Please note that low-level radioactive waste brokers and most manufacturers require a fee to accept radioactive materials for disposal. While certain limits and restrictions apply, unsealed sources may also be disposed by effluent and evaporative release and by decay-in-storage. Appendix S is a model waste transfer/disposal procedure.

15. CERTIFICATE

A radioactive materials license is a legal document. License applications and license-related correspondence must be signed and dated by an individual (certifying official) authorized to make legally binding statements for the applicant. Examples of positions that are recognized as certifying officials include owner, president, vice president, chief executive officer, chief operating officer, etc. Positions that are not recognized as certifying officials include RSO, environmental health & safety director, and laboratory manager.

A certifying official may delegate authority to make legally binding statements to specific individuals or positions (e.g., manager, director, RSO) by submitting a written statement authorizing the delegation. Exhibit H is a model form for documenting a delegation of authority.

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 submitted in letter form or on Form DH-1054, "Application For Radioactive Materials License, Non-Human Use." The request must be dated and signed by a certifying official, identify the license by name and number, be submitted in triplicate, and clearly describe the nature of the changes, additions or deletions requested. 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. To prevent the potential for identity theft, do not submit documentation that lists individuals' social security numbers or birth dates.

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. 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-1054, "Application For Radioactive Materials License, Non-Human Use" (Supplement A of this guide). Renewals require submittal of an entire new application, 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. To prevent the potential for identity theft, never submit documentation that lists individuals' social security numbers or birth dates.

VI. LICENSE TERMINATION

Prior to license termination, the licensee must properly dispose of all licensed radioactive material possessed. Complete Form DH-1059, "Certificate – Disposition of Radioactive Material" to satisfy the requirements of section 64E-5.214, F.A.C., and submit it to the Bureau before the expiration date of the license with a request that the license be terminated.

MOP DOSE LIMIT COMPLIANCE STUDY

I. *Introduction*

Section 64E-5.312, Florida Administrative Code (F.A.C.), requires licensed operations to be conducted so that the following limits are met:

- Radiation doses in unrestricted areas do not exceed **2 millirem (0.02 mSv) in any one hour**
- Doses to members of the public do not exceed **100 millirem (1 mSv) in a year**

Section 64E-5.313, F.A.C., requires surveys, calculations and/or environmental monitoring to be used to demonstrate compliance with the dose limits. A member of the public (MOP) dose compliance study (MOP study) provides documentation of compliance with both regulatory limits. This procedure describes methodologies developed by the Florida Bureau of Radiation Control (BRC), intended for use by licensees authorized to possess and use unsealed and special form sources of radiation, to demonstrate compliance with the MOP dose limits.

The below marked box indicates how this procedure has been utilized:

☐ **New license applicant**: the procedure describes the methodology that will be used to conduct the MOP study after licensed activities begin.

☐ **Renewal application**: the procedure describes the methodology and results of the completed MOP study of existing operations.

II. *Dose Limit for Unrestricted Areas*

For typical academic, in-vitro, clinical and environmental laboratories, academic, research and development, nuclear service, and other miscellaneous uses subject to Part XIII of Chapter 64E-5, F.A.C., there are generally three situations that must be addressed to demonstrate compliance with the 2 millirem in any one hour dose limit for unrestricted areas.

- Use and storage of licensed materials at approved locations;
- Transfer and storage of radioactive waste; and
- Storage of licensed materials in transport vehicles, if applicable;

Section A demonstrates compliance with the unrestricted area dose limit for shipment of licensed materials to and from approved locations of use and storage.

Section B's Method 1 describes the procedure followed when a survey meter is available to conduct radiation measurements. Compliance with the unrestricted area dose limit can also be demonstrated without direct measurements. Section B's Method 2 describes the procedure followed when a survey meter is unavailable. The marked box indicates the method selected for use in this study.

A. Transport Vehicles and Temporary Job Sites

Security procedures approved by the BRC and incorporated into the license describe measures taken by authorized users, and approved personnel working under their supervision, to ensure that public access to restricted areas, incident to the transport of licensed materials to approved locations of use and storage is prevented. During transport and storage at approved locations, procedures require licensed materials to be secured from public access or removal. While in use, licensed materials are maintained under the direct supervision of the authorized user to prevent unauthorized access. Adherence to these procedures ensures compliance with the 2 mrem in any one hour public dose limit.

II. *Dose Limit for Unrestricted Areas*

B. Permanent Facility

☐ **Method 1. Physical Surveys**

Procedures approved by the BRC prevent unauthorized public access to licensed materials at the permanent facility. When stored at other approved locations of use, as applicable, licensed materials are secured in an approved storage area. When in use, licensed materials will be continuously observed by the authorized user, or approved personnel working under his/her supervision.

A radiation detection instrument was used to measure ambient radiation levels in the unrestricted areas around the permanent and waste storage area while all possessed licensed radioactive material were in storage. This survey evaluated the "worst case scenario" – when radiation emitted from licensed operations was at their highest levels. Survey results revealing dose rates below 2 millirem per hour demonstrate compliance.

The following information is attached:

- Date of the survey and the name of the individual(s) performing the measurements.
- Information about the instrument used to perform the survey (manufacturer and model number, the types of radiation detected by the instrument, its minimum and maximum range, and the date it was last calibrated).
- Diagram of the permanent facility identifying the location of use and storage, including waste, adjacent unrestricted areas, nearby MOP workstations, and the locations where all recorded measurements were taken.
- Information about the type and quantity of licensed radioactive materials present during the survey and a description of their location and orientation within the storage area.
- Results of survey(s) of unrestricted area radiation levels, with results keyed to facility diagram.

Note: If surveys note radiation levels > 2 mR/hr, attach a description of controls in place to further restrict access to the storage area (e.g., establishment of expanded restricted area around the storage area, using barricades and/or posted notices).

☐ **Method 2. Calculations**

Radiation levels in unrestricted areas can be calculated using information provided by the respective manufacturers and/or distributors. Prior to shipment, the manufacturer and/or distributor lists the Transport Index (TI) number on the RADIOACTIVE YELLOW II labels on the transport container's exterior surface. The TI indicates the radiation levels at 1 meter (3.3 feet) from the container when it contains the radiation source. The TI value was used as the basis for the calculations. If the TI is less than 2, then radiation levels in all directions around the radiation source when it is stored in its transport container are 2 millirem per hour (or less) at 1 meter, so that is the boundary of the restricted area. In the same way, it may be presumed that the dose rate of transport containers bearing a WHITE I label, have a dose rate less than 1 millirem per hour at 1 meter. Additional distance and shielding provided by the storage area lower the dose rate even further. Storing the source in its shipping container, then storing the container in a cabinet, locker, room, etc. prevents unauthorized access to within a meter or more, so no MOP can receive 2 millirem in any one hour. When calculating for two or more radiation sources,

II. *Dose Limit for Unrestricted Areas*

B. Permanent Facility Method 2: Calculations (Continued)

each source container's TI is added together. While this method is overly conservative, it serves to ensure that the 2 mrem limit is not exceeded.

The following information is attached:

- Diagram of the permanent facility identifying the restricted area, adjacent unrestricted areas, and distance to MOP workstations.
- Information about the type and quantity of radioactive materials present and a description of the location and orientation within the storage room.
- Copies of manufacturer-provided documentation providing information on dose rates and/or TI numbers for the radiation sources being evaluated.
- Results of calculations demonstrating estimated radiation levels in unrestricted areas, with results keyed to the facility diagram.

Note: If calculations note radiation levels > 2 mR/hr, attach a description of controls in place to further restrict access to the storage area (e.g., establishment of expanded restricted area around the storage area, using barricades and/or posted notices).

III. *Annual Public Dose Limit*

A. Total Effective Dose Equivalent

Total Effective Dose Equivalent (TEDE) describes the dose from summation of internal and external radiation doses. The internal radiation dose, or Committed Effective Dose Equivalent (CEDE), and the external radiation dose, Deep Dose Equivalent (DDE), are determined separately using the following supplemental sheets.

1. If licensed only for sealed sources of radioactive material (RAM), complete Table 1.
2. If licensed for unsealed RAM, or both sealed sources and unsealed RAM, complete Table 2, using Method 1 or 2.
3. Include all additional attachments as appropriate.
4. Sum the millirem values for the TEDE boxes as directed. If a RAM use is not among the listed categories, an independent assessment of its contribution to the MOP dose must be made. Attach documentation of all dose calculations performed to complete the assessments.
5. *RAM effluent values are listed in "State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations," July 1993; this document is appended to the end of Chapter 64E-5, F.A.C.

Definitions and Acronyms referenced above and the attached supplemental sheets are defined in section 64E-5.101, F.A.C.

III. *Annual Public Dose Limit*

A. Total Effective Dose Equivalent (Continued)

Table 1. SEALED SOURCES		
☐	TEDE (mrem)	- Complete Section III.B. [Deep Dose Equivalent (DDE)] - Enter the calculated DDE value in the space provided to the left; for external doses from sealed sources; DDE = TEDE Note: To demonstrate compliance with the yearly MOP dose limit specified in 64E-5.312(1)(a), the TEDE must be ≤ 100 mrem.

Table 2. UNSEALED RAM or SEALED SOURCES & UNSEALED RAM		
☐	**Method 1.**	
	DDE (mrem)	- Complete Section III.B. [Deep Dose Equivalent (DDE)] - Enter the calculated DDE in the space provided to the left
	CEDE (mrem)	- Complete Section III.C. [Committed Effective Dose Equivalent (CEDE)] Enter the calculated CEDE in the space provided to the left
SUM	TEDE (mrem)	- Add the DDE and CEDE values to determine the TEDE (DDE + CEDE = TEDE) - Enter the TEDE value in the space provided to the left Note: To demonstrate compliance with 64E-5.312(1)(a), TEDE must be ≤ 100 mrem in a year
☐	**Method 2.**	
	DDE (mrem)	- Complete Section III.B. [Deep Dose Equivalent (DDE)] - Enter the DDE value in the space provided to the left Note: To demonstrate compliance w/ 64E-5.313(2)(b).2, DDE must be ≤ 50 mrem in a year
	Annual average effluent concentrations < values listed in *ALIs, DACs, and Effluent Concentrations**	- Attach documentation for effluent concentrations released in a 12 month period for all radionuclides possessed; the values must be ≤ values listed in *ALIs, DACs, and Effluent Concentrations** - Attach the calculations and assumptions for each radionuclide used to determine effluent concentrations; e.g., ventilation rates or volatility based on usage (heating or aerosol production, etc.)

III. *Annual Public Dose Limit*

B. Deep Dose Equivalent

Tables 1 - 4 describe four DDE calculation methodologies. Indicate the method used to calculate the DDE value.

- New licensee applicants: Mark the box indicating the procedure that *will* be used.
- Current licensees: Mark the box indicating the procedure that was used.

Following determination of the DDE value, enter it in the appropriate tables provided in Section III.A. Attach documentation of all assumptions and calculations used to make the DDE dose determination. Where appropriate, attach an annotated facility diagram to illustrate the radiological conditions present in the workplace.

Method 1. Occupational Worker Dosimetry Data

If the highest annual dose received by the maximally exposed occupational radiation worker is less than 100 millirem (mrem), it can be assumed that no MOP is likely to receive 100 mrem in a year from the same operations.

Assign a personnel monitoring (PM) device (film badge, TLD, or OSLD) to all occupational radiation workers, or at least to those likely to receive the highest exposures. The monitoring period should cover at least 12 continuous months of typical RAM use. In Table 1, record the monitoring period start and end dates, and enter the cumulative dose for the worker receiving the highest dose during the monitoring period.

Table 1. Occupational Worker Dosimetry Data

☐	DDE (millirem)	Monitoring Period Start Date: _____ End Date: _____
		Enter the highest individual cumulative external dose for the 12 month monitoring
		← period in the space provided to the left. Use this value in Section III.A.

Method 2. Dosimetry Data for the Maximally Exposed Individual Member of the Public

If the highest annual dose received by the maximally exposed MOP is less than 100 mrem, it can be assumed that no other MOP is likely to receive 100 mrem in a year from the same operations.

Determine which MOP is likely to receive the highest dose from licensed activities. Monitor the MOP's exposures for at least 12 continuous months by assigning a PM device to the individual. In Table 2, record the monitoring period start & end dates. Sum the individual's cumulative dose for the period and enter it in the space provided. Attach an annotated diagram of the facility to illustrate the radiological conditions present in the workplace.

III. *Annual Public Dose Limit*

B. Deep Dose Equivalent (Continued)

Table 2. Dosimetry Data for the Maximally Exposed Individual MOP		
☐	DDE (millirem)	Monitoring Period Start Date: _____ End Date: _____ ☐ Check to indicate that a facility diagram is attached that identifies all restricted areas and adjacent unrestricted areas, and where the monitored MOP's workstation is located ← Enter the highest cumulative individual dose for the 12 month monitoring period in the space provided to the left. Use this value in Section III.A.

Method 3. Environmental Monitoring Data

If environmental monitoring demonstrates that continuous exposure to ambient radiation levels in the workplace for a year results in doses < 100 mrem, then no MOP is likely to exceed the 100 mrem annual public dose limit due to the licensed operations generating the radiation levels. If environmental monitoring indicates that continuous occupancy would exceed the public dose limit, then occupancy factors may be used to demonstrate compliance.

Post one or more environmental TLDs in the unrestricted areas adjacent to restricted areas, or in the restricted area on a wall adjacent to unrestricted areas, for at least 12 months. Post badges where the highest radiation exposure is expected and where exposure to non-regulated sources of radiation (e.g., medical patients injected with radionuclides) will not contribute to the measurements. Record the monitoring period start and end dates in Table 3. If the results for the 12 month monitoring period total < 100 mrem, mark Box A, indicating that continuous occupancy was used for the dose determination (24 hours/day, 365.25 days/year = 8,766 hours), and enter the total value in the DDE box provided in Table 3.

If the results for the 12 month monitoring period total > 100 mrem, it may be possible to demonstrate compliance with the annual dose limit by applying a more realistic (but still very conservative) occupancy factor, such as 2000 hours for a work year (8 hour work day, 40 hours a week, 50 weeks a year = 2,000 hours). Mark Box B if using a normal work week occupancy factor to calculate the DDE.

Example: The total dose measured by the environmental badges = 280 mrem
The dose received by a MOP working 2,000 hours in the area that the badge was posted is

280 mrem/8,766 hrs = .032 mrem/hr x 2,000 hrs = 64 mrem

Using a 2000 hour occupancy factor means that any annual dose from environmental monitoring that totals < 438 mrem will demonstrate compliance

Example: 438 mrem/8,766 hrs = .049 mrem/hr x 2,000 hrs = 99.9 mrem

If the results for the 12 month monitoring period total > 438 mrem, compliance may still be demonstrated by using an even more realistic occupancy factor, provided the number can be legitimized by supporting documentation (e.g., employment records).

Example: Environmental badges total 680 mrem for the 12 month monitoring period; time sheets indicate that a conservative estimate of the most time spent by any MOP in the monitored area is 25 hours a week, 50 weeks a year = 1,250 hours.

680 mrem/8,766 hrs = .078 mrem/hr x 1,250 hrs = 97 mrem

III. *Annual Public Dose Limit*

B. Deep Dose Equivalent (Continued)

In each case, attach an annotated diagram of the facility to illustrate the radiological conditions present in the workplace and to indicate the location of posted badges.

Notes:
1. Protect posted badges from adverse environmental conditions such as excessive heat and light.
2. Only specifically designed badges are acceptable for environmental monitoring; PM badges are not appropriate. Contact the Bureau of Radiation Control for more information.

Table 3. Environmental Monitoring Data		
☐	DDE (millirem)	Monitoring Period Start Date: _____ End Date: _____ ☐ **A.** Check if calculations are based on continuous year-round occupancy (8766 hours) in unrestricted areas **OR** ☐ **B.** Check if calculations are adjusted for workplace occupancy factors (e.g., 2000 hours for a work year) in unrestricted areas ********** ☐ Check to indicate that a facility diagram identifying restricted areas, adjacent unrestricted areas, and the location of posted environmental monitor is attached ← Enter the environmental monitor's highest cumulative dose for the 12 month monitoring period. Use this value in Section III.A.

Method 4. Radiation Level Data

Survey measurements and calculations can be used to demonstrate that the radiation levels resulting from licensed operations are not likely to cause any MOP to exceed the annual public dose limit.

Radiation levels generated by RAM present in the workplace can be determined by direct measurement with survey instruments, or from indirect information, such as radioactive material package transport index values (describing radiation levels at 1 meter from a package's exterior surface). The radiation level data can then be used with the inverse square law to calculate the DDE. In Table 4, check to indicate use of either radiation survey instrument measurements (Box A-1) or RAM package Transport Index (TI) values (Box B-1) with the inverse square law to calculate the DDE.

The issue of occupancy factors is addressed by selecting one of two options provided in Table 4. Check off the Box A-2 to indicate use of the most conservative scenario -- assuming a MOP is continuously present in the unrestricted area (24 hours/day, 365.25 days/year = 8766 hours). Check Box B-2 to indicate use of a more realistic (but still very conservative) assumption -- the individual located in the unrestricted area is present during all business hours (8 hours/day x 40 hours/week x 50 weeks/year = 2,000 hours).

III. *Annual Public Dose Limit*

B. Deep Dose Equivalent (Continued)

Table 4.		Radiation Level Data
☐	DDE (millirem)	☐ **A-1.** Check to indicate use of radiation survey instrument measurements and the inverse square law to calculate the DDE **OR** ☐ **B-1.** Check to indicate use of RAM package Transport Index (TI) values or RAM package surface radiation levels and the inverse square law to calculate DDE ********** ☐ **A-2.** Check if dose is based on continuous year-round occupancy (8766 hours) in unrestricted areas **OR** ☐ **B-2.** Check if dose has been adjusted for workplace occupancy factors (e.g., 2000 hours for a work year) in unrestricted areas ********** ☐ Check to indicate that documentation of all calculations is attached, along with instrument identification, specifications and calibration information ☐ Check to indicate a facility diagram showing restricted and unrestricted areas is attached ← Enter the calculated DDE in the space provided to the left; use this value in Section III.A.

Inverse Square Law: $I_2 = \dfrac{I_1 R_1^2}{R_2^2}$

Where: I_1 = intensity (radiation dose rate) at distance R_1

I_2 = intensity (radiation dose rate) at distance R_2.

R_1 = distance from RAM with dose rate I_1

R_2 = distance from RAM where dose rate I_2 is calculated

Notes:

A. This formula has 2 limitations: (a) it only applies to gamma-emitting point sources; and (b) the closest distance should be at least 5 source diameters.

B. If using transport package exterior radiation levels, set R_1 = 1 inch.

Example of an Inverse Square Law Calculation Using Survey Meter Measurements

A lab contains a variety of sealed sources. The sources may be treated as a single point source by positioning them together for the measurement. Assuming a collective source diameter of 12 inches, a radiation measurement (I_1) is taken at a distance equal to at least 5 source diameters (R_1) from the grouped sources, shielded behind lead brick corral. The intensity (I_2) at 10 feet (R_2) is the unknown value being sought (the distance to the nearest unrestricted area).

I_1 = 0.1 mR/hr
I_2 = ? mR/hr
R_1 = 60 in. (5 x 12 in.)
R_2 = 120 in. (10 ft.)

$$I_2 = \frac{0.1 \times (60)^2}{(120)^2}$$

I_2 = .025 mR/hr

A 2,000 hour occupancy factor yields:
0.025 mR/hr x 2,000 hours
= 50 mrem
= DDE

III. *Annual Public Dose Limit*

B. Deep Dose Equivalent (Continued)

Example of an Inverse Square Law Calculation Using a Package Transport Index

A shipping case used to store a portable nuclear density gauge bears a Radioactive Yellow II label that shows its TI = 1.2. The nearest MOP workstation is located 24 feet away.

I_1 = 1.2 mR/hr
I_2 = ? mR/hr
R_1 = 3.3 feet (1 meter)
R_2 = 24 feet

$$I_2 = \frac{1.2 \times (3.3)^2}{(24)^2}$$

I_2 = 0.023 mR/hr

A 2,000 hour occupancy factor yields:
0.023 mR/hr x 2,000 hours
= 46 mrem
= DDE

C. Committed Effective Dose Equivalent

If licensed for, or seeking licensure for use of unsealed radioactive material (RAM) or both sealed and unsealed RAM, the internal as well as external radiation hazard must be evaluated to demonstrate compliance with the public dose limits described section 64E-5.312, Florida Administrative Code (F.A.C.)

Committed Effective Dose Equivalent (CEDE) refers to the dose resulting from internal radiation exposures. The CEDE is combined with the **Deep Dose Equivalent (DDE)**, the dose from external whole body exposures, to produce the **Total Effective Dose Equivalent (TEDE)**, the dose resulting from internal and external radiation exposures. Refer to section 64E-5.101, F.A.C., for complete definitions of these terms.

This procedure provides a method of calculating the CEDE value required by Section III.A.

Note: The following may be excluded from CEDE calculations:

- **Sealed sources**
- **Exposure from oral pathways or wounds**
- **Molybdenum 99 from Mo-99/Tc-99m generators based on the Mo-99 breakthrough limit of < 0.15 μCi of Mo-99 per mCi of Tc-99m**

- If any current or requested RAM use does not correspond to the listed options, perform separate calculations of their CEDE dose contributions; attach a description of each RAM type and quantity, and the CEDE calculations performed to determine their dose contribution.

- Sum the applicable mrem values from the marked boxes and enter the sum in the last box; use this value in Section III.A.

III. *Annual Public Dose Limit*

C. Committed Effective Dose Equivalent (Continued)

Description of Radioactive Materials Use -- Types & Quantities		
☐	5 mrem	For any RAM with an ALI value ≥ 100 μCi, total use ≤ 400 mCi in any 12 month period, except C-14; this includes the following RAM: **Cl-36 Cu-64 H-3 N-65 P-32 Rb-81m Sc-46** **Co-57 Fe-55 Hg-203 Na-22 P-33 S-36 Sm-153** **Co-60 Fe-59 I-123 Ni-63 Rb-81 Sb-119 Zn-65** Note: ALI values are listed in Table I, Column 2 of *ALIs, DAC, and Effluent Concentrations,* July 1993 (appended to the end of Chapter 64E-5. F.A.C.)
☐	1 mrem	**C-14** use in any form is ≤ 400 mCi in any 12 month period
☐	1 mrem	**C-14** use in non-volatile forms is ≤ 4 Ci in any 12 month period
☐	1 mrem	**I-125** use in any form is ≤ 1.2 mCi in any 12 month period
☐	1 mrem	**I-125** use in non-volatile forms (other than NaI and not involving heating or exothermic chemical reaction) is ≤ 1200 mCi in any 12 month period
☐	1 mrem	**I-125** use in non-volatile forms (other than NaI and involving heating or exothermic chemical reaction) is ≤ 120 mCi in any 12 month period
☐	1 mrem	**I-125** use as gases and volatile forms (other than NaI and not involving heating or exothermic chemical reaction) is ≤ 12 mCi in any 12 month period
☐	1 mrem	**I-125** use as gases and volatile forms (other than NaI, and involving heating or exothermic chemical reaction) is ≤ 1.2 mCi in any 12 month period
☐	1 mrem	**I-131** use in any form is ≤ 1 mCi in any 12 month period
☐	1 mrem	**I-131** use in non-volatile forms (other than NaI, and not involving heating or exothermic chemical reaction) is ≤ 1000 mCi in any 12 month period
☐	1 mrem	**I-131** use in non-volatile forms (other than NaI, and involving a heating or exothermic chemical reaction) is ≤ 100 mCi in any 12 month period
☐	1 mrem	**I-131** use as gases and volatile forms (other than NaI, and not involving heating or exothermic chemical reaction) is ≤ 10 mCi in any 12 month period
☐	1 mrem	**I-131** use as gases & volatile forms (other than NaI, and involving heating or exothermic chemical reaction) is ≤ 1 mCi in any 12 month period
☐	___ mrem	**Other RAM** not listed above; attach description of types, quantities and the calculations performed to determine their CEDE dose contribution
SUM ☒	**CEDE (mrem)**	← Sum the applicable doses and enter the calculated total CEDE value in the space provided to the left; use this value in Section III.A.

ALARA POLICY

I. *THE ALARA PHILOSOPHY*

Part III of Chapter 64E-5, Florida Administrative Code (F.A.C.), establishes standards for protection against radiation hazards. Section 64E-5.303, F.A.C., requires use, to the extent practical, of procedures and engineering controls based upon sound radiation protection principles to achieve occupational and public doses that are as low as reasonably achievable (ALARA). Management, the radiation safety officer (RSO) and all authorized users must participate in the establishment, implementation and operation of a radiation protection program that applies the ALARA philosophy of minimizing exposures to radiation.

The primary concept of the ALARA philosophy is that unnecessary exposure to radiation should be avoided, even though current occupational exposure limits provide a very low risk of injury. The objective is to reduce occupational exposures (both individual and collective) as far below regulatory limits as is reasonably achievable by means of good radiation protection planning and practice.

II. *MANAGEMENT COMMITMENT*

A. Management is committed to the ALARA philosophy of maintaining occupational and public radiation doses as low as reasonably achievable. It is a management priority for all personnel using radioactive materials to be aware of our commitment to the ALARA philosophy and for them to be instructed in the procedures used to keep their exposures as low as possible.

B. Management has delegated authority to our RSO to ensure adherence to ALARA principles. Management will support the RSO in instances where this authority must be asserted.

C. Management will make all reasonable modifications to procedures, equipment and facilities to reduce exposures, unless the cost is considered to be unjustified. We will be prepared to describe the reasons for not implementing modifications that have been recommended.

III. *WORKER COMMITMENT*

All personnel working with sources of radiation will adhere strictly to policies and procedures applicable to activities involving radiation sources, and will apply ALARA principles and good work practices to minimize their occupational radiation exposures. Time, distance and shielding will be used to keep exposures ALARA. When working with sources of radiation, minimize the time spent near the source, maximize the distance from the source, and make use of available radiation shielding. Workers must report to the RSO any conditions in the workplace that have the potential for causing unnecessary exposures.

IV. *RADIATION SAFETY OFFICER RESPONSIBILITIES*

A. The RSO will emphasize the ALARA philosophy to workers, instruct personnel on current procedures and provide guidance on relevant changes to reduce exposures.

B. The RSO will review dosimetry reports for all monitored personnel to determine if unnecessary exposures are being received. The RSO will investigate within 30 days the cause of any dose considered to be excessive. If warranted, the RSO will take corrective actions to prevent recurrence. A report of each investigation and the actions taken, if any, will be recorded and maintained for inspection purposes.

C. At least annually, the RSO will conduct a formal review of the radiation protection program's content and implementation, as required by 64E-5.303(3), F.A.C. The review will include an evaluation of equipment, procedures, dosimetry records, inspection findings, and incidents. The RSO will assess trends in occupational exposures as an index of the program's success and determine if any modifications to the program are needed. A summary of the results of each annual review, including a description of actions proposed and taken (if any) will be documented by the RSO, discussed with management, and signed and dated by both. A report on each audit will be maintained on file for 3 years from the date of the review.

D. The RSO will provide written notifications of annual radiation exposures to all monitored personnel and will be available to respond to any questions regarding the exposure reports.

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

The radiation safety officer (RSO) is responsible for ensuring compliance with license terms and conditions and the applicable requirements of Chapter 64E-5, Florida Administrative Code (F.A.C.). Management has delegated to the RSO authority to fulfill the duties and responsibilities described throughout the radiation protection program and additional duties specifically indicated below.

A. Ensure that all terms and conditions of the license and these regulations are complied with;

B. Ensure that the sealed sources are leak tested as prescribed by the license;

C. Ensure that radioactive materials are used only by individuals who are authorized by the license and that all individuals wear required personnel monitoring equipment;

D. Maintain all records required by the license and state of Florida regulations. These records shall include personnel monitoring records, leak tests records, inventory records, training records for users, and receipt, transfer and disposal records;

E. Ensure that radioactive materials are properly secured against unauthorized access or removal;

F. Serve as a contact with the department for events such as the loss, theft or damage of radioactive material; and

G. Ensure that all users read and understand emergency, operating and radiation safety procedures.

In accordance with subsection 64E-5.213(7), F.A.C., the Florida DOH Bureau of Radiation Control will be notified in writing within 30 days after the RSO permanently discontinues performance of RSO duties. Notification will identify the new RSO and include documentation demonstrating that the new RSO is qualified to use radioactive materials.

RADIATION SAFETY TRAINING PROGRAM

I. *Introduction*

The handling and use of radioactive materials is restricted to trained personnel. Individuals working with radioactive materials will either be an Authorized User (AU) -- an individual that has completed formal radiation safety training – or an individual who is supervised by an AU.

There are multiple training components, which are described below. Sections II - IV describe the applicability of and regulatory requirements for each type of training. Radiation awareness training, "Instructions to Workers" will be provided to each worker using radioactive materials and to any other worker that the radiation safety officer (RSO) determines to be likely to exceed 100 millirem/year from the company's operations. Authorized User training will be provided to workers who independently use radioactive material or supervise the use of radioactive material by other workers. Hazmat employee training will be provided to any worker responsible for preparing, receiving or transporting packages containing radioactive material. Sections II – IV provide additional details for each type of training.

Training Requirement	**Regulations**
♦ Radiation awareness training, "Instructions to Workers"	64E-5.902, F.A.C.
♦ Hazmat employee training	64E-5.1501 & 64E-5.1502, F.A.C., 49 CFR 172.700 – 172.704
♦ Authorized User (AU) training	64E-5.1307, F.A.C.

II. *Radiation Awareness Training/Instructions to Workers*

A. Prior to working with radioactive material, individuals will receive the general radiation awareness training, "Instructions to Workers" as specified in section 64E-5.902, F.A.C. The following instructions will be provided:

- ♦ Information on the company's storage, transfer, and use of radioactive material;
- ♦ The health protection problems associated with exposure to radiation and radioactive material;
- ♦ Precautions and procedures used to minimize radiation exposures;
- ♦ Applicable provisions of Florida's radiation control regulations and the company's radioactive materials license;
- ♦ Workers' responsibility to report any unsafe conditions in the workplace;
- ♦ Appropriate responses to warnings made in the event of incidents having the potential for radiation exposure; and
- ♦ Reporting requirements for occupational radiation exposures described in section 64E-5.903, F.A.C.

II. *Radiation Awareness Training*

B. Subsection 64E-5.902(2), F.A.C., states that the extent of the instructions must be commensurate with the potential radiation hazard present in the workplace. Formal training typically lasts 2 – 4 hours. The duration of the course may vary based on the instructor's determination of the attendees' comprehension of the topics covered. A question and answer session will be held at the end of the training period, and attendees will be encouraged to request clarification as necessary during or after the presentation.

C. Documentation of the training will be maintained to demonstrate compliance.

III. *Hazmat Employee Training*

A. Radioactive material is classified as hazardous material by the U.S. Department of Transportation (DOT). In accordance with DOT regulations (49 CFR Part 172, Subpart H), individuals must complete HAZMAT training prior to performing work that directly affects hazardous material transportation safety. (Exception: employees can work for 90 days without the training, provided a hazmat-trained employee directly supervises them.) Refresher training must be provided at least once every 3 years.

B. Hazmat training includes general awareness/familiarization, function specific, safety, and security awareness training. It will be provided in-house or by qualified third party trainers. The training may also be conducted concurrently with other radiation safety training (i.e., radiation awareness training and/or AU training).

C. Documentation of HAZMAT training will be maintained for the duration of each worker's employment, plus 90 days, and will include the following information:

- The employee's name and date of most recent training completed;
- Description, copy of training materials and their location;
- Name and address of the person providing the training; and
- Certification that the employee has been trained and tested as required.

IV. *Authorized User Training*

A. Radioactive materials will be used by, or under the supervision and in the physical presence, of individuals who have completed formal radiation safety training covering the applicable subjects listed in subsection 64E-5.1307(1), F.A.C. Any third party course offered by a manufacturer, distributor or independent consultant may be used, provided the bureau accepts the training.

If in-house radiation safety training is provided, it will be conducted in accordance with a training program that has been approved by the Florida Bureau of Radiation Control and incorporated into the company's radiation protection program.

IV. ***Authorized User Training***

B. Subsection 64E-5.1307(1), F.A.C., includes operating and emergency (O&E) procedures as a required training topic. Unless training in our company's O&E procedures is addressed during third party training and documentation is provided by the trainer demonstrating its inclusion in the course, in-house training in O&E procedures will be provided. O&E procedures training will be conducted by the RSO or another experienced AU, and separate documentation of O&E procedures training will be provided for each worker.

C. Documentation of compliance with Chapter 64E-5, F.A.C., Part XIII requirements for radiation safety training for each AU will be maintained on file until termination of the license.

PERSONNEL MONITORING PROCEDURES

I. *Instructions for Using PM Badges*

A. General Instructions

Whole body personnel monitoring (PM) badges will be assigned to workers using or assisting in the use of radiation sources in accordance with sections 64E-5.315, Florida Administrative Code (F.A.C.), and section 64E-5.1310, F.A.C.

Extremity PM badges will be assigned to workers using or assisting in the use of unsealed sources in accordance with subsections 64E-5.1310(5) and 64E-5.1310(6), F.A.C.

Whole body badges are worn on the front of the torso, at or above the waist and below the shoulder. Extremity badges may be worn either on the palmar side of the finger or the wrist. Badges must be returned to the RSO at the end of each monitoring period to ensure rapid processing. The RSO must be notified immediately if a PM badge is lost or damaged.

PM badges are individually assigned and cannot be shared. If a spare badge is used, it must be marked with the name, initials and/or identification number of the individual designated to wear it. Badges cannot be worn during non-occupational radiation exposures (e.g., medical or dental x-rays, etc.).

If a badge is lost or damaged, an estimate of the worker's dose for the period covered by the badge must be provided to the badge vendor and kept on file. If a spare badge is used for the remainder of the monitoring period, the dose recorded on the spare badge must be added to the estimated dose to obtain the worker's total occupational dose for the monitoring period.

Recommended Work Practices for Personnel Monitoring

- Never leave PM badges in close proximity to a source of radiation.
- Protect badges from moisture, chemicals, intense heat or light.
- When not in use, store badges with the Control badge in a low background radiation area.

B. Special Instructions for New Hires and Lost/Damaged Badges

A spare badge may be assigned to a new employee until the badge vendor can be notified to issue a badge bearing the worker's name for the next monitoring period. Spare badges may also be used to replace a badge that has been lost or damaged before the end of the monitoring period. To ensure their use by only one individual, spare badges will be imprinted with the worker's name or another form of identification. Workers using spare badges will have the dose recorded by the badge added to their occupational dose record. In the event of a lost/damaged badge, the RSO will estimate the worker's dose for the period the badge was worn, and notify the badge processor if the individual's dose record needs to be revised.

II. *PM Record Requirements*

A. Records of Prior Occupational Dose

The radiation dose received during the current year will be determined for each monitored worker. In addition, every reasonable effort will be made to obtain the lifetime cumulative occupational radiation dose from each monitored worker. If an individual is unable to provide their lifetime cumulative exposure records, the licensee will attempt to obtain these records from the individuals previous employers and document this request. The records must include all of the information required by section 64E-5.308, F.A.C., using Form DH-1623 or an equivalent form.

II. *PM Record Requirements*

B. Records of Personnel Monitoring Results

Records of doses received by each monitored worker will be reviewed by the RSO within 30 days of receipt to determine if unnecessary exposures are being received. The RSO will sign, or initial, and date each report reviewed and will investigate within 30 days the cause of any personnel exposure considered to be excessive. If warranted, the RSO will take corrective actions to prevent recurrence. A report of each investigation and the actions taken, if any, will be documented and maintained for inspection purposes.

PM records will be maintained as long as the license remains in effect. The records will be kept on Form DH-1622 or an equivalent form and will contain all of the information required by section 64E-5.339, F.A.C. These records will be updated annually.

C. Annual Reports to Monitored Individuals

Each worker assigned a PM badge will receive a written annual exposure report describing the past year's monitoring results, as required by section 64E-5.903, F.A.C. Records documenting that the reports have been furnished to monitored workers will be maintained for 3 years.

D. Termination Reports to Monitored Individuals

Within 30 days of termination of employment, or within 30 days after the individual's exposure has been determined, whichever is later, each monitored worker will receive a written exposure report summarizing the individual's occupational radiation exposure, as required by section 64E-5.903, F.A.C. Records showing reports have been furnished to monitored workers will be retained for at least 3 years.

E. Records for Female Workers and Declared Pregnancies

Upon hiring, female personnel assigned to work with sources of radiation will be provided verbal instructions concerning the potential risks involved for pregnant women exposed to radiation and a copy of U.S. NRC Regulatory Guide 8.13 (**"**Instruction Concerning Prenatal Radiation Exposure" – Rev. 3, 6/99). Following receipt of the instructions and guidance, female workers will document receipt of these instructions by signing the *Instructions for Women Working With Radiation* (Exhibit F or equivalent).

Declared pregnant women will be provided verbal instructions to always wear their assigned PM badge at waist level to estimate the embryo/fetus dose. Such workers will sign an *Instructions for Declared Pregnant Women* form (Exhibit G or equivalent) to document receipt of instructions on PM requirements during pregnancies and a *Declaration of Pregnancy* form (Exhibit H or equivalent) that includes the estimated date of conception. The forms will be retained until license termination.

Fetal doses will be kept ALARA, and will not be allowed to exceed 500 millirem during the entire pregnancy as a result of occupational exposures. Efforts will be made to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. In addition, reasonable efforts will be made to adhere to regulatory recommendations to limit the embryo or fetus exposure to 50 millirem in any one month. Records of fetal dose will be documented in an *Occupational Radiation Dose Record* (Form DH-1623 or equivalent) and the forms, with the dose records of the declared pregnant woman, will be retained until license termination.

II. *PM Record Requirements*

F. Occupational Dose Limits for Minors

Minors are not allowed to receive an annual occupational dose exceeding 500 millirem. Dose records for minors will be documented with the *Cumulative Occupational Radiation Dose Record* (Form DH-1623 or equivalent) and *Occupational Radiation Dose Record* (Form DH-1622 or equivalent) as appropriate, and the records will be retained until license termination.

G. Worker Overexposure Reports

When a report of an individual's exposure must be sent to the Florida Bureau of Radiation Control as required by section 64E-5.347, F.A.C., the exposed individual will also be notified no later than when the report is sent out.

OPERATING PROCEDURES

I. *Training*

Proper training is the most important factor contributing to safe handling, transport and use of radioactive materials.

Prior to handling or using radioactive materials, workers shall:

A. Have received radiation awareness instructions required by section 64E-5.902, Florida Administrative Code (F.A.C.);

B. Have documentation on file of their completion of an approved radiation safety training course satisfying the requirements specified in section 64E-5.1307, F.A.C., or

Work under the supervision and in the physical presence of individuals who have received the training described above; and

C. Complete applicable hazmat employee training as required by the U.S. Department of Transportation in Title 49, Code of Federal Regulations (49 CFR), Part 172, Subpart H.

II. *Availability of Procedures*

A. A complete and current copy of the company's operating and emergency procedures is maintained with the licensed device or instrument at all times. When transported, these procedures are typically kept with shipping papers. At a fixed facility, both of these documents may be posted, as is required for the emergency procedure, or are kept on file by the RSO for ready reference as indicated in the "Notice to Employees 3/01."

B. Copies of the manufacturer's operation/maintenance manual for each licensed device or instrument are kept on file by the radiation safety officer (RSO) for ready reference.

III. *Personnel Monitoring*

Individuals assigned whole body and/or extremity personnel monitoring (PM) badges will adhere to the following instructions.

A. Assigned whole body and/or extremity PM badge (film, TLD or OSLD) must be worn at all times whenever handling, transporting, or using radioactive material.

B. A PM badge is assigned to only one individual and cannot be shared. An assigned badge bears the name of the individual that has been assigned the badge. If a spare badge is used, it must be marked with the name, initials and/or identification number of the individual using it, and cannot be shared.

C. Whole body PM badges are to be worn at the chest or waist level. Extremity PM badges should be worn on the palmar side of the wrist or finger. Badges cannot be worn during non-occupational radiation exposures (e.g., medical or dental x-rays, etc.).

III. *Personnel Monitoring*

D. Do not store PM badges near a source of radiation; store them in a low background area whenever possible. They must be protected from moisture and extreme environmental conditions such as intense heat or light, or chemicals. Promptly return badges to the RSO for exchange at the required interval.

E. Immediately notify the RSO if a PM badge is lost or damaged. A record of the worker's estimated dose must be provided to the badge vendor and kept on file. A spare badge will be issued for the remainder of the monitoring period. If a spare badge is used, the dose recorded on the badge must be added to the worker's occupational exposure total by notifying the badge processor.

IV. *General Rules of Use*

A. **ALARA Philosophy.** All personnel using radiation sources must follow the ALARA philosophy – keep radiation exposures As Low As Reasonably Achievable. The objective is to reduce occupational and public exposures as far below regulatory limits as possible by means of good work practices. Apply the following methods to minimize radiation exposures:

- Minimize the **TIME** spent in close proximity to the radiation source (the shorter the time, the lower the dose);
- Maximize the **DISTANCE** from the radiation source (doubling the distance quarters radiation intensity); and
- Make use of available **SHIELDING** to block out radiation.

B. Use of a radiation source, including maintenance of devices, must be in accordance with the manufacturer's instructions and recommendations.

C. **Radiation Surveys.** If damage to a radiation source appears to have the potential to cause excessive exposures, a radiation detection instrument must be used to measure the radiation levels. If damage is suspected, immediately notify the RSO, who will arrange to have the radiation source surveyed as soon as possible. Refer to the emergency procedures for further instructions.

D. Opening or removing sealed sources from a device or instrument is prohibited. When appropriate for minimizing radiation exposure, remote handling tools will be used to manipulate radiation sources.

V. *Security*

A. Each radiation source must be secured from unauthorized access or removal when transported or stored. Additional controls may be used to enhance security.

B. When not in storage or transit, keep radiation sources under continuous surveillance and immediate control. Do not permit unauthorized persons in areas of use.

VI. *Routine Maintenance*

A. Only authorized users are allowed to perform routine maintenance and cleaning of licensed devices and instruments. Assigned PM badges must be worn at all times during such activities. A copy of the appropriate manufacturer's operation manual must be on hand, and the maintenance instructions strictly followed. If recommended, use remote handling tools as instructed.

B. Non-routine maintenance or repair that requires removal of the source is prohibited. Such operations can only be performed by the manufacturer or other specifically authorized persons.

VII. *Posting Requirements*

A. Emergency Procedures, Notice to Employees and Notices of Violations

- Emergency procedures approved by the Florida Bureau of Radiation Control must be conspicuously posted for quick reference in the event of an emergency. The Florida Bureau of Radiation Control radiological notification poster may also be posted.

- A current Florida Bureau of Radiation Control "Notice to Employees" document must be conspicuously posted for review by workers. The notice describes radiation control regulations, employer and worker responsibilities, radiation exposure reporting requirements, and inspection requirements.

- Notices of violations, proposed imposition of administrative penalties, or Florida Bureau of Radiation Control issued orders will be posted within 5 working days after receipt. Responses to such documents will be posted within 5 working days after dispatch. These documents will remain posted for a minimum of 5 working days or until action correcting the violation(s) has been completed, whichever is later.

B. Other Required Documents

The documents listed will be conspicuously posted, unless the "Notice to Employees" document is used to identify where they can be examined by workers (the form has space available to list where the other documents may be examined).

- Parts III and IX of Chapter 64E-5, Florida Administrative Code

- Radioactive materials license, conditions or documents incorporated into the license by reference and amendments thereto

- Operating procedures

VII. ***Posting Requirements***

C. Radiation Warning Signs

- "CAUTION (or DANGER), RADIOACTIVE MATERIAL(S)" sign: will be posted as required in rooms/areas/containers used to store radioactive materials; signs must include the radiation symbol described in section 64E-5.322, F.A.C.

- "CAUTION, RADIATION AREA" sign: will be posted as required in each radiation area when ambient radiation levels exceed 5 mrem (0.05 mSv) per hour; signs must include the radiation symbol described in section 64E-5.322, F.A.C.

PROCEDURES FOR ORDERING, RECEIVING, OPENING & SHIPPING PACKAGES CONTAINING RADIOACTIVE MATERIAL

To address requirements specified in Chapter 64E-5, Florida Administrative Code, and by the U.S. Department of Transportation (DOT) in Title 49, Code of Federal Regulations (49 CFR), the procedures described below will be followed.

Only personnel qualified as hazmat employees in accordance with 49 CFR Part 172 requirements are allowed to perform the transport-related functions described below.

I. *Ordering and Receipt*

A. The Radiation Safety Officer (RSO) will place or approve all orders for radioactive material and ensure that the requested material and form are authorized by the license and will not exceed possession limits specified in the license.

B. Transportation carriers must be provided instructions describing where to deliver packages containing radioactive materials.

II. *Opening Packages*

A. Visually inspect each package for signs of damage (e.g., wet or crushed). Using a calibrated survy instrument, monitor the external surfaces for contamination of all packages labeled as White I, Yellow II or Yellow III. **If any damage or excessive radiation levels are noted, immediately notify the RSO or RSO designee.**

B. Open the package with the following precautionary steps:

1. Remove the packing slip.

2. Open the outer package following the supplier's instructions when provided.

3. Open the inner package and verify that the contents agree with the packing slip.

4. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

5. If anything is other than expected, stop and notify the RSO.

C. Wipe the external surface of the final source container and remove the wipe sample to a low background area and monitor it. If the instrument indicates a reading above background, stop the procedure and notify the RSO.

D. Confirm that the material received is the material that was ordered.

E. Monitor the packing material and the empty packages for contamination, before discarding.

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

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

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

G. Section 64E-5.327, F.A.C., allows certain exemptions from package contamination monitoring for radioactive material in the form of gas, special form or for the quantities of radioactive material less than or equal to the A1 or A2 quantities defined in Part XV.

III. *Transportation*

A. **Markings and labels** on radioactive materials transport containers must be durable, legible, in English, and printed on or affixed to the package surface (e.g., a label, tag or sign). Required package labels and markings cannot be obscured by any other markings, labels or obstructions.

1. Required **markings** include:

- *Shipping name*;
- *RQ* (Reportable Quantity; applies to shipments with activities specified in 49 CFR 172.101, Appendix 2, Table A);
- *Identification number*; and
- *Package type*.

RQ Package Marking

2. Required **labels** include:

- *"Cargo Aircraft Only" label* (for shipments by air)
- *Two DOT warning labels* applied to opposite sides of the package, listing the radionuclide and activity in SI units (English units may be listed after SI units) and the package's Transport Index (TI), the dimensionless number indicating the package's radiation level at 1 meter.

Cargo Only Label

Package Labeling Criteria

Warning Label	Max. Rad. Level at Package Surface (mR/hr)	Max. Rad. Level at 1 m (TI)
RADIOACTIVE WHITE I	0.5	None
RADIOACTIVE YELLOW II	50	1
RADIOACTIVE YELLOW III	200	10

RADIOACTIVE WHITE I

RADIOACTIVE YELLOW II

RADIOACTIVE YELLOW III

III. *Transportation*

B. Packaging, Marking and Labeling Exceptions for Limited Quantity Shipments

49 CFR Section 173.421 states that if the quantity of radioactive material does not exceed the amount specified in 49 CFR Section 173.425 and conforms to the requirements specified in 49 CFR Section 173.421 it is exempted from the specifications of packaging, labeling and marking (except for the UN identification number marking requirement described in 49 CFR Section 173.422[a]). The following procedure applies to qualifying shipments of unused radioactive material and waste.

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 millirem/hour by monitoring the package prior to the 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.

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 package itself bears the marking "Radioactive."

5. The following statement will be enclosed with the package, included with the packing list or otherwise forwarded with the package: "The package conforms to the conditions and limitation specified in 49 CFR Section 173.421 for radioactive material, excepted package-limited quantity of material, UN 2910."

LIMITED SHIPMENT QUANTITES FOR EACH COMMONLY USED RADIONUCLIDES

Radioisotope	Limited Shipment Quantity (mCi) $A_2 \times 10^{-4}$	Radioisotope	Limited Shipment Quantity (mCi) $A_2 \times 10^{-4}$
Ba-133	8.1	I-131	1.9
Cr-51	81	P-32	1.4
C-14	8.1	P-33	2.7
Cs-137	1.6	Ra-226	0.0081
H-3	110	S-35	8.1
Hg-203	2.7	Sn-113	5.4
I-125	8.1	Zn-65	5.4

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. The above values have been calculated using information from 49 CFR section 173.425, Table 7 – Activity for Limited Quantities, Instruments and Articles, and 49 CFR 173.435, Table of A1 and A2 Values for Radionuclides. The values identified in these tables are may also used for determining the limited shipment quantities of special form sources and limited quantity instruments or articles.

III. *Transportation*

C. Shipping papers

The information required on a shipping paper (bill of lading) depends on the type of shipment being made, as described below.

1. **Private use shipments** are sole use shipments, with all loading, transport and unloading carried out by the licensee's trained personnel in accordance with the shipper's instructions, which must accompany the package during shipment. Private use shipments require a bill of lading with the following information.

   - *Description of shipment* (Include the proper shipping name, RQ [if applicable], identification number, hazard class, package type, name and activity of each radionuclide, category of warning label and Transport Index) (same as for common carrier shipments)
   - *Emergency response telephone number* (24-hour-monitored number of a person knowledgeable about the hazards associated with the source of radiation being shipped)
   - *Date of shipment*

   While not a requirement, the name, address and telephone number of the shipper may be included as a security enhancement.

2. **Common carrier shipments** (packages offered to third parties for transport) require a bill of lading with the information listed below. If shipped by air, the carrier will provide a "Dangerous Goods Airbill" form to document required information. Common carrier shipping papers must have all information typed in. In addition to the information described above, common carrier shipments require a bill of lading with the following information.

   - *Name and address of shipper* (can be the *consignee* [the licensee offering the package for shipment] or the *consignor* [service company shipping the package])
   - *Description of shipment* (RQ [if applicable], proper shipping name, hazard class, identification number, type of package, name and activity of each nuclide, category of labeling and Transport Index)
   - *Emergency response telephone number* (24-hour-monitored number of a person knowledgeable about the hazards associated with the source of radiation being shipped)
   - *Shipper's certification* (statement certifying that the package has been properly classified, described, packaged, marked and labeled, and is in proper condition for transportation)
   - *Signature of shipper and date of shipment*

   Additional Statements Required for Air Shipments

   - *Cargo aircraft statement*: "Cargo aircraft only"
   - *Package dimensions*
   - *Candy-stripe borders*

III. *Transportation*

C. Shipping papers (contd.)

3. Emergency response information (ERI) provides first responders (i.e., medical, fire and law enforcement personnel) with the information needed to take appropriate action in the event of an emergency. Drivers are required to have in their possession a separate ERI sheet for each type of radioactive material being transported.

4. Accessibility, Shipping papers and ERI are immediately accessible to the driver during transport. That is, the papers are within immediate reach and either readily visible to a person entering the driver's compartment or in a holder mounted to the inside of the door on the driver's side of the vehicle.

D. Inspection

Prior to shipment, transport containers will be inspected to ensure proper packaging and unimpaired physical condition of the container and its closure devices. Any defects must be promptly reported to the RSO. The RSO will tag and remove from use any package found to be defective and ensure their repair or replacement.

E. Blocking and bracing

Transport containers will be blocked and braced to prevent shifting during normal transportation conditions. Transport containers will not be transported in a vehicle's passenger compartment.

Rules of Use of Unsealed Sources

I. Laboratory coats or other protective clothing are worn at all times in areas where radioactive materials are used;

II. Disposable gloves are worn at all times while handling radioactive materials;

III. Eating, drinking, smoking, or applying cosmetics in any area where radioactive material is stored or used is prohibited;

IV. Storing food, drinks, or personal effects in areas where radioactive material is stored or used is prohibited;

V. If applicable, personnel monitoring devices are worn at all times while in areas where radioactive materials are used or stored;

VI. Dispose of radioactive waste only in designated, labeled and properly shielded receptacles; and

VII. Radioactive materials are confined in clearly labeled appropriate containers.

VIII. Ensure security of radioactive materials. Do not leave radioactive materials unattended in unsecured areas.

Contamination Control

I. *Radiation Surveys*

A. At the conclusion of each day of use or receipt, survey all areas with a radiation survey instrument where radioactive materials are received and used.

B. Survey weekly with a radiation survey instrument all areas where radioactive materials or waste are stored.

C. Surveys shall be completed with an operable and calibrated instrument adhering to the requirements specified in section 64E-5.1319, F.A.C.

II. *Removable Contamination Surveys*

A. Survey weekly for removable contamination in all areas where radioactive materials or wastes are routinely used and stored.

B. If the radioactive materials authorized by the license are not detectable with the instruments described above in section I.C. above, a removable contamination survey shall be completed at the end of each day of use of all areas where radioactive materials are routinely used.

C. Radiation detection instrumentation used for removable contamination measurements will adhere to the requirements specified in section 64E-5.1318, F.A.C. A detailed description of the instruments and procedures used for measuring contamination, in accordance with subsection 64E-5.1318(2), F.A.C., is attached.

III. *Personnel Surveys*

A. Prior to leaving the restricted area, personnel shall be monitored for contamination in a low background area.

B. Surveys shall be completed with a calibrated instrument as described in section 64E-5.314, F.A.C., and capable of measuring dose rates as low as 0.1 millirem per hour, if applicable.

IV. *Action Levels and Decontamination*

A. The action levels for removable contamination as established in paragraph 64E-5.1319(2)(c), F.A.C., are as follows:

1. 100 dpm per 100 square centimeters of any alpha-emitting radioactive materials not listed in this section;

2. 1,000 dpm per 100 square centimeters of any beta- or gamma- emitting radioactive materials not listed in this section;

3. 50 dpm per 100 square centimeters of any transuranic;

4. 2,000 dpm per 100 square centimeters of uranium; or

5. 2,000 dpm per 100 square centimeters of any radioactive material with a half-life of less than 80 hours.

IV. *Action Levels and Decontamination*

B. The action levels for dose rate surveys is 2 millirem/hour. Measured dose rates exceeding this value will be cause for implementing decontamination procedures.

C. If removable contamination or dose rate action levels are exceeded, decontamination efforts will be taken as described in emergency procedures. Following completion of decontamination efforts, the contaminated area will be resurveyed to assess effectiveness of decontamination and to ensure that it is now below the established action levels.

V. *Notification and Records*

A. Notify the Radiation Safety Officer (RSO) if the contamination detected during the surveys exceeds the action levels established in subsection 64E-5.1319(2), F.A.C.

B. Make a record of required surveys and retain a copy for 3 years. Records shall include the following information:

1. The date of the survey;

2. An annotated diagram of each area surveyed;

3. Background levels;

4. Measured dose rates or removable contamination results will be keyed to the diagram. Measured dose rates will be expressed in millirem per hour. Removable contamination results will be expressed in dpm per 100 square centimeters or counts per minute if performed with a radiation survey instrument. Corresponding action levels established for both measured dosed rates and removable contamination results will be identified on the diagram.

5. The serial number and model number of the instrument used to make the survey or analyze the samples; and

6. The initials of the person who performed the survey.

IN-VIVO BIOASSAY PROCEDURE

I. *Scope and Purpose*

In accordance with subsection 64E-5.1310(3), Florida Administrative Code (F.A.C.), and sections 64E-5.307 and 64E-5.315, F.A.C., a bioassay monitoring program is established to assess the internal exposure resulting from the use of unsealed radioisotopes.

In-vivo thyroid bioassays will be performed for individuals involved in operations using iodine-125 (I-125) or iodine-131 (I-131) in accordance with criteria specified in Table 1 of the U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

II. *In-Vivo Thyroid Bioassay Frequency and Corresponding Actions*

A. A baseline (pre-employment or pre-operational) bioassay will be performed.

B. 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.

C. The corresponding actions will be taken if the thyroid burden at the time of measurement exceeds 0.12 microcurie of I-125 or 0.04 microcurie of I-131:

1. 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.

2. 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 worker will be restricted from further exposure until the source of exposure is discovered and corrected.

3. Corrective actions, which will eliminate or lower the potential for further exposures, shall be implemented.

4. 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.

5. Notification reports must be provided as required by 64E-5.345 and 64E-5.347, or as required by conditions of the license.

D. If the thyroid burden at any time exceeds 0.5 microcurie of I-125 or 0.14 microcurie of I-131, the following actions shall be taken:

1. Carry out all steps as described in C. 1. – 5. above.

2. 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.

II. *In-Vivo Thyroid Bioassay Frequency and Corresponding Actions*

D. Continued:

3. Carry out repeated measurements at approximately one week intervals at least until the thyroid burden is less than 0.12 microcurie of iodine 125 or 0.04 microcurie of iodine 131.

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

1. The average thyroid burden for each individual working in a given area for which bioassays were performed pursuant to B., above, was less than 0.12 microcurie of iodine-125 or 0.04 microcurie of iodine-131, and less than the corresponding proportionate amount of a mixture of these nuclides during the initial 3 month.

   Refer to Appendix B (Calculation of Action Levels for Mixtures of I-125 and I-131) from U.S. NRC Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131," for additional information regarding the calculation of proportionate amounts of mixtures of iodine-125 and iodine-131.

2. 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-125 or I-131 specified in Table I, Column I, of State of Florida Bureau of Radiation Control, ALIs, DACs, and Effluent Concentrations July 1993. The appropriate proportionate amount of a mixture of a mixture of I-125 and I-131 should be used as a guide when both I-125 and I-131 are present.

3. 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 E.1. and E.2., above, will be exceeded.

4. Bioassays shall be randomly distributed over the quarter and will be done within one week after a procedure involving the handling of I-125 or I-131 to provide a representative assessment of exposure conditions.

F. If the thyroid burden performed during quarterly bioassays exceed 0.12 microcurie of I-125 or 0.04 microcurie of I-131, the following actions shall be taken:

1. Carry out all steps as described in Items C and D above.

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

G. 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.

III. *Instrumentation and Measurment*

In-Vivo I-131 Thyroid Bioassay Measurement – Instructions for determining the counting correction and calculations applicable to the measurement and determination of the in-vivo thyroid bioassay results.

A. Determine the minimum sample counting time needed to distinguish 0.04 Ci of I-131 in the thyroid from the background for the instrument. Measure the background count rate (Rb) in counts per minute (cpm) and record.

B. Measure a correction factor using an I-131 standard and record.

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

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

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

C. Calculate minimum sample counting time (tms) in minutes for the instrument.

$$\text{Lower limit of detection} = \frac{4.66}{CF}\sqrt{\frac{Rb}{t_{ms}}}$$

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

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

D. Results

Count the thyroid for at least t_{ms}

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

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

IV. *Instrumentation and Measurment*

E. Example

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

100 μCi I-131 standard measures 40,030 cpm

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

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 = $\frac{35\text{-}30}{400}$ = 0.0125 μCi

Result is < 0.04 microcurie.

IN-VITRO URINALYSIS BIOASSSAY PROCEDURE

I. *Scope and Purpose*

In accordance with subsection 64E-5.1310(3), Florida Administrative Code (F.A.C.), and sections 64E-5.307 and 64E-5.315, F.A.C., a bioassay monitoring program is established to assess the internal exposure resulting from the use of unsealed radioisotopes.

In-vitro urinalysis bioassays will be performed for individuals involved in operations using hydrogen-3 (H-3) in tritiated compounds, including HTO, in accordance with criteria specified in Table 1 of the U.S. NRC Regulatory Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program."

II. *Tritium Bioassay Frequency and Corresponding Actions*

A. A baseline (pre-employment or pre-operational) bioassay will be performed.

B. A bioassay shall be taken within 72 hours of initial use of tritium and every 2 weeks thereafter. When work with tritium is on an infrequent basis (less frequent than every 2 weeks), a bioassay shall be taken within 10 days of the last day of use.

C. Corresponding actions will be taken according to the action levels listed below:

1. If the intake of tritium within any 40-hour work period exceeds the amount that would be taken into the body from uniform exposure for 40 hours at the air concentration of 5×10^{-6} microcuries per milliliter, action will be taken to conduct evaluations, implement necessary corrective actions, and generate and maintain a record in accordance with section 64E-5.339, F.A.C.

2. If the urinary excretion rates exceed 5 microcuries per liter but are less than 50 microcuries per liter, the following actions shall be taken:

   a. An investigation of the operations involved, including air and surface contamination surveys, shall be carried out to determine the causes of exposure and to evaluate the potential for further exposures or possible involvement of other employees;

   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 sections 64E-5.304, 64E-5.310, or 64E-5.311, F.A.C., to be exceeded, the worker shall be restricted from further exposure until the source of exposure is discovered and corrected;

   c. Any reasonable corrective actions that will eliminate or lower the potential for further exposures shall be implemented;

   d. A repeat bioassay shall be taken within 1 week of the previous measurement and shall be evaluated within 1 week after the measurement. Internal dose commitments shall be estimated using at least two bioassays and other survey data, including the probable times of intake of tritium; and

   e. Notification reports must be provided as required by sections 64E-5.345, and 64E-5.347, F.A.C., or as required by conditions of the license.

II. *Tritium Bioassay Frequency and Corresponding Actions*

C. Continued:

3. If the urinary excretion rates exceed 50 microcuries per liter, the following actions shall be taken:

a. Carry out all steps described in 2. a. – e. above.

b. As soon as possible, refer the case to appropriate medical consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of tritium from the body and reduce the dose to as low as reasonably achievable.

c. Carry out repeated bioassays at approximately 1-week intervals at least until the samples show an excretion rate less than 5 microcuries per liter.

d. Provide notification if the projected dose commitment exceeds the levels for whole body as described in section 64E-5.344, F.A.C.

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

1. The average tritium concentration for specimens obtained during a 3 month period in which bioassays are performed pursuant to Item B., above, does not exceed 3 microcuries per liter.

2. If measurements of the concentration of tritium in air are required as a condition of the license, the quarterly average concentration does not exceed 25 percent of the value for tritium specified in Derived Air Concentration (DAC) in Table I, Column I in the state of Florida Bureau of Radiation Control, ALIs, DACs, and Effluent Concentrations July 1993.

3. The working conditions during the 3 month period, with respect to the potential for tritium exposure, are representative of working conditions during the period in which the quarterly urinalysis frequency is employed, and there is no reasonable expectation that the criteria given in D.1. and D.2., above, will be exceeded.

E. If the urinary excretion rate exceeds 5 microcuries per liter, the following actions shall be taken:

1. Carry out all steps as described in C.2. and 3. above; and

2. Re-institute bioassays every 2 weeks for at least the next 6 months, even if the urinary excretion falls below 5 microcuries per liter, before reestablishing quarterly bioassays.

F. Records of tritium 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.

EMERGENCY PROCEDURES

I. *Spills of Radioactive Aerosols, Gases or Fine Particulates*

A. Notify all personnel to vacate the room immediately.

B. Shut down air conditioning system, if appropriate, to prevent the spread of contamination throughout the system and other parts of facility.

C. Vacate the room. Seal the area, if possible. Close the room and lock or otherwise secure the area to prevent entry.

D. Immediately report the incident to the radiation safety officer (RSO). Do not allow anyone to return to work in the area until approved by the RSO.

E. Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO.

F. Promptly report suspected inhalations and ingestions of licensed material to the RSO. Cooperate with the RSO if a bioassay, medical exam and/or whole body count is recommended or determined to be necessary.

G. Decontaminate the area only when advised and/or supervised by the RSO.

H. If necessary, the RSO will notify the Florida Bureau of Radiation Control.

II. *Spills of Radioactive Liquids or Solids*

In the event of a spill of an unsealed liquid or solid radioactive source, implement the following procedure.

MINOR SPILLS

A. Notify persons in the area that a spill has occurred.

B. Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)

C. Wearing disposable gloves, 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.

D. Survey the area with a low-range radiation detector survey meter. If contamination remains, clean the area with Radiacwash or equivalent. Resurvey the area. Check the area around the spill. Also check hands, clothing, and shoes for contamination.

E. Report the incident to the RSO. Do not allow anyone to return to work in the area until approved by the RSO.

F. The RSO or designee will resurvey the area to determine effectiveness of decontamination efforts and will document the results.

II. *Spills of Radioactive Liquids or Solids*

MAJOR SPILLS

A. Clear the area. Notify all persons not involved in the spill to vacate the room.

B. Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

C. 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.

D. Close the room and lock or otherwise secure the area to prevent entry.

E. Immediately report the incident to the RSO. Do not allow anyone to return to work in the area until approved by the RSO.

F. 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 released by the perspiration.

G. The RSO or designee will supervise the cleanup of the spill and will complete a survey of the area to assess the effectiveness of decontamination efforts and will document the results.

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 quantities. Spills above these millicurie amounts are considered major, below are considered minor.

RELATIVE HAZARDS OF COMMON RADIONUCLIDES

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	P-33	100
Cr-51	100	I-125	1
S-35	100	I-125	1
H-3	10	I-131	1
C-14	100	Fe-55	100

III. *Stolen, Lost, or Missing Radiation Source*

In the event of a stolen, lost or missing radiation source, immediately notify the RSO. Conduct a complete search of the area with an appropriate survey meter capable of detecting the radioactive material. The RSO will notify management, appropriate local authorities and the Florida Bureau of Radiation Control.

IV. *Incidents or Unusual Events*

A. Immediately secure the incident area. Keep people at least 30 feet away until the situation is assessed and radiation levels are known. Maintain surveillance of the perimeter to prevent unauthorized entries.

B Care for life-threatening injuries first, even if individuals may be contaminated. Perform first aid and remove them from the area only when medically safe to do so. Evaluate the situation to determine if anyone may have been exposed to radiation. Notify emergency personnel and hospital staff about possible radioactive material contamination. Do not allow any potentially contaminated people to leave the scene; have them remain at least 30 feet from the damaged incident area until they can be surveyed for contamination.

C. If any equipment is involved, isolate the equipment until it can be surveyed for possible contamination.

D. As soon as possible, notify the RSO. Follow directions provided by the RSO. If necessary, the RSO will contact the Florida Bureau of Radiation Control.

E. Wait for technical assistance prior to approaching the incident scene until the extent of contamination has been determined. A survey meter must be used to determine the presence of contamination in the area or on personnel. Special precautions and protective clothing/equipment must be used to perform decontamination and disposal of any contaminated materials.

F. Arrange for a radiation survey to be conducted as soon as possible by a qualified person using appropriate radiation detection instrumentation. To accurately assess the radiation danger, it is essential that the person performing the survey be competent in the use of the survey meter.

Radiation Safety Officer: _____

RSO Phone No.: (Work):_____ **(Home):**_____

(Cell):_____

Florida Bureau of Radiation Control
24-Hour Radiological Emergency Notification No.: (407) 297-2095

LEAK TESTING PROCEDURE

Sealed sources used for calibration and reference or contained in devices must be tested at regular intervals to ensure that the radioactive material is secure within its capsule and not leaking. Leak test (LT) requirements are specified in section 64E-5.1303, Florida Administrative Code (F.A.C.).

I. *Leak Test Frequency*

Sealed sources will be leak tested at an interval not in excess of six months. Deviations from this interval, as applicable, are identified in the attached supplement along with the specific criteria specified in subsection 64E-5.1303(5), F.A.C.

II. *Leak Test Kit*

Only LT kits provided by licensed LT vendors will be used to sample (smear) sealed sources.

III. *Taking the Leak Test Sample*

LT samples will be taken only by Authorized Users, wearing their assigned personnel monitoring badges. LT samples will be taken in accordance with the written instructions provided by the supplier of the LT kit and/or the sealed source manufacturer.

IV. *Leak Test Sample Analysis*

Analysis of LT samples will be performed only by vendors specifically licensed to provide the service by the Florida Bureau of Radiation Control (BRC), the U.S. Nuclear Regulatory Commission, or other state radiation control agencies.

V. *Leak Test Records*

If a test indicates a sealed source and/or device is contaminated, the sealed source and/or device will be removed from service and the BRC will be notified immediately (407/297-2095). A written report on the leaking source will be submitted to the BRC within 5 days. The report will describe the equipment involved, the test results, and the corrective actions taken (i.e., sealed source or device removed from service until repaired; radiation surveys conducted to determine presence of contamination; decontamination as necessary).

Leak test records will be retained for 3 years for inspection purposes. The records will include the following information:

- Each source's manufacturer name, model, and serial number;
- The identity of each sealed source radionuclide and its estimated activity, expressed in millicuries (or becquerels);
- The measured activity of each leak test sample, in microcuries (or Bq);
- The date the sample was collected; and
- The signature of the Radiation Safety Officer (or the RSO's designee).

LEAK TEST ANALYSIS

Sealed sources used for calibration and reference or contained in devices must be tested at regular intervals to ensure that the radioactive material is secure within its capsule and not leaking. Leak test (LT) requirements are specified in section 64E-5.1303, Florida Administrative Code (F.A.C.).

I. *Instrumentation and Sensitivity*

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. Identify instrumentation in facility description.

II. *Determination of Sample Counting Times*

Determine the minimum sample counting times needed to distinguish 0.005 microcurie from the background for each instrument.

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

Measure the correction factor 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.

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

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

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

III. *Analysis, Reporting and Records*

A. 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

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

C. 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.

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

IV. *Calculations*

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/μCi

CF = 4000 cpm/μCi Rb = 30 cpm

$tms = \frac{868{,}624 \times 30}{(4000)(4000)}$ = 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

$R1 = \frac{159}{5}$ = 31.8 cpm

$A1 = \frac{31.8-30}{4000}$ = 0.00045 μCi

Wipe #2 164 counts in 5 minutes.

$R2 = \frac{164}{5}$ = 32.8 cpm

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

Both are < 0.005 microcurie.

INVENTORY PROCEDURE

Semiannual inventories are required to account for the sealed sources used as calibration and references sources or contained in a device that is possessed under a radioactive materials license. To ensure accountability of radioactive material, the procedure described below will be followed.

I. ***Physical Inspection***

At least every six months, evaluate the general condition of each sealed source and/or device to determine if any damage has occurred. In addition, verify that all of the identification and warning labels remain attached and are legible.

If the inspection reveals missing labels, evidence of damage, or adverse environmental conditions immediately report the problem(s) to the Radiation Safety Officer (RSO). If warranted, arrange to have the sealed source and/or device's radiation levels measured. If excessive radiation levels are discovered, notify the Bureau of Radiation Control at (407) 297-2095.

II. ***Inventory Records***

Retain inventory records for three years from the date of the inventory. The attached inventory form (or equivalent) must be used. Required inventory information includes:

- Device manufacturer, model number and serial number
- Source manufacturer, model number and serial number
- Source identity and estimated activity
- Location
- Condition
- Date of inventory
- Signature of the Radiation Safety Officer (or the RSO's designee)

RECORD RETENTION PROCEDURE

Records pertaining to licensed operations will be maintained in accordance with the requirements specified in Chapter 64E-5, Florida Administrative Code, which are described below.

DOCUMENT	RETENTION INTERVAL	REFERENCE
Chapter 64E-5, Florida Administrative Code	Until termination of license	64E-5.901
Radioactive materials license (with all active amendments and supporting documents)	Until termination of license	64E-5.901
Provisions of radiation protection program	Until termination of license	64E-5.335(2)
Rad. protection program/ALARA reviews	3 years after records are made	64E-5.335(2)
Training and testing records	Until worker's termination or 5 years, whichever is greater	64E-5.1307(3)
Hazmat employee training records	90 days from last day of employment	49 CFR 172.704(d)
Leak test records	3 years after records are made	64E-5.337
Inventory records	3 years after records are made	64E-5.1304
Copies of "IAEA Certificate of Competent Authority" for each source(s) (Special Form Source Certificate)	1 year beyond last shipment	64E-5.1502(2) 49 CFR 173.476(a)
Records of Type A package test methods & results for each package used	1 year beyond last package shipment	64E-5.1502(2) 49 CFR 173.415(a)
Copies of radioactive material shipping papers	3 years after package shipment	64E-5.1502(2) 49 CFR 172.201(e)
Copies of manufacturer's operation/safety manual for each authorized device	As long as each device model is authorized by the license	64E-5.212(2)
Receipt records	Until disposal is authorized	64E-5.103
Transfer & disposal records	Until termination of license	64E-5.340(2)
Prior occupational dose histories	3 years after records are made	64E-5.308(7)
Personnel monitoring (PM) results	Until termination of license	64E-5.339(5)
Annual PM exposure notification reports	3 years after reports are made	64E-5.903(2)
Individual PM reports following employee termination	3 years after reports are made	64E-5.903(3)
Records demonstrating compliance with individual members of the public dose limits	Until termination of license	64E-5.313(5)
Records of surveys/measurements used to determine external/internal doses	3 years after records are made	64E-5.336(1)
Records of surveys performed to evaluate radiation levels or radiation hazards	Until termination of license	64E-5.336(2)
Records of surveys performed to limit spread of unsealed sources of radioactive material	3 years after records are made	64E-5.1319(3)
Survey instrument calibration records	3 years beyond the calibration date	64E-5.336(1)

NOTIFICATION AND REPORTING PROCEDURE

I. PURPOSE AND SCOPE

Notification and reporting requirements are found in multiple parts of Chapter 64E-5, Florida Administrative Code (F.A.C.). Additional notifications and reports may be described or repeated in other procedures (e.g., personnel monitoring procedures, emergency procedures). Also, some notification/reporting requirements overlap. The radiation safety officer (RSO) has primary responsibility for completing all required notifications and reports. If there is any doubt about whether a situation requires notification, DON'T HESITATE – MAKE THE CALL.

II. LICENSE-RELATED NOTIFICATIONS

A. Change of RSO — 64E-5.213(7), F.A.C.

Notify the Bureau of Radiation Control (BRC) in writing within 30 days of a change of RSO. Include evidence of the new RSO's qualifications for the position. Subsection 64E-5.1305(2), F.A.C., lists the minimum qualifications for an RSO. As a minimum, the RSO must have sufficient training to qualify as an authorized user; additional training in administration of a radiation protection program is recommended.

B. Vacating Premises — 64E-5.349, F.A.C.

Notify the BRC in writing no less than 30 days before vacating or relinquishing possession or control of the permanent location of use and storage of radioactive materials. Have the notification dated and signed by a certifying official, and describe the relocation of all radioactive material previously located at the facility. Documentation of transferred material may be required, and radiation surveys of storage facilities may also be required.

C. Change of Ownership — 64E-5.213(2), F.A.C.

A license is only valid for the legal entity to whom it was issued; it may not be transferred, directly or indirectly. Should a change of ownership or a change in majority of controlling interests occur, immediately notify the BRC in writing, and submit an application for a new license within 30 – 45 days. A certifying official representing the original licensee must submit a separate request to terminate the old license upon issuance of the new license replacing it.

D. Bankruptcy — 64E-5.213(3), F.A.C.

Immediately notify the BRC in writing following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 of the U.S. Code by or against the licensee, a controlling entity, or an affiliate of the licensee. Identify the bankruptcy court and the date of the petition's filing in the notification.

E. License Termination — 64E-5.214, F.A.C.

Immediately notify the BRC in writing of a decision to terminate licensed activities. Form DH-1059 (Certificate – Disposition of Radioactive Materials) should be used when submitting a termination request. The notification must be dated and signed by a certifying official, and must describe the disposition of all radioactive material possessed under the license. Documentation of radioactive material transfers may be required, and radiation surveys of storage facilities may also be required.

III. REPORTS OF STOLEN, LOST OR MISSING SOURCES OF RADIATION

A. Telephone Reports

64E-5.343(1), F.A.C.

Immediately after its occurrence becomes known, report to the BRC by phone at (407) 297-2095, a stolen, lost or missing radiation source, if it appears that an exposure could result to individuals in unrestricted areas.

B. Written Reports

64E-5.343(2), F.A.C.

Follow telephone reports of stolen, lost or missing radiation sources with a written report to the BRC within 30 days after making the report. Include the information specified below.

- A description of the radiation source; for radioactive material, the kind, quantity, and chemical and physical form.
- A description of the circumstances under which the loss or theft occurred.
- A statement of disposition or probable disposition of the radiation source involved.
- Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible doses received by persons in unrestricted areas.
- Actions that have been or will be taken to recover the source.
- Procedures or measures that have been or will be implemented to prevent recurrence.

IV. *INCIDENT NOTIFICATIONS*

Incidents involving radiation sources require different types of notifications. Reports may be made by phone or fax; names of individuals who have received radiation exposures must be stated in a separate and detachable portion of the report.

A. Immediate Notifications

64E-5.344(1) & (6), F.A.C.

Immediately notify the BRC of any event involving a source of radiation that might have caused or threatens to cause any of the following: an individual to receive a total dose of 25 rem or more, a lens dose of 75 rem or more, or a skin, extremity or total organ dose of 250 rad.

Notify the BRC as soon as possible, but not later than 4 hours after the discovery of an event, such as a fire, explosion, or toxic gas release.

B. 24-Hour Notifications

64E-5.344(2) & (7), F.A.C.

Notify the BRC within 24 hours of discovery of an event involving loss of control of a radiation source that might have caused or threatens to cause any of the following: an individual to receive in a period of 24 hours a dose greater than 5 rem, a lens dose greater than 15 rem, or a skin, extremity or total organ dose greater than 50 rem.

IV. *INCIDENT NOTIFICATIONS*

B. 24 Hour Notifications (Continued)

Notify the BRC within 24 hours of discovery of:

- An unplanned contamination event that requires access to the contaminated area to be restricted for more than 24 hours;
- An event in which equipment is disabled or fails to function as designed when the equipment is required to prevent exposures exceeding regulatory limits or to mitigate the consequences of an accident, the equipment is required to be available and operable when it is disabled or fails to function, and no redundant equipment is available and operable to perform the required safety function;
- An event that requires unplanned medical treatment at a medical facility of an individual with radioactive contamination on the individual's clothing or body; or
- An unplanned fire or explosion damaging radioactive material or the device, container or equipment containing radioactive material when the damage affects the integrity of the radioactive material or its container.

C. Information Required for Immediate/24-Hour Notifications 64E-5.344(8), F.A.C.

Make reports to the BRC of events requiring immediate or 24-hour notification as described above by phone, and if available at the time of notification, include the following information:

- The caller's name and call back phone number;
- A description of the event, including date and time;
- The exact location of the event;
- The isotopes, quantities and chemical/physical forms of the radioactive material involved; and
- Any personnel radiation exposure data available.

V. *REPORTABLE EVENTS* 64E-5.345, F.A.C.

A. All events requiring immediate or 24-hour notification are classified as reportable events, and require a written report to be submitted to the BRC within 30 days after learning of the event's occurrence. The following occurrences are also classified as reportable events and require written reports to the BRC within 30 days:

- Dose exceeding the occupational dose limits for adults (total dose > 5 rem, organ dose > 50 rem, lens dose > 15 rem, or shallow dose > 50 rem);
- Dose exceeding the occupational dose limits for minors (total dose > 500 mrem, organ dose > 5 rem, lens dose > 1.5 rem, or shallow dose > 5 rem);
- Dose exceeding limit for an embryo or fetus of a declared pregnant woman (500 mrem);
- Dose exceeding limits for members of the public (2 mrem in any one hour or 100 mrem in one year); or
- Radiation levels greater than 20 mrem/hr in unrestricted areas.

V. REPORTABLE EVENTS (Continued)

B. Reports must describe the extent of exposure of individuals, including:

- Estimates of each individual's dose;
- The levels of radiation and activities of radioactive material involved;
- The causes of the elevated exposures or dose rates; and
- The corrective steps taken or planned to prevent recurrence, including a schedule for achieving conformance with applicable limits, ALARA constraints, and license conditions.

Include for each occupational overexposed individual, the person's name, social security number and date of birth. For events involving an embryo/fetus, this information applies to the declared pregnant woman. Prepare reports so that the information on exposed individuals is stated in a separate and detachable portion of the report. When submitting a report to the BRC, also provide a copy to the exposed individual(s), no later than when submitting it to the BRC, in accordance with the provisions of Part IX of Chapter 64E-5, F.A.C. (i.e., include this statement: "This report is furnished to you under the provisions of the Florida Department of Health regulation entitled Chapter 64E-5, Control of Radiation Hazards. You should preserve this record for future reference.").

VI. REPORTS OF LEAKING/CONTAMINATED SOURCES 64E-5.348, F.A.C.

Immediately notify the BRC upon learning of any leaking or contaminated sealed source. Submit a follow up written report to the BRC within 5 days, and identify the equipment involved, the test results and the corrective action taken.

VII. REPORTS OF HIGH RAD. LEVELS ON PACKAGES 64E-5.327(4), F.A.C.

Immediately notify the BRC and the final delivery carrier by phone or fax upon learning of external radiation levels exceeding 200 mrem/hr at any exterior surface, or 10 mrem/hr at one meter from any exterior surface of an incoming package containing radioactive material. These limits are specified in 49 CFR 173.441, which is referenced in subsections 64E-5.1505(9) and 64E-5.327(5), F.A.C.

RADIATION DETECTION INSTRUMENTATION CALIBRATION PROCEDURE

Radiation detection instruments used for quantitative analysis (e.g., dose rate and effluent monitoring) will be calibrated annually for the type of radiation measured. Sections 64E-5.314 and 1318, Florida Administrative Code (F.A.C.), provide additional information regarding radiation detection instrument specifications and calibration.

I. *Training*

Prior to performing independent radiation detection instrument calibrations, workers shall:

A. Have received radiation awareness instructions required by section 64E-5.902, Florida Administrative Code (F.A.C.); and

B. Have documentation on file of their completion of an approved radiation safety training course satisfying the requirements specified in section 64E-5.1307, F.A.C. This training must include opportunities to observe and obtain supervised experience conducting instrument calibration.

II. *Calibration of Portable Radiation Detection Instruments*

A. Precautions

1. Instrument calibrations should be conducted in a shielded box, irradiator chamber, or and isolated areas of the facility where egress by other workers can be minimized. If unavailable, use magenta and yellow colored barrier tape, ribbons or rope to establish a restricted area.

2. Assigned personnel dosimetry devices will be worn at all times while calibrating survey instruments.

3. A calibrated and operable survey instrument will be used to assess dose rates during survey instrument calibrations.

B. Dose Rate Instrument Calibration Procedure

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.

II. *Calibration of Portable Radiation Detection Instruments*

B. Dose Rate Instrument Calibration Procedure (Continued)

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 multidecade 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.

C. Surface Contamination Measurement Instrument Calibration Procedure

1. Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.

2. If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within 20% of the conventionally true value.

III. *Calibration of Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers*

A. Precautions

1. All individuals performing instrument calibrations shall abide by applicable Rules of Use of Unsealed Sources and the Contamination Control Program.

2. Assigned personnel dosimetry devices will be worn at all times while calibrating radiation detection instruments.

III. *Calibration of Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers*

B. Stationary Radiation Detection Instrument Calibration Procedure

1. Instrument calibration will be in accordance with the applicable manufacturer's instructions and recommendations. A copy of the manufacturer's operation/ maintenance manual for each instrument is maintained on file by the RSO for ready reference.

2. Radiation sources must approximate the geometry of the samples to be analyzed.

3. The radiation source must have its apparent source activity traceable by documented measurements to a standard certified by National Institutes of Standards and Technology (NIST).

4. The radiation source must approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

5. Calibration must produce readings within ± 20 per cent of the actual values over the range of the instrument.

6. Calibration of liquid scintillation counters will include quench correction.

IV. *Calibration Records*

A. Radiation detection instrument calibration records indicate the procedure used and the data obtained. As applicable, the reports include:

1. The owner or user of the instrument;

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

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

4. 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);

5. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);

6. 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);

IV. ***Calibration Records***

A. Continued:

7. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

8. The exposure rate or count rate from a check source, if used; and

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

B. The applicable information below is attached to the instrument, as a sticker or tag.

1. The source that was used to calibrate the instrument;

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

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

a. The average correction factor;

b. A graph or graphs from which the correction factor for each scale or decade may be deduced; or

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

4. 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.)

TRANSFER/DISPOSAL PROCEDURE

Sections 64E-5.103, .215, .328, .330, .331, and .340, Florida Administrative Code (F.A.C.), address the transfer and disposal of radioactive material. Licensed radioactive material will be transferred or disposed in accordance with these regulatory requirements.

I. *Disposal Methods*

A. Effluent and Evaporative Release

Liquids may be disposed by release to the sanitary sewer or evaporative release in accordance with the regulatory requirements.

1. Radioactive material discharged by release into the sanitary sewerage system will be readily soluble in water or is readily dispersible biological material. 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. Applicable calculations will be maintained demonstrating compliance with the requirements specified in section 64E-5.330, F.A.C.

Records will be maintained indicating the date, radionuclide, estimated activity of the release (in millicuries or microcuries), and the sink 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, radioisotope, 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 hydrogen-3 (H-3) or carbon-14 (C-14) may 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.

B. Disposal by Decay-in-Storage (DIS)

Radioactive material, other than special form (sealed) sources, having a half-life less than 90 days may be disposed by DIS.

1. Radioactive material with a physical half-life less than 90 days will be segregated according to half-life, 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 spent in-vitro kits or planchets, a second container for contaminated gloves and absorbent paper, etc., and a third container for expired reference solutions) will be used.

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

I. *Disposal Methods*

B. Disposal by Decay-in-Storage (DIS) (Continued)

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. Radioactive waste 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 waste container.

c. Monitor the waste container in a low background radiation area (less than 0.05 millirem per hour).

d. Monitor all surfaces of each individual waste container.

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

f. Radioactive waste may be discarded as in-house waste only if it cannot be distinguished from background. Make a record of the date that the waste container was sealed, the radioactive waste disposal date, and the type of material (e.g., paraphernalia, unused reference or calibration sources). At the time of disposal, remove or obliterate all radiation labels on the waste container.

g. Radioactive waste that can be distinguished from background radiation levels is returned to the storage area for further decay or transferred for burial at a low-level waste disposal facility.

7. 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 radioisotopes 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.

C. Low Level Radioactive Waste Transfer for Land Disposal

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

I. *Disposal Methods*

D. 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.

II. *Return to Manufacturer or Transfer to a Licensed Recipient*

Licensed radioactive material may be returned to the manufacturer for disposal or transferred to a licensed recipient. Prior to transferring or disposing of a radioactive source, obtain documentation of the transferee's authorization to possess the radioactive material. Retain either a copy of the other entity's radioactive materials license, or one of the other verification methods listed in subsection 64E-5.215(4), F.A.C., as evidence of an authorized transfer.

As a minimum, documentation of the transfer includes the following:

- The material being transferred (source manufacturer name, model and serial number, type and activity of radioactive material, as applicable);
- The date of the transfer;
- The name, address, and license number of the transferor and transferee; and
- The signatures of the individuals shipping and/or receiving the radiation source.

Form DH-1059 "Certificate – Disposition of Radioactive Materials" may be used to document the transfer/disposal of radioactive material; the form is available on the Bureau of Radiation Control website at http://www.doh.state.fl.us/environment/radiation. All transfer and disposal records are retained on file until license termination.

INVENTORY OF RADIOACTIVE SEALED SOURCES & DEVICES

Licensee: _____ **License No.:** _____

Date of Inventory: _____ **Radiation Safety Officer (or designee) Signature:** _____

#	GL or SL	DEVICE / INSTRUMENT MANUFACTURER & MODEL NO.	DEVICE / INSTRUMENT SERIAL NO.	SOURCE MANUFACTURER & MODEL NO.	SOURCE SERIAL NO.	ISOTOPE & ACTIVITY	LOCATION	CONDITION
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								

Note: Listing "IN STORAGE" in the CONDITON column identifies sources/devices held in secured storage with no use anticipated prior to transfer/disposal.

SHIPPING PAPER – PRIVATE USE SHIPMENT

BILL OF LADING

Shipper: _____ **Date:** _____

Address: _____

_____

_____

Phone No.: _____

RQ, Radioactive Material, Type A Package, Special Form
Hazard Class 7, UN3332

Package contains:

Cs-137, _____GBq (_____ mCi)

RADIOACTIVE YELLOW II Label

Transport Index (TI) = _____

24-HR. EMERGENCY RESPONSE INFORMATION NO.:

( )

EMERGENCY RESPONSE INFORMATION

POTENTIAL HAZARDS

IMMEDIATE HAZARDS TO HEALTH

- External radiation hazard from unshielded radioactive material.
- Low-level radioactive material; little personal radiation hazard when shielded.
- Materials in special form are not expected to cause contamination in accidents.
- Some radioactive materials cannot be detected by commonly available instruments.
- Potential internal radiation hazard from inhalation, ingestion, or breaks in skin, only if special form capsule is breached.

FIRE OR EXPLOSION

- No risk of fire or explosion.
- Radioactivity does not change flammability or other properties of the materials.

EMERGENCY PROCEDURES

IMMEDIATE PRECAUTIONS

- Isolate hazard area to within a 10-15 foot radius of the gauge and restrict access.
- Emergency response actions may be performed prior to any measurement of radiation; limit entry to shortest time possible.
- Notify local authorities and Radiation Control Authority of accident conditions.
- Detain uninjured persons, isolate equipment with suspected contamination, and delay cleanup until receiving instruction from Radiation Control Authority.

FIRE

- Do not move damaged containers; move undamaged containers out of fire zone.
- Small Fires: Dry chemical, CO_2, water spray, or regular foam.
- Large Fires: Water spray, fog (flooding amounts).

SPILL OR LEAK

- Do not touch damaged containers or exposed contents.
- Damage to outer container may not affect primary inner container.
- Special form capsules are not expected to leak as a result of an accident or fire.

FIRST AID

- Use first aid treatment according to the nature of the injury.
- Advise medical personnel that victim may be contaminated with low-level radioactive material.
- Except for the injured, detain persons exposed to radioactive material until arrival or instruction of Radiation Control Authority.

INSTRUCTIONS FOR WOMEN WORKING WITH RADIATION

I have received verbal instructions concerning the potential risks involved for pregnant women exposed to radiation, including a copy of U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" (Rev. 3, 6/99).

The radiation safety officer (RSO) has encouraged me to ask for additional information if needed, and I am aware that the RSO is available to answer any questions I may have regarding the issue of radiation exposure to an embryo/fetus.

_____

Signature

_____

Printed Name

_____

Date

_____ _____

RSO Signature Date

INSTRUCTIONS FOR DECLARED PREGNANT WOMEN

I have received verbal instructions on personnel monitoring (PM) requirements for declared pregnant women conducting activities involving sources of radiation, in accordance with the requirements of my employer's radiation safety program, the terms and conditions of my employer's radioactive materials license (and/or certification of registration, as applicable), and Chapter 64E-5, Florida Administrative Code.

I have been instructed to wear my assigned PM badge at waist level to estimate the embryo/fetus dose. I am aware that the fetal dose is not allowed to exceed 500 millirem during the entire pregnancy as a result of occupational radiation exposures (unless that dose has already been exceeded between the time of conception and submitting my declaration of pregnancy), and that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy. I must make every effort to maintain the fetal dose as low as reasonably achievable (ALARA), and I will strive to abide by the regulatory recommendation to limit fetal dose to 50 millirem or less in any one month. I understand that records of fetal dose are maintained with my dose records.

The radiation safety officer has encouraged me to ask for additional information if needed, and to review information on the potential risks involved for pregnant women exposed to radiation, particularly U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.13.

_____

Signature

_____

Printed Name

_____

Date

_____ _____

RSO Signature Date

DECLARATION OF PREGNANCY

To: _____

In accordance with Florida regulations, section 64E-5.311, Florida Administrative Code ("Dose to an Embryo or Fetus"), I am declaring that I am pregnant. I believe that I became pregnant in

_____ _____
Month Year

I understand that the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 500 millirem (unless that dose has already been exceeded between the time of conception and submitting this declaration). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

_____
Signature

_____
Printed Name

_____
Date

DELEGATION OF AUTHORITY TO MAKE LEGALLY BINDING STATEMENTS

Memo To: All Employees and the Florida Bureau of Radiation Control

From: Chief Executive Officer/President/Vice President/COO/CFO

Subject: Delegation of Authority to Make Legally Binding Statements

_____ has been delegated authority to make legally binding statements on behalf of our company in matters related to our Florida radioactive materials license.

_____

Certifying Official Signature

_____

Name (Typed or Printed)

_____

Title

_____

Date

FLORIDA DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS PROGRAM
APPLICATION FOR RADIOACTIVE MATERIALS LICENSE
NON-HUMAN USE

INSTRUCTIONS - Complete Items 1 – 15 as applicable. Item 15 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 Program, 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 APPLICATION 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 individuals 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. TRAINING AND EXPERIENCE IN RADIATION SAFETY

a. FORMAL TRAINING IN RADIATION SAFETY: Describe the formal training for each individual named in Items 4 and 5, including principles and practices of radiation protection, radioactivity measurement, monitoring techniques and the use of instruments, mathematics and calculations basic to the use and measurement of radioactivity, and biological effects of radiation. Include the name of the person or institution providing the training, duration of training and when training was received. Attach a copy of any training certificate received if applicable.

☐ **SEE ATTACHED LIST**

b. EXPERIENCE: Describe the radiation work experience for each individual named in Items 4 and 5, including where the experience was obtained or attach a copy of a radioactive materials license that identifies them by name as an authorized user. Include a list of radioisotopes and the maximum activity of each use. Work experience or on-the-job training should be commensurate with the proposed use.

☐ **SEE ATTACHED LIST**

7. RADIOACTIVE MATERIAL

a. Isotope	b. Chemical or Physical Form (If sealed sources, include manufacturer name and model numbers)	c. Maximum Amount Or Activity Possessed At Any One Time. (If sealed source, state the number of sources, maximum activity per source and total activity)
Ex. Co-60	Sealed source XYZ Corp. Model XYZ for use in XYZ Corp Model AAA therapy device or liquid/gas/powder.	30 sources, 2 curies each for a total of 60 curies.
☐ SEE ATTACHED LIST		

8. DESCRIBE THE PURPOSE FOR WHICH EACH RADIOACTIVE MATERIAL LISTED IN ITEM 7, ABOVE WILL BE USED.

(For each sealed source, include the manufacturer's name and model number of the device, gauge or storage container where the source will be used or stored. List a line item for each different type of use for the same or different isotopes.

Ex. Co-60 to be used in a xyz corporation model AAA device in a BBB source holder for the measuring of density of materials in a process vessel.

☐ SEE ATTACHED LIST

9. LIST EACH TYPE OF RADIATION DETECTION INSTRUMENT (i.e., survey meters, counters, etc.)

TYPE OF INSTRUMENTS (include manufacturer and model number of each)	**USE** (e.g., monitoring, surveying, measuring)	**RADIATION DETECTED** (beta, gamma, alpha, neutrons)	**SENSITIVITY RANGE Low –High** (mR/hr)	**NUMBER AVAILABLE**
Ex. XYX Co. Model 1 survey meter with Model 33 probe	Monitoring & surveying for removable contamination	Beta & Gamma	0.1 mR/hr – 1 R/hr	2
☐ SEE ATTACHED LIST				

10. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 9 ABOVE.

a. ☐ **Calibration by Licensed Service Company**
Calibration Frequency will be at Intervals Not to Exceed: _____ months

b. ☐ **Calibration by Applicant** (Attached is a separate sheet describing procedures, frequency and standards used for calibration of instruments.)

11. PERSONNEL MONITORING DEVICES. Complete Items a, b, & c. (Check all that are applicable)

a. ☐ Film ☐ OSLD ☐ TLD ☐ Other (See attached) (Provider Must be NVLAP Certified)

b. ☐ Whole Body: Exchange Frequency Not to Exceed: _____ Months
☐ Extremity: Exchange Frequency Not to Exceed: _____ Months

c. Radiation Detected: ☐ Beta ☐ Gamma ☐ Neutron

12. FACILITIES AND EQUIPMENT. Attach a description of facilities where radioactive material, including waste, will be used or stored. **Attach an annotated diagram of the areas of use and/or storage, including adjacent areas.** Describe equipment such as remote handling devices, storage containers, shielding, fume hoods, etc. Describe security at your facility such as locks, chains, alarms, security camera, security services, etc.

☐ Description of facilities and equipment also attached with annotated diagram of the areas of use or storage, including adjacent areas.

☐ Attached is a description of security at facilities of the areas of radioactive materials are used or stored to prevent theft or unauthorized access to radioactive materials.

13. RADIATION PROTECTION PROGRAM. Attach a radiation protection program as appropriate for the material to be used, including general radiation safety procedures, emergency procedures, security, and bioassay procedures, etc. (Note that possession of large quantities of certain isotopes, such as those used in fixed gauges, industrial radiography, or irradiators for use in research or blood products, may require additional increased controls for security measures or national source tracking as required by 64E-5.350 and 64E-5.351, FAC.)

☐ Radiation Protection Program Details Attached

14. WASTE DISPOSAL. Describe the procedures for handling, storing and disposing of radioactive wastes (solid, liquid and/or gas). Name the commercial waste disposal service employed, if applicable. If sealed sources and/or devices will be returned to the manufacturer, so state.

☐ See Attached for Details on Radioactive Waste Disposal

15. 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

Warning: KNOWINGLY MAKING FALSE STATEMENTS TO A PUBLIC SERANT IS A VIOLATION OF SECTION 837.06, FLORIDA STATUTES, AND IS PUNISHABLE BY FINE OR IMPRISONMENT

LIST OF ATTACHMENTS PROVIDED WITH APPLICATION

TABLE 1. APPENDICES

Appendix	Title	Attached	Equivalent	N/A
App. A	Member of the Public (MOP) Dose Limit Compliance Study			
App. B	ALARA Policy			
App. C	Duties and Responsibilities of the Radiation Safety Officer			
App. D	Radiation Safety Training Program			
App. E	Personnel Monitoring Procedures			
App. F	Operating Procedures			
App. G	Procedure for Ordering, Receiving, Opening and Shipping Packages Containing Radioactive Material			
App. H	General Rules of Use of Unsealed Sources			
App. I	Contamination Control Program			
App. J	In-Vivo Thyroid Bioassay			
App. K	In-Vitro Urinalysis Bioassay			
App. L	Emergency Procedures			
App. M	Leak Test Frequency, Collection and Records			
App. N	Leak Test Analysis Procedure			
App. O	Inventory Procedure			
App. P	Record Retention Procedure			
App. Q	Notification and Reporting Procedure			
App. R	Radiation Detection Instrument Calibration Procedure			
App. S	Transfer/Disposal Procedure			

TABLE 2. EXHIBITS

Exhibit	Title	Attached	Equivalent	N/A
Ex. A	Inventory Form			
Ex. B	Shipping Paper – Private Use Shipment			
Ex. C	Emergency Response Information			
Ex. D	Instructions for Women Working With Radiation			
Ex. E	Instructions to Declared Pregnant Women			
Ex. F	Instructions for Declared Pregnant Women			
Ex. G	Declaration of Pregnancy			
Ex. H	Delegation of Authority to Make Legally Binding Statements			

TABLE 3. SUPPLEMENTS

Supplement	Title	Attached	Equivalent	N/A
Supp. A	Form DH-1054 “Application for Radioactive Materials License – Non-Human Use”	**X**		
Supp. B	Attachments Table	**X**		
Supp. C	Unsealed/Sealed Sources License Application Checklist			**X**

UNSEAED/SEALED SOURCES LICENSE APPLICATION CHECKLIST

Notes: – This checklist is for applicants using DOH Form DH-1054 to apply for or renew a radioactive materials license authorizing possession and use of unsealed and/or sealed sources for In-vitro and Clinical Laboratories, Academic, Research, Nuclear Service and Other Misc. Uses, except Fixed and Portable Gauging activities. Refer to section 64E-5.204, Fla. Admin. Code, for a list of license categories. If additional assistance is needed, call the BRC Radioactive Materials Section at (850) 245-4545 or access the BRC website at <http://www.doh.state.fl.us/environment/radiation/>.

– U.S. Dept. of Transportation regulations (49 CFR) are available at <http://www.gpoaccess.gov/cfr/index.html>.

CHECK OFF IF ADDRESSED	APPLICATION ITEM		NOTES
☐	1.a.	**Name/Mailing Address**	– Unless application is for an individual, list the business name registered with the FL Div. of Corporations; verify name registration by phone (850/488-9000) or online at <http://ccfcorp.dos.state.fl.us/corpweb/inquiry/corinam.html> – If doing business under a fictitious name, verify the name's registration & include it in Item 1 as a d/b/a name; if fictitious name is not registered, include it in Item 2 – List the mailing address for license-related correspondence
☐	1.b.	**Location of Use and/or Storage**	– List the street address where RAM will be used & stored, & where records will be available for inspection; 64E-5.208(2), .213(5) – Indicate if any locations are non-contiguous
☐	2.	**License Category/Fee**	– List appropriate license category & application fee; there is no fee for license renewal applications – Annual/reclamation fees are due within 60 days of license issuance and annually thereafter (an invoice for the fees is included w/ the new license); 64E-5.204
☐	3.	**Purpose of Application**	– Check appropriate box; if applying to renew a license, list the license number
☐	4.	**Individual Users**	– List the name of the RSO & all authorized users (AUs) – individuals trained to use or supervise the use of radioactive materials; 64E-5.208(2)
☐	5.	**Rad. Safety Officer (RSO)**	– List the name of the RSO; 64E-5.208(2)
☐	6.	**Training and Experience in Radiation Safety**	– Enclose relevant documentation on the rad. safety training/experience for the RSO & each authorized user; 64E-5.208(1), .1305, .1307
☐	7.	**Radioactive Material (RAM)**	– List the element/source model no. & maximum activity for each source
☐	8.	**Use**	– List the manufacturer, model no. & intended use for each source/device
☐	9.	**Radiation Detection Instruments**	– If applicable, list the manufacturer, model no., detection capability, range & probe specifications (if equipped w/ probe) of each instrument; 64E-5.208(2) .1314, .1318 – Confirm access to an equivalent backup instrument when the primary meter is out due to calibration or repair; 64E-5.208(2), .1314, .1318
☐	10.	**Calibration of Radiation Detection Instruments**	– If applicable, list the name & address of the instrument calibration vendor (may include option of using other licensed vendors) & confirm annual calibration frequency; if conducting in-house cal., submit procedures; 64E-5.208(2), .314
☐	11.	**Personnel Monitoring (PM) Devices**	– External PM required unless able to demonstrate that workers are unlikely to exceed 500 mrem/yr TEDE; if applicable, list PM badge type (FB/OSLD/TLD), supplier & exchange frequency (monthly/bimonthly/quarterly); 64E-5.208(2), .314, .315(1) – Internal PM required for users of I-125, I-131, H-3, U-234, U-235 or U-238 per 64E-5.1310(3); also required for users of unsealed sources of RAM unless able to demonstrate workers are unlikely to exceed 10% of applicable ALIs; if applicable, describe internal PM method (e.g., bioassays); 64E-5.208(2), .307, .315(2), .1310(3)

UNSEAED/SEALED SOURCES LICENSE APPLICATION CHECKLIST

CHECK OFF IF ADDRESSED	APPLICATION ITEM		NOTES
☐	**12.**	**Facilities & Equipment**	– Annotated facility diagram shows RAM use/storage locations, access pts., adjacent areas, proximity to occupied work stations, no. of stories to bldg.; 64E-5.208(2) – Description of storage container; 64E-5.208(2) – Description of security measures in place to prevent access; 64E-5.320, .321 – Description of safety equipment; 64E-5.208(2) – Description of posting; 64E-5.323, .901
	13.	**Rad. Protection Program**	– Description of program addressing below items; 64E-5.303
☐	**A.**	**Member of Public (MOP) Dose Study**	– New applicant: procedures for demonstrating compliance w/ MOP dose limits (2 mrem in any one hr. & 100 mrem/yr.; 64E-5.208(2), .313 – License renewal: submit MOP study; 64E-5.208(2), .313 (guide available from BRC)
☐	**B.**	**ALARA Policy**	– Policy describes a) management's commitment to ALARA philosophy, & b) commitment to perform an annual ALARA/rad. protection program review; Model ALARA policy: **App. B**; 64E-5.208(2), .303
	C.	**Radiation Safety Officer**	
☐	**(1)**	**RSO Duties**	– Description of RSO duties equivalent to the duties listed in 64E-5.1305; **App. C**
☐	**(2)**	**Change of RSO Notification**	– Statement confirming that written notification will be given to BRC within 30 days of a change of RSO or other safety positions; **App. C**; 64E-5.213(7)
	D.	**Radiation Safety Training Program**	Model training program: **App. D**
☐	**(1)**	**Instructions to Workers Training**	– Description of instructions to workers/rad. awareness training provided to occupational radiation workers per 64E-5.902
☐	**(2)**	**AU Training**	– Description of training provided per 64E-5.1307(1) if any third party trainers used; info on their training programs provided; 64E-5.1307 – If seeking to conduct in-house AU training, describe instructor qualifications, course outline & duration, method of testing (w/ sample exam) & retesting & reference materials; 64E-5.1307, 1312 & .1313 (as applicable)
☐	**(3)**	**Hazmat Employee Training**	– Description of training (in-house or by third parties) & record-keeping per 49 CFR Part 172, Subpart H
☐	**E.**	**Personnel Monitoring (PM) Procedures**	– If external PM conducted, procedures provide instructions on proper use: only use assigned badge, always wear when handling RAM, do not expose to excessive heat/light/chemicals/moisture, promptly return for exchange when due; use of spare badges; dealing w/ lost/damaged badges; PM records – Model procedure: **App. E**
	F.	**Operating & Emergency (O&E) Procedures**	model procedure: **App. F**
☐	**(1)**	**PM Procedures**	– Procedures provide instructions on proper use: only use assigned badge; if a spare badge is used, mark with user's initials, always wear badge when handling radioactive materials; don't expose to moisture, chemicals, strong heat or light, promptly return for exchange when due; notify RSO if badge is lost/damaged; **App. F (Sec. III)**; .208(2), .1302(4)
☐	**(2)**	**General Rules of Use**	– Procedures provide instructions for routine work **App. F (Sec. IV)**;

UNSEAED/SEALED SOURCES LICENSE APPLICATION CHECKLIST

CHECK OFF IF ADDRESSED		APPLICATION ITEM	NOTES
	13.F.	**Operating & Emergency (O&E) Procedures**	
☐	**(3)**	**Posting**	– Instructions addressing posting requirements per Parts III, IX & XIII; **App. F (Sec. VII)**; .208(2), .323, .901, .1302
	G.	**RAM Ordering, Receiving, Opening & Shipping Procedures**	**M**odel procedure: **App. G**
☐	**(1)**	**Ordering, Receiving and Opening packages**	– Instructions for preparation & handling of incoming & outgoing shipments; **App. G (Sec. I & II)**; .208(2), .327, .336
☐	**(2)**	**Transportation**	– Procedures for transport per DOT regs [inspection, packaging, marking, labeling, blocking/bracing, security, shipping papers, emergency response info. (ERI), etc.]; **App. G (Sec. III)**; .321, .1311, .1302(5), .1501, .1502; 49 CFR
☐	**H.**	**Rules of use**	– Provide instructions to personnel addressing the safe use and handling of unsealed sources of radioactive material. **App. H**
☐	**I.**	**Contamination Control & Survey Procedures**	– Procedures address weekly surveys, survey instrument calibration, removable contamination surveys, personal surveys, action levels and decontamination, notification and records; model procedure: **App. I**, 64E-5.208(2), .314, .1318, .1319
☐	**J.**	**In-Vivo Thyroid Bioassay**	– If using unsealed radioiodine, submit bioassay frequency and corresponding action; model procedure: **App. J**, 64E-5.307, .315, .1310
☐	**K.**	**In-Vitro Urinalysis Bioassay**	– If using hyrdorgen-3 (H-3) in tritiated compounds, including HTO, submit in-vitro urinalysis bioassay monitoring program ; model procedure: **App. K**
☐	**L.**	**Emergency Procedures**	– Procedures provide instructions for handling RAM loss, theft or damage; include emer. notification numbers (RSO, BRC); model procedure: **App. L**; .208(2), .1302
☐	**M.**	**Leak Test Frequency, Collection and Records**	– Instructions for collecting leak test samples; performed only by AUs; state interval tests will be performed; list manufacturer name & model no. of LT kit used; list vendor contracted to analyze samples (may include option of using other licensed vendors); 64E-5.208(2), .1303, **App. M**
☐	**N.**	**Leak Test Analysis**	– If leak test analysis conducted in-house, detailed procedures required; **App. N**
☐	**O.**	**Inventory**	• Procedure for performance of semiannual physical inventories, including sample inventory form; model procedure: **App. O**; .208(2), .1304
☐	**P.**	**Record Retention Procedure**	• Procedure addresses record-keeping requirements specified in 64E-5; model procedure: **App. P**
☐	**Q.**	**Notification and Reporting**	• Notification and reporting requirements are specified in Parts II and III of Chapter 64E-5, F.A.C. model procedure: **App. Q**
☐	**R.**	**Instrument Calibration**	– Procedure for calibration of radiation detection instruments used in quantitative analysis (e.g., dose rate and effluent releases) Model procedure: **App. R**
☐	**S.**	**Waste Disposal**	– Procedures address RAM disposal, with commitment that RAM will be transferred only to licensed recipients; model procedure: **App. R** – For unsealed RAM, address decay-in-storage, sewer disposal & LLRW shipments as applicable; **App. R**
☐	**14.**	**Certificate**	– Application signed & dated by a certifying official (person authorized to make legally binding statements on behalf of the applicant/licensee)