

March 2007

**Bureau of Radiation Control  
RADIOACTIVE MATERIALS SECTION  
Information Notice 2007-02**

***Additional requirements for licensees who possess or transfer certain generally licensed (GL) devices***

This information notice serves to summarize and explain the additional requirements applicable to persons who possess or transfer certain generally licensed (GL) radioactive measuring, gauging or controlling devices as described in subsection 64E-5.206(4), Florida Administrative Code, (F.A.C.). Revision 6 to Part II, Subpart B, Chapter 64E-5, F.A.C., dated September 28, 2006, incorporates these additional requirements.

1. Paragraph 64E-5.206(4)(c)**10**, F.A.C., requires that a licensee obtain written authorization from the department before transferring a generally licensed device to specific licensees not identified in paragraph 64E-5.206(4)(c) and subsection 64E-5.206(7), F.A.C. Department authorization will be granted provided the specific license (to which the device will be transferred) lists the device in items 6, 7 and 8 of the license. To expedite the authorization of your transfer, include a copy of the license to which the device(s) will be transferred, with your request.
2. Paragraph 64E-5.206(4)(c)**11**, F.A.C., requires licensees to delegate authority and responsibility to a knowledgeable individual who is required to comply with applicable regulations, in a timely manner. With your next billing, the department will be requesting you to furnish the name, title, phone number and e-mail address of this individual. If applicable, provide the same information for your alternate contact person.
3. Paragraph 64E-5.206(4)(c)**12**, F.A.C., requires licensees to annually register each generally licensed device, except exit signs containing tritium. Registration sheets for new devices will be provided to each licensee at the time of the annual invoicing. These sheets will request specific information regarding the licensee, device information and device location. Previously registered device(s) will appear on an inventory sheet provided by the department. After reviewing this inventory sheet for accuracy, make applicable corrections and return it to the department.
4. Paragraph 64E-5.206(4)(c)**13**, F.A.C., requires licensees to report changes in the company's mailing addresses for each location of use, within 30 days of the effective date of the change. For portable devices, a report of address change is required for a change in the device's primary place of storage.
5. Paragraph 64E-5.206(4)(c)**14**, F.A.C., specifies that licensees may not hold devices that are not in use for longer than 2 years. Shutters must be locked in the closed position on all devices that are no longer in use. Devices kept on stand by for future use are excluded from the two-year time line if the required physical inventories are completed every three months.
6. Paragraph 64E-5.213(3)(a), F.A.C., requires that general licensees shall notify the department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code (U.S.C.).

We advise general licensees to review the enclosed attachment 1 "Select General License Regulations Listed in 64E-5 Florida Administrative Code (F.A.C.)". If you have any questions or need additional information please call us at (850) 245-4545. This document and others are available on our web site at [www.doh.state.fl.us/environment/radiation/](http://www.doh.state.fl.us/environment/radiation/).

**Attachment 1**  
**Select General License Regulation Listed in 64E-5 Florida Administrative Code (F.A.C.)**

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**64E-5.206(4) Certain Measuring, Gauging and Controlling Devices.**

- (a) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their businesses, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of (4)(b), (c) and (d), below, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.
- (b)1. The general license in (4)(a), above, applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to 64E-5.210(4) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State, which authorizes distribution of devices to persons granted a general license by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of 21 CFR Part 179.
- (b)2. The devices must have been received from one of the specific licenses described in (b)1., above or through a transfer made under subparagraph 6E-5.206(4)(c)8., F.A.C.
- (c) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in (4)(a), above;
1. Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;
  2. Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label. However,
    - a. Devices containing only krypton need not be tested for leakage of radioactive material; and
    - b. Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- or gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
  3. Shall assure that other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed:
    - a. In accordance with the instructions provided by the labels, or
    - b. By a person holding an applicable specific license from the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to perform such activities;
  4. Shall maintain records showing compliance with the requirements of (4)(c)2. and 3., above. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing testing, installation, servicing and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by (4)(c)2., above, shall be maintained for at least a year after the next required leak test is performed or until the transfer or disposal of the sealed source. Records of tests of the on-off mechanism and indicator required by (4)(c)2., above, shall be maintained for at least a year after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by (4)(c)3., above, shall be maintained for a period of at least 2 years from the date of the recorded event or until the transfer or disposal of the device;

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64E-5.206(4)(c) continued

5. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the department a report containing a brief description of the event and the remedial action taken; and in the case of removable radioactive materials or failure of or damage to a source likely to result in contamination of the premises or the environment, a plan for ensuring the premise and environment are acceptable for unrestricted use using the criteria described in Rule 64E-5.222, F.A.C.
6. Shall not abandon the device containing radioactive material;
7. Except as provided in (4)(c)8., below, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State, whose specific license authorizes him to receive the device, and within 30 days after transfer of a device to a specific licensee, shall furnish to the department a report containing identification of the device by manufacturer's or initial transferor's name and model number and serial number, the name, address, license number, where applicable, of the person receiving the device and the date of the transfer;
8. Shall transfer the device to another general licensee only:
  - a. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section, a copy of Rules 64E-5.103, 64E-5.328, and 64E-5.329, F.A.C., and any safety documents identified in the label on the device and within 30 days of the transfer, report to the department the manufacturer's or initial transferor's name and model number and serial number of device transferred, the transferor's name and mailing address for the location of use, and the name title, and phone number of the responsible individual identified by the transferee in accordance with paragraph 64E-5.206(4)(c) and subsection (11), F.A.C., to have knowledge of and authority to take actions to ensure compliance with these regulations; or
  - b. Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and
9. Shall comply with the provisions of 64E-5.343 and 64E-5.344 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Parts III and IX.
10. Shall be required to obtain written Department authorization before transferring the device to any other specific license not specifically identified in paragraph 64E-5.206(4)(c) and subsection (7), F.A.C. The Department authorization is granted provided the specific license identifies the device.
11. Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with the appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in the regard.
12.
  - a. Shall register, in accordance with sub-subparagraphs 64E-5.206(4)(c)12.b., and 64E-5.206(4)(c)12.c., F.A.C., all devices except exit signs containing tritium. Each address for a location of use as described in sub-subparagraph 64E-5.206(4)(c)12.c.(IV), F.A.C., represents a separate general license and requires a separate registration.
  - b. Shall annually register with the Department the possession of a device meeting the criteria in sub-subparagraph 64E-5.206(4)(c)12.a., F.A.C. Registration must be done by verifying, correcting or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, the general licensee holding devices that meet the criteria of sub-subparagraph 64E-5.206(4)(c)12.a., F.A.C., is subject to the bankruptcy notification requirements in subsection 64E-5.213(3), F.A.C.

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64E-5.206(4)(c)12 continued

- c. Shall provide the following information and any other information requested by the Department:
- (I) Name and mailing address of the general licensee;
  - (II) For each device, the manufacturer's name or initial transferor name, model number, serial number, the radioisotope and activity as identified on the label;
  - (III) Name, title, and telephone number of the responsible person designated a representative of the general licensee under paragraph 64E-5.206(4)(c) and subsection (11), F.A.C.;
  - (IV) Address or location at which the device(s) are used or stored. For portable devices, the address of the primary place of storage;
  - (V) Certification by the responsible representative of the general licensee that the information concerning the device(s) have been verified through a physical inventory and checking the label information; and
  - (VI) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.
- d. Persons generally licensed by other Agreement States, Licensing States, or the U.S. Nuclear Regulatory Commission with respect to devices meeting the criteria in 10 CFR 31.5(c)(13)(i) are not subject to registration requirements if the devices are used in areas subject to the Department jurisdiction for less than 180 days in any calendar year. The Department will not request registration from such licensees.

13. Shall report to the Department changes in the general licensee name and the mailing address for each location or use within 30 days of the effective date of the change. For a portable device, a report of address change is required for a change in the device's primary place of storage.

14. May not hold devices that are not in use longer than 2 years. If the devices with shutters are not being used, the shutters must be locked in the closed position. The testing required by subparagraph 64E-5.206(4)(c)2., F.A.C., need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested before use. Devices kept in standby for future use are excluded from the two year time limit if the general licensee performs physical inventories at intervals not to exceed three months while they are in standby.

(d) The general license in (4)(a), above, does not authorize the manufacture of devices containing radioactive material.

(e) The general license provided in (4)(a), above, is subject to the provisions of 64E-5.103 through 64E-5.104, 64E-5.213, 64E-5.215 and Part XV.

**64E-5.213 Specific Terms and Condition of License**

(3)(a) Each **specific or general** licensee shall notify the department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code (U.S.C.) by or against:

- 1. The licensee;
- 2. An entity, as that term is defined in 11 U.S.C. 101(14), controlling the licensee or listing the license or licensee as property of the estate; or
- 3. An affiliate, as that term is defined in 11 U.S.C. 101(2), of the licensee.

(b) This notification shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition for bankruptcy.

**Attachment 1**  
**Select General License Regulation Listed in 64E-5 Florida Administrative Code (F.A.C.)**

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Co 60	1 millicurie
Cs 37	10 millicuries
Am 241	0.001 millicuries
Ni 63	100 millicuries
Po 210	0.1 millicurie

Co 60	10 microcuries
Cs 137	100 microcuries
Am 241	0.01 microcuries
Ni 63	1000 microcuries
Po 210	1 microcurie

**64E-5.343 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.**

- (1) Telephone Reports. Each licensee or registrant shall report to the department by telephone the following:
  - (a) Stolen, lost or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling, **May 2000**, immediately after its occurrence becomes known to the licensee if it appears to the licensee that an exposure could result to individuals in unrestricted areas; or
  - (b) Lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling **May 2000**, that is still missing within 30 days after its occurrence becomes known.
  - (c) A stolen, lost, or missing radiation machine immediately after its occurrence becomes known.
- (2) Written Reports. Each licensee or registrant required to make a report as specified in 64E-5.343(1) shall make a written report to the department setting forth the following information within 30 days after making the telephone report:
  - (a) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;
  - (b) A description of the circumstances under which the loss or theft occurred;
  - (c) A statement of disposition or probable disposition of the licensed or registered source of radiation involved;
  - (d) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
  - (e) Actions that have been or will be taken to recover the source of radiation; and
  - (f) Procedures or measures that have been or will be adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.
- (3) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.
- (4) The licensee or registrant shall prepare any report filed with the department as specified in 64E-5.343 so that names of individuals who have received exposure to radiation are stated in a separate and detachable portion of the report.



**Attachment 1**  
**Select General License Regulation Listed in 64E-5 Florida Administrative Code (F.A.C.)**

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**64E-5.344 Notification of Incidents.**

- (1) Immediate Notification. Regardless of other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that might have caused or threatens to cause any of the following conditions:
  - (a) An individual to receive:
    1. A total effective dose equivalent of 25 rem (0.25 sievert) or more;
    2. A lens dose equivalent of 75 rem (0.75 sievert) or more; or
    3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 gray) or more; or
  - (b) The release of radioactive material inside or outside of a restricted area so that if an individual had been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.
- (2) Twenty-Four Hour Notification. Each licensee or registrant shall report to the department within 24 hours of discovery of the event each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that might have caused or threatens to cause any of the following conditions:
  - (a) An individual to receive in a period of 24 hours:
    1. A total effective dose equivalent exceeding 5 rem (0.05 sievert);
    2. A lens dose equivalent exceeding 15 rem (0.15 sievert); or
    3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 sievert); or
  - (b) The release of radioactive material inside or outside of a restricted area so that if an individual had been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations such as hot-cells or process enclosures.
- (3) The licensee or registrant shall prepare each report filed with the department as specified in 64E-5.344 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.
- (4) Licensees or registrants shall make the reports required by 64E-5.344(1) and (2) to the department by telephone, telegram, mailgram, or facsimile to the department.
- (5) The provisions of 64E-5.344 do not apply to doses that result from planned special exposures if such doses are within the limits for planned special exposures and are reported as specified in 64E-5.346.
- (6) Immediate notification. In addition to the other reporting requirements in these regulations, each licensee shall notify the department as soon as possible but not later than 4 hours after the discovery of an event, such as a fire, explosion, or toxic gas release, that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or to avoid releases of licensed material that could exceed regulatory limits.
- (7) Twenty-four hour report. Each licensee shall notify the department within 24 hours after the discovery of any of the following events involving licensed material:
  - (a) An unplanned contamination event that:
    1. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
    2. Involves a quantity of material greater than five times the lowest annual limit on intake of materials as specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993; and
    3. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

**Attachment 1**  
**Select General License Regulation Listed in 64E-5 Florida Administrative Code (F.A.C.)**

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64E-5.344(7) continued

- (b) An event in which equipment is disabled or fails to function as designed when:
  - 1. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposure to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
  - 2. The equipment is required to be available and operable when it is disabled or fails to function; and
  - 3. No redundant equipment is available and operable to perform the required safety function.
- (c) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body;
- (d) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed materials when:
  - 1. The quantity of material involved is five times the lowest annual limit on intake for material specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993; and
  - 2. The damage affects the integrity of the licensed material or its container.
- (8) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:
  - (a) Licensees shall make reports required by 64E-5.344(6) and (7) by telephone to the department. If the information is available at the time of notification, the information provided in these reports must include:
    - 1. The caller's name and call back telephone number;
    - 2. A description of the event, including date and time;
    - 3. The exact location of the event;
    - 4. The isotopes, quantities, and chemical and physical forms of the licensed material involved; and
    - 5. Any personnel radiation exposure data available.
  - (b) Written report. Each licensee who makes a report required by 64E-5.344(1) and (2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared as required by other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information. The reports must include the following:
    - 1. A description of the event, including the probable cause and the manufacturer and model number of any equipment that failed or malfunctioned;
    - 2. The exact location of the event;
    - 3. The isotopes, quantities, and chemical and physical form of the licensed material involved;
    - 4. Date and time of the event;
    - 5. Corrective actions taken or planned and the results of any evaluations or assessments; and
    - 6. The extent of exposure of individuals to radiation or to radioactive materials without identification of the individuals by name.