PART VI

USE OF RADIONUCLIDES IN THE HEALING ARTS

64E-5.601 License Required.

(1) Radioactive materials shall not be manufactured, produced, acquired, received, possessed, prepared, used, or transferred for medical use except as provided in a specific license.

(2) Any licensee who is licensed for one or more of the medical uses in Rule 64E-5.626, 64E-5.627, 64E-5.630, or 64E-5.632, F.A.C., also is authorized to use radioactive material under a general license in subsection 64E-5.206(8), F.A.C., for specified in vitro uses without filing the certificate required by paragraph 64E-5.206(8)(b), F.A.C., but is subject to the other provisions of subsection 64E-5.206(8), F.A.C.

(3) (a) Unless prohibited by license condition, a physician in training may receive, possess, acquire, prepare, use, or transfer radioactive materials as provided in these regulations under the supervision of an authorized user as provided in subsections 64E-5.608(1) and 64E-5.608(3), F.A.C.

(b) Current and active certified radiologic technologists as authorized in Part IV Chapter 468, F.S., may receive, possess, acquire, prepare, use, or transfer radioactive materials as provided in these regulations under the supervision of an authorized user as provided in paragraph 64E-5.607(3)(e) and subsection 64E-5.608(3), F.A.C.

(c) Unless prohibited by license condition, a medical physicist in training may receive, acquire, prepare, use, possess, or transfer radioactive materials as provided in these regulations under the supervision of an authorized medical physicist as provided in subsections 64E-5.608(2) and 64E-5.608(3), F.A.C.

(4) Unless authorized by the department, no individual shall manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive materials for medical use unless:

(a) That individual is listed on the licensee's specific license as an authorized user, authorized medical physicist, or an authorized nuclear pharmacist;

(b) Authorized by Rule 64E-5.609, F.A.C.;

(c) Authorized by subsection 64E-5.601(2), F.A.C., with approval of the radiation safety committee at medical institutions or by management for licensees that are not medical institutions; or

(d) That individual is in training, authorized by subsection 64E-5.601(3), F.A.C., and subpart I of Part VI.

R10 (5) Provisions for the protection of human research subjects are:

R10 (a) A licensee may conduct research involving human research subjects only R10 if it uses the radioactive materials specified on its license for the uses R10 authorized on its license.

R10 (b) If the research is conducted, funded, supported, or regulated by another R10 federal agency that has implemented the **"**Federal Policy for the R10 Protection of Human Subjects (Federal Policy)", as described in 45 CFR R10 Part 46, dated 11/9/2009, which is herein incorporated by reference, and R10 may be accessed at http://www.doh.state.fl.us/environment/radiation/, or R10 requested in writing from the Department of Health, Bureau of Radiation R10 Control, Bin C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741, R10 the licensee shall, before conducting research:

R10 1. Obtain review and approval of the research from an "Institutional R10 Review Board (IRB)," as defined and described in the Federal R10 Policy; and

R10 2. Obtain "informed consent," as defined and described in the Federal R10 Policy, from the human research subject.

R10 (c) If the research will not be conducted, funded, supported, or regulated by R10 another federal agency that has implemented the Federal Policy, the R10 licensee shall, before conducting research, apply for and receive a specific R10 amendment to its radioactive materials medical use license. The R10 amendment request must include a written commitment that the licensee R10 will, before conducting research:

R10 1. Obtain review and approval of the research from an IRB as defined and R10 described in the Federal Policy; and

R10 2. Obtain "informed consent", as defined and described in the Federal R10 Policy, from the human research subject.

R10 (d) Nothing in this section relieves licensees from complying with the other R10 requirements in this part.

R10 (6) Authorized nuclear pharmacists must be actively licensed as a nuclear R10 pharmacist by the Department of Health, Division of Medical Quality Assurance R10 as specified in Rule 64B16-28.903, F.A.C., and authorized medical physicists R10 must have an active medical physicist license**,** in the area they are practicing, R10 issued by the Department of Health, Division of Medical Quality Assurance.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.707, Amended 8-6-01, Amended 02-11-10.

64E-5.6011 Definitions. (Entire section New)

(1) "Authorized medical physicist" means an individual who meets the requirements:

(a) Specified in subsection 64E-5.656(1) and Rule 64E-5.658, F.A.C.; or

(b) Is identified as an authorized medical physicist or teletherapy physicist on:

1. A specific medical use license issued by the NRC or an agreement state;

2. A medical use permit issued by a NRC master material licensee;

3. A permit issued by a NRC or agreement state broad scope medical use licensee; or

4. A permit issued by a NRC master material license broad scope medical use permittee.

(2) "Authorized user" means:

(a) A physician who meets the requirements in Rule 64E-5.658 and subsection 64E-5.549(1), 64E-5.550(1), 64E-5.660(1), 64E-5.661(1), 64E-5.662(1), 64E-5.652(1), 64E-5.654(1) or 64E-5.655(1), F.A.C.; or

(b) An individual identified for medical use of radioactive materials on:

1. A NRC or agreement state license that authorizes the medical use of radioactive material;

2. A permit issued by a NRC master material licensee that is authorized to permit the medical use of radioactive material;

3. A permit issued by a NRC or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

4. A permit issued by a NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

(3) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose by surface, intracavitary, intralumimnal or interstitial application.

(4) "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(5) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method by which the licensee shall perform diagnostic clinical procedures, and provides other instructions and precautions related thereto. Each diagnostic clinical procedure shall be approved by the authorized user and shall include the radiopharmaceutical, dosage, and route of administration.

(6) "High dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(7) "Low dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

(8) "Manual brachytherapy," as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually delivered.

(9) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or humans research subjects under the supervision of an authorized user.

(10) "Medium dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(11) "Mobile medical service" means the ability to transport and use radioactive materials for medical use at the client's address.

(12) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(13) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user under Chapter 64E-5, Part VI, F.A.C., an authorized medical physicist, an authorized nuclear pharmacist or a RSO under Chapter 64E-5 Part VI, F.A.C.

(14) "Pulsed dose-rate remote afterloader," as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, provided that the source is:

(a) Approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(b) Used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

R10 (15) "Radiation Safety Officer" or "RSO" means an individual who:

R10 (a) Meets the requirements in subsection 64E-5.648(1) or paragraph
R10 64E-5.648(3)(a) and Rule 64E-5.658, F.A.C.; or

R10 (b) Is identified as a RSO on a specific medical use license issued by the
R10 NRC or an agreement state or a medical use permit issued by a NRC master material licensee.

R10 (16) "Teletherapy physicist" means an individual identified as the qualified teletherapy
R10 physicist on a department license.

R10 (17) "Therapeutic dosage" means a dosage of unsealed radioactive materials that is
R10 intended to deliver a radiation dose to a patient or human research subject for
R10 palliative or curative treatment.

R10 (18) "Therapeutic dose" means a radiation dose delivered from a source containing
R10 radioactive materials to a patient or human research subject for palliative or
R10 curative treatment.

R10 (19) "Treatment site" means the anatomical description of the tissue intended to
R10 receive a radiation dose, as described in a written directive.

R10 (20) "Unit dosage" means a dosage prepared for medical use for administration as a
R10 single dosage to a patient or human research subject without any further
R10 manipulation of the dosage after it is initially prepared.

R10 Rulemaking Authority: 404.051, 404.061.
R10 Law Implemented: 404.031, 404.061(2), 404.20, 404.22, 404.30 FS.
R10 History: New 02-11-10.

64E-5.602 License Amendments. A licensee shall apply for and receive a license amendment or departmental approval:

(1) Before using radioactive material for a method or type of medical use not permitted by the license;

R10 (2) Before permitting anyone, except a visiting authorized user, visiting authorized
R10 medical physicist, or visiting authorized nuclear pharmacist described in Rule
R10 64E-5.609, F.A.C., to work as an authorized user, authorized nuclear pharmacist,
R10 or authorized medical physicist.

R10 (3) Before changing a RSO or authorized medical physicist;

R10 (4) Before ordering or receiving radioactive material in excess of the amount, in a
R10 different form, or receiving a different radionuclide than is authorized on the license;

(5) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

(6) Before changing statements, representations, and procedures which are incorporated into the license.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1) (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.708, Amended 02-11-10.

R10 **64E-5.603 Notification. (Entire section Changed)** A licensee shall notify the
R10 department in writing within 30 days when the licensee changes its mailing address or when an
R10 authorized user, RSO, authorized nuclear pharmacist, or authorized medical physicist
R10 permanently discontinues performance of their duties under the licensee.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.709, Amended August 6, 2001, Amended 02-11-10.

SUBPART A

GENERAL ADMINISTRATIVE REQUIREMENTS

64E-5.604 ALARA Program.

(1) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable as provided in Rule 64E-5.303, F.A.C.

(2) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the radiation safety committee.

R10 (3) For licensees that are not required to have a radiation safety committee, medical institutions, management and all authorized users shall participate in the program
R10 as required by the RSO.

(4) The ALARA program shall include an annual review by the radiation safety
R10 committee for medical licensees required to have a radiation safety committee, or
R10 by management and the RSO for licensees that are not required to have a
R10 radiation safety committee. The review shall include summaries of the types, amounts and purposes of radioactive material used; occupational dose reports; and continuing education and training of all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology and the cost of improvements in relation to benefits.

(5) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(a) A commitment by management to keep occupational doses as low as reasonably achievable;

(b) A requirement that the radiation safety officer annually report to management in writing on the radiation safety program; and

(c) Categories of personnel exposure levels that, when exceeded, will initiate investigation by the radiation safety officer of the cause of the exposure and actions taken to reduce the probability of recurrence.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.710, Amended 02-11-10.

64E-5.605 Radiation Safety Officer.

R10 (1) A licensee shall appoint a RSO who agrees in writing to be responsible for
R10 implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are performed with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive materials program.

(2) The radiation safety officer shall promptly investigate and implement corrective actions as necessary regarding:

(a) Overexposures;

(b) Accidents;

(c) Spills;

(d) Losses;

(e) Thefts;

(f) Unauthorized receipts, uses, transfers, and disposals; and

(g) Other deviations from approved radiation safety practice. A written report of these investigations and the corrective actions taken shall be given to management.

(3) The radiation safety officer shall implement written policies and procedures to:

(a) Authorize the purchase of radioactive material;

(b) Receive and open packages of radioactive material;

(c) Store radioactive material;

(d) Keep an inventory record of radioactive material;

(e) Use radioactive material safely;

(f) Take emergency action if control of radioactive material is lost;

(g) Perform periodic radiation surveys;

(h) Perform checks of survey instruments and other safety equipment;

(i) Dispose of radioactive material;

(j) Train personnel who work in or frequent areas where radioactive material is used or stored; and

(k) Keep a copy of all records and reports required by department regulations, a copy of these regulations, a copy of each licensing request and license including amendments, and the written policies and procedures required by the regulations.

(4) The radiation safety officer shall approve radiation safety program changes for medical use not at a medical institution with the consent of management prior to sending to the department for licensing action.

(5) The radiation safety officer shall assist the radiation safety committee for medical use at a medical institution.

R10 (6) The RSO shall review, sign and date, at least every 3 months the occupational radiation exposure records of all personnel working with radioactive material.

R10 (7) The licensee shall retain a copy of both authority, duties, and responsibilities of
R10 the RSO and a signed copy of each RSO's agreement to be responsible for
R10 implementing the radiation safety program for the duration of the license. The
R10 records must include the signature of the RSO and licensee management.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.711, Amended 02-11-10.

R10 **64E-5.606 Radiation Safety Committee.**

R10 (1) Each license listed below shall establish a radiation safety committee to oversee the use of radioactive materials;

R10 (a) Medical institutions as defined in Rule 64E-5.101, F.A.C.; or

R10 (b) Other licenses authorized for any of the following medical uses:

R10 1. Subsection 64E-5.627(2), F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

R10 2. Subsection 64E-5.627(3), F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

R10 3. Subsection 64E-5.627(4), F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

R10 4. Any subsection of Rule 64E-5.630, F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

R10 5. Subsections 64E-5.634(1) and 64E-5.634(2), F.A.C.;

R10 6. Subsections 64E-5.634(1) and 64E-5.634(3), F.A.C.; or

R10 7. Subsections 64E-5.634(2) and 64E-5.634(3), F.A.C.

R10 (2) Membership of the radiation safety committee shall include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. Other members who are experienced in the assay of radioactive material and protection against radiation, such as an authorized medical physicist or a nuclear medicine technologist employed by or working under contract with the institution may be included as appropriate.

R10 (3) The committee shall meet at least every 6 months. To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the RSO, or designee and the management representative, or designee.

R10 (4) The minutes of each radiation safety committee meeting shall include:

(a) The date of the meeting;

(b) Members present;

(c) Members absent;

(d) Summary of deliberations and discussions;

(e) Recommended actions and the numerical results of all ballots; and

(f) Documentation of any reviews required in Rules 64E-5.604 and 64E-5.606, F.A.C.

R10 (5) The committee shall provide each member with a copy of the meeting minutes and shall retain a copy for 5 years or until the department authorizes its disposition.

R10 (6) The committee shall be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable.

R10 (7) The committee shall review and approve any individual to be an authorized user,
R10 an authorized nuclear pharmacist, the RSO, or an authorized medical physicist based on safety and the training and experience standards of this part before sending a license application or request for amendment or renewal.

R10 (8) The committee shall review and approve each proposed method of use of radioactive material based on safety.

R10 (9) The committee shall review and approve procedures and radiation safety
R10 program changes based on safety and with the advice of the RSO and the management representative prior to sending to the department for licensing action.

R10 (10) The committee shall review occupational radiation exposure records of all personnel working with radioactive material and all incidents involving radioactive
R10 material at least every 6 months, with the assistance of the RSO, to determine cause and review subsequent actions taken.

R10 (11) The committee shall review the radioactive materials program at least every
R10 12 months with the assistance of the RSO as described in subsection 64E-5.604(4), F.A.C.

R10 (12) The committee shall establish levels for occupational dose that will result in
R10 investigations and considerations of action by the RSO when exceeded.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.712, Amended 8-6-01, Amended 02-11-10.

64E-5.607 Authority and Responsibilities.

(1) A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:

(a) Identify radiation safety problems;

(b) Initiate, recommend, or provide solutions; and

(c) Require and verify implementation of corrective actions.

(2) A licensee shall establish in writing and keep current the authority, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.

(3) Authorized users shall have the following special responsibilities:

R10 (a) For written directives;

R10 1. A written directive must be dated and signed by an authorized user
R10 before the administration of I-131 as sodium iodide greater than
R10 1.11 megabecquerels (MBq) (30 microcuries ([micro]Ci)), any
R10 therapeutic dosage of unsealed radioactive material or any
R10 therapeutic dose of radiation from material; or

R10 2. Due to the emergent nature of the patient's condition, a delay in
R10 order to provide a written directive would jeopardize the patient's
R10 health, an oral directive is acceptable provided:

R10 a. The information contained in the oral directive must be
R10 documented as soon as possible in writing in the patient's
R10 record; and

R10 b. A written directive must be prepared within 48 hours of the
R10 oral directive.

R10 3. The written directive must contain the patient or human research
R10 subject's name and the following information:

R10 a. For any administration of quantities greater than 1.11 MBq
R10 (30 [micro]Ci) of sodium iodide I-131: the dosage;

R10 b. For an administration of a therapeutic dosage of unsealed
R10 radioactive material other than sodium iodide I-131: the
R10 radioactive drug, dosage, and route of administration;

R10 c. For gamma stereotactic radiosurgery: the total dose,
R10 treatment site, and values for the target coordinate settings
R10 per treatment for each anatomically distinct treatment site;

R10 d. For teletherapy: the total dose, dose per fraction, number of
R10 fractions, and treatment site;

R10 e. For high dose-rate remote afterloading brachytherapy: the
R10 radionuclide, treatment site, dose per fraction, number of
R10 fractions, and total dose; and

R10 f. For all other brachytherapy;

R10 (I) Before implantation: treatment site, the radionuclide,
R10 and dose; and

R10 (II) After implantation but before completion of the
R10 procedure: the radionuclide, treatment site, number of
R10 sources, and total source strength and exposure time
R10 (or the total dose).

R10 4. A written revision to an existing written directive may be made if the
R10 revision is dated and signed by an authorized user before the
R10 administration of the dosage of unsealed radioactive material, the
R10 brachytherapy dose, high dose remote afterloader dose, the
R10 gamma stereotactic radiosurgery dose, the teletherapy dose, or the
R10 next fractional dose; or

R10 5. Due to the emergent nature of the patient's condition, a delay in
R10 order to provide a written directive would jeopardize the patient's
R10 health, an oral directive is acceptable provided:

R10 a. The information contained in the oral directive must be
R10 documented as soon as possible in the patient's record; and

R10 b. A written directive must be prepared within 48 hours of the
R10 oral directive.

(b) Review personally the patient's case to assure that the therapeutic radiation procedure is appropriate;

R10 (c) Review personally the patient's case or develop and implement adequate
R10 written procedures to assure that the diagnostic radiation procedure is
R10 appropriate.

R10 (d) Prior to administration, the authorized user must document deviations
R10 from the diagnostic clinical procedures manual for each patient.

(e) Use radioactive material or direct technologists and physicians in training in using radioactive material;

(f) Interpret results of diagnostic procedures; and

(g) Review regularly the progress of the patient receiving therapy and modify the originally prescribed dose if needed.

R10 (4) The licensee shall retain a copy of the written directives specified in paragraph
R10 64E-5.607(3)(a), F.A.C., for three years.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.713, Amended 02-11-10.

64E-5.608 Supervision. (Entire section Changed)

R10 (1) Supervision of a physician in training to become an authorized user:

R10 (a) A licensee who permits the receipt, acquisition, possession, use, preparation, or transfer of radioactive material by a physician in training under the supervision of an authorized user as allowed by paragraph 64E-5.601(3)(a), F.A.C., shall:

R10 1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

R10 2. Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

R10 3. Require the preparation of radioactive materials use only under the supervision of an authorized user or authorized nuclear pharmacist;

R10 4. Require the authorized user to be immediately available to communicate with the supervised individual; and

R10 5. Require that only those individuals specifically designated by the authorized user be permitted to administer radionuclides or radiation to patients.

R10 (b) A licensee shall require the supervised individual receiving, possessing, acquiring, preparing, using or transferring radioactive material specified in paragraph 64E-5.601(3)(a), F.A.C., to:

R10 1. Follow the instructions of the supervising authorized user;

R10 2. Follow the written radiation and quality management program procedures established by the licensee; and

R10 3. Comply with these regulations and the license conditions regarding the use of radioactive material.

R10 (c) The licensee’s management or radiation safety committee shall provide written approval prior to any training of a physician to receive, acquire, prepare, possess or use radioactive material under the supervision of an authorized user. After the training has been completed, the licensee shall provide documentation to the supervised individual that the individual received the training and experience required by this section. The licensee shall maintain records that identify physicians currently in training and the physicians who have completed training for 7 years after the last date training was received; and

(2) Supervision of an individual in training to become an authorized medical physicist:

(a) A licensee who permits the receipt, preparation, acquisition, possession, use, or transfer of radioactive material to an individual in training under the supervision of an authorized medical physicist as allowed by paragraph 64E-5.601(3)(c), F.A.C., shall:

1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

2. Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use; and

3. Require the authorized medical physicist to be immediately available to communicate with the supervised individual.

(b) A licensee shall require the supervised individual receiving, acquiring or preparing, possessing, using or transferring radioactive material specified in paragraph 64E-5.601(3)(c), F.A.C., to:

1. Follow the instructions of the supervising authorized medical physicist;

2. Follow the written radiation and quality management program procedures established by the licensee; and

3. Comply with these regulations and the license conditions regarding the use of radioactive material.

(c) The licensee’s management or radiation safety committee shall provide written approval prior to any individual to receive, possess or use radioactive material under the supervision of an authorized medical physicist. After the training has been completed, the licensee shall provide documentation to the supervised individual that the individual received the training and experience required by this section. The licensee shall maintain records that identify individuals currently in training and the individuals who have completed training for 7 years after the last date training was received.

(3) A licensee that permits any supervised activities regarding the use of radioactive materials or radiation from radioactive materials is responsible for the acts and omissions of the supervised individual.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.714, Amended 02-11-10.

64E-5.609 Visiting Authorized User, Visiting Authorized Medical Physicist, or Visiting RSO.

(1) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(a) The licensee has a copy of a license issued by the department, the NRC, or an agreement state that identifies the visiting authorized user by name as an authorized user for medical use; and

(b) The visiting authorized user performs only those procedures for which he is specifically authorized by the license described in paragraph 64E-5.609(1)(b), F.A.C., above.

(2) For up to 60 days each year, a licensee may permit an authorized medical physicist or an individual qualified under Rules 64E-5.656 and 64E-5.658, F.A.C., to function as a visiting authorized medical physicist as authorized by the license.

(3) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a RSO, under Rules 64E-5.648 and 64E-5.658, F.A.C., to function as a visiting RSO and to perform the functions of a RSO, as provided in Rule 64E-5.605 and subsection 64E-5.607(1), F.A.C.

(4) A license amendment is not needed to permit a visiting authorized user, visiting authorized medical physicist, or visiting RSO to use licensed material or perform functions in accordance with this section.

(5) The visiting authorized user, visiting authorized medical physicist, or visiting RSO shall have the prior written permission of the licensee's management and, if the use or function occurs on behalf of a medical institution, the institution's radiation safety committee.

(6) Licensee records shall include a copy of the record described in Rule 64E-5.657, F.A.C., or some other form of documentation that verifies the individual has met the perspective training and experience requirements listed in Subpart I. A licensee shall retain copies of the records specified in Rule 64E-5.609, F.A.C., for 3 years after the last visit.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.715, Amended 02-11-10.

64E-5.610 Mobile Medical Service Requirements. The department shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(1) The mobile medical licensee shall obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive materials at the client's address and clearly delineates the authority and responsibility of the licensee and the client. A licensee providing mobile medical services shall retain this letter for 3 years after the provision of service.

(2) Mobile medical service licensees shall secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use.

(3) The mobile medical licensee shall check instruments used to measure the activity of unsealed or sealed radioactive materials for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check and shall perform all daily quality control tests on all equipment used to obtain images or information from radionuclide studies before medical use at each location of use.

(4) Before leaving a client location, mobile medical service licensees shall perform a survey of all areas where radioactive materials are used with a radiation survey instrument in order to ensure that they have complied with the requirements in Rule 64E-5.621, F.A.C., that radiation dose rates are at background levels, and that removable contamination is below 2000 disintegrations per minute per 100 square centimeters sampled. A licensee shall check each survey instrument for proper operation with a dedicated check source before each use at each location. The licensee is not required to keep records of these dedicated source survey instrument checks.

(5) Mobile medical service licensees shall retain a record of each survey required for 3 years. The record must include the date of the survey, a diagram of each area that was surveyed, the measured dose rate at several points in each area of use in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

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

(7) Radioactive material will be received at the permanent location of the mobile medical service or delivered directly to an authorized individual in the vehicle at a place of use. A mobile medical service may not have radioactive materials delivered from the manufacturer or the distributor to the client unless the client has a radioactive materials 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) Restrooms contained in mobile vehicles shall not routinely be used by patients who have been administered radioactive material.

(9) Radioactive gases or aerosols shall not be used by mobile medical service licenses.

(10) Prior to administration, the mobile medical service licensee shall assure that individuals or human research subjects meet the patient release criteria specified in Rule 64E-5.622, F.A.C.

(11) A licensee authorized to use mobile remote afterloaders for medical use shall follow the requirements specified in Rule 64E-5.6423, F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New8-25-91, Formerly 10D-91.716, Amended 02-11-10.

64E-5.611 Quality Management Program and Notifications, Records and Reports of Medical Events.

(1) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide a high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following objectives:

(a) Except where a delay to provide a written directive would jeopardize the patient's health as specified in paragraphs (b) and (c) of this section, a written directive is prepared prior to administration for the following:

1. Any teletherapy radiation dose;

2. Any gamma stereotactic radiosurgery radiation dose;

3. Any brachytherapy radiation dose;

4. Any administration of iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels);

5. Any therapeutic administration of a radiopharmaceutical other than iodine 131 as sodium iodide; or

6. Any high dose rate remote afterloader radiation dose.

(b) An oral directive is acceptable when a delay to provide a written directive would jeopardize the patient's health because of the emergent nature of the patient's condition. The information contained in the oral directive must be documented immediately in the patient's record and a written
R10 directive prepared within 48 hours of the oral directive.

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

(d) A written directive which changes an existing written directive can be made for any diagnostic or therapeutic procedure if the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma
R10 stereotactic radiosurgery dose, high dose rate remote afterloader dose,
R10 the teletherapy dose, or the next fractional dose.

R10 (e) The patient's or human research subject's identity is verified by more than one method as the individual named in the written directive prior to administration;

R10 (f) The final plans of treatment and related dose calculations, manually or
R10 computer generated, for brachytherapy, teletherapy, high dose rate
R10 remote afterloader, and gamma stereotactic radiosurgery agree with the respective written directives:

R10 (g) Verify that any computer-generated calculations are correctly transferred
R10 into the consoles of therapeutic medical units authorized by
R10 Rule 64E-5.634, F.A.C.;

R10 (h) Each administration agrees with the written directive; and

R10 (i) Any unintended deviation from the written directive is identified and
R10 evaluated and appropriate action is taken.

(2) The licensee shall develop procedures for and conduct a review of the quality management program including an evaluation of the following:

(a) A representative sample of patient administrations within the review period;

(b) All recordable events within the review period; and

R10 (c) All medical events within the review period to verify compliance with all aspects of the quality management program.

(3) The review of the quality management program specified in (2) above shall be conducted at intervals not to exceed 12 months. A record of each review shall be maintained for inspection by the department in an auditable form for 3 years and shall include evaluations and findings of the review.

(4) The licensee shall evaluate each of these reviews to determine the effectiveness of the quality management program and make modifications to meet the objectives in subsection 64E-5.611(1), F.A.C.

(5) Within 30 days of discovery of each recordable event, the licensee shall:

(a) Assemble the relevant facts including the cause;

(b) Identify any corrective action required to prevent recurrence;

(c) Retain a record in an auditable form for 3 years of the relevant facts and any corrective action taken.

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

R10 (7) Each applicant for a new license shall submit to the department a quality management program as part of the application for a license and implement the program upon issuance of the license by the department.

R10 (8) Each licensee shall maintain copies of the quality management program for the
R10 duration of the license.

R10 (9) Each licensee shall submit and maintain records and reports of medical events as required by subsections 64E-5.345(4) and (5), F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.717, Amended 02-11-10.

64E-5.612 Suppliers. A licensee shall use for medical use only:

(1) Radioactive material manufactured, labeled, packaged, and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission;

(2) Generators and reagent kits that have been manufactured, labeled, packaged, and distributed as specified in an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration unless the kits are not subject to the Federal Food, Drug, and Cosmetics Act and the Public Health Services Act.

(3) Teletherapy sources manufactured and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the
R10 NRC; or

R10 (4) Sealed sources or devices containing radioactive materials that are either;

R10 (a) Manufactured, labeled, packaged, and distributed as specified in a license
R10 issued by the department or by another agreement state, a licensing state
R10 or the NRC; or

R10 (b) Noncommercially transferred from a medical use licensee authorized by
R10 Chapter 64E-5, Part VI, F.A.C., or equivalent medical use license issued
R10 by another agreement state or the NRC.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.718, Amended 02-11-10.

SUBPART B
GENERAL TECHNICAL REQUIREMENTS

64E-5.613 Quality Control of Diagnostic Instrumentation. Each licensee shall establish written quality control procedures for all equipment used to obtain images or information from radionuclide studies. The procedures shall be recommended by equipment manufacturers or be approved by the department. The licensee shall perform quality control as specified in written procedures and retain a copy of the quality control results for 3 years.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-9191, Amended 5-13-93, Formerly 10D-91.719.

R10 **64E-5.614 Possession, Use, Calibration, and Check of Dose Calibrators in the**
R10 **Use of Unsealed Radiopharmaceuticals.**

(1) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity
R10 administered to each patient or human research subject.

R10 (2) A licensee shall check each dose calibrator before use each day of use, or during
R10 an assigned shift for facilities operating continuously, for constancy with a dedicated check source. The check shall be performed on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium 226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days. A record shall be made of each check, which shall include:

(a) The model and serial number of the dose calibrator;

(b) The identity and decay corrected activity of the radionuclide contained in the check source;

(c) The date of the check;

(d) The activity measured;

(e) The percent error;

(f) The instrument settings; and

(g) The initials of the individual who performed the check.

(3) The licensee shall test each dose calibrator for accuracy at the time of installation and at least every 12 months. The test shall be completed by assaying at least two sealed sources containing different radionuclides, the activity of which has been determined by the National Institute of Standards and Technology (NIST) or
R10 by the manufacturer who has compared their source to a source calibrated by the
R10 NIST. The sources shall have a minimum activity of 10 microcuries (370 kBq) for radium 226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide. At least one of the sources shall have a principal photon energy between 100 kilo-electron volts and 500 kiloelectron volts. A record shall be made of each test, which shall include:

(a) The model and serial number of the dose calibrator;

(b) The model and serial number of each source used and the identity of the radionuclide contained in the source and its activity;

(c) The date of the test;

(d) The results of the test;

(e) The instrument settings; and

R10 (f) The name of the individual performing this test.

(4) The licensee shall test each dose calibrator for linearity at the time of installation and at least every 3 months over the range of use between 10 microcuries (370 kBq) and the highest dosage that will be administered. A record shall be made of each test, which shall include:

(a) The model and serial number of the dose calibrator;

(b) The calculated activities;

(c) The measured activities;

(d) The date of the test; and

R10 (e) The name of the individual performing this test.

(5) The licensee shall test each dose calibrator for geometry dependence at the time of installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator. A record shall be made of each test, which shall include:

(a) The model and serial number of the dose calibrator;

(b) The configuration of the source measured;

(c) The activity measured and the instrument setting for each volume measured;

(d) The date of the test; and

R10 (e) The name of the individual performing this test.

(6) A licensee shall correct mathematically dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(7) A licensee shall also perform checks and tests required by Rule 64E-5.614, F.A.C., following adjustment or repair of the dose calibrator.

(8) A licensee shall retain a record of each check and test required by Rule 64E-5.614, F.A.C., for 3 years.

R10 (9) A licensee may calibrate instrumentation used in Rule 64E-5.614, F.A.C., using nationally recognized standards or the manufacturer's instructions. The standards or instructions used by the licensee must be available for inspection by the department.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.720, Amended 02-11-10.

R10 **64E-5.615 Use, Calibration and Check of Survey Instruments.** A licensee shall R10 ensure that the survey instruments used to comply with this part have been calibrated before R10 first use, at least every 12 months, and after repair.

R10 (1) A record shall be made of each calibration, which shall include:

(a) A description of the source used;

(b) The certified dose rates from the source;

(c) The rates indicated by the instrument being calibrated;

(d) The correction factors deduced from the calibration data;

R10 (e) The name of the individual who performed the calibration;

(f) The date of calibration.

R10 (g) The model number and serial number of the instrument being calibrated; R10 and

R10 (h) The results of the calibration.

(2) The licensee shall:

(a) Calibrate all required scale readings up to 1,000 millirems (10 mSv) per hour with a radiation source;

(b) Calibrate each linear scale instrument at two points located approximately 1/3 and 2/3 of full-scale, calibrate each logarithmic scale instrument at midrange of each decade and at two points of at least one decade, and calibrate each digital instrument at appropriate points; and

R10 (c) Conspicuously note on the instrument the date of calibration.

(3) The licensee shall:

(a) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(b) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent and a correction chart or graph is attached conspicuously to the instrument.

(4) A licensee shall check each survey instrument for proper operation with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(5) The licensee shall retain a record of each calibration required in subsection 64E-5.615(1), F.A.C., for 3 years.

(6) The licensee may use persons licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations required by subsection 64E-5.615(1), F.A.C., shall be maintained by the licensee.

(7) A licensee authorized to use radioactive material for uptake, dilution, and excretion studies or sealed sources for diagnostic purposes shall possess a portable radiation survey instrument with a range from 0.1 millirem (1.0 μSv) per
R10 hour to at least 1,000 millirem (10 mSv) per hour.

(8) A licensee authorized to use radioactive material for imaging and localization studies, radiopharmaceutical therapy or implant therapy shall possess portable radiation survey instruments with a range from 0.1 millirem (1.0 μSv) per hour to
R10 at least 1,000 millirem (10 mSv) per hour.

R10 (9) A licensee authorized to use radioactive material in Rule 64E-5.634, F.A.C., shall possess a radiation survey instrument as described in subsection (7) or (8), above.

R10 (10) The licensee shall not use survey instruments if the difference between the
R10 indicated exposure rate and the calculated exposure rate is more than 20
R10 percent.

R10 (11) A licensee may calibrate instrumentation used in Rule 64E-5.615, F.A.C., using
R10 nationally recognized standards or the manufacturer's instructions. The
R10 standards or instructions used by the licensee must be available for inspection by
R10 the department

R10 Rulemaking Authority: 404.051, 404.061 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.
R10 History: New 8-2591, Amended 5-15-96, Formerly 10D-91.721, Amended 02-11-10.

64E-5.616 Determination of Dosages of Unsealed Radioactive Material for Medical Use.

(1) The licensee shall determine by assay or direct measurement within 30 minutes before each radiopharmaceutical dosage and record the activity of each dosage before medical use. A record of the assay shall be made which shall include:

(a) The generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number; expiration date; and the radionuclide;

(b) The patient's or human research subject's name or identification number if one has been assigned;

(c) The prescribed dosage and activity of the dosage at the time of assay or a notation that the total activity assayed is less than 10 microcuries (370 kBq);

(d) The date and time of the assay and administration; and

(e) The name of the individual who performed the assay.

(2) Unless directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(3) A licensee shall retain a record of the assays listed in Rule 64E-5.616, F.A.C., for 3 years.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.722, Amended 02-11-10.

64E-5.617 Authorization for Calibration, Transmission and Reference Sources.

Any person authorized by Rule 64E-5.601, F.A.C., for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission and reference use:

(1) Sealed sources that:

(a) Do not exceed 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed by the department, the NRC, an agreement state; or

(b) Do not exceed 1.11 GBq (30 mCi) each, which are redistributed by a licensee that is authorized to redistribute sealed sources that are manufactured and distributed by a person licensed by the department, the NRC, or an agreement state, provided the redistributed sealed sources are in the original packaging and shielding, and are accompanied by the manufacturer's approved instructions;

(2) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 15 millicuries (555 MBq) each;

R10 (3) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and

R10 (4) Unless approved by the department, the maximum possession limit of radioactive
R10 materials described in subsections 64E-5.617(1), (2) and (3), F.A.C., above, shall
R10 not exceed a combined activity of 1 curie (37 GBq), This includes radioactive
R10 materials as waste in storage.

R10 (5) Unless approved by the department, the maximum possession limit for
R10 Technetium 99m in individual amounts shall not exceed 300 millicuries
R10 (11.1 GBq) each and a combined activity of 900 millicuries (33.3 GBq).

R10 Rulemaking Authority: 404.051, 404.061, 404.141, F.S.
R1 Law Implemented: 404.051(1)(4)(6)(10), 404.061(2), 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.723, Amended 5-18-98, Amended 02-11-10.

64E-5.618 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee who possesses any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the department and shall maintain the instructions for the duration of source use in a legible form and convenient to users.

(2) A licensee in possession of a sealed source shall assure that:

(a) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(b) The source is tested for leakage at least every 6 months or at intervals approved by the department, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

(c) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample, or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) each 24 hours;

(d) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(e) Teletherapy and other device source samples are taken when the source is in the off position.

(f) Leak tests are analyzed by individuals who are licensed by the department, U.S. Nuclear Regulatory Commission, an agreement state or licensing state to perform leak test services.

(3) A licensee shall retain leak test records for 3 years. The records shall contain the model number and serial number if assigned of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), the date of
R10 the test, and the name of the individual who performed the test analysis.

(4) If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(a) Immediately withdraw the sealed source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with these regulations; and

R10 (b) File a written report with the department within 5 days of receiving the leak test results describing the equipment involved, the test results, the action
R10 taken, the model number and serial number or the leaking source if
R10 assigned, the radioisotope and its estimated activity, and the date of the
R10 test.

(5) A leak test is not required on the following sources:

(a) Sources containing only radioactive material with a half-life of less than 30 days;

(b) Sources containing only radioactive material as a gas;

(c) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; and

(d) Seeds of iridium 192 encased in nylon ribbon.

(6) Leak tests are not required on calibration and reference sources stored and not being used. The licensee shall, however, clearly indicate on the inventory records that these sources are for storage only and the date placed in storage. The licensee shall test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

(7) Leak tests are not required on brachytherapy and teletherapy sources that are listed on a department license for storage only. The licensee shall test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

R10 (8) A licensee who possesses sealed sources or brachytherapy sources, except
R10 gamma stereotactic radiosurgery sources, shall conduct a physical inventory of
R10 all such sources at intervals not to exceed six months. The licensee shall retain each inventory record for 3 years. The inventory records shall contain the model number of each source and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each
R10 source, the date of the inventory, and the name of the individual who performed
R10 the inventory.

(9) A licensee who possesses a sealed source or brachytherapy source shall survey all areas where such sources are stored with a radiation survey instrument at least every 3 months. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(10) A licensee shall retain a record of each survey required in subsection 64E-5.618(9), F.A.C., for 3 years. The record shall 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
R10 survey, and the name of the individual who performed the survey.

R10 (11) Sealed sources designated as radioactive waste and held for decay in storage as
R10 in Rule 64E-5.624, F.A.C., are not required to be leak tested or inventoried as
R10 required by this section.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.724, Amended 02-11-10.

64E-5.619 Syringe Shields and Labels.

(1) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield. Each individual who prepares or administers radiopharmaceuticals shall use a syringe radiation shield unless the use of the shield is contraindicated for that patient.

(2) Unless used immediately, a licensee shall label conspicuously each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical with the patient's name or the radiopharmaceutical name or its abbreviation and the type of diagnostic study or therapy procedure to be performed.

Specific Authority: 404.051, 404.061, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.725.

64E-5.620 Vial Shields and Labels. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield and conspicuously label each vial with the radiopharmaceutical name or its abbreviation.

Specific Authority: 404.022, 404.051, 404.061, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.727.

64E-5.621 Surveys for Contamination and Ambient Radiation Dose Rate.

(1) A licensee shall survey with a radiation survey instrument at the end of each day
R10 of use, or during an assigned shift for facilities operating continuously, all areas where radiopharmaceuticals are routinely prepared for use or administered.

(2) A licensee shall survey all areas where radiopharmaceuticals or radioactive wastes are stored with a radiation survey instrument at least once each week.

(3) A licensee shall conduct the surveys required by subsections 64E-5.621(1) and (2), F.A.C., with an instrument capable of measuring dose rates as low as 0.1 millirem (1 µSv) per hour.

(4) A licensee shall establish dose rate action levels for the surveys required by subsections 64E-5.621(1) and (2), F.A.C., and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

(5) A licensee shall perform a wipe survey for removable contamination weekly of all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.

(6) A licensee shall analyze the wipe surveys required by subsection 64E-5.621(5), F.A.C., with an instrument capable of detecting contamination of 2,000 disintegrations per minute (33.3 Bq) or shall monitor each wipe sample in a low background area with a radiation survey instrument using a probe with a maximum window thickness of 2.0 mg/cm^2 and a minimum probe diameter of 1.5 inches.

(7) A licensee shall establish removable contamination action levels for the wipe surveys required by subsection 64E-5.621(5), F.A.C., and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

(8) A licensee shall retain a record of each survey required by subsection subsections 64E-5.621(1), (2), and (5), F.A.C., for 3 years. The record shall include:

(a) The date of the survey;

R10 (b) A diagram of each area surveyed;

(c) Action levels established for each area;

(d) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, or counts per minute if performed with a radiation survey instrument as described in subsection 64E-5.621(6), F.A.C.;

(e) The serial number and the model number of the instrument used to make the survey or analyze the samples; and

R10 (f) The name of the person who performed the survey.

R10 (9) The licensee does not need to perform the radiation surveys in subsection
R10 64E-5.621(1) or (2), F.A.C., in areas where patients or human research subjects
R10 are currently confined when such patients or subjects cannot be released under
R10 Rule 54E-5.622, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 04.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.729, Amended 02-11-10.

R10 **64E-5.622 Release of Patients or Human Research Subjects Treated with**
R10 **Radiopharmaceuticals, Implants or Remote Afterloader Units.**

R2 (1) Except as authorized by subsection 64E-5.622(4), F.A.C., a licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:

(a) The dose rate from the patient is less than 5 millirems (50 µSv) per hour at a distance of 1 meter; or

(b) The activity in the patient is less than 30 millicuries (1.11 GBq).

R2 (2) Except as authorized by subsection 64E-5.622(4), F.A.C., a licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 5 millirems (50 µSv) per hour at a distance of 1 meter.

(3) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation survey instrument to confirm that all sources have been removed. The licensee shall not release a patient treated by temporary implant from confinement for medical care until all sources have been removed.

R2 (4) Licensees and license applicants whose proposed procedures to release
R2 individuals who have been administered radiopharmaceuticals or permanent
R2 implants containing radioactive material from the control of licensees differ from
R2 those specified in subsections (1) and (2), above, must submit their proposed
R2 procedures to the department for approval. The procedures must:

R2 (a) Demonstrate that the total effective dose equivalent to any other individual
R2 from exposure to the released individual is not likely to exceed 500
R2 millirem (5 µSv);

R2 (b) Contain a copy of the instructions including written instructions to be given
R10 to the released individual, or the individual's parent or guardian, on
R2 actions recommended to maintain doses to other individuals as low as is
R2 reasonably achievable if the total effective dose equivalent to another
R2 individual is likely to exceed 100 millirem (1 µSv). If the dose to a breast-
R2 feeding infant or child could exceed 100 millirem (1 µSv) if there were no
R2 interruption of breast-feeding, the instructions also shall include:

R2 1. Guidance on the interruption or discontinuance of breast-feeding
R2 and

R2 2 Information on the consequences of failing to follow the guidance.

R2 (c) Specify that the licensee shall maintain a record of the basis for
R2 authorizing the release of an individual from their control who has been
R2 administered radiopharmaceuticals or permanent implants containing
R2 radioactive material for 3 years after the date of release.

R2 (5) A licensee shall maintain a record of patient surveys which demonstrates
R10 compliance with subsections 64E-5.622(3) and (6), F.A.C., for 3 years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirems (microsieverts) per hour and measured
R10 within 1 meter from the patient, and the initials of the individual who performed the survey.

R10 (6) Before releasing a patient or human research subject from licensee control, a
R10 licensee shall survey the patient or the human research subject and the remote
R10 afterloader unit with a portable radiation detection survey instrument to confirm
R10 that the source(s) has been removed from the patient or human research subject
R10 and returned to the safe shielded position.

R10 Rulemaking Authority: 404.051, 404.061, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.730, Amended 10-8-00, Amended 02-11-10.

64E-5.623 Storage of Volatiles and Gases. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container or an equivalent shield and container. A licensee shall store and use a multidose container in a properly functioning fume hood.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.731.

64E-5.624 Decay In Storage.

(1) A licensee shall hold radioactive material with a physical half life of less than
R10 120 days for decay in storage before disposal as ordinary trash. A licensee is
R10 exempt from the requirements of paragraph 64E-5.331(1)(c), F.A.C., of these regulations if:

(a) The radioactive material is held for decay a minimum of 10 half-lives;

(b) The radioactive material is monitored at the container surface before disposal as ordinary trash and its radioactivity cannot be distinguished from the background radiation level in a low background radiation area with a radiation survey instrument set on its most sensitive scale and with no interposed shielding;

(c) All radiation labels are removed or obliterated; and

(d) Each generator column is separated and monitored individually with all radiation shielding removed to ensure that its contents have decayed to background radiation levels before disposal.

(2) The licensee shall retain a record of each disposal for 3 years. The record shall include:

(a) The date of the disposal;

(b) The date on which the radioactive material was placed in storage;

(c) The radionuclides disposed;

(d) The model and serial number of the radiation survey instrument used;

(e) The background dose rate;

(f) The radiation dose rate measured at the surface of each waste container; and

(g) The name of the individual who performed the disposal.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.732, Amended 02-11-10.

64E-5.625 Safety Instructions and Precautions for Liquid Iodine,
R10 **Radiopharmaceutical Therapy, Manual Brachytherapy, Remote Afterloader Units,**
R10 **Teletherapy Units, and Gamma Stereotactic Radiosurgery.**

(1) A licensee shall provide oral and written radiation safety instructions to all
R10 personnel caring for patients or human research subjects, who cannot be
R10 released under Rule 64E-5.622, F.A.C., undergoing radiopharmaceutical therapy
R10 or manual brachytherapy. This training shall be provided initially prior to caring
R10 for patients and refresher training shall be provided at least every 12 months. The instruction shall describe the licensee's procedures for notification of the RSO
R10 and an authorized user in case of the patient’s death or medical emergency.

R10 (2) The instruction for radiopharmaceutical therapy shall be commensurate with the
R10 duties of the personnel and describe the procedures for:

R10 (a) Patient or human research subject control;

R10 (b) Visitor control, including;

R10 1. Routine visitation to hospitalized individuals in accordance with
R10 paragraph 64E-5.312(1)(a), F.A.C.; and

R10 2. Visitation authorized in accordance with subsection 63E-5.312(5),
R10 F.A.C.

(c) Contamination control; and

(d) Waste control.

(3) The instruction for manual brachytherapy shall be commensurate with the duties of the personnel and describe:

(a) Size and appearance of the brachytherapy sources;

(b) Safe handling and shielding instructions;

(c) Procedures for patient or human research subject control; and

(d) Procedures for visitor control, including;

1. Routine visitation to hospitalized individuals in accordance with paragraph 64E-5.312(1)(a), F.A.C.; and

2. Visitation authorized in accordance with paragraph 64E-5.312(5), F.A.C.

(4) A licensee shall provide instruction for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as described in Rule 64E-5.636, F.A.C.

(5) A licensee shall keep a record of individuals receiving instruction required by subsections (1), (2), (3), and (4) above, which includes a list of topics covered, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the department for 3 years.

(6) A licensee shall take the following safety precautions for each patient or human research subject receiving manual brachytherapy or radiopharmaceutical therapy who cannot be released under Rule 64E-5.622, F.A.C.

(a) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room.

(b) Measure promptly, after administration of the dosage, the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Rule 64E-5.312, F.A.C. Retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(c) Provide the patient with radiation safety guidance before authorizing release of the patient that will help to keep radiation dose to household members and the public as low as reasonably achievable.

(d) Notify the RSO and an authorized user immediately if the patient dies or has a medical emergency.

(7) Individuals receiving radiopharmaceutical therapy shall be provided a private room with a private sanitary facility or a room with another individual who is receiving unsealed radioactive materials who cannot be released under Rule 64E-5.622, F.A.C. Individuals receiving manual brachytherapy shall be provided a private room or a room with another individual who is receiving manual brachytherapy and cannot be released under Rule 64E-5.622, F.A.C. The licensee shall not place an individual receiving manual brachytherapy in the same room with a patient who is not receiving manual brachytherapy.

(8) A licensee shall take these additional safety precautions for radiopharmaceutical therapy patients or human research subjects who cannot be released by Rule 64E-5.622, F.A.C.:

(a) Monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste.

(b) Survey the patient's room and private sanitary facility for removable contamination before assigning another patient to the room. The room shall not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters or the wipe samples are equal to background when surveyed with an instrument using a probe with a maximum window thickness of 2.0 mg/cm^2 and a minimum probe diameter of 1.5 inches.

(9) For manual brachytherapy patients or human research subjects who cannot be released by Rule 64E-5.622, F.A.C., the licensee shall have the applicable emergency response equipment available near each treatment room to respond to the following:

(a) A source that is dislodged from the patient or human research subject; and

(b) A sealed source lodged within the patient following removal of the source applicators.

(10) The licensee shall establish a bioassay program to measure the thyroid burden of each individual who helps prepare, prepares or administers a dosage of unsealed iodine 131 or iodine 125 in accordance with Rule 64E-5.1320, F.A.C.

Rulemaking Authority 404.051, 404.061, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), (3), 404.081, 404.141 F.S.
History: New 5-15-96, Formerly 10D-91.721, Amended 02-11-10.

64E-5.6251 Therapy Related Computer Systems. (Entire section New) The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(1) The source-specific input parameters required by the dose calculation algorithm;

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) The accuracy of isodose plots and graphic displays; and

(4) The accuracy of the software used to determine sealed source positions from radiographic images.

The licensee shall maintain records of this acceptance testing and protocols used in performing these tests for inspection by the department.

Rulemaking Authority 404.051, 404.061, 404.081, 404.141 FS.
Law Implemented: 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), (3), 404.081, 404.141 FS.
History: New 02-11-10.

SUBPART C
UPTAKE, DILUTION, AND EXCRETION

64E-5.626 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies. **(Entire section Changed)** A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for medical use under the following conditions:

(1) When a written directive is not required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by a NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol, or a Notice of Claimed Investigational Exemption for a New Drug (IND) protocol accepted by U.S. Food and Drug Administration (FDA); or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application, or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. Except for sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or;

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.649 or 64E-5.657, F.A.C.

(2) When a written directive is required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application, or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. For sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.657, 64E-5.660, 64E-5.661, 64E-5.662 or 64E-5.663, F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.733, Amended 8-6-01, Amended 02-11-10.

SUBPART D
IMAGING AND LOCALIZATION

64E-5.627 Use of Unsealed Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies. A licensee is allowed to use any radioactive material in a diagnostic radiopharmaceutical, or any generator, or reagent kit, for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for medical use under the following conditions: **(Entire section Changed)**

(1) When a written directive is not required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

(a) Obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations; or

(b) Radioactive material is obtained from and prepared by a NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. Except for sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rules 64E-5.650, 64E-5.660 and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.; or

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.650 or 64E-5.657, F.A.C.

(2) When a written directive is required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. For sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq) a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the applicable training and experience specified in Rules 64E-5.657, 64E-5.660, 64E-5.661, 64E-5.662 or 64E-5.663, F.A.C.

(3) Only for oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) and when a written directive is required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

R10 (a) Radioactive material is obtained from a manufacturer or pharmacy
R10 licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent
R10 NRC or agreement state regulations; or

R10 (b) Radioactive material is obtained from and prepared by a NRC or
R10 agreement state licensee for use in research in accordance with a
R10 Radioactive Drug Research Committee-approved protocol or an IND
R10 protocol accepted by FDA; or

R10 (c) Radioactive material is prepared by the licensee for use in research in
R10 accordance with a Radioactive Drug Research Committee-approved
R10 application or an IND protocol accepted by FDA; or

R10 (d) Radioactive material is prepared by:

R10 1. An authorized nuclear pharmacist;

R10 2. For sodium iodide I-131 in quantities greater than 30 microcuries
R10 (1.11 MBq), a physician who is an authorized user and meets the
R10 training requirements specified in Rule 64E-5.650 or 64E-5.660,
F.A.C.; or

R10 3. An individual under the supervision of an authorized user as
R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or
R10 subsection 64E-5.608(1), F.A.C.

R10 (e) The authorized user must satisfy the applicable training and experience
R10 specified in Rules 64E-5.657, 64E-5.660 or 64E-5.661, F.A.C.

R10 (4) A licensee shall use radioactive aerosols or gases only if application on
R10 DH Form 1322 12/09 is made to and approved by the department and the
R10 requirements of Rule 64E-5.629, F.A.C., are met.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.735, Amended 8-6-01, Amended 02-11-10.

R10 **64E-5.628 Generators. (Entire section Changed)**

R10 (1) Permissible Molybdenum/Technetium Concentration.

R10 (a) A licensee shall not administer a radiopharmaceutical containing more
R10 than 0.15 microcurie of molybdenum 99 per millicurie of technetium 99m
R10 (5.55 kilo-becquerel of molybdenum 99 per 37 megabecquerel of
R10 technetium 99m).

R10 (b) A licensee preparing technetium 99m radiopharmaceuticals from
R10 molybdenum 99/technetium 99m generators shall measure the
R10 molybdenum 99 concentration in each eluate or extract.

R10 (c) A licensee who is required to measure molybdenum concentrations shall
R10 retain a record of each measurement for 3 years. The record shall include
R10 for each elution or extraction of technetium 99m:

R10 1. The measured activity of the technetium expressed in millicuries
R10 (megabecquerels);

R10 2. The measured activity of molybdenum expressed in microcuries
R10 (kilobecquerels);

R10 3. The ratio of the measures expressed as microcuries of
R10 molybdenum per millicurie of technetium (kilobecquerels of
R10 molybdenum per megabecquerel of technetium);

R10 4. The date of the test; and

R10 5. The initials of the individual who performed the test.

R10 (d) A licensee shall report immediately to the department each occurrence of
R10 molybdenum 99 concentration exceeding the limits specified in subsection
R10 64E-5.628(1), F.A.C.

R10 (2) Permissible Strontium/Rubidium Concentration.

R10 (a) A licensee shall not administer a radiopharmaceutical containing more
R10 than 0.02 microcurie of strontium 82 per millicurie of rubidium 82
R10 (0.74 kilobecquerel of strontium 82 per 37 megabecquerel of rubidium 82)
R10 or more than 0.2 microcurie of strontium 85 per millicurie of rubidium 82
R10 (7.4 kilobecquerel of strontium 85 per 37 megabecquerel of rubidium 82).

R10 (b) A licensee preparing rubidium 82 radiopharmaceuticals from
R10 strontium 82/rubidium 82 generators shall measure and calculate the
R10 strontium 82 and strontium 85 concentration on each day of use prior to
R10 the use of rubidium chloride for injection.

R10 (c) A licensee who is required to measure strontium 82 and strontium 85
R10 concentrations shall retain a record of each measurement for 3 years.
R10 The record shall include for each day of use assay:

R10 1. The measured activity of the rubidium 82 expressed in millicuries
R10 (megabecquerels);

R10 2. The measured activity of strontium 82 expressed in microcuries
R10 (kilobecquerels);

R10 3. The calculated activity of strontium 85 expressed in microcuries
R10 (kilobecquerels);

R10 4. The ratio of the measures expressed as microcuries of strontium 82
R10 per millicurie of rubidium 82 (kilobecquerels of strontium 82 per
R10 megabecquerel of rubidium 82) and the ratio of the measures
R10 expressed as microcuries of strontium 85 per millicurie of
R10 rubidium 82 (kilobecquerels of strontium 85 per megabecquerel of
R10 rubidium 82);

R10 5. The date of the test; and

R10 6. The initials of the individual who performed the test.

R10 (d) A licensee shall report immediately to the department each occurrence of
R10 strontium 82 or strontium 85 concentrations exceeding the limits specified
R10 in subsection 64E-5.628(2), F.A.C.

R10 (3) Other Permissible Parent/Daughter Concentration.

R10 (a) If a licensee seeks to utilize a Parent/Daughter concentration other that
R10 those listed in subsection (1) or (2) above, the licensee must submit a
R10 license amendment to the department for review and approval of the
R10 maximum parent isotope or other contaminate concentrations
R10 breakthrough per daughter isotope concentration allowed for
R10 administration to patients or human research subjects, and the
R10 instrumentation and procedures used in determining parent isotope or
R10 other contaminate breakthrough concentrations;

R10 (b) Each license must perform the determination listed in paragraph (3)(a),
R10 above, on each day of use prior to the administration to patients or human
R10 research subjects;

R10 (c) Retain a record of each measurement for 3 years. The record shall
R10 include for each day of use assay:

R10 1. The measured activity of the daughter isotope expressed in
R10 millicuries (megabecquerels);

R10 2. The measured activity of parent isotope(s) and other contaminates
R10 expressed in microcuries (kilobecquerels);

R10 3. The calculated activity of parent isotope(s) and other contaminates
R10 expressed in microcuries (kilobecquerels) as applicable;

R10 4. The ratio of the measures expressed as microcuries of parent
R10 isotope(s) and other contaminates per millicurie of daughter isotope
R10 (kilobecquerels of parent isotope(s) per megabecquerel of daughter isotope);

R10 5. The date of the test; and

R10 6. The initials of the individual who performed the test.

R10 (d) A licensee shall report immediately to the department each occurrence of
R10 parent isotope(s) or other contaminates concentrations exceeding the
R10 limits specified in paragraph 64E-5.628(3)(a), F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.736., Amended 02-11-10

64E-5.629 Control of Aerosols and Gases.

(1) A licensee shall only administer radioactive aerosols or gases when airborne concentrations are within the limits prescribed by State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3, and Table II.

(2) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(3) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(4) Before receiving, using, or storing radioactive gas, the licensee shall calculate the time needed after a release to reduce the concentration in the area of use to the occupational limit listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(5) A licensee shall post the time calculated in subsection 64E-5.629(4), F.A.C., at the area of use and require that individuals evacuate the room until the posted time has elapsed if a gas spill occurs.

R10 (6) A licensee shall check the operation of collection systems prior to use each
R10 month of use and measure the ventilation rates in areas of use every 6 months. Records of these checks and measurements shall be maintained for 3 years.

(7) A copy of the calculations required in subsection 64E-5.629(4), F.A.C., shall be recorded and retained for the duration of the license.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.737, Amended 02-11-10.

SUBPART E
RADIOPHARMACEUTICALS FOR THERAPY

64E-5.630 Use of Radiopharmaceuticals for Therapy. A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical that requires a written directive as described in subsection 64E-5.607(3), F.A.C., and for a therapeutic medical use provided the following is met **(Entire section Changed)**

(1) For any unsealed radiopharmaceutical including parenteral use listed in subsection 64E-5.630(4), F.A.C., and sodium iodide I-131 use listed in subsections 64E-5.630(2) and (3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 54E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.660 or 64E-5.657, F.A.C.

(2) Only for oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

R10 (c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

R10 (d) Radioactive material is prepared by:

R10 1. An authorized nuclear pharmacist;

R10 2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

R10 3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

R10 (e) The authorized user must satisfy the training and experience specified in Rule 64E-5.661 or 64E-5.657, F.A.C.

R10 (3) Only for oral administration of sodium iodide I-131 in quantities greater than 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

R10 (a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

R10 (b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

R10 (c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or.

R10 (d) Radioactive material is prepared by:

R10 1. An authorized nuclear pharmacist;

R10 2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

R10 3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

R10 (e) The authorized user must satisfy the training and experience specified in Rule 64E-5.662 or 64E-5.657, F.A.C.

R10 (4) Only parenteral use of radioactive materials the licensee must satisfy the following:

R10 (a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.663 or 64E-5.657, F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.739, Amended 8-6-01, Amended 02-11-10.

SUBPART F
SEALED SOURCES FOR DIAGNOSIS

64E-5.631 Use of Sealed Sources for Diagnosis. The licensee is allowed to use the sealed sources listed below, provided they are approved by and used as specified in, the Sealed Source and Device Registry, for diagnostic medical uses, or in research in accordance with an active IDE application accepted by the FDA and the requirements of Rule 64E-5.612, F.A.C., are met.

(1) Iodine 125 as a sealed source in a device for bone mineral analysis;

(2) Iodine 125 as a sealed source in a portable device for imaging;

(3) Gadolinium 153 as a sealed source in a device for bone mineral analysis;

(4) Americium 241 as a sealed source in a device for bone mineral analysis; or

(5) For isotopes or uses not listed in subsections 64E-5.631(1) through (4), F.A.C., above, the licensee must amend their radioactive materials license.

In order to use isotopes in accordance this Rule, an authorized user must satisfy the training and experience requirements specified in Rule 64E-5.654 or 64E-5.657, F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.743, Amended 02-11-10.

SUBPART G
SOURCES FOR BRACHYTHERAPY

R10 **64E-5.632 Use of Sources for Manual Brachytherapy**. The licensee is allowed to use the brachytherapy sources listed below, provided they are approved by and used as specified in, the Sealed Source and Device Registry, for diagnostic medical uses, or in research in accordance with an active IDE application accepted by the FDA and the requirements of Rule 64E-5.612, F.A.C., are met.

(1) Cobalt 60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(2) Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions;

(3) Palladium 103 as a sealed source in seeds for interstitial treatment of cancer;

(4) Iodine 125 as a sealed source in seeds for interstitial treatment of cancer;

(5) Cesium 137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(6) Iridium 192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(7) Gold 198 as a sealed source in seeds for interstitial treatment of cancer;

R10 (8) Radon 222 as seeds for interstitial treatment of cancer;

R10 (9) Radium 226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;

R10 (10) Cesium 131 as a sealed source in seeds for interstitial treatment of cancer; or

R10 (11) For isotopes or uses not listed in subsections 64E-5.632(1) through (10), F.A.C., above, the licensee must amend their radioactive materials license.

R10 In order to use isotopes in accordance with Rule 64E-5.632, F.A.C., an authorized user must satisfy the training and experience requirements specified in Rule 64E-5.652 or 64E-5.657, F.A.C. An authorized user of only Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions listed in subsection 64E-5.632(2), F.A.C., above must satisfy the training and experience specified in Rule 64E-5.652, 64E-5.653 or 64E-5.657, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.745, Amended 02-11-10.

R10 **64E-5.633 Manual Brachytherapy Sources Inventory and Surveys.**

R10 (1) The licensee shall maintain accountability at all times for all manual brachytherapy sources in storage or use. As soon as possible each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

R10 (2) A licensee shall make a record of the use of manual brachytherapy sources which includes:

R10 (a) For temporary implants;

R10 1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage; and

R10 2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage.

R10 (b) For permanent implants;

R10 1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage;

R10 2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage; and

R10 3. The number and activity of sources permanently implanted in the patient or human research subject.

R10 (3) Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey. This record shall contain the date and results of the survey, the survey instrument used and the name of the individual who performed the survey.

(4) A licensee shall maintain the records required in 64E-5.633(2) and (3) for 3 years.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.748, Amended 02-11-10.

R10 **64E-5.6331 Calibration Measurements of Manual Brachytherapy Sources.**
(Entire section New)

R10 (1) Before the first medical use of a brachytherapy source, the licensee shall, using published protocols currently accepted by nationally recognized bodies, determine the following:

R10 (a) Source output or activity using a dosimetry system that meets the requirements of subsection 64E-5.640(1), F.A.C.; and

R10 (b) Source positioning accuracy within applicators.

R10 (2) Instead of a licensee making its own measurements as required in subsection 64E-5.6331(1), F.A.C., the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM) that are made in accordance with subsection 64E-5.6331(1), F.A.C.

R10 (3) A licensee shall mathematically correct the outputs or activities determined in subsection 64E-5.6331(1), F.A.C., for physical decay at intervals consistent with 1 percent physical decay.

R10 (4) For each brachytherapy source the licensee shall retain the following records for three years after the last use of the source:

R10 (a) The date of calibration;

R10 (b) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

R10 (c) The source output or activity;

R10 (d) The source positioning accuracy within the applicators; and

R10 (e) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
R10 Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 02-11-10.

R10 **64E-5.6332 Decay of Strontium-90 Sources for Ophthalmic Treatments.**
(Entire section New)

R10 (1) Only an authorized medical physicist or authorized user qualified to perform procedures described in subsection 64E-5.632(2), F.A.C., shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Rule 64E-5.6331, F.A.C.

R10 (2) For each Strontium 90 source the licensee shall retain the following records for the life of the source:

(a) The date and activity of the source as determined under Rule 64E-5.6331, F.A.C.; and

(b) For each decay calculation, the date and the source activity as determined under Rule 64E-5.6332, F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 02-11-10.

SUBPART H
PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.

64E-5.634 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit. (Entire section Changed)

(1) A licensee shall use sealed sources in photon emitting gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of Rule 64E-5.612, F.A.C. are met.

(2) A licensee shall use sealed sources in photon emitting remote afterloader units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of Rule 64E-5.612, F.A.C., are met.

(3) A licensee shall use sealed sources in photon emitting teletherapy units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of Rule 64E-5.612, F.A.C., are met.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.751, Amended 02-11-10.

R10 **64E-5.635 Installation, Adjustment, Maintenance and Repair Restrictions.**
(Entire section Changed)

R10 (1) Only a person specifically licensed by the NRC or an agreement state shall
R10 install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or
R10 gamma stereotactic radiosurgery unit that involves work on the source(s)
R10 shielding, the source(s) driving unit, or other electronic or mechanical component
R10 that could expose the source(s), reduce the shielding around the source(s), or
R10 compromise the radiation safety of the unit or the source(s).

R10 (2) Except for low dose-rate remote afterloader units, only a person specifically
R10 licensed by the NRC or an agreement state shall install, replace, relocate, or
R10 remove a sealed source or source contained in other remote afterloader units,
R10 teletherapy units, or gamma stereotactic radiosurgery units.

R10 (3) For a low dose-rate remote afterloader unit, only a person specifically licensed by
R10 the NRC or an agreement state or an authorized medical physicist shall install,
R10 replace, relocate, or remove a sealed source(s) contained in the unit.

R10 (4) A licensee shall retain a record of the installation, maintenance, adjustment, and
R10 repair of remote afterloader units, teletherapy units, and gamma stereotactic
R10 radiosurgery units for 3 years. For each installation, maintenance, adjustment
R10 and repair, the record must include the date, description of the service, and
R10 name(s) of the individual(s) who performed the work.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.752, Amended 02-11-10.

R10 **64E-5.636 Safety Procedures and Instructions for Remote Afterloader Units,**
R10 **Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**
(Entire section Changed)

R10 (1) Listed below are the safety and instruction requirements for a licensee:;

R10 (a) Secure the unit, the console, the console keys, and the treatment room
R10 when not in use or unattended;

R10 (b) Permit only individuals approved by the authorized user, RSO, or
R10 authorized medical physicist to be present in the treatment room during
R10 treatment with the source(s);

R10 (c) Prevent dual operation of more than one radiation producing device in a
R10 treatment room if applicable; and

R10 (d) Develop, implement, and maintain written procedures for responding to an
R10 abnormal situation when the operator is unable to place the source(s) in
R10 the shielded position, or remove the patient or human research subject
R10 from the radiation field with controls from outside the treatment room.
R10 These procedures must include the following:

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 medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by paragraph 64E-5.636(1)(d), F.A.C., of this section must be physically located at the unit console.

(3) A licensee shall post instructions at the unit console to inform the operator of the following:

(a) The location of the procedures required by paragraph (4)(a) of this section; and

(b) The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

(4) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in the following:

(a) The procedures identified in paragraph 64E-5.636(1)(d), F.A.C., of this section; and

(b) The operating procedures for the unit.

(5) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(6) A licensee shall retain a record of individuals receiving instruction required by paragraph 64E-5.636(4), F.A.C., of this section. These records shall be maintained for 3 years and must include the list of topics covered, the date of the instruction, the name(s) of the attendee(s) and the name(s) of the individual(s) who provided the instruction.

(7) A licensee shall retain a copy of the procedures required by paragraphs 64E-5.636(1)(d) and 64E-5.636(4)(b), F.A.C., until the licensee no longer possesses the remote afterloader, teletherapy unit or gamma stereotactic radiosurgery unit.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.753, Amended 02-11-10.

64E-5.637 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units . (Entire section Changed)

(1) A licensee shall control access to the treatment room by a door at each entrance.

(2) A licensee shall equip each entrance to the treatment room with an electrical interlock system that shall:

(a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) Cause the source(s) to be shielded when an entrance door is opened; and

(c) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(3) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(4) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(6) In addition to the requirements specified in paragraphs 64E-5.637(1) through (5), F.A.C., of this section, a licensee shall:

(a) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

1. An authorized medical 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, to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either, an authorized user or an individual under, the supervision of an authorized user, who have been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(b) For high dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical 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, to be physically present during continuation of all patient treatments involving the unit.

(c) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(d) Notify the RSO, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(7) A licensee shall have applicable emergency response equipment available near each treatment room in order to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.755, Amended 02-11-10.

64E-5.638 Radiation Monitoring Devices.

(1) A licensee shall have a permanent radiation monitor in each teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room capable of continuously monitoring radiation levels.

(2) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit, medium or high dose rate remote afterloader unit, or gamma stereotactic radiosurgery unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room.

(3) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit, medium or high dose rate remote afterloader unit, or gamma stereotactic radiosurgery unit. This backup power supply may be a battery system.

(4) Each radiation monitor shall be checked daily with a dedicated check source for proper operation before the teletherapy unit, medium or high dose rate remote afterloader unit, or gamma stereotactic radiosurgery unit is used.

(5) A licensee shall maintain a record of the check required by subsection 64E-5.638(4), F.A.C., for 3 years. The record shall include the date of the check, notation what the monitor indicates when its detector is and is not exposed to the source, and the initials of the individual who performed the check.

(6) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room to use a radiation survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The radiation survey instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in subsection 64E-5.638(5), F.A.C.

(7) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.757, Amended 02-11-10.

64E-5.639 Viewing Systems. A licensee shall construct or equip each teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room to permit continuous observation of the patient, or human research subject from the teletherapy unit console during irradiation.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.758, Amended 02-11-10.

64E-5.640 Dosimetry Equipment Used With Remote Afterloading Units, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units.

(1) Except for low dose-rate remote afterloader source output or where the activity is determined by the manufacturer, a licensee shall have a dosimetry system 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 licensee's system shall not have changed by more than 2 percent. The licensee 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, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(2) The licensee 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 requirement in 64E-5.640(1), or shall be a system that has been compared with a system that has been calibrated as provided in subsection 64E-5.640(1), F.A.C. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration.

(3) The licensee 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:

R10 (a) The date, the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subsections 64E-5.640(1) and (2), F.A.C.;

(b) The correction factors that were determined;

(c) The names of the individuals who performed the calibration, intercomparison, or comparison; and

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.759, Amended 02-11-10.

R10 **64E-5.641 Full Calibration Measurements on Teletherapy Units..**

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(a) Before the first medical use of the unit;

(b) Before medical use whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(c) Before medical use following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(d) Before medical use following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(e) At least every 12 months.

(2) Full calibration measurements shall include the determination of:

(a) The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) Timer constancy and linearity over the range of use;

(e) On-off error; and

(f) The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C., to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 64E-5.641(2)(a), F.A.C., may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by subsection 64E-5.641(1), F.A.C., using the manufacturer's published protocols, published protocols as accepted by nationally recognized bodies or equivalent procedures that have been submitted to the department. An example of a nationally recognized body is the American Association of Physicists in Medicine.

(5) A licensee shall correct mathematically the outputs determined in paragraph 64E-5.641(2)(a), F.A.C., for physical decay monthly for cobalt 60 and at least every 6 months for cesium 137.

(6) Full calibration measurements required by subsection 64E-5.641(1), F.A.C., and physical decay corrections required by 64E-5.641(5) shall be performed by the authorized medical physicist.

(7) A licensee shall maintain a record of each calibration of each teletherapy unit for three years. The record shall include:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for both the teletherapy unit and the source;

(c) The model numbers and serial numbers of the instruments used to calibrate the teletherapy unit;

(d) The results and an assessment of the full calibration to include the following:

1. The tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy;

2. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The measured timer accuracy for a typical treatment time;

4. The calculated on-off error;

5. The estimated accuracy of each distance measuring or localization device; and

6. The signature of the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.760, Amended 02-11-10.

R10 **64E-5.6411 Full Calibration Measurements on Remote Afterloader Units.**
(Entire section New)

R10 (1) A licensee authorized to use a remote afterloader unit for medical use shall
R10 perform full calibration measurements on each remote afterloader unit:

R10 (a) Before the first medical use of the unit;

R10 (b) 1. Before medical use following replacement of the source or following
R10 reinstallation of the unit in a new location outside the facility; and
R10

R10 2. Before medical use following any repair of the unit that includes
R10 removal of the source or major repair of the components associated
R10 with the source exposure assembly; and

R10 (c) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate,
R10 and pulsed dose-rate remote afterloader units with sources whose half-life
R10 exceeds 75 days; and

R10 (d) At intervals not exceeding 1 year for low dose-rate remote afterloader
R10 units.

R10 (2) Full calibration measurements of remote afterloader unit shall include the
R10 determination of:

R10 (a) The output within 5 percent;

R10 (b) Source positioning accuracy to within 1 millimeter;

R10 (c) Source retraction with backup battery upon power failure;

R10 (d) Timer constancy and linearity over the range of use;

R10 (e) Length of the source transfer tubes;

R10 (f) Length of the applicators; and

R10 (g) Function of the source transfer tubes, applicators, and transfer tube-
R10 applicator interfaces.

R10 (3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C.,
R10 to measure the output for one set of exposure conditions. The remaining
R10 radiation measurements required in paragraph 64E-5.6411(2)(a), F.A.C., may be
R10 made using a dosimetry system that indicates relative dose rates.

R10 (4) A licensee shall make full calibration measurements required by subsection
R10 64E-5.6411(1), F.A.C., in accordance with published protocols accepted by
R10 nationally recognized bodies.

(5) A licensee shall correct mathematically the outputs determined in paragraph 64E-5.641(2)(a), F.A.C., for physical decay at intervals consistent with 1 percent physical decay.

(6) Full calibration measurements required by subsection 64E-5.6411(1), F.A.C., and physical decay corrections required by subsection 64E-5.641(5), F.A.C., shall be performed by the authorized medical physicist.

(7) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection 64E-5.6411(2), F.A.C., a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(8) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsections 64E-5.6411(1)-(5), F.A.C.

(9) A licensee shall maintain a record of each remote afterloader unit 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 remote afterloader unit and the source;

(c) The model numbers and serial numbers of the instruments used to calibrate the remote afterloader unit;

(d) The results and an assessment of the full calibrations.

(e) The results of the audiograph required for low dose-rate remote afterloaders; and

(f) The signature of the authorized medical physicist.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History: New 02-11-10.

64E-5.6412 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units. (Entire section New)

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each gamma stereotactic radiosurgery:

(a) Before the first medical use of the unit;

(b) 1. Before medical use whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

R10 2. Before medical use following replacement of the source or following
R10 reinstallation of the gamma stereotactic radiosurgery unit in a new
R10 location;

R10 3. Following any repair of the gamma stereotactic radiosurgery unit that
R10 includes removal of the sources or major repair of the components
R10 associated with the source assembly; and

R10 (c) At intervals not exceeding 1 year, with the exception that relative helmet
R10 factors need only be determined before the first medical use of a helmet
R10 and following any damage to a helmet.

R10 (2) Full calibration measurements of the gamma stereotactic radiosurgery unit shall
R10 include the determination of:

R10 (a) The output within 3 percent;

R10 (b) Relative helmet factors;

R10 (c) Isocenter coincidence;

R10 (d) Timer constancy and linearity over the range of use;

R10 (e) On-off timers;

R10 (f) Trunnion centricity;

R10 (g) Treatment table retraction mechanism, using backup battery power or
R10 hydraulic backups with the unit off;

R10 (h) Helmet microswitches;

R10 (i) Emergency timing circuits; and

R10 (j) Stereotactic frames and localizing devices (trunnions).

R10 (3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C.,
R10 to measure the output for one set of exposure conditions. The remaining
R10 radiation measurements required in paragraph 64E-5.6412(2)(a), F.A.C., may be
R10 made using a dosimetry system that indicates relative dose rates.

R10 (4) A licensee shall make full calibration measurements required by subsection
R10 64E-5.6412(1), F.A.C., in accordance with published protocols accepted by
R10 nationally recognized bodies.

R10 (5) A licensee shall correct mathematically the outputs determined in paragraph
R10 64E-5.6412(2)(a), F.A.C., at intervals not exceeding 1 month for cobalt-60 and at
R10 intervals consistent with 1 percent physical decay for all other radionuclides.

R10 (6) Full calibration measurements required by subsection 64E-5.6412(1), F.A.C., and
R10 physical decay corrections required by subsection 64E-5.6412(5), F.A.C., shall
R10 be performed by the authorized medical physicist.

R10 (7) A licensee shall maintain a record of each gamma stereotactic radiosurgery unit
R10 calibration for three years. The record shall include:

R10 (a) The date of the calibration;

R10 (b) The manufacturer's name, model number, and serial number for both the
R10 gamma stereotactic radiosurgery unit and the source;

R10 (c) The model numbers and serial numbers of the instruments used to
R10 calibrate the gamma stereotactic radiosurgery unit;

R10 (d) The results and an assessment of the full calibrations; and

R10 (e) The signature of the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
R10 Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History: New 02-11-10.

R10 **64E-5.642 Periodic Spot-Checks of Teletherapy Units.**

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at least every month.

(2) Spot-checks shall include the determination of:

(a) Timer constancy and timer linearity over the range of use;

(b) On-off error;

(c) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) The accuracy of all distance measuring and localization devices used for medical use;

(e) The output for one typical set of operating conditions; and

(f) The difference between the measurement made in paragraph 64E-5.642(2)(e), F.A.C., and the anticipated output, expressed as a percentage of the anticipated output, which is the value obtained at the last full calibration corrected mathematically for physical decay.

(3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C., to make the spot-check required in paragraph 64E-5.642(2)(e), F.A.C.

(4) A licensee shall perform spot-checks required by subsection 64E-5.642(1),
R10 F.A.C., following procedures established by the authorized medical physicist.

R10 (5) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days and promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification for 3 years.

(6) A licensee authorized to use a teletherapy unit for medical use shall perform
R10 safety spot-checks of each teletherapy facility monthly and after each source
R10 installation.

(7) Safety spot-checks shall assure proper operation of:

(a) Electrical interlocks at each teletherapy room entrance;

(b) Electrical or mechanical stops installed to limit use of the primary beam of radiation, restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam on-off mechanism;

R10 (c) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

R10 (d) Viewing and intercom systems;

(e) Treatment room doors from inside and outside the treatment room; and

(f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

R10 (8) If the results of the checks required in subsection 64E-5.642(7), F.A.C., of this
R10 section indicate the malfunction of any system, a licensee shall lock the control
R10 console in the off position and not use the unit.

(9) A licensee shall promptly repair any system identified in subsection 64E-5.642(7), F.A.C. that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.

(10) A licensee shall maintain a record of each spot-check required by 64E-5.642(1)
R10 and (6) for 3 years and a copy of the procedures required by subsection
R10 64E-5.641(4), F.A.C., until the licensee no longer possesses the teletherapy unit. The record shall include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for both the teletherapy unit and source;

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

(d) The timer linearity and constancy;

(e) The calculated on-off error;

(f) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(g) The determined accuracy of each distance measuring or localization device;

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

(i) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors; and

R10 (j) The name of the individual who performed the periodic spot-check and the
R10 signature of the authorized medical physicist who reviewed the record of
R10 the spot check.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.761, Amended 02-11-10.

R10 **64E-5.6421 Periodic Spot-Checks for Remote Afterloader Units. (Entire section New)**

R10 (1) A licensee authorized to use a remote afterloader unit for medical use shall
R10 perform the following spot-checks:

R10 (a) Before the first use of a high dose-rate, medium dose-rate, or pulsed
R10 dose-rate remote afterloader unit on a given day;

R10 (b) Before each patient treatment with a low dose-rate remote afterloader unit;
R10 and

R10 (c) After each source installation.

R10 (2) Spot-checks shall include the determination of:

R10 (a) Electrical interlocks at each remote afterloader unit room entrance;

R10 (b) Source exposure indicator lights on the remote afterloader unit, on the
R10 control console, and in the facility;

R10 (c) Viewing and intercom systems in each high dose-rate, medium dose-rate,
R10 and pulsed dose-rate remote afterloader facility;

R10 (d) Emergency response equipment;

R10 (e) Radiation monitors used to indicate the source position;

R10 (f) Timer accuracy;

R10 (g) Clock (date and time) in the unit's computer; and

R10 (h) Decayed source(s) activity in the unit's computer.

R10 (3) If the results of the checks required in subsection 64E-5.6421(2), F.A.C., of this
R10 section indicate the malfunction of any system, a licensee shall lock the control
R10 console in the off position and not use the unit except as may be necessary to
R10 repair, replace, or check the malfunctioning system.

R10 (4) A licensee shall perform spot-checks required by subsection 64E-5.6421(2), F.A.C., following procedures established by the authorized medical physicist.

R10 (5) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days and promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for 3 years.

R10 (6) A licensee shall retain a copy of the procedures required by subsection 64E-5.6421(4), F.A.C., until the licensee no longer possesses the remote afterloader unit.

R10 (7) A licensee shall maintain a record of each spot-check required by subsection 64E-5.6421(2), F.A.C., for 3 years and a copy of the procedures required by subsections 64E-5.6421(4) and (5), F.A.C., until the licensee no longer possesses the remote afterloader unit. The record shall include:

R10 (a) The date of the spot-check;

R10 (b) The manufacturer's name, model number, and serial number for both the remote afterloader unit and source;

R10 (c) An assessment of timer accuracy;

R10 (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

R10 (e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
R10 Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History: New 02-11-10.

R10 **64E-5.6422 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units (Entire section New)**

R10 (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform the following spot-checks:

R10 (a) Monthly:

R10 (b) Before the first use of the unit on a given day; and

R10 (c) After each source installation.

R10 (2) Spot-checks shall include the determination of:

R10 (a) Assure the proper operation of the:

1. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

2. Helmet microswitches;

3. Emergency timing circuits; and

4. Stereotactic frames and localizing devices (trunnions).

(b) Determine the following elements:

1. The output for one typical set of operating conditions measured with the dosimetry system described in subsection 64E-5.640(2), F.A.C.;

2. The difference between the measurement made in subparagraph 64E-5.6422(2)(b)1, F.A.C., and the anticipated output, expressed as a percentage of the anticipated output value obtained at last full calibration corrected mathematically for physical decay;

3. Source output against computer calculation;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. Trunnion centricity.

(3) A licensee shall perform spot-checks required by subsection 64E-5.6422(1), F.A.C., following procedures established by the authorized medical physicist.

(4) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days and promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for 3 years

(5) To satisfy the requirements of paragraphs 64E-5.6422(1)(b) and (c), F.A.C., the licensee's spot-checks must assure proper operation of the following:

(a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Timer termination;

(e) Radiation monitors used to indicate room exposures; and

(f) Emergency off buttons.

R10 (6) If the results of the checks required in subsection 64E-5.6422(5), F.A.C., of this
R10 section indicate the malfunction of any system, a licensee shall lock the control
R10 console in the off position and not use the unit except as may be necessary to
R10 repair, replace, or check the malfunctioning system.

R10 (7) A licensee shall arrange for the repair of any system identified in subsection
R10 64E-5.6422(2), F.A.C., that is not operating properly as soon as possible.

R10 (8) A licensee shall maintain a record of each spot-check required by subsections
R10 64E-5.6422(2) and (5), F.A.C., for 3 years and a copy of the procedures required
R10 in subsections 64E-5.5422(2) and (3), F.A.C., until the licensee no longer
R10 possesses the gamma stereotactic radiosurgery unit. The record shall include:

R10 (a) The date of the spot-check;

R10 (b) The manufacturer's name, model number, and serial number for the
R10 gamma stereotactic radiosurgery unit;

R10 (c) The manufacturer's name, model number and serial number of the
instrument used to measure the output of the gamma stereotactic
radiosurgery unit;

R10 (d) The timer linearity and constancy;

R10 (e) The calculated on-off error;

R10 (f) A determination of trunnion centricity;

R10 (g) The difference between the anticipated output and the measured output;

R10 (h) An assessment of source output against computer calculations;

R10 (i) Notations indicating the operability of radiation monitors, helmet
R10 microswitches, emergency timing circuits, emergency off buttons,
R10 electrical interlocks, source exposure indicator lights, viewing and intercom
R10 systems, timer termination, treatment table retraction mechanism, and
R10 stereotactic frames and localizing devices (trunnions); and
R10

R10 (j) The name of the individual who performed the periodic spot-check and the
R10 signature of the authorized medical physicist who reviewed the record of
R10 the spot-check.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
R10 Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History: New 02-11-10.

R10 **64E-5.6423 Additional Technical Requirements for Mobile Remote Afterloader Units. (Entire section New)**

R10 (1) A licensee providing mobile remote afterloader service for medical use shall perform the following:

R10 (a) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

R10 (b) Account for all sources before departure from a client's address of use.

R10 (2) In addition to the periodic spot-checks required by Rule 64E-5.6421, F.A.C., a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of the following:

R10 (a) Electrical interlocks on treatment area access points;

R10 (b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

R10 (c) Viewing and intercom systems;

R10 (d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

R10 (e) Radiation monitors used to indicate room exposures;

R10 (f) Source positioning (accuracy); and

R10 (g) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

R10 (3) In addition to the requirements for checks in subsection 64E-5.6423(2), F.A.C., a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

R10 (4) If the results of the checks required in subsection 64E-5.6423(2), F.A.C., indicate the malfunction of any system, a licensee 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.

R10 (5) The licensee shall keep a copy of each check for mobile remote afterloader unit required by subsection 64E-5.6423(2), F.A.C., for three years. The records shall include:

R10 (a) The date of the check;

R10 (b) The manufacturer's name, model number, and serial number of the remote afterloader unit;

R10 (c) Notations accounting for all sources before the licensee departs from a facility;

R10 (d) Notations indicating the operability of each entrance door electrical
R10 interlock, radiation monitors, source exposure indicator lights, viewing and
R10 intercom system, applicators, source transfer tubes, and transfer tube
R10 applicator interfaces, and source positioning accuracy; and

R10 (e) The signature of the individual who performed the check.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
R10 Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History: New 02-11-10.

64E-5.643 Radiation Surveys for Teletherapy Facilities.

(1) The licensee shall perform radiation surveys with an operable radiation survey
R2 instrument calibrated as provided in Rule 64E-5.615, F.A.C., before medical use,
after each installation of a teletherapy source, and after making any change for
R2 which an amendment is required by Rule 64E-5.636, F.A.C.

(a) The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field shall not exceed 10 millirems (100 µSv) per hour and 2 millirems (20 µSv) per hour.

(b) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, radiation levels in restricted areas shall be unlikely to
R2 cause any occupationally exposed individuals to receive a dose in excess
R2 of the limits specified in Rule 64E-5.304, F.A.C.; and radiation dose rates
R2 of any individual member of the public in unrestricted areas shall not
R2 exceed the limits specified in paragraph 64E-5.312(1)(c), F.A.C.

(2) If the results of the surveys required in subsection 64E-5.643(1), F.A.C., indicate any radiation levels in excess of the limits specified, the licensee shall lock the control in the off position and shall not use the unit:

(a) Except to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

(b) Until the licensee has received a specific exemption from the department.

(3) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include:

(a) The date of the measurements;

(b) The reason the survey is required;

(c) The manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels;

(d) Each dose rate measured around the teletherapy source while in the off position and the average of all measurements;

(e) A plan of the areas surrounding the treatment room that were surveyed;

(f) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;

(g) The calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and

R10 (h) The signature of the RSO or the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-994, Formerly 10D-91.762, Amended 10-8-00, Amended 02-11-10.

R10 **64E-5.644 Radiation Surveys for Remote Afterloader and Gamma Stereotactic**
R10 **Radiosurgery Facilities. (Entire section Changed)**

R10 (1) The licensee shall perform radiation surveys with an operable radiation survey
R10 instrument calibrated as provided in Rule 64E-5.615, F.A.C., to ensure that the
R10 maximum radiation levels and average radiation levels from the surface of the
R10 main source safe with the source(s) in the shielded position do not exceed the
R10 levels stated in the Sealed Source and Device Registry.
R10

R10 (2) The licensee shall make the survey specified in subsection 64E-5.644(1), F.A.C.,
R10 at the installation of a new source and following repairs to the source(s)
R10 shielding, the source(s) driving unit, or other electronic or mechanical component
R10 that could expose the source, reduce the shielding around the source(s), or
R10 compromise the radiation safety of the unit or the source(s).

R10 (3) A licensee shall retain a record of the radiation surveys required by subsection
R10 64E-5.644(1), F.A.C., for the duration of the license. These records shall include:
R10

R10 (a) The date of the measurements;

R10 (b) The manufacturer's name, model number and serial number of the
R10 treatment unit, source, and instrument used to measure radiation levels;

R10 (c) Each dose rate measured around the source while the unit is in the off
R10 position and the average of all measurements; and

R10 (d) The signature of the RSO or authorized medical physicist who performed
R10 the test.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.763, Amended 02-11-10.

64E-5.645 Therapy-Related Computer Systems. (Entire section Changed) The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. An example of a nationally recognized body is the American Association of Physicists in Medicine. At a minimum, the acceptance testing must include, as applicable, verification of the following:

(1) The source-specific input parameters required by the dose calculation algorithm;

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) The accuracy of isodose plots and graphic displays;

(4) The accuracy of the software used to determine sealed source positions from radiographic images; and

(5) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.764, Amended 10-8-00, Amended 02-11-10.

64E-5.646 Reports of Teletherapy Surveys, Checks, Tests, and Measurements. A licensee shall furnish a copy of the records required in Rules 64E-5.643, 64E-5.644, and 64E-5.645, F.A.C., and the output from the teletherapy source expressed as rads (grays) per hour at 1 meter from the source as determined during the full calibration required in Rule 64E-5.641, F.A.C., to the department within 30 days following completion of the action that initiated the record requirement.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.765.

64E-5.647 Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at least every 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) This inspection and servicing shall only be performed by persons specifically licensed to do so by the department, an agreement state, or the U.S. Nuclear Regulatory Commission.

(3) A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain:

(a) The inspector's name;

R10 (b) The inspector's radioactive materials license number;

(c) The date of inspection;

(d) The manufacturer's name and model number and serial number for both
R10 the treatment unit and source;

(e) A list of components inspected;

(f) A list of components serviced and the type of service;

(g) A list of components replaced; and

(h) The signature of the inspector.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.766, Amended 02-11-10.

SUBPART I
TRAINING AND EXPERIENCE REQUIREMENTS

64E-5.648 Radiation Safety Officer. Except as provided in Rule 64E-5.657, F.A.C.,
R10 the licensee shall require the RSO as provided in Rule 64E-5.605, F.A.C., to be an individual who: **(Entire section Changed)**

R10 (1) Is certified by a specialty board whose certification process has been recognized
R10 by the NRC or an agreement state and who meets the requirements in
R10 subsections 64E-5.648(4) and (5), F.A.C., of this section. (The names of board
R10 certifications which have been recognized by the NRC or an agreement state will
R10 be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-
R10 use-toolkit/spec-board-cert.html.) To have its certification process recognized, a
R10 specialty board shall require all candidates for certification to:

R10 (a) 1. Hold a bachelor's or graduate degree from an accredited college or
R10 university in physical science or engineering or biological science
R10 with a minimum of 20 college credits in physical science;

R10 2. Have 5 or more years of professional experience in health physics
R10 (graduate training may be substituted for no more than 2 years of
R10 the required experience) including at least 3 years in applied health
R10 physics; and

R10 3. Pass an examination administered by diplomates of the specialty
R10 board, which evaluates knowledge and competence in radiation
R10 physics and instrumentation, radiation protection, mathematics
R10 pertaining to the use and measurement of radioactivity, radiation
R10 biology, and radiation dosimetry; or

(b) 1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have 2 years of full-time practical training and/or supervised experience in medical physics either:

a. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the NRC or an agreement state; or

b. In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in Rule 64E-5.657, 64E-4.650 or 64E-5.660, F.A.C.;

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) Have completed a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

5. Radiation dosimetry.

(b) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a NRC or agreement state license or permit issued by a NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

3. Securing and controlling radioactive material;

4. Using administrative controls to avoid mistakes in the administration of radioactive material;

R10 5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

R10 6. Using emergency procedures to control radioactive material; and

R10 7. Disposing of radioactive material; or

R10 (3) (a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an agreement state under subsection 64E-5.656(1), F.A.C., and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO and who meets the requirements in subsections 64E-5.648(4) and (5), F.A.C., of this section; or

R10 (b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities; and

R10 (4) Have obtained written attestation, signed by a preceptor RSO, or residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category as designated by the applicant seeking authorized status) who meets the requirements in subsection 64E-5.648(5) and in subparagraphs 64E-5.648(1)(a)1., and 64E-5.648(1)(a)2., or 64E-5.648(1)(b)1., and 64E-5.648(1)(b)2., or subsection 64E-5.648(2) or paragraph 64E-5.648(3)(a), F.A.C., of this section, and has demonstrated the ability to function independently as a RSO to fulfill the radiation safety related duties for a medical use licensee; and

R10 (5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.767, Amended 02-11-10.

64E-5.649 Training for Uptake, Dilution, or Excretion Studies. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a
R10 radiopharmaceutical listed in subsection 64E-5.626(1), F.A.C., to: **(Entire section Changed)**

R10 (1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.649(3)(b), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

R10 (a) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraph 64E-5.649(3)(a) and subparagraph 64E-5.649(3)(a)2., F.A.C., of this section; and

R10 (b) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

R10 (2) Be an authorized user under Rule 64E-5.650 or 64E-5.660, F.A.C., or equivalent agreement state requirements; or

R10 (3) (a) Have completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include the following:

R10 1. Classroom and laboratory training in the following areas:

R10 a. Radiation physics and instrumentation;

R10 b. Radiation protection;

R10 c. Mathematics pertaining to the use and measurement of radioactivity;

R10 d. Chemistry of radioactive material for medical use; and

R10 2. Work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.649, 64E-5.650 or 64E-5.660, F.A.C., or equivalent agreement state requirements, involving the following:

R10 a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Administering dosages of radioactive drugs to patients or human research subjects.

(b) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657, 64E-5.649, 64E-5.650 or 64E-5.660, F.A.C., or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.649(1)(a) or 64E-5.649(3)(a), F.A.C., of this section and has demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses authorized under subsection 64E-5.626(1), F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.769, Amended 02-11-10.

64E-5.650 Training for Imaging and Localization Studies for Which a Written Directive Is Not Required. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user specified in subsection 64E-5.627(1), F.A.C., to:
(Entire section Changed)

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.650(3)(b), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in subparagraphs 64E-5.650(3)(a)1. and 64E-5.650(3)(a)2., F.A.C., of this section; and

(b) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) Be an authorized user under Rule 64E-5.660, F.A.C., and meet the requirements in sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C., or equivalent agreement state requirements; or paragraph 64E-5.650(3)(a), F.A.C.; or

(3) (a) Have completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum the following:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use;

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.650 or sub-subparagraph 64E-5.650(3)(a)2.g., and Rule 64E-5.660, F.A.C., or equivalent agreement state requirements, involving the following:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

f. Administering dosages of radioactive drugs to patients or human research subjects; and

g. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(3) (b) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657, 64E-5.650, 64E-5.660, and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C., or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.650(1)(a) or 64E-5.650(3)(a) or 64E-5.650(3)(a), F.A.C., of this section and has demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses authorized under subsections 64E-5.626(1) and 64E-5.627(1), F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.770, Amended 02-11-10.

64E-5.651 Repealed 02-11-10 (See Rules 64E-5.660, 64E-5.661, 64E-5.662 & 64E-5.663)

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.771, Repealed 02-11-10.

64E-5.652 Training for Use of Manual Brachytherapy Sources. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a brachytherapy source specified in 64E-5.632, F.A.C., to: **(Entire section Changed)**

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and who meets the requirements in paragraph 64E-5.652(2)(c), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2) (a) Have completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes-

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657 or 64E-5.652, F.A.C., or equivalent agreement state requirements at a medical institution, clinic, or private practice facility**,** involving the following:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Checking survey meters for proper operation;

c. Preparing, implanting, and removing brachytherapy sources;

d. Maintaining running inventories of material on hand;

e. Using administrative controls to prevent a medical event involving the use of radioactive material;

f. Using emergency procedures to control radioactive material; and

(b) Have completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule 64E-5.657 or 64E-5.652, F.A.C., or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph 64E-5.652(2)(a)2., F.A.C., of this section; and

R10 (c) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.652, F.A.C., or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.652(1)(a) or 64E-5.652(2)(a) and 64E-5.652(2)(b), F.A.C., of this section and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses of manual brachytherapy sources authorized under Rule 64E-5.632, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.772, Amended 02-11-10.

64E-5.653 Training for Ophthalmic Use of Strontium 90. Except as provided in 64E-5.657, the licensee shall require the authorized user of only strontium 90 for ophthalmic R10 radiotherapy to: **(Entire section Changed)**

R10 (1) Be authorized user under Rule 64E-5.652, F.A.C., or equivalent agreement state requirements; or

R10 (2) (a) Have completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include the following:

R10 1. Radiation Protection and instrumentation;

R10 2. Radiation Protection;

R10 3. Mathematics pertaining to the use and measurement of radioactivity: and

R10 4. Radiation biology; and

R10 (b) Have supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve the following:

1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

R10 4. Follow-up and review of each individual's case history; and

(c) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.652, 64E-5.653, F.A.C., or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in paragraphs 64E-5.653(2)(a) and 64E-5.653(2)(b), F.A.C., of this section and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized for strontium-90 for ophthalmic use.

Rukemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.773, Amended 02-11-10.

64E-5.654 Training for Use of Sealed Sources for Diagnosis. Except as provided in 64E-5.657, the licensee shall require the authorized user of a sealed source in a device specified in 64E-5.631, F.A.C., to: **(Entire section Changed)**

(1) Be certified by a specialty board whose certification process includes all of the requirements in subsections 64E-5.654(2) and (3), F.A.C., of this section and whose certification has been recognized by the NRC or an agreement state. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or

(2) Have completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include the following:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology; and

(3) Have completed training in the use of the device for the uses requested.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.774, Amended 02-11-10.

64E-5.655 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. Except as provided in 64E-5.657, the licensee shall require the authorized user of a sealed source specified in 64E-5.634. F.A.C., to:

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.655(2)(c) and subsection 64E-5.655(3), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2) (a) Have completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes the following:

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657 or 64E-5.655, F.A.C., or equivalent agreement state requirements at a medical institution, clinic, or private practice facility, involving the following:

a. Reviewing full calibration measurements and periodic spot-checks;

b. Preparing treatment plans and calculating treatment doses and times;

c. Using administrative controls to prevent a medical event involving the use of radioactive material;

d. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

e. Checking and using survey meters;

f. Selecting the proper dose and how it is to be administered; and

(b) Have completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in Rule 64E-5.657 or 64E-5.655, F.A.C., or equivalent agreement state requirements as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph 64E-5.655(2)(a)2., F.A.C., of this section; and

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 64E-5.655(1)(a) or 64E-5.655(2)(a) and 64E-5.655(2)(b) and subsection 64E-5.655(3), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee for each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.655, F.A.C., or equivalent agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(3) Have received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.775, Amended 02-11-10.

R10 **64E-5.656 Training for an Authorized Medical Physicist.** Except as provided in
R10 Rule 64E-5.657, F.A.C., the licensee shall require the authorized medical physicist to:
(Entire section Changed)

R10 (1) Be certified by a specialty board whose certification process has been
R10 recognized by the NRC or an agreement state and who meets the requirements
R10 in paragraph 64E-5.656(2)(b) and subsection 64E-5.656(3), F.A.C., of this
R10 section. (The names of board certifications which have been recognized by the
R10 NRC or an agreement state will be posted on the NRC's Web page at
R10 http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To
R10 have its certification process recognized, a specialty board shall require all
R10 candidates for certification to:

R10 (a) Hold a master's or doctor's degree in physics, medical physics, other
R10 physical science, engineering, or applied mathematics from an accredited
R10 college or university;

R10 (b) Have 2 years of full-time practical training and/or supervised experience in
R10 medical physics:

R10 1. Under the supervision of a medical physicist who is certified in
R10 medical physics by a specialty board recognized by the NRC or an
R10 agreement state; or

R10 2. In clinical radiation facilities providing high-energy, external beam
R10 therapy (photons and electrons with energies greater than or equal
R10 to 1 million electron volts) and brachytherapy services under the
R10 direction of physicians who meet the requirements for authorized
R10 users in Rule 64E-5.657, 64E-5.652 or 64E-5.655, F.A.C.; and

R10 (c) Pass an examination, administered by diplomates of the specialty board,
R10 that assesses knowledge and competence in clinical radiation therapy,
R10 radiation safety, calibration, quality assurance, and treatment planning for
R10 external beam therapy, brachytherapy, and stereotactic radiosurgery; or

R10 (2) (a) Hold a master's or doctor's degree in physics, medical physics, other
R10 physical science, engineering, or applied mathematics from an accredited
R10 college or university; and has completed 1 year of full-time training in
R10 medical physics and an additional year of full-time work experience under
R10 the supervision of an individual who meets the requirements for an
R10 authorized medical physicist for the type(s) of use for which the individual
R10 is seeking authorization. This training and work experience must be
R10 conducted in clinical radiation facilities that provide high-energy, external
R10 beam therapy (photons and electrons with energies greater than or equal
R10 to 1 million electron volts) and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;

2. Performing decay corrections;

3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Have obtained written attestation that the individual has satisfactorily completed the requirements in subsection 64E-5.656(3) and paragraphs 64E-5.656(1)(a) and (b) or 64E-5.656(2)(a) and subsection 64E-5.656(3), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized medical physicist to fulfill the radiation safety related duties for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.656 or 64E-5.657, F.A.C., or equivalent agreement state requirements, for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.776, Amended 02-11-10.

64E-5.657 Training for Experienced RSO, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist. (Entire section Changed)

(1) (a) An individual identified as a RSO, a teletherapy or medical physicist, or a nuclear pharmacist on a NRC or agreement state license or a permit issued by a NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope, need not comply with the training requirements of Rule 64E-5.648, 64E-5.656 or 64E-5.659, F.A.C., respectively.

(b) An individual identified as a RSO, an authorized medical physicist, or an authorized nuclear pharmacist on a NRC or agreement state license or a permit issued by a NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope, need not comply with the training requirements of Rule 64E-5.648, 64E-5.656 or 64E-5.659, F.A.C., respectively.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or agreement state, a permit issued by a NRC master material licensee, a permit issued by a NRC or agreement state broad scope licensee, or a permit issued by a NRC master material license broad scope permittee who perform only those medical uses for which they were authorized, need not comply with the training requirements of Rule 64E-5.649, 64E-5.650, 64E-5.660, 64E-5.661, 64E-5.662, 64E-5.663, 64E-5.652, 64E-5.653, 64E-5.654 or 64E-5.655, F.A.C.

(3) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on department radioactive materials licenses for the same uses for which these individuals are authorized.

Rulemaking Authority: 404.051, 404.061, 404.071, F.S.
Law Implemented: 404.022, 404.051(1)(4)(10)(11), 404.061(2)(3), 404.071(3) 404.141, F.S.
History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.777, Amended 02-11-10.

64E-5.658 Recentness of Training. The training and experience specified in Rules 64E-5.648 , 64E-5.649, 64E-5.650, 64E-5.652, 64E-5.653, 64E-5.654, 64E-5.655, 64E-5.656, 64E-5.657,64E-5.659, 64E-5.660, 64E-5.661,64E-5.662 and 64E-5.663, F.A.C., shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education or experience since the required training and experience was completed and within the 7 years preceding the date of application.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.779, Amended 02-11-10.

R10 **64E-5.659 Training for an Authorized Nuclear Pharmacist.** Except as provided in Rule
R10 64E-5.657, F.A.C., the licensee shall require the authorized nuclear pharmacist to:
(Entire section New)

R10 (1) Be certified by a specialty board whose certification process has been
R10 recognized by the NRC or an agreement state and who meets the requirements
R10 in paragraph 64E-5.659(2)(b), F.A.C., of this section. (The names of board
R10 certifications which have been recognized by the NRC or an agreement state will
R10 be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-
R10 use-toolkit/spec-board-cert.html.) To have its certification process recognized, a
R10 specialty board shall require all candidates for certification to:

R10 (a) Have graduated from a pharmacy program accredited by the American
R10 Council on Pharmaceutical Education (ACPE) or have passed the Foreign
R10 Pharmacy Graduate Examination Committee (FPGEC) examination;

R10 (b) Hold a current, active license to practice pharmacy;

R10 (c) Provide evidence of having acquired at least 4000 hours of
R10 training/experience in nuclear pharmacy practice. Academic training may
R10 be substituted for no more than 2000 hours of the required training and
R10 experience; and

R10 (d) Pass an examination in nuclear pharmacy administered by diplomats of
R10 the specialty board, that assess knowledge and competency in
R10 procurement, compounding, quality assurance, dispensing, distribution,
R10 health and safety, radiation safety, provision of information and
R10 consultation, monitoring patient outcomes, research and development; or

R10 (2) (a) Have completed 700 hours in a structured educational program consisting
R10 of both:

R10 1. 200 hours of classroom and laboratory training in the following
R10 areas:

R10 a. Radiation physics and instrumentation;

R10 b. Radiation protection;

R10 c. Mathematics pertaining to the use and measurement of
R10 radioactivity;

R10 d. Chemistry of radioactive material for medical use; and

R10 e. Radiation biology; and

R10 2. Supervised practical experience in a nuclear pharmacy involving:

R10 a. Shipping, receiving, and performing related radiation
R10 surveys;

R10 b. Using and performing checks for proper operation of
R10 instruments used to determine the activity of dosages,
R10 survey meters, and, if appropriate, instruments used to
R10 measure alpha or beta-emitting radionuclides;

R10 c. Calculating, assaying, and safely preparing dosages for
R10 patients or human research subjects;

R10 d. Using administrative controls to avoid medical events in the
R10 administration of radioactive material; and

R10 e. Using procedures to prevent or minimize radioactive
R10 contamination and using proper decontamination
R10 procedures; and

R10 (b) Have obtained written attestation, signed by a preceptor authorized user
R10 or a residency program director who represents a consensus of residency
R10 program faculties (as long as at least one member of the residency
R10 program faculty is an authorized individual in the same category
R10 designated by the applicant seeking authorized status) who meets the
R10 requirements in paragraphs 64E-5.659(1)(a), 64E-5.659(1)(b) and
R10 64E-5.659(1)(c) or 64E-5.659(2)(a), F.A.C., of this section and have
R10 demonstrated the ability to function independently as an authorized
R10 nuclear pharmacist to fulfill the radiation safety related duties for a medical
R10 use licensee.

R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
R10 Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History-New 02-11-10

64E-5.660 Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of unsealed radioactive materials specified in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., which require a written directive to: **(Entire section New)**

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in sub-subparagraphs 64E-5.660(2)(a)2.g. and paragraph 64E-5.660(2)(b), F.A.C., of this section. (Specialty boards whose certification processes have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subparagraph 64E-5.660(2)(a)1. through sub-subparagraph 64E-5.660(2)(a)2.e., F.A.C., of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(2) (a) Have completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include the following:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

R10 2. Work experience, under the supervision of an authorized user who
R10 meets the requirements in Rule 64E-5.657 or 64E-5.660, F.A.C., or
R10 equivalent agreement state requirements. A supervising authorized
R10 user, who meets the requirements in subsection
R10 64E-5.660(2), F.A.C., must also have experience in administering
R10 dosages in the same dosage category or categories (i.e., sub-
R10 subparagraph 64E-5.660(2)(a)2.g., F.A.C.,) as the individual
R10 requesting authorized user status. The work experience must
R10 involve the following:

R10 a. Ordering, receiving, and unpacking radioactive materials
R10 safely and performing the related radiation surveys;

R10 b. Performing quality control procedures on instruments used
R10 to determine the activity of dosages, and performing checks
R10 for proper operation of survey meters;

R10 c. Calculating, measuring, and safely preparing patient or
R10 human research subject dosages;

R10 d. Using administrative controls to prevent a medical event
R10 involving the use of unsealed radioactive material;

R10 e. Using procedures to contain spilled radioactive material
R10 safely and using proper decontamination procedures;

R10 f. Performing checks for proper operation of survey meters;
R10 and

R10 g. Administering dosages of radioactive drugs to patients or
R10 human research subjects involving a minimum of three
R10 cases in each of the following categories for which the
R10 individual is requesting authorized user status as listed
R10 below:

R10 (I) Oral administration of less than or equal to
R10 1.22 gigabecquerels (33 millicuries) of sodium iodide
R10 I-131, for which a written directive is required or sub-
R10 sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.;

R10 (II) Oral administration of greater than 1.22
R10 gigabecquerels (33 millicuries) of sodium iodide I-131;

R10 (III) Parenteral administration of any beta emitter, or a
R10 photon-emitting radionuclide with a photon energy
R10 less than 150 keV, for which a written directive is
R10 required; and/or

R10 (IV) Parenteral administration of any other radionuclide,
R10 for which a written directive is required; and

(b) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 64E-5.660(1)(a) and subparagraph 64E-5.660(2)(a)2.g., or paragraph 64E-5.660(2)(a), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., that require a written directive. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.660, F.A.C., or equivalent agreement state requirements. The preceptor authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must have experience in administering dosages in the same dosage category or categories specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C., as the individual requesting authorized user status.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History-New 02-11-10

64E-5.661 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries). Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to: **(Entire section New)**

(1) Be certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 64E-5.661(3)(a) and 64E-5.661(3)(b), F.A.C., of this section and whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.661(3)(c), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or

(2) Be an authorized user under Rule 64E-5.660, F.A.C., or uses listed in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), or Rule 64E-5.662, F.A.C., or equivalent agreement state requirements; or

(3) (a) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include the following:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(b) Have work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.660, 64E-5.661 or 64E-5.662, F.A.C., or equivalent agreement state requirements. A supervising authorized user who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), F.A.C. The work experience must involve the following:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

6. Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 64E-5.661(3)(a) and 64E-5.661(3)(b), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee that required a written directive under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657, 64E-5.660, 64E-5.661 or 64E-5.662, F.A.C., or equivalent agreement state requirements. A preceptor authorized user, who meets the requirement in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History-New 02-11-10

64E-5.662 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries). Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to: **(Entire section New)**

(1) Be certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 64E-5.662(3)(a) and 64E-5.662(3)(b), F.A.C., of this section, and whose certification has been recognized by the NRC or an agreement state, and who meets the requirements in paragraph 64E-5.662(3)(c), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or

(2) Be an authorized user under Rule 64E-5.660, F.A.C., for uses listed in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C., or equivalent agreement state requirements; or

(3) (a) Have successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(b) Have work experience, under the supervision of an authorized user who meets the requirements in Rules 64E-5.657, 64E-5.660 or 64E-5.662, F.A.C., or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C. The work experience must involve the following:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

6. Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 64E-5.662(3)(a) and 64E-5.662(3)(b), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., that require written directives. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.660, 64E-5.662, F.A.C., or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History-New 02-11-10

64E-5.663 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the parenteral administration requiring a written directive, to: **(Entire section New)**

(1) Be an authorized user under Rule 64E-5.660, F.A.C., for uses listed in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C., or equivalent agreement state requirements; or

(2) Be an authorized user under Rule 64E-5.652 or 64E-5.655, F.A.C., or equivalent agreement state requirements and who meets the requirements in subsection 64E-5.663(4), F.A.C. of this section; or

(3) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under Rule 64E-5.652 or 64E-5.655, F.A.C., and who meets the requirements in subsection 64E-5.663(4), F.A.C., of this section.

(4) (a) Have successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include the following:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(b) Have work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.660 or 65E-5.663, F.A.C., or equivalent agreement state requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in Rule 64E-5.660, F.A.C., or equivalent agreement state requirements, must have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C., or equivalent agreement state requirements. The work experience must involve the following:

1. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

2. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

5. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

R10 6. Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

R10 (c) Have obtained written attestation that the individual has satisfactorily completed the requirements in subsection 64E-5.663(2) or 64E-5.663(3), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized for the parenteral administration of unsealed radioactive material requiring a written directive. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657, 64E-5.660 or 65E-5.663, F.A.C., or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements in Rule 64E-5.660, F.A.C., must have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C.

R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
R10 Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History-New 02-11-10

SUBPART J
OTHER MEDICAL USES OR RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

64E-5.664 Other Medical Uses of Radioactive Material or Radiation From Radioactive Material . A licensee may use radioactive materials or a radiation source from radioactive materials approved for medical use which is not specifically addressed in Rule 64E-5.626, 64E-5.627, 64E-5.630, 64E-5.631, 64E-5.632 or 64E-5.634, F.A.C., provided the following are satisfied: **(Entire section New)**

(1) The applicant or licensee has received written approval from the department in a license or license amendment and uses the material in accordance with the regulations and specific license conditions the department considers necessary for the medical use of the material;

(2) The applicant or licensee has submitted the information required by Rules 64E-5.207 and 64E-5.208, F.A.C.; and

(3) The licensee shall provide specific information on the following:

(a) Radiation safety precautions and instruction;

(b) Methodology for measuring dosages or doses to be administered to patients or human research subjects;

(c) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(d) Security of radioactive materials, training or experience of individuals involved in these uses or other information not specified in paragraph 64E-5.665(3)(a)(b) or (c), F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History-New 02-11-10