August 2007

Bureau of Radiation Control
RADIOACTIVE MATERIALS PROGRAM
Information Notice 2007-05

Revision 7 Filing Instructions: Changes to Chapter 64E-5, Florida Administrative Code (F.A.C.)

Changes to "Control of Radiation Hazard Regulations," Chapter 64E-5, F.A.C., became effective August 16, 2007. **These changes are indicated as Revision 7 or (R7) in the margin.**

These instructions apply to the complete version (brown cover) of Chapter 64E-5, F.A.C. Be sure that Revisions 1, 2, 3, 4, 5 and 6 changes have been inserted before making these changes. This may be verified by checking page ii of the index. **Visit our website at www.doh.state.fl.us/environment/radiation/ to download R7 pages to replace.**

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Cover	Cover	Cover
Index	i through xii	i through xii
Part I General Provisions	Part I Index Part I Pages 3/4, 11/12, 21/22	Part I Index Part I Pages 3/4, 11/12, 21/22
Part II Licensing of Radioactive Materials	Part II Index Part II Pages 9c/10, 11/12, 13/14, 15/16, 41/42, 43/43a, 43b/43c, 53/54	Part II Index Part II Pages 9c/10, 11/12, 13/14, 15/16, 41/42, 43/43a, 43b/43c, 53/54
Part V X-Ray in the Healing Arts	Part V Index Pages 11/12, 23/24, 25/26, 27/28, 35/36, 67/68, 69/70	Part V Index Pages 11/12, 23/24, 25/26, 27/28, 35/36, 67/68, 69/70
Part XV Transportation of Radioactive Materials	Part XV Index Pages 7/8	Part XV Index Pages 7/8
Attachment - Transfers of Industrial Devices Report 04-2007	All pages of Transfers of Industrial Devices Report 10-2003	All pages of Transfers of Industrial Devices Report 04-2007 (Date Change Only)
Attachment- New Radiation Machine Facility Registration Form DH 1107, 3/07	NA	New Radiation Machine Facility Registration Form DH 1107, 3/07

Below is a brief summary of the substantial changes. Please see rule text for details.

Part I: Definitions to support the terms C-Arm and Mobile C-Arm Systems as used in the Parts IV and V by the Radiation Machine Programs.

Part II: Radioactive materials license fee increased ~ 20 percent. Last fee increase was in 1998. Additional specific license categories created for fixed gauges, mobile nuclear medicine, HDR, gamma knife, and sealed source or device registrations.

Part V: User of fluoroscopic systems identified, measuring of entrance exposure rates clarified, use of remotely operated fluoroscopic system requirements, use and training requirements for hand held intraoral dental radiographic system specified, registration requirements with new form, etc.

Part XV Low level radioactive waste transportation inspection fee increased. This is the first fee increase since 1988.

Visit our website at www.doh.state.fl.us/environment/radiation/ to download pages to replace in your “brown cover” version of the “Control of Radiation Hazard Regulations”, 64E-5, F.A.C.

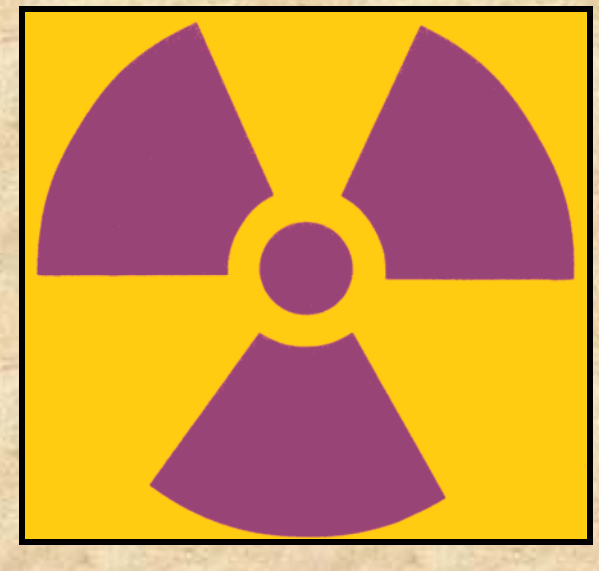
No specific actions nor written response is required. If you have any questions or need additional information, please contact us.

FLORIDA DEPARTMENT OF HEALTH

Bureau of Radiation Control

Division of Environmental Health

CONTROL OF RADIATION HAZARD REGULATIONS



Chapter 64E-5
Florida Administrative Code

July 3, 1997 Includes

Revision 1	**(May 18, 2000);**
Revision 2	**(October 8, 2000);**
Revision 3	**(August 6, 2001);**
Revision 4	**(September 11, 2001;**
Revision 5	**(December 19, 2001)**
Revision 6	**(September 28, 2006); and**
Revision 7	**(August 16, 2007)**

RULES OF THE STATE OF FLORIDA
DEPARTMENT OF HEALTH
CHAPTER 64E-5
CONTROL OF RADIATION HAZARD REGULATIONS

This copy of these regulations may not contain certain parts applicable to a particular section. Contact the applicable Bureau of Radiation Control Section or the Bureau of Environmental Toxicology – Radon and Indoor Air Quality Section for a copy of parts not herein contained.

PARTS I, III, IV, V, VII, VIII, IX and Attachments

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Bureau of Radiation Control
Radiation Machine Section
Suite 300
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Orange Park, FL 32073
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PARTS I, II, III, IV, VI, IX, X, XI, XIII, XIV, XV and Attachments

Department of Health
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This is an "unofficial" copy that has been re-formatted for ease of use and to provide attachments. Electronic versions of these regulations are posted on the Bureau's website: http://www.doh.state.fl.us/environment/radiation. Chapter 64E-5 and all other Florida Administrative Codes are available at https://www.flrules.org/.

Chronology of Rule Revisions

Revision	Effective Date	Sections Affected
R1	May 18, 1998	64E-5.101, 64E-5.204, 64E-5.213, 64E-5.214, 64E-5.319, 64E-5.332, 64E-5.333, 64E-5.334, 64E-5.347, 64E-5.402, 64E-5.422, 64E-5.502, 64E-5.504, 64E-5.510, 64E-5.617, 64E-5.902, 64E-5.1513, Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997.
R2	October 8, 2000	64E-5.101, 64E-5.201, 64E-5.203, 64E-5.204, 64E-5.214, 64E-5.216, 64E-5.301, 64E-5.303, 64E-5.304, 64E-5.309, 64E-5-311, 64E-5.312, 64E-5.314, 64E-5.315, 64E-5.323, 64E-5.326, 64E-5.334, 64E-5.339, 64E-5.344, 64E-5.345, 64E-5.414, 64E-5.420, 64E-5.422, 64E-5.505, 64E-5.622, 64E-5.625, 64E-5.643, 64E-5.645, 64E-5.1103, 64E-5.1112, 64E-5.1310, 64E-5.1406, 64E-5.1418, 64E-5.1502, 64E-5.1513 Radioactive Material Requiring Labeling, May 2000
R3	August 6, 2001	64E-5.101, 64E-5.201, 64E-5.603, 64E-5.606. 64E-5.626, 64E-5.627, 64E-5.630
R4	September 11, 2001	64E-5.401 - 64E-5.422 repealed and replaced with sections 64E-5.423, 64E-5.424, 64E-5.425, 64E-5.426, 64E-5.427, 64E-5.428, 64E-5.429, 64E-5.430, 64E-5.431, 64E-5.432, 64E-5.433, 64E-5.434, 64E-5.435, 64E-5.436, 64E-5.437, 64E-5.438, 64E-5.439, 64E-5.440, 64E-5.441
R5	December 19, 2001	64E-5.101, 64E-5.214, 64E-5.221, 64E-5.222, 64E-5.223, 64E-5.224, 64E-5.225, 64E-5.226, 64E-5.901, Notice to Employees 3/01
R6	September 28, 2006	64E-5.101, 64E-5.204, 64E-5.206, 64E-5.210 , 64E-5.213, 64E-5.304, 64E-5.318, 64E-5.319, 64E-5.427, 64E-5.429, 64E-5.434, 64E-5.440, 64E-5.441, 64E-5.1104, 64E-5.1107, 64E-5.11071, 64E-5.11072, 64E-5.11073, 64E-5.1112, 64E-5.1119, 64E-5.1311, 64E-5.1502, Bureau of Radiation Control Respiratory Protection Factors May 2006, Transfers of Industrial Devices Report 10-2003
R7	August 16, 2007	64E-5.101, 64E-5.204, 64E-5.210, 64E-5.502, 64E-5.504, 64E-5.506, 64E-5.511, 64E-5.1508, Transfers of Industrial Devices Report 04/2007, Radiation Machine Facility Registration DH 03/2007

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PART IV RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Sections 64E-5.401 – 64E-5.422 repealed and replaced with sections 64E-5.423 – 64E-5.441

PART V X-RAYS IN THE HEALING ARTS

PART VI USE OF RADIONUCLIDES IN THE HEALING ARTS

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

ATTACHMENTS

PART I GENERAL PROVISIONS

(17) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the
R5 environment from the testing of nuclear explosive devices or from past nuclear
R5 accidents such as Chernobyl that contribute to background radiation.
Background radiation does not include sources of radiation from radioactive materials regulated by the department.

R4 (18) "Baggage x-ray system" means a cabinet x-ray system with a maximum energy
R4 less than 120 kVp that produces only fluoroscopic images and that is used for
R4 packages or carry-on baggage.

R4 (19) "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (s^{-1}).

R4 (20) "Bioassay" means the determination of kinds, quantities or concentrations, and in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

R4 (21) "Brachytherapy" means a method of radiation therapy in which sealed sources are used to deliver a radiation dose by surface, intracavitary, or interstitial application.

R4 (22) "Byproduct material" means:

(a) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface waste resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute byproduct material within this definition.

R7 (193) "C-arm system" means a fluoroscopic C-arm routinely used with the same patient
R7 support device which will have interlocks, detents or positioning marks to allow
R7 reproducible geometry. Measurements of patient entrance exposure for this type
R7 of system will be measured in accordance with paragraph
R7 64E-5.504(3)(e) 2, 3, and 5.

R7 (23) "Cabinet x-ray system or Cabinet x-ray" means an x-ray system with the x-ray
R7 tube installed in an enclosure independent of existing architectural structures. A
R7 cabinet x-ray system is intended to contain the material being irradiated, and
R7 exclude personnel from its interior during generation of radiation. To be certified
R7 as a cabinet x-ray, the cabinet must be shielded so that every location on the
R7 exterior meets the conditions of 0.5 mRem (0.005 millisievert) in any one hour, at
R7 a distance of 5 cm. An x-ray tube used within a shielded part of a building or x-
R7 ray equipment that may temporarily or occasionally incorporate portable shielding
R7 is not considered a cabinet x-ray system.

R4 (24) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin on January 1 and subsequent calendar quarters shall be arranged so that no day is included in more than 1 calendar quarter, no calendar quarter, or part thereof, is included in more than 1 calendar year, and no day in any 1 year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him to determine calendar quarters for purposes of these rules except at the beginning of a calendar year.

R4 (25) "Calibration" means:

(a) The determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(b) The determination of the strength of a source of radiation relative to a standard.

R4 (26) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier or by civil aircraft.

R4 (27) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

R4 (28) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

R4 (29) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

R4 (30) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).

R4 R2 (31) “Constraint” or “dose constraint” means a value above which specified licensee actions are required.

R6 R5 (177) “Critical Group” means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

R4 (32) "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps).

2. When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and the prescribed dosage exceeds 30 microcuries.

(b) A therapeutic radiopharmaceutical dosage other than iodine 123, iodine 125 or iodine 131 as sodium iodide:

R2 1. Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or

2. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(c) A gamma stereotactic radiosurgery radiation dose:

R2 1. Involving the wrong individual or wrong treatment site; or

2. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

(d) A teletherapy, particle accelerator or therapeutic x-ray machine radiation dose:

R2 1. Involving the wrong individual, wrong mode of treatment, or wrong treatment;

2. When treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

3. When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

4. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(e) A brachytherapy radiation dose:

R2 1. Involving the wrong individual, wrong radioisotope, or wrong treatment site, excluding, for permanent implants, seeds that were implanted in the correct site but which migrated outside the treatment site;

2. Involving a sealed source that is leaking;

3. When, for a temporary implant, one or more seeds are not removed upon completion of the procedure; or

4. When the calculated administered dose differs from the prescribed dose by more than 20 percent from the prescribed dose.

(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of iodine 123, iodine 125 or iodine 131 as sodium iodide, both:

R2 1. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

R2 2. When the dose to the individual exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

R7 (192) "Mobile C-arm" means a mobile fluoroscopic machine that is designed for and used without a patient support device such as a radiographic table, cradle or radiolucent stretcher. This would include machines moved from room to room to assist in surgical procedures. Measurements of patient entrance exposure for this type of system will be measured in accordance with paragraph 64E-5.504(3)(e) 2, 3, and 4.

R4 (89) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, radiation monitoring and radiation protection monitoring are equivalent terms.

R4 (90) "NARM" means any naturally occurring or accelerator-produced radioactive material. To meet the definition of licensing state, NARM only refers to discrete sources of NARM. Diffuse sources of NARM, which are large in volume and low in activity, are excluded from consideration by the Conference of Radiation Control Program Directors, Inc., for licensing state designation purposes.

R4 (91) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

R4 (92) "Nonstochastic effect" means a health effect the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

R4 (93) "Normal form" means radioactive material which has not been demonstrated to qualify as "special form"; also referred to as "nonspecial form."

R4 (94) "Normal operating procedures" means operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.

R4 (95) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

R4 (96) "Occupational dose" means the dose received by an individual in the course of employment which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background R2 radiation, from any medical administration the individual has received, from R2 exposure to individuals administered radioactive material and released as R2 specified in Rule 64E-5.622, F.A.C., from voluntary participation in medical research programs, or as a member of the public.

*The 0.30 weighting factor for remainder results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

**To weight the external whole body dose to add it to the internal dose, a single weighting factor, W_T = 1.0, has been specified. The department will consider the use of other weighting factors for external exposure.

R6 (165) "Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed

R6 (166) “Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

R6 (167) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

R6 (168) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

R6 (169) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

R6 (170) "Worker" means an individual engaged in work in a restricted area under the authority of a license or registration issued by the department.

R6 (171) "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3 x 10^5 MeV of potential alpha particle energy. The short-lived radon daughters are:

(a) For radon 222: polonium 218, lead 214, bismuth 214, and polonium 214;

(b) For radon 220: polonium 216, lead 212, bismuth 212, and polonium 212.

R6 (172) "Working level month" (WLM) means an exposure to 1 working level for 170 hours. Two thousand working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

R6 (173) "Written directive" means a written order for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, which shall contain the following information:

(a) For a therapeutic administration of a radiopharmaceutical other than iodine 123, iodine 125 or iodine 131 as sodium iodide, the radiopharmaceutical, dosage, and route of administration;

(b) For any administration of iodine 123, iodine 125 or iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels), the dosage;

(c) For gamma stereotactic radiosurgery, target coordinates, collimator size, plug pattern, and total dose;

(d) For teletherapy, particle accelerator or therapeutic x-ray machine, the total dose, dose per fraction, treatment site, and overall treatment period;

(e) For high dose rate remote afterloading brachytherapy, the radioisotope, treatment site, and total dose; and

(f) For all other brachytherapy,

1. Prior to implantation, the radioisotope, number of sources, and source strengths; and

2. After implantation but prior to completion of the procedure, the radioisotope, treatment site, total source strength and exposure time or total dose.

R6 (174) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant can change the starting date of the year used to determine compliance by the licensee or registrant if the change is made at the beginning of the year and if no day is omitted or duplicated in consecutive years.

Editor's Note: Definitions have been alphabetized effective, May 15, 1996. (Principal activity (175) added alphabetically May 18, 1998. Authorized Nuclear Pharmacist (176) added August 8, 2001 (177) Critical Group, (178) Distinguishable from background, (179) Residual radioactivity added alphabetically December 19, 2001. and renumbered as above September 28, 2006) The following definitions have been alphabetized effective, September 28, 2006. ((189) Annual or Annually, (180) "Assigned protection factor" or "APF", (181) "Atmosphere-supplying respirator", (191) Daily, (182) "Energy compensation source" or "ECS, (183) "Fit factor", (184) "Fit test", (185) "Self-contained breathing apparatus" or "SCBA", (190) Semiannual or Semiannually, (186) "Supplied-air respirator" or "air-line respirator", (187) "Tritium neutron generator target source", (188) "User seal check" or "fit check"added and alphabetized effective August 16, 2007 (192) "Mobile C-arm", (193) "C-arm system")

Specific Authority: 404.051, 404.061, F.S.

Law Implemented: 404.031, 404.061, 404.20, 404.22, 404.30, F.S.

History: New July 17, 1985, Amended April 4, 1989, Amended May 12, 1993, Amended January 1, 1994, Amended May 15, 1996, Formerly 10D-91.102, Amended May 18, 1998, Amended October 8, 2000., Amended August 6, 2001, Amended September 11, 2001, Amended December 19, 200, Amended September 28, 2006, Amended August 16, 2007

64E-5.102 Exemptions.

(1) The department may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property or the environment.

(2) Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, transports or acquires sources of radiation:

(a) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

PART II LICENSING OF RADIOACTIVE MATERIALS

SUBPART G RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

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SUBPART A
LICENSE TYPES AND FEES

64E-5.204 Types of Licenses. Licenses for radioactive materials are of two types: general and specific.

(1) Some general licenses provided in this part may be effective without the filing of
R7 applications with the department or the issuance of licensing documents to the
R7 particular persons, although the filing of a certificate with the department for general licenses pursuant to 64E-5.206(7) or (8) shall be required of the
R6 particular general licensee prior to the receipt of radioactive material and the
R7 department requires registration of certain general licenses described in
R6 subsection 64E-5.206(4), F.A.C.. The payment of a fee is also required by all persons possessing general licensed material described in (1)(c), below. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

(a) The annual registration fee set forth in this section for general licenses shall be payable every July 1, for as long as the license remains in effect.

(b) The annual fee for a general license set forth in 64E-5.216 under
R7 reciprocal agreement shall be paid before the first entrance into the state and on each anniversary date thereafter, if applicable. Manufacturers, manufacturer's representatives, distributors, and waste treatment, storage or disposal companies servicing Florida radioactive materials license
R7 applicants or licensees are not exempt from this fee.

(c) Payment of the indicated annual fee pursuant to (1)(a), above, is required for the following types of devices held or activities performed under a general license:

1. Static elimination devices
R7 as described in 64E-5.206(1)(a). ..... $30.00 per unit.

2. Measuring, gauging, and control devices
R7 as described in 64E-5.206(4)..... $30.00 per unit.

3. *In Vivo* testing
R7 as described in 64E-5.206(7)..... $150.00 per license.

4. *In Vitro* testing
R7 as described in 64E-5.206(8)..... $150.00 per license.

5. Depleted uranium
R7 as described in 64E-5.205(4)..... $150.00 per license.

(d) Those persons who hold a specific license from the U.S. Nuclear Regulatory Commission, an agreement state or licensing state and conduct activities under a reciprocal agreement with this State shall meet the requirements of 64E-5.216(1), and pay the annual fee as specified in (2)(e), below.

(2) Specific licenses require the submission of an application to the department and the issuance of a licensing document by the department. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document. The licensee is subject to the payment of fees as authorized under section 404.131, Florida Statutes and as outlined below:

(a) The requirements of this part apply to a person who is an applicant for, or holder of a specific radioactive materials license issued pursuant to Subpart III C, and for a special review of safety designs of sealed sources and devices, whether or not in conjunction with a license application on file or which may be filed.

(b) All communications concerning the requirements of this part should be
R2 addressed to or delivered in person to the Department of Health, Bureau
R2 of Radiation Control, Bin #C21, 4052 Bald Cypress Way, Tallahassee, FL
R2 32399-1741.

(c) No additional fees shall be required for amendments to licenses.

(d) Payment of fees.

1. Application fees. Each application for a specific license for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. No application will be processed prior to payment of the fee specified herein. The application fee is not refundable except in those cases where the department has determined that a license is not required. The department will consider any application abandoned if the department does not receive a reply within 90 days to its most recent request for additional information. In such cases, the applicant must submit a new application with the application fee specified herein.

2. Annual fees. All current specific licenses that were in effect on January 1, 1979, are subject to payment of the annual fee prescribed herein and on every January 1, thereafter, as long as the license remains in effect. All specific licenses issued after January 1, 1979, are subject to payment of the annual fee specified in this section within 60 days of issuance of the license and on each anniversary date thereafter. The annual fee is not refundable except in those cases where the department has determined that the fee is not required.

3. Method of payment. Checks, drafts or money orders for payment of fees shall be payable to DOH, Bureau of Radiation Control; and
R2 sent to: Department of Health, Bureau of Radiation Control, Bin
R2 #C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741.

(e) Below is the schedule of fees for specific radioactive materials licenses:

			APPLICATION FEE	ANNUAL FEE
	1.	**SOURCE MATERIAL**.		
R7	a.	Licenses for concentration of uranium from phosphate ores forthe production of uranium as "yellow cake" or powdered solid;	$8,288	$14,330
R7	b.	License for concentration of uranium from phosphate ores for the production of “green cake” or equivalent, moist or solid;	$4,522	$8,927
R7	c.	All other specific source material licenses excluding depleted uranium used as shielding and counterweights.	$653	$275
	2.	**SPECIAL NUCLEAR MATERIAL (SNM)**.		
R7	a.	Licenses for use of SNM in sealed sources contained in devices used in measuring systems;	$784	$622
R7	b.	Licenses for use of SNM not sufficient to form a critical mass, except as in 2.a., above, and 2.c. and 5.e., below	$1,608	$2,333
R7	c.	Licensed for use of SNM to be used as calibration and reference sources	$246	$131
	3.	**BY-PRODUCT, NATURALLY OCCURING OR ACCELERATOR PRODUCED MATERIAL**		
R7	a.	Licenses for processing or manufacturing for commercial distribution or industrial uses;	$3,508	$3,362
R7	b.	Licenses for processing or manufacturing and distribution of radiopharmaceuticals. This category includes radiopharmacies;	$3,072	$4,608
R7	c.	Licenses industrial radiography performed only in an approved shielded radiography installation;	$1,870	$2,593
R7	d.	Licenses for industrial radiography performed only at the address indicated in the license, or at temporary job sites of the licensee;	$1,972	$3,188

	3.	**BY-PRODUCT, NATURALLY OCCURING OR ACCELERATOR PRODUCED MATERIAL**		
R7	e.	Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials where the source is not removed from the shield and is less than 10,000 curies;	$726	$726
R7	f.(I)	Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is not removed from the shield and is greater than 10,000 curies and less than 100,000 curies or where the source is less than 100,000 curies and is removed from the shield;	$1,697	$1,956
R7	f.(II)	Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is greater than 100,000 curies and less than 1,000,000 curies;	$4,391	$4,753
R7	f.(III)	Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is greater than 1,000,000 curies;	$11,736	$5,278
R7	g.	Licenses issued to distribute items containing radioactive materials to persons under a general license;	$1,972	$2,580
R7	h.	Fixed gauging devices;	$726	$1,159
	i.	**Well logging**		
R7	(I)	Sealed sources or sub-surface tracer studies	$1,362	$1,798
R7	(II)	Sub-surface tracer studies and sealed sources	$1,723	$1,913
R7	j.	Nuclear Laundry;	$3,840	$6,781
R7	k.	Industrial or Medical Research and Development	$1,421	$1,769
R7	**l.(I)**	**Portable gauging devices**	$726	$1,159
R7	(II)	In Vitro and clinical laboratory	$870	$1,102
R7	(III)	Academic	$1,174	$1,405
R7	(IV)	Possession of uranium or thorium,or their decay products as a result of mining or processing	$1,174	$1,044
R7	(V)	All other specific license except otherwise noted	$870	$1,202

	3.	**BY-PRODUCT, NATURALLY OCCURING OR ACCELERATOR PRODUCED MATERIAL**		
	m.	**Licenses of broad scope**		
R7	(I)	Academic	$3,840	$8,815
R7	(II)	Medical	$3,840	$6,569
R7	(III)	Industrial or Research and Development	$3,840	$5,482
R7	n.	Gas chromatography devices	$521	$377
R7	o.	Reference or calibration sources equal to or less than one millicurie total;	$377	$158
R7	p.	Nuclear service licenses, such as, leak testing, instrument calibration, etc.;	$622	$492
	4.	**WASTE DISPOSAL OR PROCESSING**		
R7	a.	Commercial waste disposal or treatment facilities, including burial or incineration	$331,010	$300,666
R7	b.	All other commercial facilities involving compaction, repackaging storage or transfer.	$32,501	$29,965
R7	c.	Commercial treatment of radioactive materials for release to unrestricted areas	$6,913	$6,882
	5.	**MEDICAL USE**		
R7 R7	a.(I)	Teletherapy or gamma stereotactic radiosurgery including gamma knife devices;	$1,838	$1,791
R7	a.(II)	High dose rate remote afterloading devices;	$1,697	$1,654
R7 R7 R7	a.(III)	High dose rate remote afterloading devices and gamma stereotactic radiosurgery including gamma knife devices or teletherapy devices;	$1,838	$1,791
R7 R7	b,	Medical institutions, including hospitals, except 5.a.(I), 5.a.(II), 5.a.(III), 5.e. and 5.f.;	$1,972	$2,290
R7 R7	c.	Private practice physicians except category 5.a.(I), 5.a.(II), 5.a.(III), 5.d. and 5.f.;	$1,421	$1,608
R7 R7 R7	d.	Private practice physicians using only strontium 90 eye applicators, or materials authorized by 64E-5.630, or materials authorized by 64E-5.631	$726	$898
R7	e.	Nuclear powered pacemakers	$521	$319
R7	f.(I)	Mobile nuclear medicine services	$1,697	$1,950
R7 R7 R7	f.(II)	Mobile high dose rate remote afterloading therapy device when the treatment is only performed on the mobile vehicle.	$2,970	$3,308

			APPLICATION FEE	ANNUAL FEE
R7	**6.**	**CIVIL DEFENSE**	**$653**	**$985**
	7.	**DEVICE, PRODUCT, OR SEALED SOURCE SAFETY EVALUATION**		
R7	a.	Safety evaluation of devices or products containing radioactive material, except reactor fuel devices, for commercial distribution or in accordance with the unique specifications of, and for use by, a single applicant; per device remaining in active status. Devices or products in inactive status more than 5 years must submit another application fee and be re-evaluated;	$4,500	$2,570
R7	b.	Safety evaluation of sealed sources containing radioactive material, for commercial distribution or in accordance with the unique specifications of, and for use by, a single applicant; per source remaining in active status. Sources in inactive status more than 5 years must submit another application fee and be re-evaluated.	$2,400	$2,900

Specific Authority: 404.051, 404.061, 404.131, F.S.
R7 Law Implemented: 404/032, 404.061, 404.051, 404.081, 404.131, 404.141 F.S.
History: New July 17, 1985, amended April 4, 1989, Amended September 9, 1990, Amended August 25, 1991,
R1 Amended May 12, 1993, Amended November 6, 1994, Formerly 10D-91.304, Amended May 18, 1998,
R7 Amended September 28, 2006, Amended August 16, 2007

SUBPART B
GENERAL LICENSES

64E-5.205 General Licenses - Source Material.

(1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local governmental agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any given time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any calendar year.

(2) Persons who receive, possess, use or transfer source material pursuant to the general license issued in (1), above, are exempt from the provisions of Parts III and IX to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.

(3) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

(4) Depleted Uranium in Industrial Products and Devices.

(a) A general license is hereby issued to receive, acquire, possess, use or transfer, in accordance with the provisions of (4)(b), (c), (d) and (e), below, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(b) The general license in (4)(a), above, applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 64E-5.210, or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to general licensees of the U.S. Nuclear Regulatory Commission or an agreement state.

(c) 1. Persons who receive, acquire, possess or use depleted uranium pursuant to the general license established by (4)(a), above, shall submit the information requested on DH Form 1619, entitled "General License for Depleted Uranium", which is herein incorporated by reference effective July 17, 1985, with the department. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall submit a fee as required in 64E-5.204(1)(c).

2. The registrant possessing or using depleted uranium under the general license established by (4)(a), above, shall report in writing to the department any changes in information furnished by him in the "Registration Certificate - Use of Depleted Uranium Under General License" form. The report shall be submitted within 30 days after the effective date of such change.

(d) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by (4)(a), above:

1. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

2. Shall not abandon such depleted uranium;

(c) In the event the applicant desires that the general licensee under 64E-5.206 or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the limits specified in 64E-5.304.

R6 (d) If a device containing radioactive material is transferred for use under the general license described in subsection 64E-5.206(4), F.A.C., each person that is licensed under subsection 64E-5.210(4), F.A.C., shall provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to the initial transfer to the intermediate person. The required information includes the following:

R6 1. A copy of the general license contained in subsection 64E-5.206(4), subparagraph 64E-5.206(4)(c)2.,3. and 4. or 64E-5.206(4)(c)12., F.A.C., do not apply to the particular device, those paragraphs may be omitted;

R6 2. A copy of Rules 64E-5.103, 64E-5.328, and 64E-5.329, F.A.C.;

R6 3. A list of services that can only be performed by a specific licensee;

R6 4. Information on acceptable disposal options including costs of disposal; and

R6 5. An indication that department policy is to issue high civil penalties for improper disposal.

R6 (e) If a device containing radioactive material is transferred for use under an equivalent general license of an Agreement State or the U.S. Nuclear Regulatory Commission, each person that is licensed under subsection 64E-5.210(4), F.A.C., shall provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to the initial transfer to the intermediate person. The required information includes the following:

1. A copy of the Agreement States or U.S. Nuclear Regulatory Commission equivalent to Rules 64E-5.103, 64E-5.328, and 64E-5.329, F.A.C. If a copy of the U.S. Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement States regulations, it shall be accompanied by a note explaining that the use of the device is regulated by the Agreement State. If certain parts of the regulations do not apply to the particular device, those regulations may be omitted;

2. A list of services that can only be performed by a specific licensee;

3. Information on acceptable disposal options including costs of disposal; and

4. The name or title, address, and phone number of the contact at the Agreement State regulatory agency or U.S. Nuclear Regulatory Commission, as applicable, from which additional information may be obtained.

(f) Each device that is transferred must meet the labeling requirements in subparagraphs 64E-5.210(4)(d)3. through 5., F.A.C.

(g) If a notification of bankruptcy has been made under subsection 64E-5.213(3), F.A.C., or the license is to be terminated, each person licensed under subsection 64E-5.210(4), F.A.C., shall provide, upon request, to the department, U.S. Nuclear Regulatory Commission and to any appropriate Agreement State, records of final disposition required under paragraph 64E-5.210(4)(j), F.A.C.

(h) Each person licensed under subsection 64E-5.210(4), F.A.C., shall comply with the following reporting and record keeping requirements.

1. Report all transfers of devices to persons for use under the general license described in subsection 64E-5.206(4), F.A.C., and all receipts of devices from persons licensed under subsection 64E-5.206(4), F.A.C., to the department. This report must be submitted at intervals not to exceed 3 months and contain all of the information described in “Transfers of Industrial Devices Report 04/2007” herein incorporated by reference and is available at the address listed in paragraph 64E-5.204(2)(b) or at http://www.doh.state.fl.us/environment/radiation/.

2. This report must be clear and legible and contain the following data:

R6 a. The identity of each general licensee by name and mailing address for the location of use; if no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;

R6 b. The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

R6 c. The date of transfer;

R6 d. The type, model number, and serial number of the device transferred; and

R6 e. The quantity and type of radioactive materials contained in the device.

R6 3. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person and clearly designate the intermediate person(s).

R6 4. For devices received from a subsection 64E-5.206(4), F.A.C., general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial numbers of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

R6 5. If the licensee makes changes to the device possessed by a subsection 64E-5.206(4), F.A.C., general licensee, such that the label must be changed to update required information, this report must identify the general licensee, the device, and the changes to information on the device label.

R6 6. The report must clearly identify the specific licensee submitting the report and include the licenses number of the specific licensee.

R6 7. If no transfers have been made to or from persons generally licensed under subsection 64E-5.206(4), F.A.C., during the reporting period, the report must so indicate.

R6 (i) Each person licensed under subsection 64E-5.210(4), F.A.C., shall comply with the following additional reporting and record keeping requirements for transfers and receipt of devices to Agreement States.

R6 1. Report all transfers of devices to persons for use under the general
R6 license in an Agreement State that are equivalent to subsection
R6 64E-5.206(4), F.A.C., and all receipts of devices from persons
R6 licensed under a general license in Agreement State jurisdiction to
R6 the responsible Agreement State agency. This report must contain
R6 all of the information described in “Transfers of Industrial Devices
R7 Report 04/2007.”

R6 2. The report must be clear and legible and contain the following data:

R6 a. The identity of each general licensee by name and mailing
R6 address for the location of use; if no mailing address for the
R6 location of use, an alternative address for the general
R6 licensee shall be submitted along with information on the
R6 actual location of use;

R6 b. The name, title, and phone number of the person identified
R6 by the general licensee as having knowledge of and
R6 authority to take required actions to ensure compliance with
R6 the appropriate regulations and requirements;

R6 c. The date of transfer;

R6 d. The type, model number, and serial number of the device
R6 transferred; and

R6 e. The quantity and type of radioactive materials contained in
R6 the device.

R6 3. If one or more intermediate persons will temporarily possess the
R6 device at the intended place of use before its possession by the
R6 user, the report must include the same information for both the
R6 intended user and each intermediate person and clearly designate
R6 the intermediate person(s).

R6 4. For devices received from a general licensee, the report must
R6 include the identity of the general licensee by name and address,
R6 the type, model number, and serial numbers of the device received,
R6 the date of receipt, and, in the case of devices not initially
R6 transferred by the reporting licensee, the name of the manufacturer
R6 or initial transferor.

R6 5. If the licensee makes changes to the device possessed by a
R6 general licensee, such that the label must be changed to update
R6 required information, this report must identify the general licensee,
R6 the device, and the changes to information on the device label.

R6 6. The report must clearly identify the specific licensee submitting the
R6 report and include the license number of the specific licensee.

R6 7. If no transfers have been made to or from a particular Agreement
R6 State during the reporting period, this information shall be reported
R6 to the responsible Agreement State agency upon request of the
R6 agency.

R6 8. The report must cover each calendar quarter and must be filed
R6 within 30 days of the end of the calendar quarter and must clearly
R6 indicate the period covered by the report.

R7 (j) The persons shall maintain all information concerning transfers and
R6 receipts of devices that supports the reports required by subsection
R6 64E-5.210(4), F.A.C. Records and reports described in subsection
R6 64E-5.210(4), F.A.C., shall be maintained for inspection by the department
R7 for a period of 3 years following the date of the recorded event.
R6

(5) Special Requirements for the Manufacture, Assembly or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium 147 for use in aircraft, for distribution to general licensees under 64E-5.206(5) will be approved if the requirements of Sections 32.53, 32.54, 32.55, 32.56 and 32.101 of 10 CFR Part 32, or their equivalent and the general requirements specified in 64E-5.208 are satisfied.

(6) Special Requirements for License to Manufacture Calibration Sources Containing Americium 241, Plutonium or Radium 226 for Distribution to Persons Generally Licensed Under 64E-5.206(6). An application for a specific license to manufacture calibration and reference sources containing americium 241, plutonium or radium 226 to general licensees under 64E-5.206(6) will be approved if the requirements of Sections 32.57, 32.58, 32.59 and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70, or their equivalent and the general requirements of 64E-5.208 are satisfied.

(7) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In addition to requirements set forth in 64E-5.208, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in 64E-5.206(7) will be issued if

(a) The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biological product issued by the Secretary, U.S. department of Health and Human Services; and

(b) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:

1. This radioactive drug may be received, possessed and used only by physicians licensed by the State of Florida to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

2. This radioactive drug may be received, possessed and used only by physicians licensed by the State of Florida to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of a Licensing State.

_____
Name of Manufacturer

1. U. S. department of Health and Human Services Publication FDA 81-8025 June 1981, Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM), which is herein incorporated by reference and which is available from the department.

2. U. S. Nuclear Regulatory Commission Regulatory Guide 10.10 March 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations and Registration of Devices Containing By-product Material, which is herein incorporated by reference and which is available from the department

3. U. S. Nuclear Regulatory Commission Regulatory Guide 10.11 June 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations of Sealed Sources Containing By-product Material, which is herein incorporated by reference and which is available from the department.

4. American National Standards Institute Standard N538, Classification of Industrial Ionizing Radiation Gauging Devices October 1979, which is herein incorporated by reference and which is available from the department.

5. American National Standards Institute Standard N540, Classification of Radioactive Self-Luminous Light Sources January 1976, which is herein incorporated by reference and which is available from the department.

6. American National Standards Institute Standard N432, Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography January 1980, which is herein incorporated by reference and which is available from the department.

7. American National Standards Institute Standard N542, Sealed Radioactive Sources Classification July 1978, which is herein incorporated by reference and which is available from the department.

(d) The licensee or applicant shall not distribute devices or products containing sealed sources unless the devices or sealed sources are manufactured and distributed in accordance with the registration and as authorized by a specific radioactive materials license issued by the department for such manufacture or distribution.

(e) The department shall not perform registration of devices or products containing sealed sources for persons outside the state.

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
R7 Law Implemented: 404.022, 404.051, 404.061, 404.081, 404.141, F.S.
History: New July 17, 1985, Amended August 25, 1991, Amended May 12, 1993, Amended January 1, 1994,
R6 Amended May 15, 1996, Formerly 10D-91.311, Amended August 6, 2001., Amended September 28, 2006,
R7 Amended August 16, 2007

64E-5.211 Special Requirements for Issuance of Specific Licenses for Source Material Milling. In addition to the requirements set forth in 64E-5.208, a specific license for source material milling will be issued if the applicant submits to the department an application as described herein and meets the other conditions specified below:

(1) An application for a license to

(2) receive title to, receive, possess and use source material for milling or by-product material as defined in Part I shall address the following:

(a) Description of the proposed project or action;

(b) Area or site characteristics including geology, topography, hydrology and meteorology;

(c) Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;

(d) Environmental effects of accidents;

(e) Long-term impacts including decommissioning, decontamination and reclamation; and

(f) Site and project alternatives.

(2) The applicant shall not commence construction of the project until the department has weighed the environmental, economic, technical and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

(3) At least 1 full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential longterm effects.

(4) Prior to issuance of the license, the applicant shall establish financial surety arrangements consistent with the requirements of 64E-5.217.

PART V X-RAYS IN THE HEALING ARTS

5. Gonad shields of not less than 0.25 millimeter lead equivalent shall be used for patients who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

6. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits the following:

    a. Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and a proper prescription has been provided.

    b. Exposure of an individual for the purpose of healing arts self-referral program except when authorized by 64E-5.502(1)(a)10.

    c. Advertisement of free x-ray examinations unless the advertisement states that a determination of need will be made prior to the x-ray examination.

7. When a patient or film must be provided with auxiliary support during a radiation exposure:

    a. Mechanical holding devices shall be used when the technique permits;

    b. Written safety procedures shall be available to indicate the requirements for selecting a holder, list the individual projections where holding devices cannot be used and describe the procedure the holder shall follow;

    c. The human holder shall be protected as required by (1)(a)4., above; and,

    d. No individual shall be used routinely to hold film or patients.

8. Exposure Procedures Designed to Minimize Patient and Personal Exposure

    a. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objectives of the examination.

    b. The radiation exposure to the patient shall be the minimum required to produce images of good diagnostic quality.

c. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.

d. X-ray systems subject to 64E-5.505 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

R7 R7 R7 e. A person shall not perform fluoroscopic imaging or otherwise expose a human to x-rays from a fluoroscopic system unless the person is a:

R7 R7 (I) Licensed practitioner as that term is defined in section 468.301, Florida Statutes; or

R7 R7 R7 (II) Certified radiologist assistant practicing in accordance with the requirements of Chapter 468, Part IV, Florida Statutes; or

R7 R7 R7 (III) Certified general radiographer practicing in accordance with the requirements of Chapter 468, Part IV, Florida Statutes; and

R7 R7 R7 (A) The general radiographer has been trained and authorized in writing by the licensed practitioner in charge to perform the specified imaging; and

R7 R7 R7 R7 (B) The specified imaging does not rely upon the general radiographer to provide any diagnostic interpretation, or to determine suspicious areas for additional imaging, or to otherwise modify the scope of authorization for the imaging; and

R7 R7 R7 R7 (C) The specified imaging is designed to prevent or reduce exposure to patients by facilitating proper location and positioning for the authorized radiographic imaging.

9. Personnel Monitoring. All individuals who are associated with the operation of an x-ray system are subject to the occupational exposure limits and the requirements for the determination of the doses stated in 64E-5.304 and 64E-5.308, FAC. In addition, when protective clothing or devices are worn on portions of the body and a personnel monitoring device is required, at least one such device shall be utilized as follows:

a. When a protective apron is worn, the monitoring device shall be worn at the collar outside of the apron

b. The dose to the whole body shall be recorded in the records required by 64E-5.339, FAC. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

R1 R1 10. Healing arts self-referral. Only healing arts self-referral programs for mammography screening will be authorized by the department.

64E-5.504 Fluoroscopic X-ray Systems. All fluoroscopic x-ray systems shall meet the following requirements:

(1) Limitation of the Useful Beam.

(a) The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire cross section of the useful beam.

(b) A means shall be provided between the x-ray source and the patient for stepless adjustment of the size of the x-ray field.

(c) With the collimating shutters adjusted to the closed position, the minimum field size at the maximum SID shall not be greater than five by five centimeters when measured at the point where the beam enters the patient.

(d) Limitation to the Imaging Surface.

1. The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the useable area of the largest image receptor at any SID.

2. The longitudinal and transverse dimensions of the x-ray field produced by image-intensified fluoroscopic equipment shall not extend beyond the corresponding dimensions of the image receptor by more than three percent of the SID in either dimension in the plane of the image receptor and the sum of the excess shall be no greater than four percent of the SID. If the collimation is automatically accomplished, the x-ray field dimension criteria above shall apply to all film sizes and portions thereof that the spot film device accommodates and to the dimensions of the input phosphor, as appropriate. If collimation is not automatic, the x-ray field dimension criteria shall apply to the useful area of the input phosphor.

R1 R7 R1 R1 R1 R7 R1

3. Compliance shall be determined with the beam axis perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which passes through the center of the visible area of the image receptor.

4. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent of the SID.

5. Adjustable automatic and manual collimators shall operate smoothly throughout the entire range of use.

6. For fluoroscopic systems with spot film capability, means shall be provided for adjustment of the x-ray field size in the plane of the film to a size smaller than the selected portion of the film.

(e) The requirements of (1)(b) and (c), above, are not applicable to mobile fluoroscopic systems.

(2) Activation of the Fluoroscopic Tube. A control of the dead-man type shall be incorporated into each fluoroscopic system such that x-ray production will be terminated at any time pressure is released from the switch except during the recording of serial fluoroscopic images with equipment in which means have been provided to permit completion of any single exposure of the series in progress.

R1 (3) Allowable Entrance Exposure Rate Limits for Fluoroscopic Equipment.

R1 (a) Fluoroscopic equipment manufactured after June, 1995, operable at any combination of tube potential and current that results in an exposure rate greater than five roentgens (1.29×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure control. Provision for manual selection of technique factors can be provided.

(b) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of ten roentgens (2.58×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient except:

1. During the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

2. When an optional high-level control is activated. When the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 20 roentgens (5.16×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient. Special means to activate high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator.

(c) Special means to activate high level controls such as additional pressure applied continuously by the operator shall be required to avoid accidental use.

(d) A continuous signal audible to the fluoroscopist shall indicate when the high level control is being employed.

(e) Measuring Compliance of Entrance Exposure Rate Limits. Compliance with this subsection shall be determined as follows:

1. Movable grids and compression devices shall be removed from the useful beam during the measurement.

R7 2. If the source can be operated below the patient support device, the exposure rate shall be measured at least one centimeter above the R7 patient support device and corrected for distance to show the actual entrance exposure rate.

R7 3. If the source can be operated above the patient support device, the exposure rate shall be measured at 30 centimeters above the R7 patient support device with the end of the beam-limiting device or spacer assembly positioned as closely as possible to the point of measurement.

R7 4. In a mobile C-arm type of fluoroscope, not associated with a R7 specific patient support device, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

R7 5. If the source can be operated laterally to the patient support device, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

6. X-ray systems that incorporate automatic exposure controls such as automatic brightness control shall have sufficient lead or lead equivalent placed in the useful beam to produce the maximum output of the x-ray system.

7. X-ray systems that do not incorporate automatic exposure control shall use the maximum combination of current and potential to produce the highest output. Attenuating materials shall be placed in the useful beam to protect the imaging system.

R1 (f) Periodic Measurement of Entrance Exposure Rates. The entrance R1 exposure rate shall be measured before use on humans after the R1 completion of any initial or subsequent installation and after any R1 maintenance of the system that might affect the exposure rate.

R1 (g) For cinefluoroscopy, the maximum exposure at the face of the input R1 phosphor with the grid removed and with an attenuation block in the beam R1 shall not exceed 40 microroentgens (0.01 μC per kg) per frame. The R1 maximum exposure shall be measured before use on humans after the R1 completion of any initial or subsequent installation and after any R1 maintenance of the system which might affect the maximum exposure.

R1 (4) Barrier Transmitted Radiation Limits.

R1 (a) The exposure rate due to transmission through the primary protective barrier and frame assembly with the attenuation block in the useful beam combined with radiation from the image intensifier if provided shall not exceed 2 milliroentgens (0.516 μC per kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic image assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

R1 (b) Measuring Compliance with Barrier Transmission Limits

R1 1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area no greater than 100 square centimeters with no linear dimension greater than 20 centimeters.

R1 2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly position 30 centimeters above the tabletop.

R1 3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam limiting device or spacer assembly as close to the table top as it can be placed but not closer than 30 centimeters.

R1 4. Movable grids and compression devices shall be removed from the useful beam during the measurements.

R1 5. The attenuation block shall be positioned in the useful beam 10 centimeters toward the input surface of the imaging assembly from the point at which the entrance exposure rate was measured.

R1 6. The maximum beam size shall be used during measurements.

R1 (5) Indication of Potential and Current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.

R1 (6) Source-to-Skin Distance. Positive means shall be provided to assure the source-to-skin distance shall not be less than:

(a) Thirty-eight centimeters on stationary fluoroscopes installed after January 1, 1977,

(b) Thirty-five and one-half centimeters on stationary fluoroscopes installed prior to January 1, 1977,

(c) Thirty centimeters on all mobile fluoroscopes,

(d) Twenty centimeters for image intensified fluoroscopes used for specific surgical applications. Written safety procedures must be provided and precautionary measures followed during the use of this device.

R1 (7) Fluoroscopic Timer. A cumulative timing device activated by the fluoroscopic exposure switch shall be provided, the maximum cumulative time of which shall not exceed five minutes without resetting. The timer shall indicate the passage of the predetermined period of exposure by an audible signal or termination of the exposure. If such a signal is utilized, it shall continue while x-rays are produced until the timing device is reset.

R1 (8) Mobile Fluoroscopes. In addition to the other requirements of this section, mobile fluoroscopes shall provide intensified imaging.

R1 (9) Control of Scatter Radiation.

(a) Fluoroscopic table designs shall be such that scattered radiation which originates beneath the tabletop is attenuated by not less than 0.25 mm lead equivalent, and that no unprotected part of any staff or ancillary person's body shall be exposed to unattenuated scattered radiation.

(b) Fluoroscopic equipment configuration shall be such that no portion of any staff or ancillary person's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless:

1. Such person is at least 120 centimeters from the center of the useful beam, or

2. The radiation has passed through not less than 0.25 millimeter lead equivalent material.

(c) Exceptions to (10)(b), above, may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the department shall not permit such exception.

R1 (10) Photofluorographic Medical x-ray Systems.

(a) In addition to other applicable sections of these regulations, photo-fluorographic x-ray systems shall conform with the following requirements:

1. Usage shall be limited to diagnostic radiography of the lungs and other soft tissues of the thoracic region.

2. Personnel monitoring shall be provided for all individuals who operate photofluorographic apparatus.

3. The average exposure, including backscatter, for chests measuring 25 centimeters in thickness shall not exceed 100 millirems (1.0 mSv) at the point where the x-ray beam enters the patient.

(b) Photofluorographic x-ray systems shall not be installed unless specifically approved by the department.

R1 (11) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of (1), (3), (4), (5) and (8), above, provided that:

(a) Such systems are designed and used in such a manner that no person other than the patient is in an unprotected area during periods of time when the system is producing x-rays; and

(b) Systems that do not meet the requirements of (8), above, are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. In such cases, the timer shall be reset between examinations

(c) The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 20 roentgens (5.16 mC per kg) per minute, except during the recording of fluoroscopic images.

R7 (12) For remotely operated fluoroscopic systems:

R7 (a). The control panel shall be arranged or configured to allow the operator to
R7 have both auditory and visual communication with the patient during
R7 exposures.

R7 (b). The operator's protective barrier shall have a window or mirror system
R7 arranged so that the operator can keep the patient under constant visual
R7 surveillance during exposures.

R7 (c). Windows shall have lead equivalent shielding equal to that required in the
R7 operator's protective barrier.

Specific Authority: 404.051, 404.22, F.S.
R7 Law Implemented: 404.05, 404.22, F.S.
R1 History: New July 17, 1985, amended April 4, 1989., March 17, 1992,
R7 Amended January 5, 1995, Formerly 10D-91.605, Amended May 18, 1998, Amended August 16, 2007.

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(c) The x-ray control shall provide visual indication observable at or from the operator's position whenever x-rays are produced.

(d) A sound audible to the operator shall indicate that the exposure has terminated or is in progress.

(5) Operating Controls.

(a) The dentist, operator or assistant shall not hold the film in place for the patient during the exposure. Patient and film holding devices shall be used when the techniques permit.

(b) No person other than the patient shall be exposed to the useful beam.

(c) Neither the tube housing nor the position indicating device shall be held during an exposure.

(d) The x-ray system shall be arranged and operated in such a manner that the useful beam at the patient's skin does not exceed the dimensions specified in (2)(a), above.

(e) Dental fluoroscopy without image intensification is prohibited.

R7 (f) Each user of intraoral units that are specifically designed to be handheld shall:

1. Have and use individual monitoring devices to document safe use practices; and

2. Successfully complete training provided by the manufacturer using electronic media such as CD/DVD or a website. Training on the safe use of the unit shall be documented and include at a minimum:

a. Proper positioning of the unit to ensure an adequate protected position;

b. Limitations on the use of position indicating devices that require longer distances to the patients face;

c. Diagrams (ie: drawings, illustrations, schematics, etc.) of protected position and location in relationship to the unit;

d. Diagrams (ie, drawings, illustrations, schematics, etc.) of the effect of improper distance or removal of shielding device; and

e. Diagrams (ie. drawings, illustrations, schematics, etc.) of common examples of improper positioning of the unit and or location of the operator.

R7 Specific Authority: 404.051, 404.22, F.S.
R7 Law Implemented: 404.022, 404.051, 404.22, F.S.
History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.607, Amended August 16, 2007

64E-5.507 Therapeutic X-Ray Systems of Less Than 1 MeV.

(1) Equipment Requirements.

(a) Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the following classification of that x-ray system:

1. Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 μC/kg) per hour at five centimeters from the surface of the tube housing assembly.

2. Zero to 150 kVp Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 μC/kg) per hour at one meter from the source.

3. 151 to 999 kVp Systems. The leakage radiation shall not exceed 0.1 percent of the useful beam one meter from the source, for any of its operating conditions.

(b) Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

(c) Removable and Adjustable Beam Limiting Devices.

1. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

2. Adjustable beam limiting devices shall transmit not more than five percent of the useful beam at the maximum kilovoltage and with the maximum treatment filter in the useful beam.

(d) Filter System. The filter system shall be so designed that:

1. The filters cannot be accidentally displaced at any possible tube orientation;

2. The radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.7 mC per kg) per hour under any operating conditions;

3. Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray; and

(b) Clinical image interpretation. To ensure that quality clinical images are produced routinely at the facility, each facility shall submit clinical images to the department for review as required by the department. Each facility also will establish a system to review outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports.

(c) Surveys. A medical physicist who meets the qualifications specified in (12), above, and who establishes, monitors, evaluates, and directs the
R1 equipment quality control program must perform an on-site survey of the facility to assure that it meets quality control and equipment standards. These surveys shall be performed at least annually and shall be available for inspection by the department. Each survey report shall be retained by the facility until the next annual survey is completed satisfactorily.

(d) Medical records.

1. Each facility shall maintain mammograms and associated records in a permanent medical record of the patient as follows:

a. For at least five years, or, if no additional mammograms of the patient are performed at the facility, for at least ten years; or

b. Until the records are transferred as requested by the patient to a medical institution, to a physician of the patient, or to the
R1 patient.

2. Each facility shall prepare a written report of the results of each mammography examination. This report shall be completed as soon as reasonably possible and shall:

a. Be signed by the interpreting physician; and

b. Be provided to the patient's physician or to the patient if the patient's physician is not available or if the patient does not have a physician. If this report is sent to the patient, it shall include a summary written in language easily understood by a lay person. A copy of the report shall be maintained in the patient's medical record.

(14) In addition to the above requirements, effective October 1, 1994, no facility can conduct mammography procedures unless the facility also obtains a certificate issued by the U.S. Food and Drug Administration as described in Public Law 102-539, the Mammography Quality Standards Act of 1992.

R1 Specific Authority: 404.051, 404.22, F.S.
R1 Law Implemented: 404.051(1)(4), 404.141, 404.22(1)(3)(6), F.S.
History: New March 17, 1992, Amended January 1, 1994
R1 Amended November 20, 1994, Formerly 10D-91.611, Amended May 18, 1998

64E-5.511 Registration of Radiation Machines.

(1) Exemptions.

(a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from registration and notification requirements if the dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 millirem (five μSv) per hour at five centimeters from any accessible surface of the equipment. The production, testing or factory servicing of such equipment shall not be exempt.

R7 R7 R7 (b) Radiation machines that are non-operational and under the control of a registered vendor prior to final installation are exempt from the registration and fee requirements of this section.

(2) Application and Fees for Registration of Radiation Machines.

(a) Each person who acquires a radiation machine or an additional radiation machine shall:

R7 R7 R7 R7 1. Apply for registration of the radiation machine with the department within 30 days after acquisition and before use. Application for registration shall be on DH 1107 3/07, which is herein incorporated by reference and available from the department at http://www.doh.state.fl.us/environment/radiation/.

2. Designate an individual who will be responsible for radiation protection.

3. Prohibit any person who is not registered with the department as a provider of services as specified in (3), below, from furnishing radiation machine servicing or services to his radiation machine

(b) An annual fee for the registration and inspection of radiation machines shall be paid according to the following schedule:

Medical or Chiropractic or Osteopathic or Naturopathic	One Tube .....$ 145 Each Additional Tube .....$ 85
Veterinary	One Tube .....$ 50 Each Additional Tube .....$ 34
Educational or Industrial	One Tube .....$ 47 Each Additional Tube .....$ 23
Dental or Podiatry	One Tube .....$ 31 Each Additional Tube .....$ 11
Medical Accelerator	One Unit .....$ 258 Each Additional Unit .....$ 148

Non Medical	One Unit .....$ 81 Each Additional Unit .....$ 48

1 Renewal fees are due before October 28 annually.

2. Registration fees are due within 30 days after acquiring a radiation machine. If the machine is acquired within 120 days before the October 28 annual renewal date, the registration fee will be due on October 28 and shall be the annual renewal fee.

(3) Application for Registration of Servicing and Services.

(a) Each person who installs or offers to install radiation machines or furnishes or offers to furnish radiation machine servicing or services in Florida shall apply to the department to register such services before furnishing or offering to furnish such services.

(b) Application for registration shall be completed on DH Form 1113, which is herein incorporated by reference and which is available from the department.

(c) Services include the installation or servicing of radiation machines and associated radiation machine components.

(4) Report of Changes. The registrant shall report in writing within 30 days any changes to the information in the Certificate of Registration. The report shall include name, address of installation change, receipt, sale, transfer, or disposal of any radiation machine or major component.

(5) Assembler or Transferor Obligation.

(a) Any person who sells, leases, transfers, relocates, lends, assembles, installs or disposes of radiation machines or major components of such machines shall notify the department within 15 days after such action. Notification shall be made on DH Form 1114, which is herein incorporated by reference and available from the department, or, if the system contains certified components, on FORM FDA 2579, which is herein incorporated by reference and which is available from the department.

(b) No person shall sell, offer to sell, lease, transfer, lend or install radiation machines unless such machines meet the requirements of these regulations.

(6) Out-of-State Radiation Machines.

(a) Any person proposing to bring a radiation machine into Florida shall notify the department in writing at least ten days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration and scope of use; and the exact location where the radiation machine will be used. If the 10-day period is an undue hardship, the department can grant permission to proceed sooner.

(b) Any person proposing to bring a radiation machine into Florida shall register the machine with the department and pay the registration fee.

(c) Any out-of-state person using a radiation machine in Florida shall notify the department when the use of the machine has been completed.

(7) Enforcement. The General Statement of Policy and Procedure for Radiation Machine Enforcement Actions, August 1996, which is available from the department and which is herein incorporated by reference, will be used to determine enforcement actions to be taken.

R7 Specific Authority 404.051, F.S.
R7 Law Implemented 404.071, 404.091, 404.101, 404.141, 404.161, 404.162, 404.163, 404.22, F.S.
History--New December 12, 1996, Formerly 10D-91.612, Amended August 16, 2007

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

ATTACHMENTS

(b) Proposed route of the shipment to the low-level radioactive waste facility;

(c) Estimated time of arrival of the shipment at the low-level radioactive waste facility;

(d) The carrier's name;

(e) A complete and legible copy of the bill of lading; and

(f) A complete and legible copy of the radioactive shipment manifest.

(4) If the shipment of low-level radioactive waste is found to be in compliance with the regulations of the U.S. Department of Transportation, the department's representative shall affix his initials on the bill of lading and the shipment may then proceed to the low-level radioactive waste facility. If the shipment of low-level radioactive waste is found to be in violation of the regulations of the U.S. Department of Transportation by the department's representative, the licensee shall not allow the shipment to leave the boundaries of his facility until the violation is corrected and the department's representative affixes his initials on the bill of landing signifying the shipment is in compliance.

(5) Licensees or nuclear power plant licensees of the U.S. Nuclear Regulatory Commission shall, within 72 hours of receiving notice of arrival of their shipment at its destination for unloading, notify the department of such arrival. The licensee shall also forward to the department within 2 weeks of receiving notice of the arrival of the shipment at a destination for unloading, records of receipt and any other records indicating that a shipment was found in violation of the low-level radioactive waste treatment, storage or disposal facility's or host state's rules or regulations.

(6) Each generator of radioactive waste whose shipment is inspected by the department's representative will be billed quarterly by the department a fee of
R7 $1.95 per cubic foot (0.02832 cubic meter) of waste shipped or $150.00 per shipment inspected, whichever is greater. This quarterly billing will be paid to the department within 30 days of receipt of the bill.

Specific Authority: 404.051, 404.061, 404.071, 404.20, F.S.
R7 Law Implemented: 404.022, 404.051), 404.061, 404.071, 404.20, F.S.
R7 History: New July 17, 1985, Amended July 5, 1988, Formerly 10D-91.2009, Amended August 16, 2007.

64E-5.1509 Permit Requirements.

(1) Any carrier who transports low-level radioactive waste destined for a low-level radioactive waste treatment, storage or disposal facility, prior to entrance into the state of Florida, shall obtain a permit from the department for transporting such waste into the state.

(a) An application for a permit must contain the following information or material:

1. Name, address and telephone number of the carrier; and

2. Certification statement that the carrier will comply with this part and the regulations of the U.S. Department of Transportation.

(b) Each application for a permit must be accompanied by an annual fee of $100. Permits shall be valid for 365 days following the date of issue. Permit fees are not refundable. Permits may not be transferred or assigned to another carrier.

(2) (a) Before any shipment of low-level radioactive waste may be transported into or through the state, the permitted carrier shall give written or telephonic notice to the department not less than 48 hours prior to the date of the arrival of the shipment at the borders of the state. The carrier must provide the department with the following information in the notice:

1. The expected date and time the shipment will arrive at the borders of the state;

2. The estimated time the shipment will remain in the state;

3. An estimate of the radioisotopes contained within the shipment;

4. An estimate of the total activity, in curies, contained within the shipment;

5. An estimate of the total volume, in cubic feet, contained within the shipment; and

6. The proposed route over which the shipment will be transported.

(b) The carrier must immediately notify the department of any cancellations or changes of information provided in the prior notification, such as changes in the date of shipment arrival, the length of time the shipment will remain in the state, or the description or quantity of the radioactive waste contained within the shipment.

(3) Any permit issued pursuant to 64E-5.1509(1), may be suspended if the department has reasonable cause to suspect that the continued shipment of low-level radioactive waste presents a hazard to the public health. Grounds for suspension of a permit may include failure to include the information requested pursuant to 64E-5.1509(2), falsification of information submitted on the application for a permit, or violation of Florida law or department regulations. Prior to the suspension of a permit, the holder of the permit shall be notified in writing that the permit will be suspended and that an opportunity for an administrative hearing will be provided, if requested in writing within 30 days of the receipt of the notice of the intent to suspend the permit. The department may remove the suspension at any time if the department determines that the suspected hazard no longer exists.

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL
Transfers of Industrial Devices Report 04/2007
64E-5.210(4)

TRANSFERS OF INDUSTRIAL DEVICES REPORT (TO GENERAL LICENSEES)

(Also use below "FROM GENERAL LICENSES or LABEL CHANGES", as appropriate)

Department of Health
Bureau of Radiation Control
4052 Bald Cypress Way - Bin #C21
Tallahassee Florida 32399-1741

For each "licensee" to whom a device(s) has been transferred during the reporting period, supply the following:

NAME OF VENDOR	REPORTING PERIOD	
	FROM	TO
LICENSE NUMBER		

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE		MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE		MAILING ADDRESS AT THE LOCATION OF USE *(No., P.O. Boxes, include Zip Code)*
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL
Transfers of Industrial Devices Report 04/2007 Continued
64E-5.210(4)

TRANSFERS OF INDUSTRIAL DEVICES REPORT (TO GENERAL LICENSEES)

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

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NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
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NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL
Transfers of Industrial Devices Report 04/2007 Continued
64E-5.210(4)

TRANSFERS OF INDUSTRIAL DEVICES REPORT (TO GENERAL LICENSEES)

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

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NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

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GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE		MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

TRANSFERS OF INDUSTRIAL DEVICES REPORT (FROM GENERAL LICENSEES)

For each "licensee" from whom a device(s) has been received during the reporting period, supply the following:

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

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STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL
Transfers of Industrial Devices Report 04/2007 Continued
64E-5.210(4)

TRANSFERS OF INDUSTRIAL DEVICES REPORT (FROM GENERAL LICENSEES)

For each "licensee" from whom a device(s) has been received during the reporting period, supply the following:

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL
Transfers of Industrial Devices Report 04/2007 Continued
64E-5.210(4)

TRANSFERS OF INDUSTRIAL DEVICES REPORT (LABEL CHANGES)

For each device for which required label information has been changed, supply the following:

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL
Transfers of Industrial Devices Report 04/2007 Continued
64E-5.210(4)

TRANSFERS OF INDUSTRIAL DEVICES REPORT (LABEL CHANGES)

For each device for which required label information has been changed, supply the following:

GENERAL LICENSEE USER INFORMATION

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FLORIDA DEPARTMENT OF HEALTH

Bureau of Radiation Control, Radiation Machine Program

RADIATION MACHINE FACILITY REGISTRATION

A. The information provided is to inform the bureau of:

☐ New Facility Registration ☐ Changes to an existing registration - JR# _____

B. ADDRESS INFORMATION for the physical location of the radiation machine(s)

Name of Facility posted at this location

Doctor or other responsible party at this location

Street Address of Facility (no PO Boxes, etc.)

Facility Telephone Number

City, State and Zip code

Facility FAX Number (optional)

County

E-mail address (optional)

C. BILLING/MAILING INFORMATION if different from address information

Billing/Mailing Name

Contact person for billing purposes

Billing/Mailing Address

Billing Telephone Number

Billing/Mailing City, State and Zip code

Billing FAX Number (optional)

D. COMPLIANCE INFORMATION if different from address information

Organization Name

Contact person for compliance

Address

Telephone Number

City, State and Zip code

FAX Number (optional)

If you have questions or need guidance on the registration process, please contact this office at:

Department of Health
Bureau of Radiation Control, Radiation Machine Program
P. O. Box 210, Jacksonville, Florida 32231
Phone: (904)359-6363 Fax: (904)359-6362
www.myfloridaeh.com/radiation/ion1.htm

E. New Registrants only: Identify the facility category you are registering. If you meet two or more categories, a separate registration form must be submitted for each facility category.

- ☐ HS Licensed as a Hospital under Chapter 395, Florida Statutes
- ☐ DI Diagnostic Imaging Center (accept outside referrals for diagnostic imaging services)
- ☐ MO Licensed as a Portable X-ray provider under 42 CFR, Part 486, Subpart C, sections 486.100 – 110 as administered by the Agency for Health Care Administration, State of Florida
- ☐ MA Screening/Diagnostic Mammography provider certified by the FDA under MQSA
- ☐ MB Biopsy Mammography only
- ☐ DS Dentist licensed under Chapter 466, Florida Statutes
- ☐ DC Chiropractic Physician licensed under Chapter 460, Florida Statutes
- ☐ DO Osteopathic Physician licensed under Chapter 459, Florida Statutes
- ☐ MD Medical Doctor licensed under Chapter 458, Florida Statutes
- ☐ PM Podiatric Physician licensed under Chapter 461, Florida Statutes
- ☐ AM Medical Accelerator
- ☐ TH Therapy treatment planners and other non-accelerator therapy related machines
- ☐ AN Industrial Particle Accelerator
- ☐ ED Educational Institution
- ☐ IN Industrial
- ☐ VM Veterinarian licensed under Chapter 474, Florida Statutes

RADIATION MACHINE FACILITY REGISTRATION

F. Radiation Machine Information (use additional copies of this page if necessary)

1.

Manufacturer's Name	Model Name	Control Serial Number	Installation Date	Room

☐ Machine recently installed (attach copy of installation form) ☐ Machine present at time of occupancy of facility

☐ Machine removed from this location ☐ Machine rendered inoperable

2.

Manufacturer's Name	Model Name	Control Serial Number	Installation Date	Room

☐ Machine recently installed (attach copy of installation form) ☐ Machine present at time of occupancy of facility

☐ Machine removed from this location ☐ Machine rendered inoperable

3.

Manufacturer's Name	Model Name	Control Serial Number	Installation Date	Room

☐ Machine recently installed (attach copy of installation form) ☐ Machine present at time of occupancy of facility

☐ Machine removed from this location ☐ Machine rendered inoperable

4.

Manufacturer's Name	Model Name	Control Serial Number	Installation Date	Room

☐ Machine recently installed (attach copy of installation form) ☐ Machine present at time of occupancy of facility

☐ Machine removed from this location ☐ Machine rendered inoperable

G. COMMENTS: Please use the following space to enter additional information

H. By the signature below the applicant acknowledges this is an accurate record of the machine(s) in their use and acknowledges their responsibility to inform the bureau of any future changes to this registration within thirty days.

Signature Title or Position

Print Name Date