

## PART XIII

### RADIATION SAFETY REQUIREMENTS FOR POSSESSION AND USE OF SEALED OR UNSEALED SOURCES OF RADIOACTIVE MATERIALS

**64E-5.1301 Sealed or Unsealed Sources of Radioactive Material.** The rules in this part establish radiation safety requirements for licensees possessing or using sealed or unsealed sources of radioactive materials not otherwise specified in a license or addressed in these rules. The requirements of this part are in addition to and not in substitution for other applicable requirements of these rules. Licenses of broad scope are exempt from the requirements of Rule 64E-5.1313, subsections 64E-5.1318(2), and 64E-5.1319(1), (2), (3) and (4), F.A.C. **Except for Rule 64E-5.1320, F.A.C.,** the requirements of this part do not apply to persons licensed as specified in Parts IV, VI, and XI. General licensees as specified in subsections 64E-5.206(7) and (8), F.A.C., are exempt from the requirements of this part.

R10 **Rulemaking** Authority: 404.051, 404.061, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(10), 404.061(2)(3), 404.081(1), F.S.

R10 History: New 5-12-93, Amended 5-15-96, Formerly 10D-91.1401, **Amended 02-11-10.**

#### SUBPART A GENERAL REQUIREMENTS

**64E-5.1302 Operating and Emergency Procedures.** The licensee's operating and emergency procedures shall be posted in accordance with 64E-5.901 and shall accompany portable devices at all times. The procedures shall include instructions in the following as applicable to the type of use:

- (1) The uses of sources of radiation so that exposures are maintained as low as reasonably achievable and no individual is likely to be exposed to radiation doses in excess of the standards in Part III;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods and occasions for locking and securing sources of radiation;
- (4) Personnel monitoring and the use of personnel monitoring equipment;
- (5) Minimizing exposure of individuals in the event of an accident;
- (6) Notifying proper personnel in the event of damage, loss, theft, or accident involving sources of radiation;
- (7) General guidelines for the safe handling and use of unsealed sources of radioactive materials;
- (8) Maintenance of records;
- (9) Procedures for picking up, receiving and opening packages containing radioactive materials; and

- (10) The transportation of radioactive sources to temporary job sites, including the packaging, marking, labeling and placing of such sources in vehicles, placarding of vehicles, securing the sources during transportation and possessing proper shipping papers and emergency response information.

Specific Authority: 404.051, 404.061, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Amended January 1, 1994, Amended May 15, 1996, Formerly 10D-91.1403.

**64E-5.1303 Leak Test Requirements for Possession of Sealed Sources.**

- (1) A licensee in possession of a sealed source shall assure that:
- (a) The sealed source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the sealed source was tested semiannually before transfer to the licensee;
  - (b) The sealed source is tested for leakage at least semiannually or at intervals approved by the department;
  - (c) Leak tests are capable of detecting 0.005 microcurie (185 Bq) of radioactive material on the test sample, or, in the case of radium, the escape of radon of 0.001 microcurie (37 Bq) each 24 hours;
  - (d) Test samples are taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate; and
  - (e) Device test samples are taken when the sealed source is in the off or shielded position.
  - (f) Leak tests are analyzed by individuals who are licensed by the department, U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform leak test services.
- (2) A licensee shall retain leak test records for 3 years. The records shall contain the manufacturer's name, the model and serial numbers of each sealed source tested, the identity of each sealed 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 or designee.

- (3) 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.
- (4) A leak test is not required on the following sealed sources:
- (a) Sealed sources containing only radioactive material with a half-life of less than 30 days;
  - (b) Sealed sources containing only radioactive material as a gas;
  - (c) Sealed 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) Sealed sources that are listed on a department license for storage only. The licensee shall test each such sealed 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.
- (5) The department is authorized to approve leak test frequencies other than semiannually. Criteria used to determine these frequencies include:
- (a) The isotope and activity;
  - (b) The requested usage;
  - (c) The environmental hazards to which the sealed sources may potentially be exposed;
  - (d) The manufacturer's recommended frequency; and
  - (e) Specific information on the sealed source or device provided by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, including:
    - 1. Sealed Source and Device Registry sheets;
    - 2. Naturally Occurring or Accelerator Produced Radioactive Materials Sealed Source and Device Registry sheets.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1404.

**64E-5.1304 Inventory Requirements.** A licensee who possesses sealed sources shall conduct a physical inventory of all such sealed sources semiannually unless another interval is specified in the license. Inventory records shall be retained for 3 years. Inventory records shall contain the following:

- (1) The model and serial number of each sealed source;
- (2) The identity of each sealed source radionuclide and its estimated activity;
- (3) The location of each sealed source;
- (4) The date of the inventory; and
- (5) The signature of the radiation safety officer or designee.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1405.

**64E-5.1305 Training Requirements, Authority, Duties and Responsibilities of the Radiation Safety Officer.**

- (1) The licensee shall appoint a radiation safety officer with the authority to fulfill the duties and responsibilities listed in this part.
- (2) The radiation safety officer shall have sufficient training and experience with radioactive materials to be a user of the requested licensed materials, unless otherwise specified in the license. This training shall include practical experience in the safe use of radioactive materials and knowledge of procedures, facilities and equipment.
- (3) The duties and responsibilities of the radiation safety officer shall include the following:
  - (a) Ensure that all terms and conditions of the license and these regulations are complied with;
  - (b) Ensure that the sealed sources are leak tested timely and as prescribed by the manufacturer or by the license;
  - (c) Ensure that radioactive materials are used only by individuals who are authorized by the license and that all individuals wear required personnel monitoring equipment;
  - (d) Maintain all records required by the license and these regulations. These records shall include personnel monitoring records, leak test records, inventory records, training records for users and receipt, transfer and disposal records;
  - (e) Ensure that radioactive materials are properly secured against unauthorized access or removal;

- (f) Serve as a contact with the department for events such as the loss, theft or damage of radioactive material; and
- (g) Ensure that all users read and understand the licensee's emergency, operating and radiation safety procedures.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1406.

**64E-5.1306 Opening Sealed Sources.** Unless otherwise specifically licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such services, the licensee shall not open sealed sources.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1407.

**64E-5.1307 Training Requirements for Authorized Users.**

- (1) Radioactive materials shall be used by individuals who are qualified by training and experience to protect public health, safety and the environment. A description of this training must be submitted and approved by the department and include the following:
  - (a) Principles and fundamentals of radiation protection and safety practices related to the use of radioactive materials, including ALARA principles;
  - (b) Radioactivity measurements;
  - (c) Use of radiation detection instruments and monitoring techniques;
  - (d) Biological effects of radiation;
  - (e) Transportation of radioactive materials;
  - (f) Practical experience with the use of radioactive materials; and
  - (g) Licensee's operating and emergency procedures.
- (2) For licensees who propose to train their own personnel to be authorized users, the following must be provided to and approved by the department:
  - (a) Instructor qualifications, including training and experience with radioactive materials specifically relating to the topics of instruction;
  - (b) A detailed training program, including duration of training for each of the topics listed in (1) of this section;
  - (c) The method of testing the knowledge of students, such as a written and practical examination, and whether the examination is open or closed book; and

- (d) If an examination is used, the passing score, method of retesting students who do not pass and an example of the examination with the correct answers indicated.
- (3) Records of training shall be maintained during the employment of the individual or 5 years, whichever is greater.
- (4) Unless otherwise specified in the license, a licensee's authorized user training program is not transferable to another licensee.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1409.

**64E-5.1308 Additional Requirements for General Licenses.** Specific licensees authorized for a general license described in 64E-5.205(4), 64E-5.206(1), 64E-5.206(4) or 64E-5.206(6), shall comply with the regulations that are applicable to that general license and 64E-5.1304 and 64E-5.1305. Specific licensees authorized for the general license in 64E-5.205(4), or possess generally licensed devices described in 64E-5.206(1) or (4) are not required to remit the annual fees specified in 64E-5.204(1)(c)1., 2., or 5.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1410.

**64E-5.1309 Training for Current Authorized Users.** Individuals who are authorized users on a department, U.S. Nuclear Regulatory Commission, agreement state or licensing state license on May 12, 1993 who perform only those procedures for which they are authorized on that date need not comply with the training requirements in 64E-5.1307, 64E-5.1312 and 64E-5.1313.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1411.

**64E-5.1310 Personnel Monitoring.**

- R2 (1) Unless otherwise specified in the license, no licensee shall permit any individual to use or to assist in the use of sealed sources of radiation in portable devices unless such individual wears a film badge, **OSLD**, or a TLD.
- R2 (2) Unless otherwise specified in the license, no license shall permit any individual to perform installations, maintenance or service, initial radiation surveys, relocations or removal from service of sealed sources in fixed devices unless such individual wears a film badge, **OSLD**, or a TLD.
- (3) Licensees who use iodine 125, iodine 131, hydrogen 3, uranium 234, uranium 235 or uranium 238 and are required to have a bioassay program must submit a description of their bioassay program for approval by the department.

- R2 (4) A whole body film badge, OSLD, or TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of any gamma-emitting isotope with a gamma ray energy greater than 50 kiloelectron volts or the use of any beta-emitting isotope with a maximum beta energy of 300 kiloelectron volts or more.
- R2 (5) An extremity film badge or, OSLD, TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of 1,000 microcuries (37 MBq) or more of beta-emitting isotopes with a maximum beta energy of 1,000 kiloelectron volts or more in any month or by any individual who receives a dose of 40 millirem (400 µSv) or more on a whole body film badge, OSLD, or TLD for 2 consecutive months.
- R2 (6) Each film, OSLD, and TLD badge shall be assigned to and worn by only one individual. Film badges and extremity OSLDs and TLDs must be replaced monthly. Whole body OSLDs and TLDs must be replaced quarterly. After replacement, each film badge, OSLD, and TLD must be promptly processed.

Specific Authority 404.051, 404.061, 404.081, F.S.  
Law Implemented 404.022, 404.051(1), (4), (6), (10), 404.061(2), 404.081(1)(2), F.S.  
R2 History--New May 15, 1996, Formerly 10D-91.1411, Amended October 8, 2000.

**SUBPART B**  
**REQUIREMENTS FOR THE POSSESSION AND USE OF**  
**SEALED SOURCES IN PORTABLE DEVICES**

**64E-5.1311 Storage, Security and Transportation Precautions**

- (1) Each sealed source of radioactive material shall be provided with a storage or transport container. The container shall be equipped with a lock or tamper seal to prevent unauthorized removal of or exposure to the source of radiation.
- R6 (2) All portable gauge licensees must comply with either paragraph (2)(a) or (2)(b) below. Effective January 1, 2007, portable gauge licensees must comply only with paragraph (2)(b).
  - R6 (a) Sealed sources must have a minimum of two locks between the device and the public when being transported or stored.
  - R6 (b) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.
- (3) Transport containers shall be physically secured in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal. The sealed source shall be transported as far away from occupied areas of the vehicle as possible.
- (4) Sealed sources not in storage or being transported must be under the constant surveillance and immediate control of the licensee.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.  
Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.  
R6 History: New May 12, 1993, Formerly 10D-91.1412, Amended September 28, 2006.

**64E-5.1312 Training and User Requirements.**

- (1) Users of sealed sources in portable devices must have completed a minimum of 8 hours of training from individuals approved by the department. This training must include the areas described in 64E-5.1307.
- (2) Documentation of training for each user must be maintained for the duration of employment or 5 years, whichever is greater.
- (3) Sealed sources in portable devices may be used by individuals who are under the direct supervision and in the physical presence of an authorized user.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1415.

**SUBPART C  
REQUIREMENTS FOR THE POSSESSION AND USE OF  
SEALED SOURCES IN FIXED DEVICES**

**64E-5.1313 Training and User Requirements.** Unless otherwise specifically licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such services, the licensee shall not remove sealed sources from source holders; remove source holders containing sealed sources from devices; perform maintenance or repair of devices or source holders containing sealed sources, including repair or maintenance of the shutter; perform installations, replacement, removal from service, relocations, or disposal of sealed sources, source holders or devices containing sealed sources; or perform initial radiation surveys of devices or source holders.

- (1) Users of sealed sources in fixed devices must have completed a minimum of 8 hours of training from individuals approved by the department. This training must include the areas described in 64E-5.1307.
- (2) Individuals who perform installations, maintenance or service, initial radiation surveys, relocations, or removal from service must have completed a minimum of 40 hours of training from individuals approved by the department. This training must include the following:
  - (a) The principles and fundamentals of radiation protection and safety practices related to the use of radioactive material;
  - (b) Radiation measurements, use of radiation detection instruments and monitoring techniques;
  - (c) Biological effects of radiation;
  - (d) Procedures for performing services; and
  - (e) Actual practice in performing the services.



- (3) Documentation of training for each user must be maintained for the duration of employment or 5 years, whichever is greater.
- (4) Sealed sources in fixed devices may be used by individuals under the supervision of an authorized user. An authorized user must be available at all times when sealed sources in fixed devices are being used.
- (5) Installations, maintenance or service, initial radiation surveys, relocations or removal from service may be performed by individuals who are under the direct supervision and in the physical presence of an individual who is an authorized user for these operations.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1418.

**64E-5.1314 Possession of Survey Instruments.** A licensee authorized to perform installations, maintenance or service, initial radiation surveys, relocations or removal from service of sealed sources in fixed devices shall possess portable radiation survey instruments with a range from 1 millirem (10  $\mu$ Sv) per hour to 200 millirem (2 mSv) per hour. The instruments shall be operable and calibrated as provided in 64E-5.314.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Amended January 1, 1994, Formerly 10D-91.1419.

**64E-5.1315 Additional Requirements.** A licensee must post and provide to personnel lock-out procedures that prevent employees from entering the radiation beam during maintenance, repairs, or other work in, on, or around a bin, tank, hopper or pipe on which a device is mounted. The department is authorized to require a physical barrier around certain types of devices where the possibility exists that an individual could be exposed to the beam of radiation.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1420.

## SUBPART D REQUIREMENTS FOR POSSESSION AND USE OF UNSEALED SOURCES OF RADIOACTIVE MATERIALS

**64E-5.1316 General Rules for the Safe Use of Unsealed Sources of Radioactive Materials.** The licensee shall assure that all individuals who handle unsealed sources of radioactive materials comply with the following, unless otherwise specified in the license:

- (1) Laboratory coats or other protective clothing are worn at all times in areas where radioactive materials are used;
- (2) Disposable gloves are worn at all times while handling radioactive materials;
- (3) Eating, drinking, smoking, or applying cosmetics in any area where radioactive material is stored or used is prohibited;

- (4) Storing food, drinks, or personal effects in areas where radioactive material is stored or used is prohibited;
- (5) If applicable, personnel monitoring devices are worn at all times while in areas where radioactive materials are used or stored;
- (6) Radioactive waste is disposed of only in designated, labeled, and properly shielded receptacles; and
- (7) Radioactive materials are confined in clearly labeled appropriate containers.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1422.

**64E-5.1317 Storage and Control of Volatiles and Gases.**

- (1) A licensee shall store volatile radioactive materials and radioactive gases in the shippers' radiation shield and container or an equivalent shield and container.
- (2) Unless otherwise specified in the license, a licensee shall store and use radioactive volatiles and gases in a properly functioning glove box or fume hood that will maintain airborne concentrations within the limits prescribed by State of Florida Bureau of Radiation Control, ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 2 and Table II, Column 1.
- (3) Unless otherwise specified in the license, the glove box or fume hood shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the volatile or gas.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Amended January 1, 1994, Formerly 10D-91.1423.

**64E-5.1318 Instrumentation**

- (1) The licensee shall have instruments available to detect radioactive materials listed on the license, unless otherwise authorized by the department. Instrumentation shall be sensitive enough to detect activities required for adequate contamination control described in this part.
- (2) The licensee must submit a description of the equipment and procedures to be followed in measuring contamination for departmental approval. These procedures shall include the following:
  - (a) Type of instrument detection system used, such as a Geiger-Mueller or scintillation detector with a scaler, single or multichannel analyzer, and type of radiation detected;
  - (b) Background counting times and average background counts;
  - (c) Sample counting times;

- (d) Instrument efficiency and calculation of efficiency determination;
  - (e) Instrument's lower limit of detection using the sample counting time and the isotope and activity of calibration standards;
  - (f) Sample calculation converting counting results into activity or activity per unit time, if applicable; and
  - (g) Frequency of instrument calibration.
- (3) If portable radiation survey instruments are used to determine compliance with the contamination control action levels described in this part, the instruments shall be operable and calibrated as provided in 64E-5.314.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Amended January 1, 1994, Formerly 10D-91.1425.

**64E-5.1319 Contamination Control Program.** The licensee shall establish and submit for department approval a contamination control program to limit the spread of unsealed sources of radioactive materials. This program shall include contamination action levels, corresponding actions taken if these levels are exceeded, frequency of measurement and maintenance of records.

- (1) Unless otherwise specified in the license, the licensee shall perform the following:
- (a) A survey with a radiation survey instrument shall be completed at the end of each day of use or receipt of all areas where radioactive materials are used or received.
  - (b) A weekly survey with a radiation survey instrument shall be completed of all areas where radioactive materials or radioactive waste are stored.
  - (c) A wipe survey shall be completed for removable contamination weekly during weeks of use of all areas where radioactive materials or waste are routinely used or stored.
  - (d) Surveys required by (1)(a)(b) and (f) of this section shall be completed with an instrument capable of measuring dose rates as low as 0.1 millirem (1  $\mu$ Sv) per hour, if applicable.
  - (e) A wipe survey shall be completed for removable contamination at the end of each day of use of all areas where radioactive materials are routinely used if the radioactive materials authorized by the license are not detectable with instruments described in (1)(d) above.
  - (f) Monitoring shall be performed of individuals for contamination prior to leaving the restricted area.
  - (g) The radiation safety officer shall be notified if the contamination detected during the surveys required by this section exceeds the action levels specified in (2), below.

- (2) Unless otherwise specified in the license, the licensee shall take the following actions if the corresponding action levels are exceeded:
- (a) Follow decontamination procedures and resurvey to determine effectiveness of decontamination efforts if the action levels are exceeded when conducting surveys described in (1)(a)(b) or (f) above;
  - (b) Follow emergency procedures if the radiation detected during the survey required in (1)(f) of this section is above action levels; and
  - (c) Follow decontamination procedures and resurvey to determine effectiveness of decontamination efforts if the action levels listed below are exceeded for the survey required in (1)(c) or (e) above;
    - 1. 100 dpm per 100 square centimeters of any alpha-emitting radioactive materials not listed in this section;
    - 2. 1,000 dpm per 100 square centimeters of any beta- or gamma-emitting radioactive materials not listed in this section;
    - 3. 50 dpm per 100 square centimeters of any transuranic;
    - 4. 2,000 dpm per 100 square centimeters of uranium; or
    - 5. 2,000 dpm per 100 square centimeters of any radioactive material with a half-life of less than 80 hours.
- (3) The licensee shall retain a record of each survey required by this section for 3 years. These records shall include:
- (a) The date of the survey;
  - (b) An annotated diagram of each area surveyed;
  - (c) Background levels;
  - (d) Measured dose rates, keyed to the diagram, expressed in millirem (microsieverts) per hour or the removable contamination, keyed to the diagram, expressed in dpm per 100 square centimeters, or counts per minute if performed with a radiation survey instrument, with the action level described in (2)(a) of this section;
  - (e) The serial number and 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.
- (4) Records of surveys described in (1)(f) need not be recorded unless the action level described in (2)(a) of this section is exceeded.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1426.

R10 **64E-5.1320 Bioassay Program.** The licensee shall establish and submit for  
 R10 department approval a bioassay program used to evaluate internal doses. At a minimum an  
 R10 acceptable program shall include the following action levels for organ uptakes, corresponding  
 R10 actions taken if these levels are exceeded, frequency of measurement and maintenance of  
 R10 records.

R10 (1) Routine bioassay is required when an individual handles in open form unsealed  
 R10 quantities of radioactive iodine that exceed those shown in the table 1 below.  
 R10 The quantities shown apply to both the quantity handled at any one time or  
 R10 integrated as the total amount of activity introduced into a process by an  
 R10 employee over any 3-month period.

R10

TABLE 1		
I-125 or I-131 Activity Handled in Unsealed Form Requiring Bioassay		
Type of Operation	Volatile or Dispersible	Bound to Nonvolatile Agent
Processes in open room or bench, with possible escape of iodine from process vessels	1.0 mCi (37 MBq)	1.0 mCi (37 MBq)
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	1.0 mCi (37 MBq)	10.0 mCi (370 MBq)
Processed carried out within glove boxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	10.0 mCi (370 MBq)	100.0 mCi (3700 MBq)

R10 (a) A bioassay shall be taken within 72 hours of initial use of radioiodine and  
 R10 every 2 weeks thereafter. When radioiodine use is on an infrequent basis  
 R10 (less than every 2 weeks), a bioassay shall be taken within 10 days of the  
 R10 last day of use.

R10 (b) If the thyroid burden at the time of measurement exceeds 0.12 microcurie  
 R10 (4.44 KBq) of iodine 125 or 0.04 microcurie (1.48 KBq) of iodine 131, the  
 R10 following actions shall be taken:

- R10 1. An investigation of the operations involved, including air and other  
 R10 facility surveys, shall be carried out to determine the cause(s);
- R10 2. Corrective actions that will eliminate or lower the potential for  
 R10 further exposures shall be implemented;
- R10 3. A repeat bioassay shall be taken within 2 weeks of the previous  
 R10 measurement and shall be evaluated within 24 hours after the  
 R10 measurement in order to confirm the presence of internal  
 R10 radioiodines; and

R10 4. Notification reports must be provided as required by Rules  
 R10 64E-5.345, and 64E-5.347, F.A.C., or as required by conditions of  
 R10 the license; and

R10 (c) A record of each bioassay shall be maintained for inspection by the  
 R10 department in an auditable form for 3 years and shall include the date of  
 R10 the bioassay, the name of the individual, and the thyroid burden at the  
 R10 time of the measurement.

R10 (2) Routine bioassay is required when an individual handles in open form unsealed  
 R10 quantities of tritium that exceed those shown in table 2 below. The quantities  
 R10 shown apply to both the quantity handled at any one time or integrated as the  
 R10 total amount of activity introduced into a process by an employee over a 1-month  
 R10 period.

R10

TABLE 2		
Tritium Activity Handled in Levels or Concentrations Requiring Bioassay		
Type of Operation	HTO and Other Tritiated Compounds (Including Nucleotide Precursors)	Tritium (HT or T) Gas in Sealed Process Vessels
Processes in open room or bench with possible escape of tritium from process vessels	0.1 Ci ( 3.70 GBq)	100 Ci (3.7 TBq)
Processes with possible escape of tritium carried out within a fume hood of adequate design, face velocity, and performance reliability	1 Ci (37 GBq)	1,000 Ci (37 TBq)
Processes carried out within glove boxes that are ordinarily closed but with possible release of tritium <sup>1</sup> from process vessels and occasional exposure to contaminated box and leakage	10 Ci (370 GBq)	10,000 Ci (370 TBq)

R10 (a) A bioassay shall be taken within 72 hours of initial use of tritium and every  
 R10 2 weeks thereafter. When work with tritium is on an infrequent basis (less  
 R10 frequent than every 2 weeks), a bioassay shall be taken within 10 days of  
 R10 the last day of use.

R10 (b) If the urinary tritium concentration exceed 5 microcuries (185 KBq) per liter  
 R10 at the time of the measurement the following actions shall be taken:

R10 1. An investigation of the operations involved, including air and other  
 R10 facility surveys, shall be carried out to determine the cause(s);

R10 2. Corrective actions that will eliminate or lower the potential for  
 R10 further exposures shall be implemented;

- R10 3. A repeat bioassay shall be taken within 1 week of the previous  
R10 measurement and shall be evaluated within 1 week after the  
R10 measurement. Internal dose commitments shall be estimated using  
R10 at least two bioassays and other survey data, including the  
R10 probable times of intake of tritium; and
- R10 4. Notification reports must be provided as required by Rules  
R10 64E-5.345, and 64E-5.347, F.A.C., or as required by conditions of  
R10 the license; and
- R10 (c) A record of each bioassay shall be maintained for inspection by the  
R10 department in an auditable form for 3 years and shall include the date of  
R10 the bioassay, the name of the patient, and the urinary tritium concentration  
R10 at the time of the measurement.

R10 Rulemaking Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081 FS.

R10 Law Implemented: 404.022, 404.042, 404.051(1), (4), (6), (9), (10), 404.061(2), (3), 404.071(1), 404.081(1) FS..

R10 History: New 02-11-10

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