STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

REGULATORY GUIDE

Regulatory Guide 1.70

Issuance Date: June 2012

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS INCLUDING GAMMA KNIFE DEVICES

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

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

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

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

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Enclosure A

Fees*

Specific License categories for gamma stereotactic radiosurgery:

Category	Description	Application Fee	Annual Fee	Reclamation Fee	Annual and Reclamation Fee
3M(II)	Medical Broad Scope	3,840	6,569	328.45	6,897.45
5A(I)	Teletherapy or gamma stereotactic radiosurgery including gamma knife devices	$1,838	$1,791	$89.55	$1,880.55
5A(III)	High dose rate remote afterloading devices and gamma stereotactic radiosurgery including gamma knife devices or teletherapy devices	$1,838	$1,791	$89.55	$1,880.55

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

Effective August, 2007

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I. INTRODUCTION

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

The department issues a single radioactive material license to cover an entire radionuclides program except for teletherapy, high dose rate remote afterloaders, gamma stereotactic radiosurgery, nuclear-powered pacemakers, and irradiators.

PURPOSE OF GUIDE

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

APPLICABLE TYPES OF LICENSES

This guide is only for persons who want to apply for a specific medical use gamma stereotactic radiosurgery license.

1. Specific License Category 5A(I) or 5A(III)

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

2. Specific License of Broad Scope Category 3M(II)

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

APPENDICES, EXHIBITS AND SUPPLEMENTS

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

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

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

IMPORTANT NOTICE:

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

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

APPLICABLE REGULATIONS

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

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

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

Part I	"General Provisions"
Part II	"Licensing of Radioactive Materials"
Part III	"Standards for Protection Against Radiation"
Part IX	"Notices, Instructions and Reports to Workers; Inspections"
Part XIII	"Radiation Safety Requirements for Possession and Use of Sealed or Unsealed Sources of Radioactive Materials"
Part XV	"Transportation of Radioactive Materials"

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

LICENSE REQUIREMENTS AND RESTRICTIONS

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

License Items

Item No. and Title	Description
1. Name	Lists the legal name of the licensee (individual or business). If the license is issued to a business, Item 1 must list the company's name as it is registered with the Florida Department of State, Division of Corporations; 850-245-6052 or http://www.sunbiz.org. If a business operates under another name, Item 1 must list both the registered name and the registered 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 materials are used and stored. If the two addresses are different, the physical address must be listed in Condition 10; if they are the same, Condition 10 will reference the address listed in Item 2.
3. License Number	Lists the number assigned to the license by the bureau. The number should be referenced in all license-related correspondence.
4. Expiration Date	Lists the date the license is due to expire. A radioactive materials license is valid for 5 years from the date issued. A renewal application must be received by the bureau at least 30 days prior to the expiration date to ensure that the license remains valid. The bureau sends out reminder notices as the license nears its expiration date.
5. Category	Lists the license category: e.g. 5A(I), or 5A(III). Activities involving possession and use of radioactive materials are divided into license categories. Organizations seeking to conduct more than one category of licensed activity must obtain separate licenses for each category of use. Refer to section 64E-5.204, F.A.C., or Regulatory Guide 6.20, Revision 5, for a complete listing of license types and fees. Regulatory Guide 6.20, Revision 5 is available at http://www.doh.state.fl.us/environment/radiation/matform.htm.
6. Radioactive Material	Describes the type (element and mass number, e.g. Cobalt 60) of radioactive material the license authorizes for possession and use.
7. Chemical And/Or Physical Form	Describes the form (e.g. sealed source) of radioactive material the license authorizes for possession and use. Include the sealed source manufacturer and model designation.
8. Possession Limit	Lists the maximum activity possession limit and number of radioactive sources. Possession of more sources than authorized is a license violation and may result in enforcement actions.
9. Authorized Use	Describes the types of uses that are approved for the sources listed in the previous items. Describes the devices in which the sources may be used or stored. Improper use of radioactive material is a license violation and may result in enforcement actions.

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

II. FILING AN APPLICATION

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

Applicants for a materials license must complete Items 1 through 35 of the department's form DH-1322, "Application for a Radioactive Materials License, Human Use." Use supplemental sheets as necessary. For Items 7 through 34, be sure to check the appropriate box for each item. Each separate sheet or document submitted with the application should be identified and keyed to the Item number on the application to which it refers. All typed pages, sketches, and if possible, drawings should be on 8.5 x 11 inch paper to facilitate handling and review.

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

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

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

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

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

Because the gamma stereotactic radiosurgery unit uses risk significant radioactive materials, licensees are required to implement an Increased Controls security program. The program shall comply with the requirements described in NRC Order EA-07-305 (the Order) dated December 5, 2007, and its attachments titled "Table1: Radionuclides of Concern" and "Attachment 3: Specific Requirements Pertaining to Fingerprinting and Criminal Records Checks." The licensee shall complete implementation of EA-07-305 by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" contained within the Order. NRC documents are available at www.nrc.gov.

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 "Enclosure A, Fees" section of this guide, 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 application 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 "Enclosure A, Fees" of this guide, section 64E-5.204, F.A.C., or Regulatory Guide 6.20 for a description of annual fees. For new licenses annual fees are due within 60 days of issuance of the new license; an invoice for this fee is included with the new license cover letter.

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; the fee is included with the annual fee on the invoice that is in the cover letter accompanying a new license.

Notes:

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

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

III. CONTENTS OF AN APPLICATION

ITEM 1.a. NAME AND MAILING ADDRESS OF APPLICANT

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

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

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

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

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

ITEM 3 THIS IS AN APPLICATION FOR:

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

ITEM 4 INDIVIDUAL USERS (AUTHORIZED USERS)

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

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

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

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

If a physician or authorized therapeutic radiological physicist, (TRP), is certified by an organization listed in the appropriate section of Part VI of Chapter 64E-5, F.A.C., submit a copy of the certification and a Florida Preceptor Attestation APPENDIX 3 or APPENDIX 5. If a physician seeking authorization for gamma stereotactic radiosurgery is not certified appropriately, then submit a completed Florida Preceptor Attestation, APPENDIX 3.

Physicians or authorized therapeutic radiological physicists not previously authorized by a radioactive materials license and not certified by a preceptor/applicant appropriate organization must submit a complete description of their training and experience. Regulatory Guide 1.30, Preceptor Attestation for Medical Authorized Users APPENDIX 3 or APPENDIX 5, can be accessed at http://www.doh.state.fl.us/environment/radiation/matform.htm. The documentation will be evaluated for approval, to determine if it demonstrates training and experience consistent with the requirements listed in Part VI of Chapter 64E-5, F.A.C. This training must have been received within the last seven years or the physician must have completed appropriate documented continuing education.

ITEM 5.a. RADIATION SAFETY OFFICER (RSO)

State the name and title of the person designated by, and responsible to, the applicant's management as the RSO. If the RSO is not one of the proposed authorized users or authorized therapeutic radiological physicists, submit a complete description of the individual's training and experience pursuant to 64E-5.648, F.A.C., using a Florida Preceptor Attestation APPENDIX 4. The RSO must agree in writing to be the RSO.

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

ITEM 5.b. ALTERNATE EMERGENCY CONTACT

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

ITEM 6.a RADIOACTIVE MATERIAL FOR MEDICAL USE

Check the items requested. All gamma stereotactic radiosurgery therapy procedures (64E-5.634, F.A.C.) require a written directive. Gamma stereotactic radiosurgery requires a separate license. Indicate only the type of use requested.

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

Enter the sealed source manufacturer's name, model number and maximum activity per source, and total number of sources. Enter the device manufacturer's name and the device model number or designation.

ITEM 7 FACILITIES AND EQUIPMENT

Describe the available facilities, equipment (e.g., remote handling and emergency equipment, storage containers, and shielding) where radioactive material will be used. See Exhibit 1. Include a description of the areas assigned for receipt of radioactive materials shipments.

Submit an annotated drawing of the rooms and adjacent areas where radioactive material (e.g. the gamma stereotactic radiosurgery unit) will be used. See Exhibit 1 for an example.

Indicate the following:

1. Room numbers and principal use of each room or area and use/storage locations;
2. Restricted and adjacent unrestricted areas;
3. Diagrams may include emergency stop switches, independent high dose radiation monitor (inside treatment room), video camera, audio speaker and receiver, and other emergency equipment; and
4. All facility diagrams and security descriptions must be marked with the statement **"Security System Plan, Withhold from Public Disclosure Under 119.071(3), Florida Statutes."**

ITEMS 8 THROUGH 34 MODEL PROCEDURES

Submit a copy of each model procedure being adopted or submit an equivalent procedure. Complete the application by marking the appropriate box for each procedure.

ITEM 35 CERTIFICATE

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

IV. LICENSE AMENDMENTS

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

V. LICENSE RENEWAL

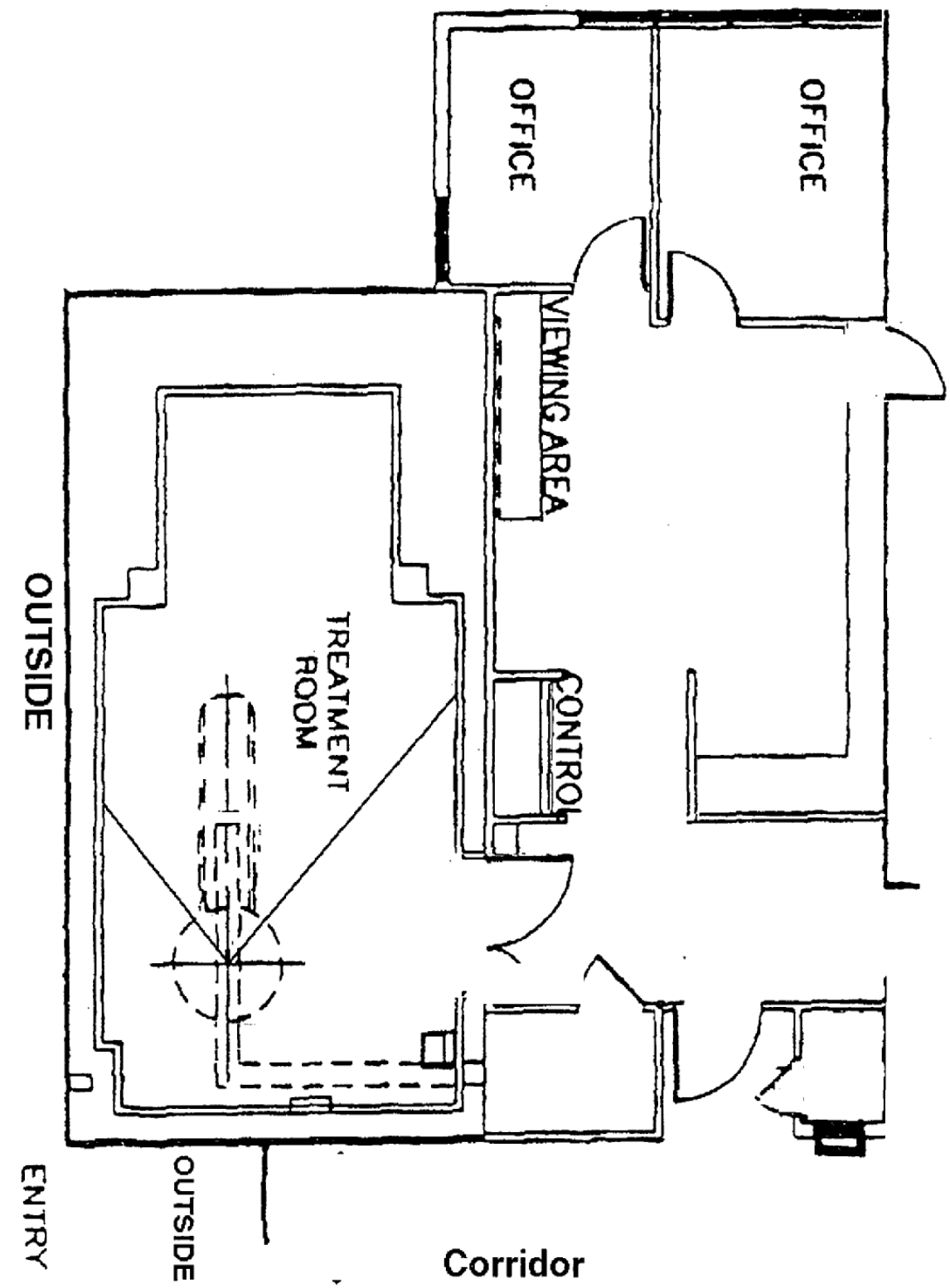
Absent any actions by the department or the licensee, a license remains in effect for five years. An application for license renewal must be received by the department at least 30 days prior to the expiration date. Mail the original and one copy to the department. This filing will ensure that the license does not expire until final action on the application has been taken, as provided for by subsection 64E-5.207(3), F.A.C. If the application is received less than 30 days before the expiration date, the facility or individual may be without a valid license when the license expires. Renewal applications should be filed using Form DH 1322, "Application for Radioactive Materials License, Human Use."

VI. LICENSE TERMINATION

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

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

B. Refer to regulations 64E-5.214, 64E-5.314 and 64E-5.621, F.A.C., which provide instructions for performing the closeout survey. A confirmatory inspection may be performed by an area inspector if deemed necessary by this office.



FACILITY DIAGRAM - Gamma Knife Dept

"Security System Plan, Withhold from Public Disclosure Under 119.071(3), Florida Statutes."

Exhibit 1:
Sample facility diagram and description

Facility Description

Shielding: Shielding specifications and calculations are attached.

Electromagnetic: The gamma stereotactic radiosurgery unit shall not be installed in close proximity to equipment that produces a high level of electromagnetic disturbance as determined by the manufacturer. (SS&D Registry and 64E-5.208)

Postings: The door to the treatment area will be posted with a "High Radiation Area" sign and a "Caution Radioactive Materials" sign. "Caution Radioactive Materials" labels with the radiation trefoil symbol and the radionuclide intended for use are secured to the treatment unit. The “Notice to Employees 3/01”, emergency procedures and emergency contact names and telephone numbers shall also be posted.

Door Interlock: The unit’s access will be controlled by an interlocked door at the entrance. The interlock is designed to prevent treatment initiation unless the door is closed or to cause the sources to be shielded when the door is opened during operation. If terminated by a door interlock trip, a reset operation is required prior to continuing the treatment. An interlock or safety device will prevent dual operation of more than one radiation producing device in a treatment room, if applicable.

Intercom /Video Viewing System: The system allows for continuous viewing of the patient during treatment from the unit console during irradiation. An intercom allows for two-way aural communication with the patient during treatment.

Security: The gamma stereotactic radiosurgery unit, the console, console keys, and the treatment room will be secured when unattended or not in use.

Indicators and Alarms: Various indicators on the control panel and on the unit notify the operator when the source is shielded or unshielded and indicate the status of various system components. An alarm sounds if the control system detects an error that requires immediate operator action. (SS&D Registry)

Emergency-Off Switches: Emergency-off switches are on the treatment console and on the treatment unit.

Room Area Monitors: An independent radiation area monitor capable of continuously monitoring radiation levels is installed in the treatment room. The monitor will have a visible indicator observable by an individual entering the room. The monitor will be equipped with a backup power supply (e.g. battery system) separate from the power supply to the unit.

Required By All Gamma Stereotactic Radiosurgery Devices Applicants

FACILITY DIAGRAM AND DESCRIPTION (Refer to Exhibit 1 for guidance)

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

Not Applicable For Gamma Stereotactic Radiosurgery Use

APPENDIX D	Procedures for Calibrating a Dose Calibrator
APPENDIX N	Radiation Safety During Radiopharmaceutical Therapy
APPENDIX O	Implant Therapy
APPENDIX P	Monitoring, Calculating, and Controlling Air Concentrations When Using Noble Gases or Radioactive Aerosols
APPENDIX U	Iodine-131 In-Vivo Thyroid Bioassay Program
APPENDIX Y	Use of Diagnostic Radiopharmaceuticals
APPENDIX Z	Mobile Medical Service

NOTE: High Dose Rate Remote Afterloaders (HDR), SIR-Spheres®, and Theraspheres®, require model procedures not listed in this guide. You may access our website at http://www.doh.state.fl.us/environment/radiation/matform.htm for guidelines.

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DELEGATION OF AUTHORITY TO MAKE LEGALLY BINDING STATEMENTS (OPTIONAL)

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

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

Memo To: All Employees and the Bureau of Radiation Control

From: Corporate Officer

Subject: Delegation of Authority to Make Legally Binding Statements

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

_____
License Certifying Official (signature)

_____
Name (typed or printed)

_____
Title

_____
Date

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APPENDIX A

Radiation Safety Officer Responsibilities and Radiation Safety Committee Charter

RADIATION SAFETY OFFICER (RSO) RESPONSIBILITIES

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

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

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

4. Identify program problems and solutions.

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

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

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

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

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

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

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

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

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

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

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

RADIATION SAFETY OFFICER

I _____ am responsible for implementing the radiation safety program
Radiation Safety Officer's name (type/print)
along with ensuring that radiation safety activities are performed with approved procedures and regulatory requirements in the daily operation.

_____
Radiation Safety Officer's (signature)

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

DELEGATION OF AUTHORITY FOR THE RADIATION SAFETY OFFICER

Memo To: All Employees

From: Corporate Officer

Subject: Delegation of Authority

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

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

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

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

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

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

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

Check appropriate box:

☐ This application does NOT require a Radiation Safety Committee.

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

Charge. The committee shall:

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

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

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

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

5. Identify program problems and solutions.

Responsibilities. The committee shall:

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

Administrative Information

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

APPENDIX B

Radiation Detection Instrumentation

SURVEY INSTRUMENTS (For use with a gamma stereotactic radiosurgery unit)

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

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

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

Check appropriate box:

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

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

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

OTHER RADIATION DETECTION INSTRUMENTS (64E-5.638)

(e.g. permanent radiation monitor, survey instrument, audible alarm, personal dosimeter, etc.)

Type of Instrument	Manufacturer	Model Number	Serial Number

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APPENDIX C

Quality Control of Gamma Stereotactic Radiosurgery

Quality control and preventative maintenance for the gamma stereotactic radiosurgery unit is performed according to manufacturer's specifications. Written quality control and preventative maintenance procedures are available for review.

Only a person specifically licensed by the NRC or an agreement state shall install, maintain, adjust, or repair a gamma stereotactic radiosurgery unit or conduct work involving the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

A record of the installation, maintenance, adjustment, and repair of the gamma stereotactic radiosurgery unit will be kept for 3 years. For each installation, maintenance, adjustment and repair, the record will include the date, description of the service, and name(s) of the individual(s) who performed the work. (64E-5.635)

Dosimetry System Requirements

A dosimetry system for spot-check and full calibration measurements shall be available for use that will be calibrated as specified below in either paragraph 1 or 2. (64E-5.640)

1. The system will be calibrated using a system or source traceable to the NIST and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the AAPM. The calibration will be performed within the previous 2 years and after any servicing that may affect system calibration.

2. The system will be calibrated within the previous 4 years and will be intercompared 18 to 30 months after the calibration at an intercomparison meeting with another dosimetry system that has been calibrated within the previous 2 years by the NIST or by a calibration laboratory accredited by the AAPM. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The calibration factor of the system shall not have changed by more than 2 percent. The intercomparison result will not be used to change the calibration factor. A comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide will be used when intercomparing dosimetry systems. 64E-5.640(1)

The dosimetry system for spot-check measurements may also be a system that has been compared with a system that has been calibrated as stated above. The comparison will take place within the previous year and after each servicing that may affect the system calibration.

Record Keeping

A record will be maintained for the duration of the license for each system calibration, intercomparison, and comparison. The record shall include:

- The date, the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared;
- The correction factors that were determined; and
- The names of the individuals who performed the calibration, intercomparison, or comparison.

Full Calibration Requirements

Full calibration measurements for the gamma stereotactic radiosurgery unit will be in accordance with published protocols accepted by nationally recognized bodies and will be performed: 64E-5.6412(4)

1. Before the first medical use and at intervals not exceeding 1 year; 64E-5.6412(2)
2. Before medical use whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for decay and following replacement of the source or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
3. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly.

For units with helmets, relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

Units designed for use without helmets (Perfexion) are not tested for helmets, relative helmet factors, helmet microswitches, hydraulic backups, trunnions, a trunnion centricity point, or a source exposure indicator light on the unit. The TRP shall establish additional daily spot-check procedures to assure the proper operation of the: (from NRC Guidance)

1. Frame adapter;
2. Docking device; and
3. The source exposure indicator light on the wall of the treatment room.
4. Location and function of the sectors.
5. Patient bed.

For units designed for use without helmets (Perfexion) the TRP shall establish additional monthly procedures to assure the proper location of the radiation focal point with respect to the table position, and collision table location. (NRC Guidance)

Full calibration measurements of the gamma stereotactic radiosurgery unit shall be conducted by an authorized medical physicist and will include the determination of: 64E-5.6412(2)

1. The output within 3 percent (the output is corrected mathematically at intervals not exceeding 1 month for Co-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.);
2. Isocenter coincidence;
3. On-off timers; timer constancy and linearity over the range of use; emergency timing circuits;
4. Stereotactic frames and localizing devices (trunnions) and trunnion centricity;
5. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off; and
6. Relative helmet factors and helmet microswitches.

The required dosimetry system will be used to measure the output for one set of exposure conditions. The remaining full calibration radiation measurements may be made using a dosimetry system that indicates relative dose rates.

Full Calibration Requirements Continued:

Records of each unit calibration shall be maintained for 3 years. The record shall include:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number for both the gamma stereotactic radiosurgery unit and the source;
3. The model numbers and serial numbers of the instruments used to calibrate the unit;
4. The results and an assessment of the full calibrations; and
5. The signature of the authorized medical physicist. 64E-5.642(7)

Periodic Spot-Checks

A. Spot-checks of the gamma stereotactic radiosurgery unit are performed monthly; before the first use of the unit on a given day; and after each source installation. The authorized therapeutic radiological physicist (TRP) shall establish spot-check procedures to assure the proper operation of the: (64E-5.6422)
    1. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
    2. Helmet microswitches;
    3. Emergency timing circuits; LAMP TEST PUSH BUTTON
    4. Stereotactic frames and localizing devices (trunnions);
    5. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
    6. Source exposure indicator lights on the unit, on the control console, and in the facility;
    7. Viewing and intercom systems;
    8. Timer termination;
    9. Radiation monitors used to indicate room exposures; and
    10. Emergency off buttons;

B. And shall determine the following elements:
    1. The output for one typical set of operating conditions measured with the dosimetry system;
    2. The difference between the measurement made above in paragraph B.1., and the anticipated output, expressed as a percentage of the anticipated output value obtained at last full calibration corrected mathematically for physical decay;
    3. Source output against computer calculation;
    4. Timer accuracy and linearity over the range of use;
    5. On-off error; and
    6. Trunnion centricity.

Periodic Spot-Checks – Continued:

C. Units designed for use without helmets (Perfexion) are not tested for helmets, relative helmet factors, helmet microswitches, hydraulic backups, trunnions, a trunnion centricity point, or a source exposure indicator light on the unit. For these units the TRP shall establish additional daily spot-check procedures to assure the proper operation of the: (64E-5.6422 & NRC Guidance)

   1. Frame adapter;
   2. Docking device; and
   3. The source exposure indicator light on the wall of the treatment room.

D. For units designed for use without helmets (Perfexion) the TRP shall establish additional monthly spot-check procedures to assure the proper location of the radiation focal point with respect to the table position, and collision table location and a 6 month spot-check procedure (with exact date subject to vendor service availability) for verification of correct sector movement and location. (NRC Guidance)

Spot-Check Results Indicate A Malfunction

If the results of the checks required above in A. 5 - 10 indicate the malfunction of any system, the unit shall be locked with the control console in the off position and will not be used except as may be necessary to repair, replace, or check the malfunctioning system.

If the results of the checks required above in A. 1-5 and B. 1-6 indicate that any system is not operating properly, we shall arrange for the repair as soon as possible.

Periodic Spot-Check Records

A copy of the established spot-check procedures shall be maintained until the license is terminated. The authorized TRP shall review and document the results of each spot-check within 15 days. A copy of the physicist documentation and the results of each spot-check shall be maintained for 3 years. The spot-check record shall include:

- The date of the spot-check;
- The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit;
- The manufacturer's name, model number and serial number of the instrument used to measure the output of the gamma stereotactic radiosurgery unit;
- The timer linearity and constancy;
- The calculated on-off error;
- A determination of trunnion centricity;
- The difference between the anticipated output and the measured output;
- An assessment of source output against computer calculations;
- Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
- The name of the individual who performed the periodic spot-check and the signature of the authorized TRP who reviewed the record of the spot-check.

Therapy-Related Computer Systems

Acceptance testing on the treatment planning system of gamma stereotactic radiosurgery unit related computer systems shall be performed in accordance with published protocols accepted by nationally recognized bodies, such as the American Association of Physicists in Medicine. At a minimum, the acceptance testing must include, as applicable, verification of the following:

- The source-specific input parameters required by the dose calculation algorithm;
- The accuracy of dose, dwell time, and treatment time calculations at representative points;
- The accuracy of isodose plots and graphic displays;
- The accuracy of the software used to determine sealed source positions from radiographic images; and
- The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Five Year Inspection for Gamma Stereotactic Radiosurgery Units

Each gamma stereotactic radiosurgery unit will be fully inspected and serviced during source replacement or at least every 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism. This inspection and servicing shall only be performed by persons specifically licensed to do so.

A record will be maintained of the inspection and servicing for the duration of the license. The record shall contain:

- The inspector's name; The inspector's radioactive materials license number; The date of inspection;
- The manufacturer's name and model number and serial number for both the treatment unit and source;
- A list of components inspected; A list of components serviced and the type of service;
- A list of components replaced; and
- The signature of the inspector.

Perfexion™ Specific Commitments (from NRC Guidance)

- Before each patient use, we will confirm that the frame adapter is functioning correctly and that it can be appropriately attached to the coordinate frame. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the unit. All test results records will be kept for 3 years.
- Before the first use of the Perfexion™ unit each day, we will confirm that the docking device is securely mounted to the table and that the frame adapter can be correctly docked in the docking device. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.
- Before the first use of the unit each day, we will confirm proper functioning of the source exposure indicator light on the treatment room wall. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the unit. All test results records will keep for 3 years.

Perfexion™ Specific Commitments Continued:

- On a monthly basis, we will confirm that the location of the radiation focal point, with respect to the table position, is within the specifications provided by the manufacturer. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Perfexion™ unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years. (Note: At this time, the test can only be performed with the diode centered in the test tool. If a test is developed that uses a diode or other radiation measurement precisely located in an off-centered position, this test should also be performed to verify table position.)

- On a monthly basis, we will confirm that the location of the table at a number of off center positions is within the collision specifications provided by the manufacturer. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Perfexion™ unit.

- We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years. (Note: At this time the clearance test check tool is used to test for collisions. If this tool or another can be used to test the off center positions of the table, the tool or test should also be used to verify table position accuracy.

- Approximately every six months (with exact date subject to vendor service availability), we will confirm that each sector moves correctly to each position within appropriate tolerance limits. This test and the description of the record of the test will be included in the spot-check procedures. The test will also be performed during the full calibration measurements of the Perfexion ™ unit. We will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years. (Note: At this time, the vendor can demonstrate at time of installation or major repair for the licensee's verification that the sector locations and numbers agree with the computer screen display and the vender can perform a physical measurement of each sector rod location at each position during the routine 6 month service. The licensee may use data from the vendor's measurements to assess sector movement and alignment. If, at a later time, a test is developed that permits the licensee to determine each sector's alignment and proper movement, this test should also be used to verify sector alignment and proper movement.)

- If the frame adapter fails to perform as designed, we will remove it from service until repaired.

- If the docking device, sector location, sector movement, or table positioning fail to perform as designed, we will lock the control console in the off position and not use the unit except as necessary to repair, replace, or check the malfunctioning system.

- If either the clearance test tool or the "QA" test tool fails to function as specified by the manufacturer, we will have the tool repaired or replaced before the next patient treatment requiring the proper function of that tool.

- Removal or major repair of the components associated with the sector assemblies will be considered a major repair of the source assembly and will require full calibration.

We will commit to have each Perfexion™ gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism. This inspection and servicing will only be performed by persons specifically licensed to do so.

APPENDIX D

Procedures for Calibrating a Dose Calibrator

Not Applicable

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APPENDIX E

Personnel External Exposure Monitoring Program

PROGRAM

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

RECORDS

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

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APPENDIX F

Training Program

Manufacturer's Training in Gamma Stereotactic Radiosurgery Unit Safety:

All authorized users (AU), radiation therapy technologists (RTT), and authorized therapeutic radiological physicists (TRP) will complete operating and emergency procedures specific to the device, prior to operating the unit or related equipment. Only AUs or certified RTT's who have completed the training can operate the gamma stereotactic radiosurgery unit and related equipment for patient treatments. The operating and emergency procedures for the unit will be retained until removal of the unit.

Annual Refresher Training:

Annual re-training will be provided to all personnel, as described above. The manufacturer will provide re-training, if possible, or it will be provided by one of the AUs or TRPs, listed on the license.

Records will be maintained for all individuals, who operate the unit, as appropriate to the individual's assigned duties, receiving initial and annual instructions on operating and emergency procedures, and these records will include the date of instruction, names of the attendees, list of topics covered, and the name of the individual who gave the instructions. Instruction records will be maintained for three years.

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

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

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

☐ Security ☐ Ancillary ☐ Housekeeping ☐ Others _____

The method of training will include the following:

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

Hazardous Material Training

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

The training will include the following:

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

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

Training will be conducted every three years.

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

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

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

The method of training will include the following:

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

As required in section 64E-5.625, F.A.C., all personnel caring for patients undergoing brachytherapy treatment will receive the following training.

Records will be maintained for individuals receiving instructions, and these records will include the date of instruction and the name of the individual who gave the instructions. Records will be maintained for three years.

The method of training will include the following:

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

APPENDIX G

Ordering and Receiving Radioactive Material

Ordering Radioactive Materials

The radioactive sources ordered or received are used in the gamma stereotactic radiosurgery unit. Replacement sources are received from a person specifically licensed by the NRC or an agreement state at intervals of approximately 5 – 7 years. The supplier has a copy of the radioactive materials license authorizing purchase.

Source Security:

Appropriate increased controls security provisions will be implemented for the receipt and storage of the sources.

Receipt of Radioactive Packages:

Following established requirements in section 64E-5.327, F.A.C., upon receipt of a new source package, the shipping container is placed, unopened, into the treatment room, or other designated radiation storage location, until a person specifically licensed by the NRC or an agreement state arrives to exchange the source. If the package is damaged in shipment, the receiver shall notify the radiation safety officer or designee immediately and before moving the package. In the case of such damage, the radiation safety officer or designee will survey the package for leakage of radioactive material before the package is moved to a storage area.

Documentation Required:

The person receiving the source upon delivery will record receipt of the source and the condition of the shipping container, and perform a radiation survey at contact and 1 meter from the source container on a form and will be kept with the gamma stereotactic radiosurgery unit records.

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APPENDIX H

Opening Packages Containing Radioactive Material and Return of Sources

Source exchanges are conducted by the manufacturer's representative or a person specifically licensed by the NRC or an agreement state. The gamma stereotactic radiosurgery, source-shipping container is to be opened only by the manufacturer's personnel or a person specifically licensed by the NRC or an agreement state.

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APPENDIX I

Use Records

All daily checks will be documented and available for inspection.
Daily check forms must be kept on file for at least 3 years.

A record of the installation, maintenance, adjustment, and repair of the gamma stereotactic radiosurgery unit will be kept for 3 years. For each installation, maintenance, adjustment and repair, the record will include the date, description of the service, and name(s) of the individual(s) who performed the work. Appendix C

Records of the permanent radiation monitor check required by subsection 64E-5.638(4), F.A.C., will be maintained for 3 years. The record shall include the date of the check, notation what the monitor indicates when its detector is and is not exposed to the source, and the initials of the individual who performed the check. Appendix J

The licensee shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include; the date, the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared; the correction factors that were determined; and the names of the individuals who performed the calibration, intercomparison, or comparison. Appendix C

Records will be maintained of each gamma stereotactic radiosurgery unit calibration for three years. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for both the unit and the source; the model numbers and serial numbers of the instruments used to calibrate the unit; the results and an assessment of the full calibrations; and the signature of the authorized medical physicist. Appendix C

Records will be maintained of each spot-check for 3 years and a copy of the procedures until the licensee no longer possesses the gamma stereotactic radiosurgery unit.
The record shall include: Appendix C

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit;

(c) The manufacturer's name, model number and serial number of the instrument used to measure the output of the gamma stereotactic radiosurgery unit;

(d) The timer linearity and constancy;

(e) The calculated on-off error;

(f) A determination of trunnion centricity;

(g) The difference between the anticipated output and the measured output;

(h) An assessment of source output against computer calculations;

(i) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(j) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

We shall retain a record of the radiation surveys for the duration of the license. These records shall include; the date of the measurements; the manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the RSO or authorized medical physicist who performed the test. Appendix L

A record will be maintained of the 5 year inspection and servicing for the duration of the license. The record shall contain: Appendix C

- The inspector's name; The inspector's radioactive materials license number; The date of inspection;
- The manufacturer's name and model number and serial number for both the treatment unit and source;
- A list of components inspected; A list of components serviced and the type of service;
- A list of components replaced; and
- The signature of the inspector.

APPENDIX J

Rules of Use for Gamma Stereotactic Radiosurgery Units

The sealed sources in a photon emitting gamma stereotactic radiosurgery unit for therapeutic medical uses shall only be used as approved in the Sealed Source and Device Registry (SSDR), or in research in accordance with an active IDE application accepted by the FDA, provided the licensing, labeling and packaging requirements of Rule 64E-5.612, F.A.C. are met.

1. During patient treatments, the gamma stereotactic radiosurgery unit is operated by an Authorized User or by a Florida Certified Radiation Therapy Technologist (RTT), under the direct supervision of an Authorized User (AU). The AU, the authorized Therapeutic Radiological Physicist (TRP), and the RTT will be trained in the approved procedures of the unit, unit software, and all associated equipment.

2. Operating and emergency procedures are physically located at the gamma stereotactic radiosurgery unit console.

3. Other than the patient, no person will be present and no person will enter the treatment room under normal operating conditions, until the radiation unit's shield doors are fully closed. Only individuals permitted by the Radiation Safety Officer (RSO), AU, or TRP may be present in the treatment room during treatment with the source(s). 64E-5.636(1)(b)

4. An AU and an authorized TRP will be physically present throughout all patient treatments involving the unit. 64E-5.637(6)(c)

5. For units with helmets, the unit operator and TRP shall initial a record for each patient immediately prior to the treatment which includes: the patient's name and date of treatment; the collimator size of the patient's helmet; and that both individuals have confirmed that the helmet collimator size agrees with the AU's prescription/therapy treatment plan for the patient. reference SSDR

6. For Perfexion™ units, the operator must perform clearance tests for each treatment, to confirm the patient, with the coordinate frame in position, will safely enter the radiation unit and not come in contact with any parts of the unit, and the operator must perform a radiation focus precision check at prescribed intervals. reference SSDR

7. Dual operation of more than one radiation producing device in the treatment room will be prevented with an interlock or safety device.

8. The gamma stereotactic radiosurgery unit, the console, the console keys, and the treatment room will be secured when unattended.

9. Prior to patient use, all daily checks of the unit will be conducted and documented. Prior to first use of the unit and following source exchanges, an authorized TRP must calibrate the unit. Only an authorized TRP will perform calibrations, dosimetry, and monthly quality assurance on the unit.

10. The intercom/video system in the treatment room will allow for continuous observation of the patient from the console and will be operational before use of the unit. No treatment of patients is allowed if the system is inoperable. 64E-5.639

11. A permanent radiation monitor will be located in the gamma stereotactic radiosurgery room that is capable of continuously monitoring radiation levels and is checked daily as specified in 64E-5.638, F.A.C. If the monitor is inoperable, any individual entering the gamma stereotactic radiosurgery room is required to use a radiation survey instrument or audible alarm personal dosimeter to monitor for an exposed source. The radiation survey instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. Records will be maintained as specified in subsection 64E-5.638(5), F.A.C.

12. The permanent radiation monitor will be promptly repaired or replaced if inoperable. The record including the date of the check, notation what the monitor, instrument, or dosimeter indicates when it's detector is and is not exposed to the source, and the initials of the individual who performed the monitor, radiation survey instrument, or audible alarm personal dosimeter check will be kept for three years. The radiation monitor shall be repaired promptly if it is inoperable. 64E-5.638

13. Except for micro-switch adjustments on the helmet in accordance with the manufacturer's instructions, general cleaning, and replacement of lamps and microphones, only a person specifically licensed by the NRC or an agreement state shall perform any maintenance, modifications, or adjustments to any components on the radiation unit, operating table, helmet, or control system. reference SSDR

14. An emergency power source will be provided that assures operation of all TV monitoring/recording equipment, and emergency lighting for the treatment and control rooms, in the event of a power failure during treatment.

15. Equipment that produces a high level of electromagnetic disturbance (i.e. short wave equipment) shall not be installed or used in close proximity to the gamma stereotactic radiosurgery unit. reference SSDR

APPENDIX K

Emergency Procedures and Posting Requirements

Written emergency procedures will be developed, implemented, and maintained for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or to remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures will address the means of controlling radiation exposures to personnel while manually closing the shield doors; and/or removing a patient from the unit. Emergency procedures will be submitted to the bureau for review. A copy of the operating and emergency procedures are physically located at the unit console. 64E-5.636

The emergency procedures include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
3. The names and telephone numbers of the authorized users, the authorized therapeutic radiological physicist, and the RSO to be contacted if the unit or console operates abnormally or if the patient or human research subject has a medical emergency or dies.

STOLEN, LOST OR MISSING RADIOACTIVE MATERIAL

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

POSTING REQUIREMENTS

A. A copy of our emergency notification notice, and a “Notice to Employees 3/01” will be conspicuously posted at our facility as required by 64E-5.901, F.A.C. Current copies of Chapter 64E-5, F.A.C. Part III and Part IX, the license, and conditions, documents incorporated into the license by reference and amendments thereto are not required to be posted provided that a “Notice to Employees 3/01” is posted which describes the documents and states where they may be examined. Increased Controls and Security related documents shall not be posted nor made generally available.

B. The door to the treatment area will be posted with a "High Radiation Area" sign and a "Caution Radioactive Materials" sign.

C. Instructions are posted at the unit consol providing the names and telephone numbers of individuals to contact if the unit or console operates abnormally and providing the location of the emergency procedures. 64E-5.636(3)

D. The location of use for radioactive material will be posted with the proper signage as described in 64E-5.323 and 64E-5.324, F.A.C.

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APPENDIX L

Procedures for Area Surveys

Radiation surveys will be performed with an operable radiation survey instrument calibrated as provided in Appendix V and according to 64E-5.615, Florida Administrative Code, (F.A.C.), to ensure the maximum radiation levels and average radiation levels from the **surface of the main source safe** with the source**(s)** in the shielded position, do not exceed the levels stated in the Sealed Source and Device Registry. 64E-5.644

These surveys will be performed at the installation of new sources and following repairs to the source**(s)** shielding, the source**(s)** driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the sources.

Records will be maintained of the radiation surveys for the duration of the license. These records will include:

1. The date of the measurements;

2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

4. The signature of the RSO or authorized therapeutic radiological physicist who performed the test.

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APPENDIX M

Procedures for Conducting a Member of the Public Dose Compliance Study

If licensed for, or seeking licensure for possession and use of radioactive material, in accordance with section 64E-5.313, Florida Administrative Code (F.A.C), the radiation hazard resulting from licensed operations must be evaluated to demonstrate compliance with the member of public (MOP) dose limits described in section 64E-5.312, F.A.C. Be advised, the dose in any unrestricted area from external sources must be less than 2 mr/hr and 100mr/yr.

Calculate Total Effective Dose Equivalent (TEDE) and keep calculations on file for inspection purposes.
DDE = TEDE

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

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

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

Select one of the following methods:

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

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

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

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

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

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APPENDIX N

Radiopharmaceutical Therapy

Not Applicable

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APPENDIX O

Implant Therapy

Not Applicable

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APPENDIX P

Radioactive Gases & Aerosols

Not Applicable

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APPENDIX Q

Quality Management Program (QMP)

Written and Oral Directives for Gamma Stereotactic Radiosurgery Administration

Prior to administration of a radiation dose, an authorized user must date and sign a written directive specifying the target coordinates settings per treatment for each anatomically distinct treatment site, collimator size, plug pattern, and total dose. Any revision of a written directive must be signed and dated by an authorized user prior to the administration of the dose. Any unintended deviation from the written directive that is identified will be evaluated by the authorized user, and appropriate action will be taken.

An oral directive for administration is acceptable when the delay required to complete a written directive would jeopardize the patient's health because of the emergent nature of the patient's condition. The information contained in the oral directive must be documented immediately in the patient's record and a written directive prepared within 48 hours of the oral directive.

Any oral revision to a written directive is acceptable when the delay required to prepare a written revision to the written directive would jeopardize the patient's health. The oral revision must be documented immediately in the patient's record and a revised written directive must be signed by the authorized user within 48 hours of the oral revision.

A written directive which changes an existing written directive can be made for any therapeutic procedure if the revision is dated and signed by an authorized user prior to the administration of the gamma stereotactic radio surgery dose.

Verification of Patient Identity

The patient's or human research subject's identity is verified by more than one method as the individual named in the written directive prior to administration.

Verification of Details of Gamma Stereotactic Radiosurgery Administration

Final plans of treatment and related calculations, manually or computer generated for gamma stereotactic radiosurgery will be compared and verified that they agree with the written directive. Verify that any computer-generated calculations are correctly transferred into the consoles of the therapeutic medical units authorized by Rule 64E-5.634, F.A.C.

Computer-generated dose calculations are checked by examining the computer printout to verify that correct data for the patient were used in the calculations and are checked to ensure that they were correctly input to the gamma stereotactic radiosurgery unit.

Each administration agrees with the written directive.

Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.

Documentation of Gamma Stereotactic Radiosurgery Administration

The licensee shall retain in an auditable form for 3 years each written directive and a record of each administered radiation dose where a written directive is required by subsection 64E-5.611(1), F.A.C.

Periodic Review of the Gamma Stereotactic Radiosurgery Administrations

An annual review of a representative sample of the procedures performed in the last 12 months will be made (1) to compare a representative sample of patient administrations within the review period, (2) to review all recordable events within the review period and (3) to review all medical events within the review period.

Deviations from the written directive will be noted, as will be the cause of the deviation and the action required to prevent recurrence.

Any medical events which have occurred since the last annual analysis will be studied to determine the cause of the event and steps to prevent such future occurrence will be implemented. Within 30 days of discovery of each recordable event, the licensee shall (1) Assemble the relevant facts including the cause, (2) Identify any corrective action required to prevent recurrence and (3) retain a record in an auditable form for 3 years of the relevant facts and any corrective action taken. Each licensee shall submit and maintain records and reports of medical events as required by subsections 64E-5.345(4) and (5), F.A.C.

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

Lot Tolerance Percent Defective (Percent Error)

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

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

APPENDIX R

ALARA Component of the Radiation Protection Program including Radiation Safety Committees

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

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

1. Management Commitment

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

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

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

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

2. Radiation Safety Committee

   A. Review of Proposed Authorized Users and Uses

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

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

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

2. B. Delegation of Authority

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

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

C. Review of the ALARA Component

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

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

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

3. Radiation Safety Officer

A. Annual, Biannual and Quarterly Review

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

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

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

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

B. Education Responsibilities for ALARA Program

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

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

3. C. Cooperative Efforts for Development of ALARA Procedures

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

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

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

D. Reviewing Instances of Deviation from Good ALARA Practices

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

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

4. Authorized Users

A. New Methods of Use Involving Potential Radiation Doses

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

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

B. Authorized User's Responsibility to Supervise Individuals

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

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

5. Individuals Who Receive Occupational Radiation Doses

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

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

6. Investigational Levels to Monitor Individual Occupational Radiation Doses

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

Investigational Levels

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

A. Personnel dose less than Investigational Level I.

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

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

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

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

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

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

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

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

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

APPENDIX S

ALARA Component of the Radiation Protection Program

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

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

1. Management Commitment

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

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

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

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

2. Delegation of Authority

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

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

3. Authorized Users

   A. New Methods of Use Involving Potential Radiation Doses

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

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

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

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

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

Investigational Levels

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

A. Personnel dose less than Investigational Level I.

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

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

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

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

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

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

APPENDIX T

Procedure for Leak-Testing Sealed Sources

Each source shall be leak tested by the source manufacturer at least 6 months prior to installation into the gamma stereotactic radiosurgery unit. New sources are delivered with a leak test certificate.

Prior to the initial operation and at intervals not to exceed 6 months, leak tests will be performed by smearing the outer (convex) surfaces of all the collimator helmets.

For the Perfexion™ unit, leak tests will be performed by smearing the outer (convex) surfaces of the collimator cap. For other units designed for use without a helmet, leak test procedures will be obtained from the unit manufacturer and will be submitted to the bureau for review.

Leak tests will be conducted using an approved leak test kit. A person specifically licensed by the NRC or an agreement state will conduct the analysis and provide documentation. Records of the leak tests are for at least 3 years.

Source exchanges are typically performed at anywhere from 5 to 10 year intervals, depending on the unit manufacturer. During source removal operations, each source shall be tested for leakage prior to shipment.

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APPENDIX U

Bioassay Program

Not Applicable

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APPENDIX V

Survey Meter Calibrations

CHECK APPLICABLE ITEMS

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

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

RECORDS

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

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

This record will be maintained for 3 years for inspection.

PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

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

1. The source used is approximately a point source.
2. Either the apparent source activity - *or* - the exposure rate at a given distance is traceable by documented measurements, to a standard certified by the National Institute of Standards and Technology, within 5% accuracy.
3. A source having approximately the same photon energy as the environment in which the calibrated device is employed is used for the calibration.
4. The source is of sufficient strength to give an exposure rate of approximately 30 mR/hr at 100 cm. (Typical minimum activities are 85 mCi of Cs-137 and 21 mCi of Co-60).
5. The inverse square law and the radioactive decay law are used to correct for changes in distance or source decay.
6. A record is made of each survey meter calibration.
7. A single point on a survey meter scale is considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10%, - *or* - 20% if a correction chart or graph is attached conspicuously to the instrument.
8. Meters offering a linear scale are calibrated on at least two points on each scale. The points are at approximately 1/3 and 2/3 of full scale.
9. Meters offering a multi-decade logarithmic scale are calibrated at no less than one point on each decade - *and* - no less than two points on one of the decades. Those points are approximately 1/3 and 2/3 of the decade.

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

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

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

    A. The owner or user of the instrument;

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

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

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

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

    F. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);

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

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

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

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

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

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

        (1) The average correction factor;

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

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

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

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

APPENDIX W

Procedures for Waste Disposal

Radioactive Material Storage

The manufacturer or a person specifically licensed by the NRC or an agreement state will perform the source exchanges.

Prior to a source exchange, the new source will be temporarily stored in a hot cell, the treatment room or other approved storage area until exchange of the source.

Following the exchange of sources, the old sources will be properly packaged and labeled and may be stored in a hot cell, the treatment room or other approved storage area.

Radioactive Material Disposal

All gamma stereotactic radiosurgery sources will be returned to the manufacturer or other authorized licensee following the source exchange. All packages containing radioactive material will be shipped in accordance with U.S. Department of Transportation regulations.

Documentation Required

Source exchange must be documented and kept with the gamma stereotactic radiosurgery unit records for at least 3 years.

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APPENDIX X

Inventory

Gamma stereotactic radiosurgery sources are not subject to the inventory requirements specified in 64E-5.618(8), F.A.C.

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APPENDIX Y

Diagnostic Radiopharmaceuticals

Not Applicable

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APPENDIX Z

Mobile Medical Service Requirements

Not Applicable

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OTHER

Increase Controls Procedures (IC)

The purpose of the Increased Controls for radioactive sources is to enhance security of radioactive material in risk significant quantities (i.e. quantities of concern). The U.S. Nuclear Regulatory Commission document titled "Increased Controls For Licensees That Possess Sources Containing Radioactive Material Quantities Of Concern" shall be used to guide the development of our program.

Increased Controls Procedures shall comply with the requirements described in NRC Order EA-07-305 (the Order) dated December 5, 2007, and its attachments titled "Table1: Radionuclides of Concern" and "Attachment 3: Specific Requirements Pertaining to Fingerprinting and Criminal Records Checks." Implementation of EA-07-305 shall be completed by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern".

The Florida Bureau of Radiation Control (BRC) – Radioactive Materials Section will be provided a certification that the Trustworthiness and Reliability (T&R) Official (and any subsequent T&R Official) is themselves deemed trustworthy and reliable by us as required in B.2., of the Order. The NRC's Headquarters Operations Office shall be notified at 301-816-5100 and the FL BRC at 407-297-2095, within 24 hours, if the results from a criminal history records check indicate that an individual is identified on the FBI's Terrorist Screening Data Base.

Access to the details and documents concerning our security system for our gamma stereotactic radiosurgery unit will be restricted to individuals who have been deemed trustworthy and reliable and who have completed the FBI's fingerprinting and criminal records review.

Some of the documents concerning our IC program will contain security sensitive information. Sensitive documents will not be posted. We will endeavor to identify documents with sensitive information describing our security measures and all sensitive diagrams by prominently marking each with the phrase:

"**Security System Plan, Withhold from Public Disclosure under 119.071(3), *Florida Statutes***."

IC Program Parameters

In order to ensure the safe handling, use, and control of licensed material in use and in storage, we have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to radioactive material quantities of concern and devices.

1. Access to radioactive materials is controlled at all times. Methods used to control access may include barriers, personnel, and/or entry control devices.
2. Trustworthy and Reliability determinations are established and documented.
    A. Personnel who require access to the radioactive material to perform job duties who are not approved for unescorted access are escorted by an approved individual.
    B. Only trustworthy and reliable individuals, approved in writing shall have unescorted access to radioactive material in quantities of concern and devices containing such radioactive material.
    C. Documentation of the basis for concluding that there is reasonable assurance that an individual granted unescorted access is trustworthy and reliable, and does not constitute an unreasonable risk for unauthorized use of radioactive material in quantities of concern, shall be maintained.

IC Program Parameters Continued:

3. Methods shall be implemented to monitor and immediately detect, assess, and respond to unauthorized access to radioactive material.
    A. Security monitoring shall be enhanced during periods of source delivery or shipment.
    B. Methods shall be implemented to establish the capability to immediately respond to any actual or attempted theft, sabotage, or diversion of radioactive material.
        (1) Methods shall include a pre-arranged response plan established with the appropriate Local Law Enforcement Agency (LLEA), for their assistance in response to any actual or attempted theft, sabotage, or diversion of radioactive material.
        (2) The pre-arranged response plan shall be consistent in scope and timing with a realistic potential vulnerability of the radioactive material.
        (3) The pre-arranged response plan shall be updated when changes to the facility design or operation affect the potential vulnerability of the sources.
4. A dependable means shall be established to transmit information between and among the various security system components that are used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.
5. Loss of primary power will be a consideration used in the development of security and communications systems.
6. A process shall be established to notify the Florida Bureau of Radiation Control and the United States Nuclear Regulatory Commission in the event of any actual or attempted theft, sabotage, or diversion of radioactive material.
7. Documentation describing each instance of unauthorized access and any necessary corrective actions to prevent future instances of unauthorized access, shall be maintained.

Nationally Tracked Sources

Upon receipt of nationally tracked sources, we shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. Our name, address, and radioactive materials license number;
2. The name of the individual preparing the report;
3. The name, address, and license number of the person that provided the source;
4. The manufacturer, model, and serial number of each source or, if not available, other information to uniquely identify the sources;
5. The radioactive material in the source;
6. The initial or current source strength in Becquerels (Curies);
7. The date for which the source strength is reported; and
8. The date of receipt.

Nationally Tracked Sources Continued:

Upon disposal of a nationally tracked source, we shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The waste manifest number;
4. The container identification with the nationally tracked source;
5. The date of disposal; and
6. The method of disposal.

The National Source Tracking Transaction Report required for receipt or disposal of sources must be submitted to the NRC by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

- The on-line National Source Tracking System;
- Electronically using a computer-readable format;
- By facsimile;
- By mail to the address on the NRC Form 748 National Source Tracking Transaction Report Form; or
- By telephone with follow-up by facsimile or mail.

Any error in previously filed reports shall be corrected or we will file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Every year we shall reconcile the inventory of nationally tracked sources that we possess against our data in the National Source Tracking System.

The reconciliation is conducted during January, of each year, and must resolve any discrepancies between the National Source Tracking System and the actual inventory. To reconcile each transaction, we shall file a report for missed transactions or file a corrected report for previously submitted reports containing inaccuracies. By January 31 of each year, we will submit confirmation to the National Source Tracking System that the data in the National Source Tracking System is correct.

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FLORIDA DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS SECTION
APPLICATION FOR RADIOACTIVE MATERIALS LICENSE
HUMAN USE

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

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

FEI #_____

Telephone # _____

Fax # _____

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

☐ Same as 1.a.

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

_____

b. LICENSE FEE ENCLOSED: $_____

3. THIS IS AN APPLICATION FOR:

☐ **a.** New License

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

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

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

☐ SEE ATTACHED LIST

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

Name: _____

RSO Phone #:_____

RSO E-Mail: _____

5.b. ALTERNATE EMERGENCY CONTACT:

Name: _____

Contact Phone #: _____

Contact E-Mail: _____

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

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

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

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

35. CERTIFICATE

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

Certifying Official (Signature)

Name (typed or printed)

Title

Date