

## 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, 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 64E-5.626, 64E-5.627, 64E-5.630, or 64E-5.632 also is authorized to use radioactive material under a general license in 64E-5.206(8) for specified in vitro uses without filing the certificate required by 64E-5.206(8)(b), but is subject to the other provisions of 64E-5.206(8).
- (3) Unless prohibited by license condition, a physician, dentist, or podiatrist in training may receive, possess, use, or transfer radioactive materials as provided in these regulations under the supervision of an authorized user as provided in 64E-5.608.
- (4) Unless authorized by the department, no individual shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive materials for medical use unless:
  - (a) That individual is listed on the licensee's specific license as an authorized user **or an authorized nuclear pharmacist**;
  - (b) Authorized by 64E-5.609;
  - (c) Authorized by 64E-5.601(2) with approval of the radiation safety committee at medical institutions or by management for licensees that are not medical institutions; or
  - (d) Authorized by 64E-5.601(3) and Subpart I of Part VI.

R3

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.

R3 History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.707, **Amended August 6, 2001**.

**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;
- (2) Before permitting anyone, except a visiting authorized user described in 64E-5.609, to work as an authorized user;
- (3) Before changing a radiation safety officer or teletherapy physicist;

- (4) Before ordering or receiving radioactive material in excess of the amount 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.

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 August 25, 1991, Formerly 10D-91.708.

**64E-5.603 Notification.** A licensee shall notify the department in writing within  
R3 30 days when an authorized user, radiation safety officer, **authorized nuclear pharmacist**, or teletherapy physicist permanently discontinues performance of these duties for the licensee.

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.

R3 History: New August 25, 1991, Formerly 10D-91.709, **Amended August 6, 2001**.

## 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 64E-5.303.
- (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.
- (3) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.
- (4) The ALARA program shall include an annual review by the radiation safety committee for medical institution licensees, or by management and the radiation safety officer for licensees that are not medical institutions. 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.

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 August 25, 1991, Amended January 1, 1994, Formerly 10D-91.710.

#### **64E-5.605 Radiation Safety Officer.**

- (1) A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, 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.
- (6) The radiation safety officer shall review at least every 3 months the occupational radiation exposure records of all personnel working with radioactive material.

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 August 25, 1991, Formerly 10D-91.711.

**64E-5.606 Radiation Safety Committee.** Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

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

- (3) 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 64E-5.604 and 64E-5.606.
- (4) 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.
- (5) The committee shall be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable.
- R3 (6) The committee shall review and approve any individual to be an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy R3 physicist based on safety and the training and experience standards of this part before sending a license application or request for amendment or renewal.
- (7) The committee shall review and approve each proposed method of use of radioactive material based on safety.
- (8) The committee shall review and approve procedures and radiation safety program changes based on safety and with the advice of the radiation safety officer and the management representative prior to sending to the department for licensing action.
- (9) The committee shall review occupational radiation exposure records of all personnel working with radioactive material and all incidents involving radioactive material at least every 6 months, with the assistance of the radiation safety officer, to determine cause and review subsequent actions taken.
- (10) The committee shall review the radioactive materials program at least every 12 months with the assistance of the radiation safety officer as described in 64E-5.604(4).
- (11) The committee shall establish levels for occupational dose that will result in investigations and considerations of action by the radiation safety officer when exceeded.

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.

R3 History: New August 25, 1991, Formerly 10D-91.712, Amended August 6, 2001.

**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:
  - (a) Review personally the patient's case or develop and implement adequate written procedures to assure that the diagnostic radiation procedure is appropriate;
  - (b) Review personally the patient's case to assure that the therapeutic radiation procedure is appropriate;
  - (c) For therapy procedures or diagnostic procedures involving more than 30 microcuries (1.11 MBq) of iodine 123, iodine 125 or iodine 131 as sodium iodide, prepare a written directive;
  - (d) For all other diagnostic procedures, prepare a written directive or assure that the procedure is in accordance with a diagnostic clinical procedures manual;
  - (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.

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 August 25, 1991, Amended May 12, 1993, Formerly 10D-91.713.

**64E-5.608 Supervision.**

- (1) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 64E-5.601 shall:

- (a) 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;
  - (b) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;
  - (c) Require the authorized user to be immediately available to communicate with the supervised individual;
  - (d) Require the authorized user to be able to be physically present and available to the supervised individual within 1 hour; and
  - (e) Require that only those individuals specifically designated by the authorized user be permitted to administer radionuclides or radiation to patients.
- (2) A licensee shall require the supervised individual receiving, possessing, using or transferring radioactive material specified in 64E-5.601 to:
- (a) Follow the instructions of the supervising authorized user;
  - (b) Follow the written radiation and quality management program procedures established by the licensee; and
  - (c) Comply with these regulations and the license conditions regarding the use of radioactive material.

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 August 25, 1991, Amended January 1, 1994, Formerly 10D-91.714.

#### **64E-5.609 Visiting Authorized User.**

- (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 visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of a medical institution, the institution's radiation safety committee;
  - (b) The licensee has a copy of a license issued by the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state that identifies the visiting authorized user by name as an authorized user for medical use; and
  - (c) The visiting authorized user performs only those procedures for which he is specifically authorized by the license described in 64E-5.609(1)(b) above.

- (2) A license amendment is not needed to permit a visiting authorized user to use licensed material as described in 64E-5.609(1).
- (3) A licensee shall retain copies of the records specified in 64E-5.609(1) for 5 years after the last visit.

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 August 25, 1991, Formerly 10D-91.715.

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

- (1) Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material.
- (2) Mobile nuclear medicine 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) Mobile nuclear medicine service licensees shall check dose calibrators as required by 64E-5.614, and shall perform all required gamma camera quality control tests before medical use at each location of use.
- (4) Mobile nuclear medicine service licensees shall perform a survey of all areas of radiopharmaceutical use with a radiation survey instrument before leaving a client location.
- (5) Mobile nuclear medicine service licensees shall retain a record of each survey required above for 3 years. The record must include the date of the survey, a plan 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 radiopharmaceuticals are administered. An authorized user shall be able to be physically present and available within 1 hour.
- (7) Radioactive material shall not be stored in the mobile vehicle overnight when vehicle is located at its permanent location. The vehicle shall be monitored for contamination after all sources of radiation have been removed.
- (8) Radioactive material will be received at the permanent location of the mobile nuclear medicine service or delivered directly to an authorized individual in the vehicle at a place of use.

- (9) All use of radioactive material shall be in the mobile vehicle unless there is written documentation by the attending physician that the use of radioactive materials within the facility is in the best interest of the patient. All radioactive waste generated shall be stored on the vehicle for subsequent removal at the permanent location of the mobile nuclear medicine service.
- (10) Restrooms contained in mobile vehicles shall not routinely be used by patients who have been administered radioactive material. If the patient's condition requires the use of the restroom, the sewage holding tank of the vehicle shall be emptied and thoroughly rinsed into a sanitary sewer system at the permanent location of the mobile nuclear medicine service.
- (11) Radioactive gases shall not be used in mobile vehicles.

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 August 25, 1991, Formerly 10D-91.716.

#### **64E-5.611 Quality Management Program and Notifications, Records and Reports of Misadministrations.**

- (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 (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 123, iodine 125 or iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels); or
  5. Any therapeutic administration of a radiopharmaceutical other than iodine 123, iodine 125, or iodine 131 as sodium iodide;
- (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 directive prepared within 24 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 stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.
  - (e) The patient's identity is verified by more than one method as the individual named in the written directive prior to administration;
  - (f) The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery agree with the respective written directives:
  - (g) Each administration agrees with the written directive; and
  - (h) Any unintended deviation from the written directive is identified and 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
  - (c) All misadministrations 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 64E-5.611(1).
- (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 64E-5.611(1).
- (7) The licensee may make modifications to the quality management program to increase the program's efficiency if the program's effectiveness is not decreased. The licensee is required to submit the modifications to the department within 30 days after the modifications have been made.
- (8) 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.
- (9) Each existing licensee shall submit to the department by July 1, 1994, a copy of their quality management program with a written certification that the quality management program has been implemented.
- (10) Each licensee shall submit and maintain records and reports of misadministrations as required by 64E-5.345(4) and (5).

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 August 25, 1991, Amended January 1, 1994, Formerly 10D-91.717.

**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 U.S. Nuclear Regulatory Commission.

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 August 25, 1991, Formerly 10D-91.718.

## 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 August 25, 1991, Amended May 13, 1993, Formerly 10D-91.719.

### **64E-5.614 Possession, Use, Calibration, and Check of Dose Calibrators.**

- (1) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient.
- (2) A licensee shall check each dose calibrator before use each day of use 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 or by the manufacturer who has compared their source to a source calibrated by the National Institute of Standards and Technology. 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 kiloelectron 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
  - (f) The signature of the radiation safety officer.
- (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
  - (e) The signature of the radiation safety officer.
- (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
  - (e) The signature of the radiation safety officer.
- (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 64E-5.614 following adjustment or repair of the dose calibrator.
- (8) A licensee shall retain a record of each check and test required by 64E-5.614 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 August 25, 1991, Formerly 10D-91.720.

#### **64E-5.615 Use, Calibration and Check of Survey Instruments.**

- (1) A licensee shall ensure that the survey instruments used to comply with this part have been calibrated before first use, at least every 12 months, and after repair. 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;
  - (e) The signature of the individual who performed the calibration; and
  - (f) The date of 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
- (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 64E-5.615(1), 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 64E-5.615(1) 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  $\mu$ Sv) per hour to 50 millirem (500  $\mu$ Sv) 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  $\mu$ Sv) per hour to 1,000 millirem (10 mSv) per hour.
- (9) A licensee authorized to use radioactive material in a teletherapy unit shall possess a radiation survey instrument as described in (7) or (8), above.

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 August 25, 1991, Amended May 15, 1996, Formerly 10D-91.721.

#### **64E-5.616 Assay of Radiopharmaceutical Dosages.**

- (1) A licensee shall assay within 30 minutes before use the activity of each photon-emitting radiopharmaceutical dosage. 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 name and 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 initials of the individual who performed the assay.
- (2) A licensee shall retain a record of the assays required by 64E-5.616(1), 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 August 25, 1991, Amended May 12, 1993, Formerly 10D-91.722.

**64E-5.617 Authorization for Calibration and Reference Sources.** Any person authorized by 64E-5.601 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

- R1
- (1) Sealed sources manufactured and distributed by persons specifically licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state that do not exceed 15 millicuries (555 MBq) each;
  - (2) Samarium 153 and any radioactive material listed in 64E-5.626 or 64E-5.627 with a half-life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq) each;
  - (3) Any radioactive material listed in 64E-5.626 or 64E-5.627 with a half-life greater than 100 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and
  - (4) Technetium 99m in individual amounts not to exceed 100 millicuries (3.7 GBq) each.

R1 Specific 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.

R1 History: New August 25, 1991, Formerly 10D-91.723, Amended May 18, 1998.

**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 the test, and the signature of the radiation safety officer.
- (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
  - (b) File a report with the department within 5 days of receiving the leak test results describing the equipment involved, the test results, and the action taken.
- (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.

- (8) A licensee who possesses a brachytherapy or teletherapy source shall conduct a physical inventory of all such sources at least every 3 months. A licensee who possesses other sealed sources shall conduct a physical inventory of all such sources at least every 6 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 source, the date of the inventory, and the signature of the radiation safety officer.
- (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 64E-5.618(9) 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 survey, and the signature of the radiation safety officer.

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 August 25, 1991, Amended May 12, 1993, Formerly 10D-91.724.

#### **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 August 25, 1991, Amended May 15, 1996, 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 August 25, 1991, Amended May 15, 1996, 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 of use 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 64E-5.621(1) and (2) with an instrument capable of measuring dose rates as low as 0.1 millirem (1  $\mu$ Sv) per hour.
- (4) A licensee shall establish dose rate action levels for the surveys required by 64E-5.621(1) and (2) 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 64E-5.621(5) 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<sup>2</sup> and a minimum probe diameter of 1.5 inches.
- (7) A licensee shall establish removable contamination action levels for the wipe surveys required by 64E-5.621(5) 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 64E-5.621(1), (2), and (5) for 3 years. The record shall include:
  - (a) The date of the survey;
  - (b) A sketch 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 64E-5.621(6);
  - (e) The serial number and the model number of the instrument used to make the survey or analyze the samples; and
  - (f) The initials of the person who performed the survey.

Specific 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.

History: New August 25, 1991, Formerly 10D-91.729.

### 64E-5.622 Release of Patients Containing Radiopharmaceuticals or Permanent Implants.

- R2 (1) Except as authorized by 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  $\mu$ Sv) 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 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  $\mu$ Sv) 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 (1) and (2), above, must submit their proposed procedures to  
R2 the department for approval. The procedures must:
- (a) Demonstrate that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (5  $\mu$ Sv);
- (b) Contain a copy of the instructions including written instructions to be given to the released individual on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to another individual is likely to exceed 100 millirem (1  $\mu$ Sv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1  $\mu$ Sv) if there were no interruption of breast-feeding, the instructions also shall include:
1. Guidance on the interruption or discontinuance of breast-feeding and
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  
R2 compliance with Rule 64E-5.622(3), 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 within 1  
meter from the patient, and the initials of the individual who made the survey.

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.

R2 History: New August 25, 1991, Amended May 15, 1996, Formerly 10D-91.730, Amended October 8, 2000.

**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 August 25, 1991, 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 90 days for decay in storage before disposal as ordinary trash. A licensee is exempt from the requirements of 64E-5.328 of these regulations if:

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- (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.

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 August 25, 1991, Amended January 1, 1994, Formerly 10D-91.732.

**64E-5.625 Safety Instruction and Precautions for Radiopharmaceutical Therapy, Brachytherapy, and Teletherapy.**

- (1) A licensee shall provide oral and written radiation safety instructions to all personnel caring for patients undergoing radiopharmaceutical therapy or brachytherapy and to personnel who operate a teletherapy unit. Refresher training shall be provided at least every 12 months. The instruction shall describe the licensee's procedures for notification of the radiation safety officer or authorized user in case of the patient's death or medical emergency.
- (2) The instruction for radiopharmaceutical therapy shall describe the procedures for:
  - (a) Patient control;
  - (b) Visitor control;

- (c) Contamination control; and
  - (d) Waste control.
- R2 (3) The instruction for brachytherapy shall describe:
  - (a) Size and appearance of the brachytherapy sources;
  - (b) Safe handling and shielding instructions in case of a dislodged source;
  - (c) Procedures for patient control; and
  - (d) Procedures for visitor control.
- R2 (4) A licensee shall provide instruction and post conspicuously written instructions at the teletherapy unit console. These instructions shall inform the operator of:
  - (a) The procedure to be followed to ensure that only the patient is in the treatment room before turning on the primary beam of radiation or after a door interlock interruption;
  - (b) The procedure to be followed if the operator is unable to turn off the primary beam of radiation with controls outside the treatment room or any other abnormal operation occurs; and
  - (c) The names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.
- R2 (5) A licensee shall keep a record of individuals receiving instruction required by (1), (2), and (3), above, which includes a description of the instruction, 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.
- R2 (6) A licensee shall take the following safety precautions for each patient receiving brachytherapy or radiopharmaceutical therapy and hospitalized:
  - (a) Post the patient'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) Authorize visits by individuals under 18 years of age only with the approval of the authorized user after consultation with the radiation safety officer.

- (c) 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 64E-5.312. 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.
- (d) 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.
- (e) Notify the radiation safety officer or the authorized user immediately if the patient dies or has a medical emergency.

R2 (7) A licensee shall provide a private room with a private sanitary facility for a radiopharmaceutical therapy patient. The licensee shall not place a brachytherapy patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of 64E-5.312(1)(c), at a distance of 1 meter from the implant.

R2 (8) A licensee shall take these additional safety precautions for radiopharmaceutical therapy patients who are hospitalized:

- (a) Monitor material and items removed from the patient'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<sup>2</sup> and a minimum probe diameter of 1.5 inches.
- (c) Establish a bioassay program to measure the thyroid burden of each individual who helped prepare or administer a dosage of liquid iodine 131 within 3 days after administering the dosage, and retain for the period required by 64E-5.339(5) a record of each thyroid burden measurement, the date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. Action levels and corresponding actions will be in accordance with the U.S. Nuclear Regulatory Commission's Regulatory Guide 8.20, Revision 1, September, 1979.

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 May 15, 1996, Formerly 10D-91.721.

**SUBPART C**  
**UPTAKE, DILUTION, AND EXCRETION**

**64E-5.626 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion**

R3 **Studies.** A licensee is allowed to use any radioactive material in a radiopharmaceutical for a  
R3 diagnostic use involving measurements of uptake, dilution, or excretion for medical use that is  
R3 either:

R3 (1) Obtained from a manufacturer or pharmacy licensed as specified in  
R3 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory Commission or  
R3 Agreement State regulations; or

R3 (2) Prepared by an authorized nuclear pharmacist as specified in Rule  
R3 64B16-28.903, F.A.C., or by a physician who is an authorized user.

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.

R3 History: New August 25, 1991, Formerly 10D-91.733, Amended August 6, 2001.

**SUBPART D**  
**IMAGING AND LOCALIZATION**

**64E-5.627 Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.**

(1) A licensee is allowed to use any radioactive material in a diagnostic radiopharmaceutical, except in an aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for medical use that is either:

R3 (a) Obtained from a manufacturer or pharmacy licensed as specified in  
R3 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory  
R3 Commission or Agreement State regulations; or

R3 (b) Prepared by an authorized nuclear pharmacist as specified in Rule  
R3 64B16-28.903, F.A.C., or by a physician who is an authorized user.

(2) A licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the department and the requirements of 64E-5.629 are met.

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.

R3 History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.735, Amended August 6, 2001.

**64E-5.628 Permissible Molybdenum 99 Concentration.**

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

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

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

- (a) The measured activity of the technetium expressed in millicuries (megabecquerels);
  - (b) The measured activity of molybdenum expressed in microcuries (kilobecquerels);
  - (c) The ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium);
  - (d) The date of the test; and
  - (e) The initials of the individual who performed the test.
- (4) A licensee shall report immediately to the department each occurrence of molybdenum 99 concentration exceeding the limits specified in 64E-5.628(1).

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 August 25, 1991, Formerly 10D-91.736.

#### **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 64E-5.629(4) at the area of use and require that individuals evacuate the room until the posted time has elapsed if a gas spill occurs.
- (6) A licensee shall check the operation of collection systems monthly 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 64E-5.629(4) shall be recorded and retained for the duration of the license.

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 August 25, 1991, Amended January 1, 1994, Formerly 10D-91.737.

## SUBPART E RADIOPHARMACEUTICALS FOR THERAPY

**64E-5.630 Use of Radiopharmaceuticals for Therapy.** A licensee may use any R3 radioactive material in a radiopharmaceutical and for a therapeutic **medical use that is either:**

- R3 (1) Obtained from a manufacturer or pharmacy licensed as specified in  
R3 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory Commission or  
R3 Agreement State regulations; or
- R3 (2) Prepared by an authorized nuclear pharmacist as specified in Rule  
R3 64B16-28.903, F.A.C., or by a physician who is an authorized user.

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.

R3 History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.739, Amended August 6, 2001.

## SUBPART F SEALED SOURCES FOR DIAGNOSIS

**64E-5.631 Use of Sealed Sources for Diagnosis.** A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for diagnosis:

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

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 August 25, 1991, Formerly 10D-91.743.

## SUBPART G SOURCES FOR BRACHYTHERAPY

**64E-5.632 Use of Sources for Brachytherapy.** A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for brachytherapy:

- (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;
- (8) Radon 222 as seeds for interstitial treatment of cancer; and
- (9) Radium 226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer.

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 August 25, 1991, Formerly 10D-91.745.

### **64E-5.633 Brachytherapy Sources Inventory.**

- (1) 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.
- (2) A licensee shall make a record of the use of brachytherapy sources which includes:
  - (a) The names of the individuals permitted to handle the sources;
  - (b) The number and activity of sources removed from storage, the room number of use and patient's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and
  - (c) The number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.
- (3) Immediately after implanting sources in a patient and immediately after removal of sources from a patient, the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.
- (4) A licensee shall maintain the records required in 64E-5.633(2) and (3) 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 August 25, 1991, Formerly 10D-91.748.

## SUBPART H TELE THERAPY

**64E-5.634 Use of Sealed Source in a Teletherapy Unit.** A licensee shall follow the manufacturer's radiation safety and operating instructions and use only cobalt 60 or cesium 137 as a sealed source in a teletherapy unit for medical use.

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 August 25, 1991, Formerly 10D-91.751.

**64E-5.635 Maintenance and Repair Restrictions.** Only a person specifically licensed by the department, the U.S. Nuclear Regulatory Commission, or an agreement state to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source. Only such a person shall maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

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 August 25, 1991, Formerly 10D-91.752.

**64E-5.636 Amendments.** In addition to the requirements specified in 64E-5.602, a licensee shall apply for and receive a license amendment or departmental approval before:

- (1) Making any change in the treatment room shielding;
- (2) Making any change in the location of the teletherapy unit within the treatment room;
- (3) Using the teletherapy unit in a manner that could increase radiation levels in areas outside the teletherapy treatment room;
- (4) Relocating the teletherapy unit; or
- (5) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

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 August 25, 1991, Formerly 10D-91.753.

### **64E-5.637 Doors, Interlocks, and Warning Systems.**

- (1) A licensee shall control access to the teletherapy room by a door at each entrance.
- (2) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:
  - (a) Prevent the operator from turning on the primary beam of radiation unless each treatment room entrance door is closed;
  - (b) Turn off the beam of radiation immediately when an entrance door is

opened; and

- (c) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

- (3) A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.

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 August 25, 1991, Formerly 10D-91.755.

#### **64E-5.638 Radiation Monitoring Devices.**

- (1) A licensee shall have a permanent radiation monitor in each teletherapy room capable of continuously monitoring beam status.
- (2) Each radiation monitor shall be capable of providing visible notice of a teletherapy 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 room.
- (3) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy 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 is used.
- (5) A licensee shall maintain a record of the check required by 64E-5.638(4) 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 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 64E-5.638(5).
- (7) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

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 August 25, 1991, Formerly 10D-91.757.

**64E-5.639 Viewing Systems.** A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

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 August 25, 1991, Formerly 10D-91.758.

**64E-5.640 Dosimetry Equipment.**

- (1) A licensee shall have a dosimetry system available for use calibrated by (a) or (b) below.
  - (a) The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine within the previous 2 years and after any servicing that may have affected the 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 National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. 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 cobalt 60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt 60 source. When intercomparing dosimetry systems to be used for calibrating cesium 137 teletherapy units, the licensee shall use a teletherapy unit with a cesium 137 source.
- (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 64E-5.640(1). 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:
  - (a) The date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 64E-5.640(1) and (2);
  - (b) The correction factors that were determined;

- (c) The names of the individuals who performed the calibration, intercomparison, or comparison; and
- (d) Evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

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 August 25, 1991, Formerly 10D-91.759.

**64E-5.641 Full Calibration Measurements.**

- (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 64E-5.640 to measure the output for one set of exposure conditions. The remaining radiation measurements required in 64E-5.641(2)(a) may be made using a dosimetry system that indicates relative dose rates.
- (4) A licensee shall make full calibration measurements required by 64E-5.641(1) using either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, which is herein incorporated by reference effective May 12, 1993; or procedures recommended by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213, which is herein incorporated by reference effective May 12, 1993; or equivalent procedures that have been approved by the department.
- (5) A licensee shall correct mathematically the outputs determined in 64E-5.641(2)(a) for physical decay monthly for cobalt 60 and at least every 6 months for cesium 137.
- (6) Full calibration measurements required by 64E-5.641(1) and physical decay corrections required by 64E-5.641(5) shall be performed by the teletherapy physicist named on the licensee's license.
- (7) A licensee shall maintain a record of each calibration for the duration of the license. 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 tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy;
  - (e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
  - (f) The measured timer accuracy for a typical treatment time;
  - (g) The calculated on-off error;
  - (h) The estimated accuracy of each distance measuring or localization device; and
  - (i) The signature of the teletherapy physicist.

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 August 25, 1991, Amended May 12, 1993, Formerly 10D-91.760.

### **64E-5.642 Periodic Spot-Checks.**

- (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 64E-5.642(2)(e) 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 64E-5.640 to make the spot-check required in 64E-5.642(2)(e).
- (4) A licensee shall perform spot-checks required by 64E-5.642(1) following procedures established by the teletherapy physicist.
- (5) A licensee shall have the teletherapy 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 safety spot-checks of each teletherapy facility monthly.
- (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;
  - (c) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

- (d) Viewing 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.
- (8) A licensee shall lock the control console in the off position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the department.
- (9) A licensee shall promptly repair any system identified in 64E-5.642(7) 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) and (6) for 3 years. 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
  - (j) The signature of the individual who performed the periodic spot-check.

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 August 25, 1991, Formerly 10D-91.761.

**64E-5.643 Radiation Surveys for Teletherapy Facilities.**

- R2 (1) The licensee shall perform radiation surveys with an operable radiation survey 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 which an amendment is required by Rule 64E-5.636, F.A.C.
- R2 (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  $\mu$ Sv) per hour and 2 millirems (20  $\mu$ Sv) per hour.
- R2 (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 cause any occupationally exposed individuals to receive a dose in excess of the limits specified in Rule 64E-5.304, F.A.C.; and radiation dose rates of any individual member of the public in unrestricted areas shall not exceed the limits specified in Rule 64E-5.312(1)(c), F.A.C.
- R2 (2) If the results of the surveys required in 64E-5.643(1) 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

(h) The signature of the radiation safety officer or the teletherapy physicist.

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.

R2 History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.762, **Amended October 8, 2000.**

#### **64E-5.644 Safety Spot-Checks for Teletherapy Facilities.**

- (1) A licensee shall promptly spot-check all systems listed in 64E-5.642(7) for proper functioning after each installation of a teletherapy source and after making any change for which an amendment is required by 64E-5.636.
- (2) If the results of the safety spot-checks required in 64E-5.644(1) indicate the malfunction of any system specified in 64E-5.642, the licensee shall lock the control console in the off position and not use the unit except to repair, replace, or check the malfunctioning system.
- (3) A licensee shall maintain a record of the facility spot-checks following installation of a source for 3 years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer or the teletherapy physicist.

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 August 25, 1991, Formerly 10D-91.763.

#### **64E-5.645 Modification of Teletherapy Unit or Room Before Beginning a**

R2 **Treatment Program.** If the survey required by **Rule 64E-5.643, F.A.C.**, indicates that **any**  
 R2 individual **member of the public is likely to receive a dose in excess of those specified in Rule**  
 64E-5.312(1)(c), **F.A.C.**, before beginning the treatment program the licensee shall comply  
 with (1) or (2) below:

- R2 (1) Equip the unit with stops or add additional radiation shielding to ensure  
 R2 compliance with **Rule 64E-5.312(1)(c), F.A.C.**; perform the survey required by  
 R2 **Rule 64E-5.643, F.A.C.**, again; and include in the report required by **Rule**  
 R2 64E-5.646, **F.A.C.**, the results of the initial survey, a description of the  
 R2 modification made to comply with **Rule 64E-5.645(1), F.A.C.**, and the results of  
 the second survey.
- (2) Request and receive a license amendment as provided in 64E-5.312(3) that  
 authorizes radiation levels in unrestricted areas greater than those permitted by  
 64E-5.312(1)(c).

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.

R2 History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.764, **Amended October 8, 2000.**

#### **64E-5.646 Reports of Teletherapy Surveys, Checks, Tests, and Measurements.**

A licensee shall furnish a copy of the records required in 64E-5.643, 64E-5.644, and 64E-5.645 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 64E-5.641 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 August 25, 1991, Formerly 10D-91.765.

### **64E-5.647 Five Year Inspection.**

- (1) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy 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;
  - (b) The inspector's license number;
  - (c) The date of inspection;
  - (d) The manufacturer's name and model number and serial number for both the teletherapy 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.

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 August 25, 1991, Formerly 10D-91.766.

## **SUBPART I TRAINING AND EXPERIENCE REQUIREMENTS**

**64E-5.648 Radiation Safety Officer.** Except as provided in 64E-5.657, the licensee shall require the radiation safety officer to be certified as specified in (1) below or to complete 200 hours of classroom and laboratory training as specified in (2) below or to be an authorized user identified on the licensee's license.

- (1) Certification shall be by:
  - (a) American Board of Health Physics in Comprehensive Health Physics;
  - (b) American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics;

- (c) American Board of Nuclear Medicine;
  - (d) American Board of Science in Nuclear Medicine; or
  - (e) Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science.
- (2) Classroom and laboratory training shall consist of the following:
- (a) One hundred hours of radiation physics and instrumentation;
  - (b) Thirty hours of radiation protection;
  - (c) Twenty hours of mathematics pertaining to the use and measurement of radioactivity;
  - (d) Twenty hours of radiation biology;
  - (e) Thirty hours of radiopharmaceutical chemistry; and
  - (f) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer on a department, agreement state, licensing state, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material.

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 August 25, 1991, Formerly 10D-91.767.

**64E-5.649 Training for Uptake, Dilution, or Excretion Studies.** Except as provided in 64E-5.657, the licensee shall require the authorized user of a radiopharmaceutical listed in 64E-5.626 to be certified as specified in (1) below or to complete training and experience as specified in (2) below or to complete training as specified in (3) below.

- (1) Certification shall be in:
- (a) Nuclear medicine by the American Board of Nuclear Medicine;
  - (b) Diagnostic radiology by the American Board of Radiology;
  - (c) Diagnostic radiology or radiology within the previous 5 years by the American Osteopathic Board of Radiology; or
  - (d) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine.
- (2) Training and experience shall be as follows:
- (a) Forty hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, including:
    - 1. Fifteen hours of radiation physics and instrumentation;

2. Ten hours of radiation protection;
  3. Five hours of mathematics pertaining to the use and measurement of radioactivity;
  4. Five hours of radiation biology; and
  5. Five hours of radiopharmaceutical chemistry.
- (b) Twenty hours of training under the supervision of an authorized user including:
1. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
  2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
  3. Administering dosages to patients and using syringe radiation shields;
  4. Collaborating with the authorized user in the interpretation of radionuclide test results; and
  5. Patient follow-up.
- (3) Training shall be a 6 month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and shall include classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 64E-5.649(2).

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 August 25, 1991, Formerly 10D-91.769.

**64E-5.650 Training for Imaging and Localization Studies.** Except as provided in 64E-5.657, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 64E-5.627 to be certified as specified in (1) below or to complete training and experience as specified in (2) below or to complete training as specified in (3) below.

- (1) Certification shall be in:
- (a) Nuclear medicine by the American Board of Nuclear Medicine;
  - (b) Diagnostic radiology by the American Board of Radiology;
  - (c) Diagnostic radiology or radiology within the previous 5 years by the American Osteopathic Board of Radiology; or
  - (d) Nuclear medicine by the American Osteopathic Board of Nuclear

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- (2) Training and experience shall be as follows:
- (a) Two hundred hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, including:
1. One hundred hours of radiation physics and instrumentation;
  2. Thirty hours of radiation protection;
  3. Twenty hours of mathematics pertaining to the use and measurement of radioactivity;
  4. Thirty hours of radiopharmaceutical chemistry; and
  5. Twenty hours of radiation biology.
- (b) Five hundred hours of work experience under the supervision of an authorized user at a medical institution including:
1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
  3. Calculating and safely preparing patient dosages;
  4. Using administrative controls to prevent the misadministration of radioactive material;
  5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
  6. Eluting technetium 99m from generator systems, assaying and testing the eluate for molybdenum 99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium 99m labeled radiopharmaceuticals.
- (c) Five hundred hours of clinical experience under the supervision of an authorized user at a medical institution including:
1. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
  2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

3. Administering dosages to patients and using syringe radiation shields;
  4. Collaborating with the authorized user in the interpretation of radionuclide test results; and
  5. Patient follow-up.
- (d) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.
- (3) Training shall be a 6 month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and shall include classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 64E-5.650(2).

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 August 25, 1991, Formerly 10D-91.770.

**64E-5.651 Training for Therapeutic Use of Radiopharmaceuticals.** Except as provided in 64E-5.657, the licensee shall require the authorized user of a radiopharmaceutical listed in 64E-5.630 for therapy to be certified as specified in (1) below or to complete training and experience as specified in (2) below.

- (1) Certification shall be by one of the following groups:
  - (a) The American Board of Nuclear Medicine; or
  - (b) The American Board of Radiology in radiology, radiation oncology, or therapeutic radiology.
- (2) Training and experience shall be as follows:
  - (a) Eighty hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals including:
    1. Twenty five hours of radiation physics and instrumentation;
    2. Twenty five hours of radiation protection;
    3. Ten hours of mathematics pertaining to the use and measurement of radioactivity; and
    4. Twenty hours of radiation biology.
  - (b) Clinical experience under the supervision of an authorized user at a medical institution, including:

1. Use of iodine 131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals;
  2. Use of soluble phosphorus 32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;
  3. Use of iodine 131 for treatment of thyroid carcinoma in three individuals; and
  4. Use of colloidal chromic phosphorus 32 or of colloidal gold 198 for intracavitary treatment of malignant effusions in three individuals.
- (c) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.

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 August 25, 1991, Formerly 10D-91.771.

**64E-5.652 Training for Therapeutic Use of Brachytherapy Sources.** Except as provided in 64E-5.657, the licensee shall require the authorized user of a brachytherapy source specified in 64E-5.632 to be in the active practice of therapeutic radiology. In addition, the individual shall be certified as specified in (1) below or shall complete training and experience as specified in (2) below.

- (1) Certification shall be in:
  - (a) Radiology, radiation oncology or therapeutic radiology by the American Board of Radiology;
  - (b) Radiation oncology by the American Osteopathic Board of Radiology;
  - (c) Radiology, with a specialization in radiotherapy, as a British Fellow of the Faculty of Radiology or Fellow of the Royal College of Radiology; or
  - (d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.
- (2) Training and experience shall be as follows:
  - (a) Two hundred hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources including:

1. One hundred and ten hours of radiation physics and instrumentation;
  2. Forty hours of radiation protection;
  3. Twenty five hours of mathematics pertaining to the use and measurement of radioactivity; and
  4. Twenty five hours of radiation biology.
- (b) Five hundred hours of work experience under the supervision of an authorized user at a medical institution including:
1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  2. Checking survey meters for proper operation;
  3. Preparing, implanting, and removing sealed sources;
  4. Using administrative controls to prevent the misadministration of radioactive material; and
  5. Using emergency procedures to control radioactive material.
- (c) Three years of supervised clinical experience including 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution, including:
1. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
  2. Selecting the proper brachytherapy source, dose, and method of administration;
  3. Calculating the dose; and
  4. Post-administration follow-up and review of case histories in collaboration with the authorized user.

- (d) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.

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 August 25, 1991, Formerly 10D-91.772.

**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 radiotherapy to be in the active practice of therapeutic radiology or ophthalmology. In addition, the individual shall be certified as specified in (1) below or shall complete training and experience as specified in (2) below.

- (1) Certification shall be in radiology, radiation oncology or therapeutic radiology by the American Board of Radiology.
- (2) Training and experience shall be as follows:
- (a) Twenty four hours of instruction in basic radionuclide handling techniques applicable to the use of strontium 90 for ophthalmic radiotherapy, including:
1. Six hours of radiation physics and instrumentation;
  2. Six hours of radiation protection;
  3. Four hours of mathematics pertaining to the use and measurement of radioactivity; and
  4. Eight hours of radiation biology.
- (b) Clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, including the use of strontium 90 for the ophthalmic treatment of five individuals that includes:
1. Examination of each individual to be treated;
  2. Calculation of the dose to be administered;
  3. Administration of the dose; and
  4. Follow-up and review of each individual's case history.
- (c) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.

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 August 25, 1991, Formerly 10D-91.773.

**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 to be a physician, dentist, or podiatrist who is certified as specified in (1) below or who has completed the training as specified in (2) below.

- (1) Certification shall be in:
  - (a) Radiology, diagnostic radiology, radiation oncology, or therapeutic radiology by the American Board of Radiology;
  - (b) Nuclear medicine by the American Board of Nuclear Medicine;
  - (c) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
  - (d) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine.
- (2) Training shall be 8 hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device, including:
  - (a) Three hours of radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
  - (b) Three hours of radiation biology; and
  - (c) Two hours of radiation protection and training in the use of the device for the purposes authorized by the license.

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 August 25, 1991, Formerly 10D-91.774.

**64E-5.655 Training for Teletherapy.** Except as provided in 64E-5.657, the licensee shall require the authorized user of a sealed source specified in 64E-5.634 in a teletherapy unit to be in the active practice of therapeutic radiology. In addition, the individual shall be certified as specified in (1) below or shall complete training and experience as specified in (2) below.

- (1) Certification shall be in:
  - (a) Radiology, radiation oncology, or therapeutic radiology by the American Board of Radiology;
  - (b) Radiation oncology by the American Osteopathic Board of Radiology;
  - (c) Radiology, with specialization in radiotherapy, as a British Fellow of the Faculty of Radiology or Fellow of the Royal College of Radiology; or

- (d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.
- (2) Training and experience shall be as follows:
- (a) Two hundred hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, including:
    - 1. One hundred and ten hours of radiation physics and instrumentation;
    - 2. Forty hours of radiation protection;
    - 3. Twenty five hours of mathematics pertaining to the use and measurement of radioactivity; and
    - 4. Twenty five hours of radiation biology.
  - (b) Five hundred hours of work experience under the supervision of an authorized user at a medical institution, including:
    - 1. Review of the full calibration measurements and periodic spot checks;
    - 2. Preparing treatment plans and calculating treatment times;
    - 3. Using administrative controls to prevent misadministrations;
    - 4. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
    - 5. Checking and using survey meters.
  - (c) Three years of supervised clinical experience including 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution, including:
    - 1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
    - 2. Selecting the proper dose and how it is to be administered;
    - 3. Calculating the teletherapy doses and collaborating with the authorized user in the review of patient's progress and consideration of the need to modify originally prescribed doses as warranted by patient's reaction to radiation; and

4. Post administration follow-up and review of case histories.
  - (d) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.

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 August 25, 1991, Formerly 10D-91.775.

**64E-5.656 Training for Teletherapy Physicist.** The licensee shall require the teletherapy physicist to be certified as specified in (1) below or meet the requirements specified in (2) below.

- (1) Certification shall be by the American Board of Radiology in:
  - (a) Therapeutic radiological physics;
  - (b) Roentgen-ray and gamma-ray physics;
  - (c) X-ray and radium physics; or
  - (d) Radiological physics.
- (2) Education and training shall be a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full-time training in therapeutic radiological physics and also 1 year of full-time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 64E-5.618, 64E-5.641, 64E-5.642, and 64E-5.643 under the supervision of a teletherapy physicist during the year of work experience.

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 August 25, 1991, Formerly 10D-91.776.

**64E-5.657 Training for Experienced Authorized Users or Radiation Safety Officers.** Authorized users or radiation safety officers identified on a department, U.S. Nuclear Regulatory Commission, agreement state or licensing state license on August 25, 1991 who perform only those methods of use for which they were authorized on that date need not comply with the applicable training requirements of 64E-5.648 through 64E-5.658.

Specific 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 August 25, 1991, Amended May 15, 1996, Formerly 10D-91.777.

**64E-5.658 Recentness of Training.** The training and experience specified in 64E-5.648 through 64E-5.656 shall have been obtained within the 5 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 5 years preceding the date of application.

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 August 25, 1991, Formerly 10D-91.779.