



STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL



REGULATORY GUIDE

Regulatory Guide 1.60

Issuance Date: October 2011

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR HIGH DOSE RATE REMOTE AFTERLOADERS

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 | 4.) Radioactive Waste |
| 2) Inspection and Enforcement | 5) Transportation |
| 3) General Health Physics | 6) General |

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

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MEDICAL APPLICATION

Enclosure A

Fees*

The categories are:

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

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

Effective August, 2007

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I. INTRODUCTION

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

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

PURPOSE OF GUIDE

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

TYPES OF LICENSES

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

1. General License

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

2. Specific License

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

3. Specific License of Broad Scope

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

APPENDICES, EXHIBITS AND SUPPLEMENTS

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

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

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

IMPORTANT NOTICE:

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

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

APPLICABLE REGULATIONS

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

Under authority of Chapter 404, Florida Statutes (the Florida Radiation Protection Act), the bureau issues licenses to users of radioactive material and performs inspections to ensure safe operations and compliance with Chapter 64E-5, Florida Administrative Code (F.A.C.), the department's radiation control regulations. Chapter 64E-5, F.A.C., is available on the Internet at <http://www.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 in portable devices and should be used in conjunction with these instructions:

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

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

LICENSE REQUIREMENTS AND RESTRICTIONS

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

License Items

| <u>Item No. and Title</u> | <u>Description</u> |
|--------------------------------|--|
| 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 material are used and stored. If the two addresses are different, the physical address must be listed in Condition 10; if they are the same, Condition 10 will reference the address listed in Item 2. |
| 3. License Number | Lists the number assigned to the license by the bureau. The number should be referenced in all license-related correspondence. |
| 4. Expiration Date | Lists the date the license is due to expire. A radioactive materials license is valid for 5 years from the date issued. A renewal application must be received by the bureau at least 30 days prior to the expiration date to ensure that the license remains valid. The bureau sends out reminder notices as the license nears its expiration date. |
| 5. Category | Lists the license category: e.g. 5A(II), 5A(III), 5F(II). Activities involving possession and use of radioactive materials are divided into license categories. Organizations seeking to conduct more than one category of licensed activity must obtain separate licenses for each category of use. Refer to section 64E-5.204, F.A.C., or Regulatory Guide 6.20, Revision 5, for a complete listing of license types and fees at http://www.doh.state.fl.us/environment/radiation/matform.htm . |
| 6. Radioactive Material | Describes the type (element and mass number, e.g. Iridium 192) of radioactive material the license authorizes for possession and use. |
| 7. Form | Describes the form of radioactive material the license authorizes for possession and use. Include the sealed source manufacturer and model designation. |
| 8. Possession Limit | Lists the maximum possession limit for radioactive sources. <u>Possession of more sources than authorized is a license violation and may result in enforcement actions.</u> |
| 9. Use | Describes the types of uses that are approved for the sources and devices listed in the previous items. <u>Improper use of radioactive material is a license violation and may result in enforcement actions.</u> |

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.

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

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

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

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

LICENSE FEES

The following fees are assessed:

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

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

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

- Notes:
1. Annual and reclamation fees are assessed on the anniversary of the license issuance date. An invoice is sent to the licensee 60 days in advance of the due date.
 2. Fees are not assessed for license renewals, amendment requests, licensing actions, inspections initiated by the department, license terminations, or requests for regulatory information (except for document copying costs).

III. CONTENTS OF AN APPLICATION

ITEM 1.a. NAME AND MAILING ADDRESS OF APPLICANT

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

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

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

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

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

ITEM 3 THIS IS AN APPLICATION FOR:

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

ITEM 4 INDIVIDUAL USERS (AUTHORIZED USERS)

Provide a separate attachment listing the full names of all physicians and authorized therapeutic radiological physicists 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. If a physician seeks authorization other than what is defined by their certification then submit a Florida Preceptor Attestation.

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 can be accessed at <http://www.doh.state.fl.us/environment/radiation/matform.htm>. The documentation will be evaluated for approval, if it demonstrates training and experience consistent with the requirements listed in Part VI of Chapter 64E-5, F.A.C. This training must have been received within the last seven years or the physician must have completed appropriate documented continuing education.

ITEM 5.a. RADIATION SAFETY OFFICER (RSO)

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

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

ITEM 5.b. ALTERNATE EMERGENCY CONTACT

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

ITEM 6.a RADIOACTIVE MATERIAL FOR MEDICAL USE

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

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

Enter the sealed source manufacturer's name, model number and maximum activity per source. Enter the device manufacturer's name and the device model number. Make a separate line entry if selecting a greater than 30 mCi calibration, a reference or transmission source.

ITEM 7 FACILITIES AND EQUIPMENT

Describe the available facilities, equipment (e.g., remote handling and emergency equipment, storage containers, and shielding) and security measures where radioactive material will be used. Include a description of the areas assigned for receipt, storage (including waste), preparation and measurement of radioactive material. See Exhibit 3.

Submit an annotated drawing of the rooms and adjacent areas where radioactive material will be used. See Exhibit 1 or Exhibit 2 for an example.

Indicate the following:

1. The direction of North;
2. Room numbers and principal use of each room or area and use/storage locations;
3. Restricted and unrestricted areas; and
4. Locations of emergency stop switches, independent high dose radiation monitor (inside treatment vault), video camera, audio speaker and receiver.

ITEMS 8 THROUGH 34 MODEL PROCEDURES

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

NOTE: Gamma Stereotactic Radiosurgery (gamma knife), Sir-Spheres, and Theraspheres require additional model procedures not listed in this guide. You may access our web-site at <http://www.doh.state.fl.us/environment/radiation/matform.htm> for guidelines.

ITEM 35 CERTIFICATE

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

IV. LICENSE AMENDMENTS

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

V. LICENSE RENEWAL

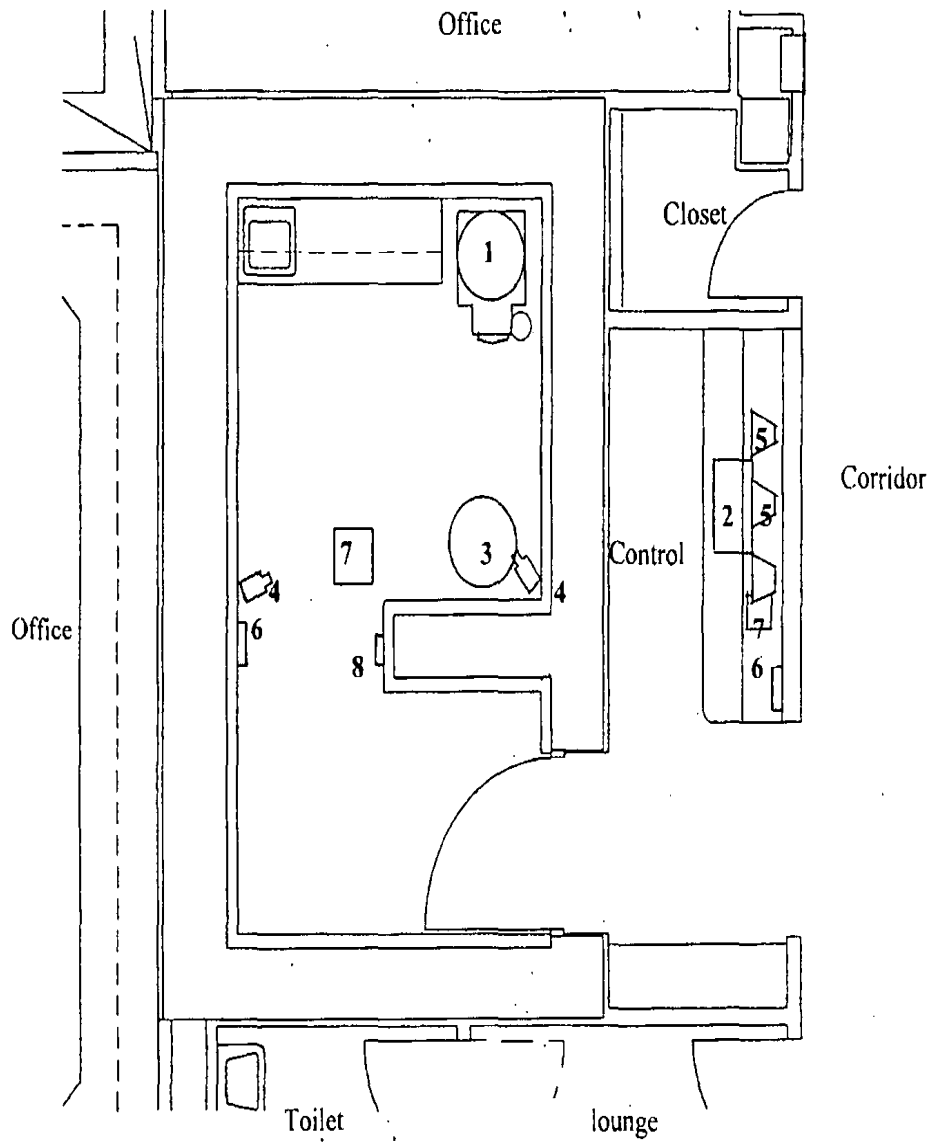
Absent any actions by the department or the licensee, a license remains in effect for five years. An application for license renewal must be received by the department at least 30 days prior to the expiration date. Mail the original and one copy to the department. This filing will ensure that the license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

VI. LICENSE TERMINATION

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

- A. Complete the department's Form DH-1059, "Certificate – Disposition of Radioactive Material" to satisfy the requirements of 64E-5.214, F.A.C., and submit it to the department before the expiration date of the license with a request that the license be terminated.
- B. A close-out survey to release facilities for unrestricted use must be performed. The survey results should be keyed to a diagram showing the locations where the wipes were taken. Include the name of the person(s) who performed the survey and analyzed the results, and submit the manufacturer's name, model number, and detection range of the instrumentation used to perform the survey and analyze the wipes. Please refer to regulations 64E-5.214, 64E-5.314 and 64E-5.621, F.A.C., which provides instructions for performing the closeout survey. A confirmatory inspection may be performed by an area inspector if deemed necessary by this office.

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



- | | |
|----------------------------------|------------------------------|
| 1. HDR treatment unit | 2. HDR control unit |
| 3. Storage - HDR exchange source | 4. CCTV camera |
| 5. CCTV monitor | 6. Radiation Alarm / monitor |
| 7. Intercom | 8. Emergency off |

Scale: 1/4 inch = 1 foot

Exhibit 1: Sample facility diagram

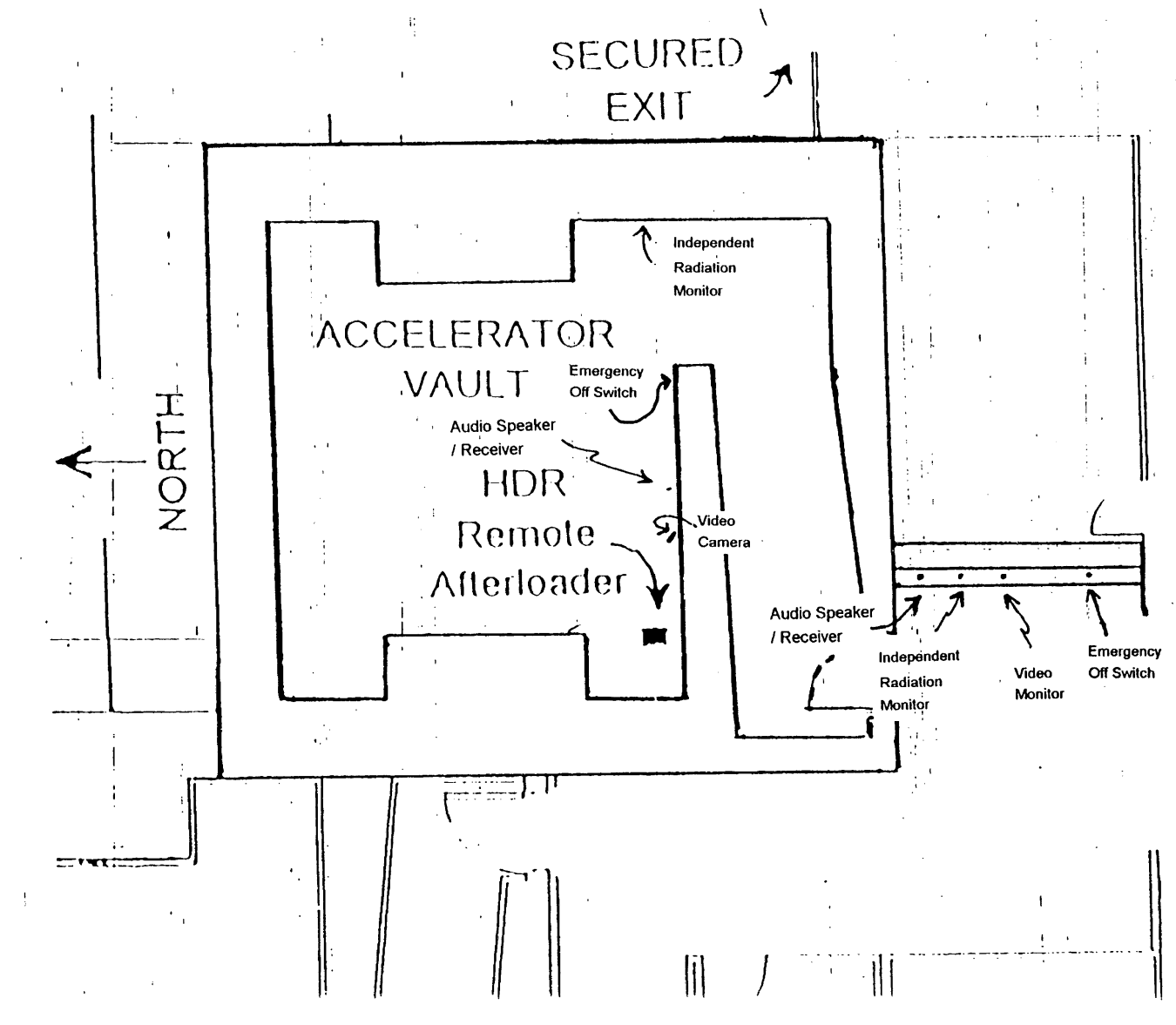


Exhibit 2: Sample facility diagram

Facility Description

Shielding:

HDR unit is located inside a linear accelerator vault.
Submittal of shielding specifications and calculations are not required.

HDR unit is **NOT** located inside a linear accelerator vault.
Shielding specifications and calculations are attached.

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. Emergency procedures and Notice to Employees document 3/01 are also posted.

Door Interlock: The unit's access will be controlled by a door at the entrance. The door interlock is designed to prevent movement of the source from its unshielded container unless the vault door is closed, and causes automatic retraction of the source if the door is opened during operation. A reset operation is required prior to the continuance of treatment, if terminated by a door interlock trip. 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.

Back-up Timer: A back-up timer is in place to independently verify treatment times.

Software: The manufacturer's software will be used for the treatment planning system and HDR unit operation and no modifications will be made without FDA approval.

Additional Safety Equipment: Emergency equipment maintained in the room include a lead container with a mouth wide enough for a source applicator, forceps/tongs for moving an exposed source into the shielded container, and wire cutters for cutting the source cable if necessary.

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

Warning Alarms: An indicator on the HDR control unit notifies the operator when the source is "out" or "safe". A second indicator on the treatment unit inside the vault shows the radiation source has been returned into the shielded safe. An alarm sounds if the source does not correctly return to the safe at the termination of treatment. A sign illuminates above the door to the vault during treatment.

Emergency-Off Switches: Three emergency-off switches are provided, one located on the treatment console, one located within the treatment vault, and one located on the treatment unit. The master emergency switch located in the control area contains a keyed reset.

Room Area Monitors: An independent radiation area monitor capable of continuously monitoring radiation levels is installed in the treatment room and set to alarm at radiation levels in excess of 2.5 mR/hr. The monitor will have a visible indicator observable by an individual entering the room. A duplicate display is located at the treatment console. The monitor will be equipped with a backup power supply (e.g. battery system) separate from the power supply to the unit.

Exhibit 3

Required By All HDR Applicants

FACILITY DIAGRAM AND DESCRIPTION (Refer to Exhibits 1, 2, and 3 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 |
| APPENDIX Z | Mobile or Transportable HDRs Only – include a diagram of the mobile vehicle |
| OTHER | Optional as needed |

Not Applicable According To HDR 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 |

NOTE: Gamma Stereotactic Radiosurgery (gamma knife), Sir-Spheres, and Theraspheres require additional model procedures not listed in this guide. You may access our web-site at <http://www.doh.state.fl.us/environment/radiation/matform.htm> for guidelines.

DELEGATION OF AUTHORITY TO MAKE LEGALLY BINDING STATEMENTS (OPTIONAL)

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

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

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

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 μ Sv) 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/cm² 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.

| <u>Quantity</u> | <u>Manufacturer</u> | <u>Survey Meter Model No.</u> | <u>Min. to Max. Range in mR/hr</u> | <u>Probe Model No.</u> | <u>Minimum Probe Sensitivity</u> |
|-----------------|---------------------|-------------------------------|------------------------------------|------------------------|----------------------------------|
| | | | | | |
| | | | | | |
| | | | | | |

OTHER RADIATION DETECTION INSTRUMENTS

(e.g. electrometer, independent radiation monitor, dosimeter, ion chamber, etc.)

| <u>Type of Instrument</u> | <u>Manufacturer</u> | <u>Model Number</u> | <u>Serial Number</u> |
|---------------------------|---------------------|---------------------|----------------------|
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APPENDIX C

Quality Control

Quality control and preventative maintenance 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 the remote afterloader unit involving work on the source shielding, the source 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 source.

Only a person specifically licensed by the NRC or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in the remote afterloader unit.

A record of the installation, maintenance, adjustment, and repair of the remote afterloader 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.

Dosimetry Equipment

1. A dosimetry system will be available for use calibrated by paragraph (a) or (b) below.
 - (a) The system must have been 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 must have been performed within the previous 2 years and after any servicing that may have affected system calibration.
 - (b) The system shall have been calibrated within the previous 4 years and shall have been 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. We shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, we shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at our facility.
- (2) We shall have available for use a dosimetry system for spot-check measurements. The spot-check system shall be the same system used to meet the requirements above or shall be a system that has been compared with a system that has been calibrated as stated above. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration.
- (3) We shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:
 - (a) The date, the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required above;
 - (b) The correction factors that were determined; and
 - (c) The names of the individuals who performed the calibration, intercomparison, or comparison.

Full Calibration Measurements

- (1) We shall perform full calibration measurements on each remote afterloader unit:
 - (a) Before the first medical use of the unit;
 - (b)
 1. Before medical use following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
 2. Before medical use following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - (c) At intervals not exceeding 1 quarter for units with sources whose half-life exceeds 75 days.
- (2) Full calibration measurements shall include the determination of:
 - (a) The output within 5 percent;
 - (b) Source positioning accuracy to within 1 millimeter;
 - (c) Source retraction with backup battery upon power failure;
 - (d) Timer constancy and linearity over the range of use;
 - (e) Length of the source transfer tubes;
 - (f) Length of the applicators; and
 - (g) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
- (3) We shall use the dosimetry system described above, to measure the output for one set of exposure conditions. The remaining radiation measurements may be made using a dosimetry system that indicates relative dose rates.
- (4) We shall make full calibration measurements in accordance with published protocols accepted by nationally recognized bodies.
- (5) We shall correct mathematically the outputs determined in paragraph (2)(a) above, for physical decay at intervals consistent with 1 percent physical decay.
- (6) Full calibration measurements and physical decay corrections shall be performed by the authorized therapeutic radiological physicist.
- (7) We shall maintain a record of calibration for three years. The record shall include the following:
 - (a) The date of the calibration;
 - (b) The manufacturer's name, model number, and serial number for both the unit and the source;
 - (c) The model numbers and serial numbers of the instruments used to calibrate the unit;
 - (d) The results and an assessment of the full calibrations; and
 - (e) The signature of the authorized therapeutic radiological physicist.

Calibration equipment will be conditioned to ambient temperature of room where calibration will be performed if shared within facilities.

Periodic Spot-Checks

- (1) We shall perform the following spot-checks:
 - (a) Before first use on a given day;
 - (b) After each source installation.
- (2) Spot-checks shall include the determination of:
 - (a) Electrical interlocks at each room entrance;
 - (b) Source exposure indicator lights on the unit, the control console, and in the facility;
 - (c) Viewing and intercom systems;
 - (d) Emergency response equipment;
 - (e) Radiation monitors used to indicate the source position;
 - (f) Timer accuracy;
 - (g) Clock (date and time) in the unit's computer; and
 - (h) Decayed source activity in the unit's computer.
- (3) If the results of the spot-checks indicate the malfunction of any system, we shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (4) We shall perform spot-checks following procedures established by the authorized therapeutic radiological physicist.
- (5) We shall have the authorized therapeutic radiological physicist review the results of each spot-check within 15 days and promptly notify us in writing of the results of each spot-check.
We shall keep a copy of each written notification for 3 years.
- (6) We shall retain a copy of the spot-check procedures until we no longer possess the unit.
- (7) Records of spot-checks shall include:
 - (a) The date of the spot-check;
 - (b) The manufacturer's name, model number, and serial number for both the unit and source;
 - (c) An assessment of timer accuracy;
 - (d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
 - (e) The name of the individual who performed the periodic spot-check and the signature of the authorized therapeutic radiological physicist who reviewed the record of the spot-check.

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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), or optically stimulated luminescent dosimeter (OSLD).
2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film, TLD, or OSLD whole body 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 and evaluated by a dosimetry provider holding NVLAP accreditation.

RECORDS

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

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APPENDIX F

Training Program

Manufacturer's training in HDR safety:

The manufacturer will provide initial training in the operating and emergency procedures specific to the device. The operating and emergency procedures for the device will be retained until removal of the device. All authorized users, radiation therapy technologists (RTT), and authorized therapeutic radiological physicists will complete the training. Manufacturer's training, together with in-house training on specific licensing procedures, is required of all HDR operators prior to operating the HDR unit or related equipment. Only authorized users or certified RTT's who have completed the training can operate the HDR device and related equipment for patient treatment. We will ensure operators, authorized therapeutic radiological physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

Annual HDR brachytherapy refresher training:

Annual re-training will be provided to all personnel, as described above. Re-training will be provided by the manufacturer, whenever possible. If, for some reason, the manufacturer's representative is not available to provide re-training, it will be provided by one of the authorized users or therapeutic radiological physicists listed on the license who have previously completed the manufacturer's training.

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.

- ◆ Instructions for a Remote Afterloader will be physically located at the Remote Afterloader console as required by 64E-5.636, F.A.C.

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

The method of training will include the following:

Lectures Videos Self-study Demonstrations Other _____

APPENDIX G

Ordering and Receiving Radioactive Material

Ordering Radioactive Materials

The radioactive source ordered or received is used in the HDR unit. Replacement sources are received from a person specifically licensed by the NRC or an agreement state at intervals of approximately three months. The supplier has a copy of the radioactive materials license authorizing purchase.

Receipt of Radioactive Packages:

Upon receipt of a new source package, the shipping container is placed, unopened, into the HDR 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 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 HDR 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, a person specifically licensed by the NRC or an agreement state, or a trained authorized therapeutic radiological physicist listed on the license. The HDR source-shipping container is to be opened only by the manufacturer's personnel, a person specifically licensed by the NRC or an agreement state, or a trained authorized therapeutic radiological physicist listed on the license.

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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.

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APPENDIX J

Rules of Use

1. The High Dose Rate Brachytherapy (HDR) Unit is operated by a Florida certified Radiation Therapy Technologist (RTT) or Authorized User. All HDR operators will be trained regarding the applicable use of all equipment to be employed in a procedure prior to use.
2. All operators will be trained in the Operating and Emergency Procedures physically located at the HDR unit's console. When sources are placed within a patient or human research subject's body, treatments will only be conducted allowing for expeditious removal of a decoupled or jammed source. Emergency response equipment such as a wire cutting tool, forceps, tongs, and a shielded source container will be available near the treatment room in order to respond to a source remaining in the unshielded position or lodged within the patient.
3. No person, other than the patient, will be present in the HDR treatment room when the source is outside the shielded position of the HDR unit, except for individuals approved by the authorized user, RSO, or authorized therapeutic radiological physicist.
4. An authorized user and an authorized therapeutic radiological physicist will be physically present during the initiation of all patient treatments involving the unit. Also, an authorized therapeutic radiological physicist and either, an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the unit.
5. Dual operation of devices in the treatment room will be prevented with an interlock or safety device.
6. The HDR unit, the console, console keys, and treatment room will be secured when unattended.
7. Prior to patient use, all daily checks of the HDR unit will be conducted and documented. Prior to first use of the HDR unit and following a source exchange, a physicist listed on the radioactive materials license must calibrate the unit. Only an authorized therapeutic radiological physicist will perform calibrations, dosimetry and monthly quality assurance on the unit.
8. The intercom/video system in the treatment room will allow for continuous observation of the patient and will be operational before HDR use. No treatment of patients is allowed if the system is inoperable.
9. The radiation monitor in the treatment room will be checked with a dedicated check source daily before the unit is used. If the monitor is inoperable, a radiation survey instrument or audible alarm personal dosimeter will be used and daily checked with a dedicated check source before use to determine source retraction or exposure. The 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.
10. When a patient treatment is concluded with the HDR unit, the patient will immediately be surveyed with a radiation survey meter to verify that the source has been retracted into the storage container in the HDR unit. If the survey meter indicates the presence of radiation, immediate action must be taken to retrieve the source referencing the emergency procedures.

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APPENDIX K

Emergency Procedures

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. Emergency procedures will be provided by the manufacturer or model procedures submitted to the department for review. A copy of the operating and emergency procedures will be physically located at the unit console.

The emergency procedures will 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. RSO will contact the Bureau of Radiation Control at (407) 297 -2095.
5. Within 30 days after making the initial report, submit a written report to the bureau that includes all of the information identified in subsection 64E-5.343(2), Florida Administrative Code (F.A.C.).
6. Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information as required by 64E-5.343(3), F.A.C.

POSTING REQUIREMENTS

- A. A copy of our emergency procedures, emergency notification notice, and a Notice to Employees document 3/01 will be conspicuously posted at our facility as required by 64E-5.901, F.A.C. Current copies of Part III and Part IX, the license, conditions or documents incorporated into the license by reference and amendments thereto, are not required to be posted provided that a notice is posted which describes the documents and states where they may be examined. The door to the treatment area will be posted with a "High Radiation Area" sign and a "Caution Radioactive Materials" sign.
- B. The radiation safety officer's name and phone number and our 24 hour emergency notification number are listed in our emergency procedures.
- C. The location of use for radioactive material will be posted with the proper signage as described in 64E-5.323 and 64E-5.324, Florida Administrative Code.

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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, F.A.C, to ensure the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

The survey will be performed at the installation of a new source and following repairs to the source shielding, the source 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 source.

We will retain a record of the radiation surveys for the duration of the license.

These records will include:

- (a) The date of the measurements;
- (b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
- (c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
- (d) The signature of the RSO or authorized therapeutic radiological physicist who performed the test.

Radiation surveys will be performed of all storage areas with a radiation survey instrument at least every 3 months. We will retain a record of each survey for 3 years. The record will include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the name of the individual who performed the survey.

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APPENDIX M

Procedures for Conducting a Member of the Public Dose Compliance Study

If licensed for, or seeking licensure for possession and use of radioactive material, in accordance with section 64E-5.313, Florida Administrative Code (F.A.C), the radiation hazard resulting from licensed operations must be evaluated to demonstrate compliance with the member of public (MOP) dose limits described in section 64E-5.312, F.A.C.

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 \leq 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 \leq 100 mrem.
To demonstrate compliance w/ 64E-5.313(2)(b)2., DDE must be \leq 50 mrem.

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APPENDIX N

Radiopharmaceutical Therapy

Not Applicable

APPENDIX O
Implant Therapy
Not Applicable

APPENDIX P

Radioactive Gases & Aerosols

Not Applicable

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APPENDIX Q

Quality Management Program (QMP)

Written and Oral Directives for High Dose Rate Brachytherapy Administration

Prior to administration of HDR, an authorized user must date and sign a written directive specifying the dose per fraction, number of fractions, total dose and area to be treated. Any revision of a written directive must be signed and dated by an authorized user prior to the administration of the Brachytherapy 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 only 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. In the case an oral directive is given, it must be documented immediately in the patient's record and a written directive must be signed by an authorized user within 24 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. Any oral revision must be documented immediately in the patient's chart and a revised written directive must be signed by an authorized user within 48 hours of the oral revision.

Verification of Patient Identity

Prior to administration of any HDR dose, the patient identity must be established by confirming the name given by the patient with information in the patient's chart. In addition, the identity must be further verified by confirming the stated birth date, address or social security number with the patient's chart, or by comparison of the patient's signature with the signature in the patient's chart.

Verification of Details of High Dose Rate Brachytherapy Administration

Prior to administration of the HDR dose, a computer treatment plan is used to determine dwell times for the radioactive source. A dosimetrist, physician or physicist will verify that the treatment plan details match the written directive in respect to total dose to be administered, site of administration and any special details of administration.

Radiographs, or other comparable images, of dummy sources in catheters implanted in patients are used in the treatment planning procedure for localization of source positions. Computer dose calculations are verified by checking that proper input data were used. A manual calculation of a single point is also made for verification of the computer treatment plan. Verification is also made on the dose calculation data (channel numbers, source positions and treatment times) transferred to the computer from the HDR control is correct.

If the authorized user determines that the time required for checking of dose calculations will jeopardize the patient's health due to the emergent nature of the patient's medical condition, checks will be performed within two days of the treatment.

Documentation of High Dose Rate Brachytherapy Administration

Immediately following the administration of an HDR dose, an authorized user or a qualified person (physicist, dosimetrist or clinic nurse) must document the administered dose in the patient's chart. Such documentation must include the dose administered, the date and the signature or initials of the person completing the record.

Patient Surveys

Immediately following completion of administration of an HDR dose, the patient will be surveyed with a radiation survey meter to determine that the source has been retracted into the shielded position. Posted emergency procedures will be followed if the source has failed to retract.

Written Directive Implementation

Any person involved with administering or documentation of administration of a HDR dose that has any question or lack of understanding of the procedures described in the written directive or treatment plan must seek guidance from an authorized user (physician) prior to the commencement of the procedure so that a clear understanding of the procedure and individual responsibility is certain.

Acceptance Testing of Therapy-Related Computer Systems

We will perform acceptance testing on the treatment planning system of the therapy-related computer system in accordance with published protocols accepted by nationally recognized bodies. We will maintain records of this acceptance testing and protocols used in performing these tests for inspection by the department. At a minimum, the acceptance testing must include, as applicable, verification of; 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; and the accuracy of the software used to determine sealed source positions from radiographic images.

Periodic Review of High Dose Rate Administration

An annual review of a representative sample of the HDR administrations performed in the last 12 months will be made (1) to compare doses administered to doses prescribed in the written directive and (2) 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.

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 **As Low As Reasonably Achievable**.

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

1. Management Commitment
 - A. We, the management of the facility, are committed to keep individual and collective doses as low as is reasonably achievable (ALARA) as described herein. In accord with this commitment, we hereby describe an administrative organization for radiation safety and have established the necessary written policies, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a radiation safety committee (RSC) and a radiation safety officer (RSO).
 - B. We will be an active member of the RSC and will consider any modifications or changes as recommended by the RSO as a result of the annual review of the radiation safety program performed by the RSO.
 - C. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
 - D. In addition to maintaining doses to individuals as low as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.
2. Radiation Safety Committee
 - A. Review of Proposed Authorized Users and Uses
 - (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
 - (2) When considering a new use of radioactive material, the RSC will review the procedures to maintain exposure ALARA.
 - (3) The RSC will ensure that authorized users justify their procedures and that individual and collective doses will be ALARA.

- B. Delegation of Authority
 - (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
 - (2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the RSC meeting.
 - C. Review of the ALARA Component
 - (1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
 - (2) The RSC will perform a review of occupational radiation exposure every six months with particular attention to instances in which the investigational levels are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program effectiveness and to decide if action is warranted when investigational levels are exceeded.
 - (3) The RSC will evaluate the annual review performed by the RSO regarding our institution's overall efforts for maintaining doses ALARA and will make any necessary recommendations. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.
3. Radiation Safety Officer
- A. Annual, Biannual and Quarterly Review
 - (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts and will prepare and present this review to the RSC. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants. Reviews of specific methods of use may be conducted on a more frequent basis.
 - (2) Biannual review of occupational exposures and records of radiation surveys. Every six months the RSO will prepare a summary report for the RSC reviewing occupational exposures and survey results.
 - (3) Quarterly review of occupational exposures. The RSO will review and initial at least every three months the radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the Investigational Levels of this program.
 - (4) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter.
 - B. Education Responsibilities for ALARA Program
 - (1) The RSO will coordinate briefings and educational sessions to inform workers of ALARA program efforts.
 - (2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

3. C. Cooperative Efforts for Development of ALARA Procedures

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

 - (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
 - (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.
- D. Reviewing Instances of Deviation from Good ALARA Practices
 - (1) The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
 - (2). The RSO will be notified when there is a radioactive spill and will be responsible for decontamination of the area and any involved personnel. The RSO will be responsible for releasing the area to use when the area is at background levels of radiation.
4. Authorized Users
 - A. New Methods of Use Involving Potential Radiation Doses
 - (1) The authorized user will consult with the RSO and/or RSC during the planning stage before starting new radioactive material uses.
 - (2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.
 - B. Authorized User's Responsibility to Supervise Individuals
 - (1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
 - (2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.
5. Individuals Who Receive Occupational Radiation Doses
 - A. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
 - B. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
6. Investigational Levels to Monitor Individual Occupational Radiation Doses

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

Investigational Levels

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

- A. Personnel dose less than Investigational Level I.
Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than values for the Investigational Level I.
- B. Personnel dose equal to or greater than Investigational Level I but less than Investigation Level II.
The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the committee. The committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the committee minutes.
- C. Personnel dose equal to or greater than Investigational Level II.
The RSO will investigate the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.
- D. Establishment of new investigational levels above those listed in the table.
In cases where a worker's or a group of worker's doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.
The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

| | Bimonthly(mrem) | | Quarterly(mrem) | |
|---|------------------------|-----------------|------------------------|-----------------|
| | Level I | Level II | Level I | Level II |
| Total effective dose equivalent (sum of deep dose equivalent and committed effective dose equivalent) | 84 | 250 | 125 | 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 **As Low As Reasonably Achievable**.

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

APPENDIX T

Procedure for Leak-Testing Sealed Sources

Leak testing of the HDR source is performed and documented by manufacturer's personnel or a person specifically licensed by the NRC or an agreement state. Source exchanges are typically performed at three month intervals.

New sources are delivered with a leak test certificate. If a source is not exchanged in a six month period, leak tests will be conducted with an approved leak test kit on each source at least every 6 months or 3 months for an Omnitron device. The manufacturer or a person specifically licensed by the NRC or an agreement state will conduct the analysis and provide documentation.

Records of the leak tests are maintained with the HDR shipment/receipt records at the HDR unit for 3 years.

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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 its shipping container, in the HDR treatment room or other approved storage area until exchange of the source.

Following the source exchange, the old source will be stored in the shipping container and will be properly packaged and labeled for return to the manufacturer. Prior to retrieval of the source by the common carrier, it will be stored in the HDR treatment room or other approved storage area.

Radioactive Material Disposal

All HDR sources will be returned to the manufacturer immediately 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 HDR records for at least 3 years.

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APPENDIX X

Inventory

Sealed Source Inventory Requirements

An inventory of sealed sources will be performed at intervals not to exceed six months and records will be maintained for three years for inspection as required by section 64E-5.618(8), Florida Administrative Code.

The inventory record will contain the following information:

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

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APPENDIX Y

Diagnostic Radiopharmaceuticals

Not Applicable

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APPENDIX Z

Mobile HDR Medical Service Requirements

Vehicle Identification Number (VIN): _____

1. Our mobile HDR afterloader service for medical use will perform the following:
 - (a) Checks on survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
 - (b) Account for all sources before departure from a client's address of use.
2. In addition to the periodic spot-checks required, we will perform checks on each unit before use at each address of use. At a minimum, checks must be made to verify the operation of the following:
 - (a) Electrical interlocks on treatment area access points;
 - (b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 - (c) Viewing and intercom systems;
 - (d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;
 - (e) Radiation monitors used to indicate room exposures;
 - (f) Source positioning (accuracy); and
 - (g) Radiation monitors used to indicate whether the source has returned to a safe shielded position.
3. In addition to the requirements in paragraph (2) above we will ensure overall proper operation of the unit by conducting a simulated cycle of treatment before use at each address of use.
4. If the results of the requirements in paragraph (2) above indicate the malfunction of any system, we will lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
5. We will keep a copy of the requirements in paragraph (2) above for three years. The records will include:
 - (a) The date of the check;
 - (b) The manufacturer's name, model number, and serial number of the unit;
 - (c) Notations accounting for all sources before we depart from a facility;
 - (d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and
 - (e) The signature of the individual who performed the check.
6. A letter of authorization is obtained from each client location, where mobile medical services are provided. The letter is signed by the management of each client location and it authorizes the use at their location. Each letter will be retained for three years after the provision of services.
7. Radioactive material will be received at the permanent location of the mobile medical service. A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a radioactive material license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

8. Radioactive material is secured from unauthorized access or is kept under constant surveillance and under the immediate control of the radiation therapy technologist, authorized therapeutic radiological physicist or an authorized user named on the license.
9. An authorized user and an authorized therapeutic radiological physicist will be physically present during the initiation of all patient treatments involving the unit; and an authorized therapeutic radiological physicist and either, an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the unit at each client's address at the time of use.
10. When a patient treatment is concluded with the HDR unit, the patient will immediately be surveyed with a radiation survey meter to verify that the source has been retracted into the storage container in the HDR unit. Records of survey results are retained for 3 years.
11. Optimum temperature and humidity of the vehicle will always be maintained to prevent damage to sensitive equipment on board the mobile vehicle.
12. Shipping papers: Packages, including radioactive waste transported on the vehicle require a "Bill of Lading" and "Shippers Certificate". The Bill of Lading notes the contents, activity and form of the material shipped. The certificate is a signed portion of the document attesting to compliance with the U.S. Department of Transportation requirements. These documents are important in case of accident, loss or theft. These documents must be kept within immediate reach of the seat-belted driver.
13. All packages containing radioactive material, except exclusive gaseous and "Special Form" shipments must be wipe tested on the exterior of the package for contamination. The limit is 22 dpm/cm² over 300 cm² or 6600 dpm.
14. Package labels, signs and measurements will be as specified by the U.S. Department of Transportation. Normal Form packages must contain the exterior labeling "Radioactive Material N.O.S. UN2982" and Limited Quantity packages must be labeled "UN2910" as international accepted content designations. Package interior must contain a Radioactive Materials sign. This can be on a syringe or lead container. Yellow II and Yellow III packages require the notation of a "Transport Index" (TI) which is the rounded-up one meter exposure reading.
15. Emergency response information (ERI): it will be kept within reach of the seat-belted driver, whenever the vehicle is in transit or parked on Department of Transportation maintained roads. The ERI must contain the following:
 - Description and technical name of the hazardous material;
 - Immediate health hazards;
 - Risk of fire and explosion;
 - Immediate precautions;
 - Immediate method of handling fire;
 - Handling spills; and
 - First aid.
16. Packages/Containers: A Security Seal is required for all Normal Form packages. This seal must be able to show if the package integrity has been breached. Therefore, padlocks are not acceptable.
17. The driver authorized to ship radioactive materials will receive HAZMAT training.
18. Radioactive material will be blocked and braced and secured during transit.



RADIOACTIVE MATERIALS SECTION
APPLICATION FOR RADIOACTIVE MATERIALS LICENSE
HUMAN USE



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

1.a. LEGAL NAME, MAILING ADDRESS

(Include ZIP code), FEI #, Phone & Fax Numbers:

FEI # _____

Telephone # _____

Fax # _____

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

Same as 1.a.

2.a. LICENSE FEE CATEGORY

(See 64E-5.204, F.A.C., for license descriptions)

b. LICENSE FEE ENCLOSED: \$ _____

3. THIS IS AN APPLICATION FOR:

- a. New License**
- b. Amendment To License Number:** _____
- c. Renewal Of License Number:** _____

4. INDIVIDUAL USERS & REQUESTED USES

(Name all Authorized Users & Authorized 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: _____

Florida Bureau of Radiation Control - Application For Radioactive Materials License
HUMAN USE

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

Florida Bureau of Radiation Control - Application For Radioactive Materials License
HUMAN USE

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 | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8 | A | Radiation Safety Committee | <input type="checkbox"/> | <input type="checkbox"/> |
| 9 | B | Instrumentation | <input type="checkbox"/> | <input type="checkbox"/> |
| 10 | C | Quality Control | <input type="checkbox"/> | <input type="checkbox"/> |
| 11 | D | Dose Calibrator | <input type="checkbox"/> NA | <input type="checkbox"/> |
| 12 | E | Personnel Monitoring | <input type="checkbox"/> | <input type="checkbox"/> |
| 13 | F | Training Program | <input type="checkbox"/> | <input type="checkbox"/> |
| 14 | G | Ordering And Receiving | <input type="checkbox"/> | <input type="checkbox"/> |
| 15 | H | Opening Packages | <input type="checkbox"/> | <input type="checkbox"/> |
| 16 | I | Use Records | <input type="checkbox"/> | <input type="checkbox"/> |
| 17 | J | Rules Of Use | <input type="checkbox"/> | <input type="checkbox"/> |
| 18 | K | Emergency Procedures | <input type="checkbox"/> | <input type="checkbox"/> |
| 19 | L | Area Surveys | <input type="checkbox"/> | <input type="checkbox"/> |
| 20 | M | Members Of Public Dose Study | <input type="checkbox"/> | <input type="checkbox"/> |
| 21 | N | Radiopharmaceutical Therapy | <input type="checkbox"/> NA | <input type="checkbox"/> |
| 22 | O | Implant Therapy | <input type="checkbox"/> NA | <input type="checkbox"/> |
| 23 | P | Radioactive Gases & Aerosols | <input type="checkbox"/> NA | <input type="checkbox"/> |
| 24 | Q | Quality Management Program | <input type="checkbox"/> | <input type="checkbox"/> |
| 25 | R | ALARA Program (Radiation Safety Committee Required) | <input type="checkbox"/> | <input type="checkbox"/> |
| 26 | S | ALARA Program (No Radiation Safety Committee) | <input type="checkbox"/> | <input type="checkbox"/> |
| 27 | T | Leak Testing | <input type="checkbox"/> | <input type="checkbox"/> |
| 28 | U | Bioassay | <input type="checkbox"/> NA | <input type="checkbox"/> |
| 29 | V | Survey Meter Calibration | <input type="checkbox"/> | <input type="checkbox"/> |
| 30 | W | Waste | <input type="checkbox"/> | <input type="checkbox"/> |
| 31 | X | Inventory | <input type="checkbox"/> | <input type="checkbox"/> |
| 32 | Y | Diagnostic Radiopharmaceuticals | <input type="checkbox"/> NA | <input type="checkbox"/> |
| 33 | Z | Mobile Medical Service | <input type="checkbox"/> | <input type="checkbox"/> |
| 34 | Other | | <input type="checkbox"/> | <input type="checkbox"/> |

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