

#### February 2008

### Bureau of Radiation Control RADIOACTIVE MATERIALS PROGRAM Information Notice 2008-02

#### Revision 8 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 February 28, 2008. The requirements for nationally tracking certain radioactive sources described in Sections 64E-5.350 and 64E-5.351 does not become effective until January 31, 2009. These changes are indicated as Revision 8 or (R8) 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, 6 and 7 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 R8 pages to replace.** 

DADT	DA OFO TO DE DEMOVED	DAGES TO BE INCEDTED
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 9/10, 11/12,13/14, 15/16, 17/18, 21/22	Part I Index Part I 9/10, 11/12,13/14, 15/16, 17/18, 21/22
Part II Licensing of Radioactive Materials	Part II Index Part II Pages 17/18, 19/20, 20a/20b, 29/30, 41/42, 43/43a, 43b/43c, 53/54, 65/66	Part II Index Part II 17/18, 19/20, 20a/20b, 20c/20d (new), 29/30, 41/42, 43/43a, 43b/43c, 53/54, 65/66
Part III Standards for Protection Against Radiation	Part III Index Pages (None)	Part III Index Pages 47/48 (new), 49/50 (new) 51/52 (new) Effective Date 01/31/2009
Part IV Radiation Safety Requirements for Industrial Radiographic Operations	Part IV Index Pages 9/10, 21/22, 23/24	Part IV Index Pages 9/10, 21/22, 23/24
Part X Environnemental Radiation Standards	Part X Index Pages 1/2	Part X Index Pages 1/2
Part XI Radiation Safety Requirements For Wireline Service Operations And Subsurface Tracer Studies	Part XI Index Pages 5/6	Part XI Index Pages 5/6
Part XV Transportation of Radioactive Materials	Part XV Index Pages 1/2	Part XV Index Pages 1a/1b (new), 1c/2 (new)

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

- Part I: Definitions to support the terms National Source Tracking requirements added to Part III and minor changes to definitions of radiographic exposure device, sealed source, low specific activity material (LSA), and package to remain compatible with U.S. Nuclear Regulatory Commission (NRC).
- Part II: Minor changes to the general license device requirements to remain compatible with the NRC such as longer record keeping requirements and following NRC regulations to export devices. Requires manufacturers of general licensed devices to use unique serial numbers for the tracking these devices. As required by NRC, reciprocity licensees may be in Florida no more than 180 days in a calendar year.
- Part III: Adds reporting requirements to the NRC to track the movements of sealed sources of certain isotopes above quantities of concern. This reporting requirement does not become effective until January 31, 2009 or later if authorized by 10 CFR 20.2207(h). SEE RULE TEXT FOR DETAILS.
- Part IV Requires industrial radiography licensees to have "written procedures" for inspection and maintenance of equipment. It also requires licensees to notify the department if they are conducting radiographic operations more than 180 days at a location not listed on the license.
- Part X Increases the fees for environmental radiological testing for pre- and post mining.
- Part XI Corrects a reference regarding the use of energy compensation sources and protection of fresh water aquifers as required to be compatible with the NRC.
- Part XV Transportation regulations updated to reflect the current regulations required by the U.S. Department of Transportation and the U.S. Nuclear Regulatory Commission.

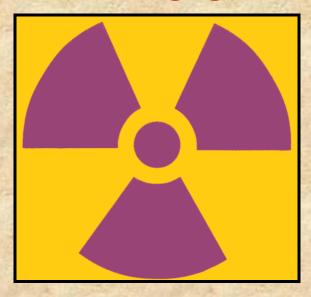
Visit our website at <a href="www.doh.state.fl.us/environment/radiation/">www.doh.state.fl.us/environment/radiation/</a> to download pages to replace in your "brown cover" version of the "Control of Radiation Hazard Regulations", 64E-5, F.A.C.

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





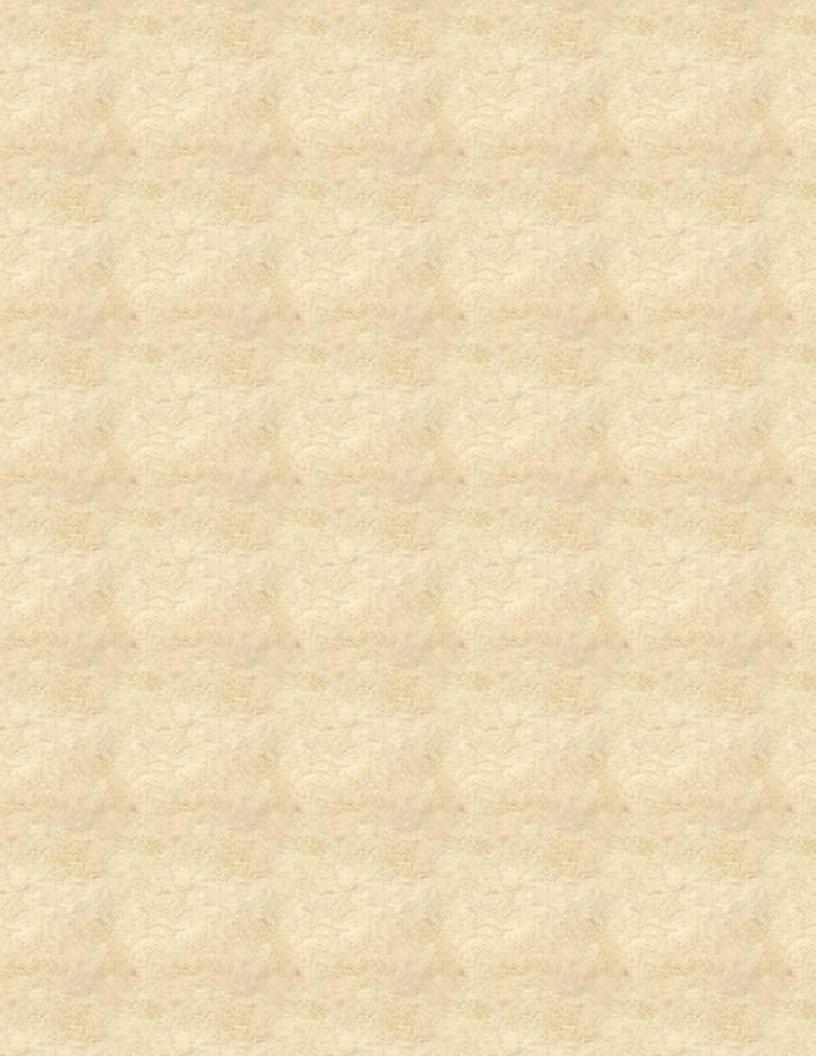
# CONTROL OF RADIATION HAZARD REGULATIONS



## Chapter 64E-5 Florida Administrative Code

Effective Date 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)
<b>Revision 6</b>	(September 28, 2006);
Revision 7	(August 16, 2007) and
<b>Revision 8</b>	(February 28, 2008)



## 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

Department of Health Bureau of Radiation Control Radiation Machine Section Suite 300 705 Wells Road, Orange Park, FL 32073

Telephone: (904) 278-5730 Fax: (904) 278-5737

PARTS I, II, III, IV, VI, IX, X, XI, XIII, XIV, XV and Attachments

Department of Health
Bureau of Radiation Control
Radioactive Materials Section
Bin #C21
4052 Bald Cypress Way
Tallahassee, FL 32399-1741

Telephone: (850) 245-4545 Fax: (850) 921-6364

#### PARTS X and XII

Department of Health
Bureau of Facilities Program
Radon and Indoor Air Quality Section
Bin #C22
4052 Bald Cypress Way
Tallahassee, FL 32399-1742

Telephone: (850) 245-4277 Fax: (850) 487-0864

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	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		
R8	February 28, 2008	64E05.101, 64E-5.206, 64E-5.206, 64E-5.210, 64E-5.216, <b>New</b> 64E-5.350, <b>New</b> 64E-5.351, 64E-5.430, 64E-5.440, 64E-5.441, 64E-5.1003, 64E-5.11702, 64E-5.1501, 64E-5.1502		

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- R4 (72) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the department.
- R4 (73) "Licensee" means any person who is licensed by the department in accordance with these rules and the Act.
- R4 (74) "Licensing State" means any state with rules equivalent to the Suggested State Regulations for Control of Radiation for the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.
- R4 (75) "Local components" means parts of an analytical x-ray system and includes areas that are struck by x-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but does not include power supplies, transformers, amplifiers, readout devices and control panels.
- R4 (76) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.
- R4 (77) "Logging tool" means a device used subsurface to perform well-logging.
- R4 (78) "Lost or missing licensed material" means licensed material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.
- R8 (79) "Low specific activity material (LSA)" means that as defined in 49 C.F.R.
  R8 173.403. (Pursuant to 120.54(6) Florida Statutes, 64E-5.101(79) is substantively identical to 49 CFR 173.403 published on 10/01/2007.)
- R4 (80) "Lung class" (see "Class").
- R4 (81) "Major processor" means a user processing, handling or manufacturing radioactive material exceeding A<sub>2</sub> quantities as unsealed sources or material, or exceeding 4 times A<sub>1</sub> quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. A<sub>1</sub> and A<sub>2</sub> quantities can be found in Part XV.
- R4 (82) "Management" means the chief executive officer or that individual's designee.
- R4 (83) "Medical institution" means any establishment that:
  - (a) Offers services more intensive than those required for room, board, personal services, and general nursing care, and offers facilities and beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care for illness, injury, deformity, infirmity, abnormality, disease, or pregnancy; and
  - (b) Regularly makes available at least clinical laboratory services, diagnostic x-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment of similar extent.

R4 "Medical use" means the intentional internal or external administration of (84)radioactive material, or the radiation therefrom, to humans in the practice of the healing arts. R4 (85)"Member of the public" means any individual except when that individual is receiving an occupational dose. R4 (86)"Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas. "Minor" means an individual less than 18 years of age. R4 (87)"Misadministration" means the administration of: R4 (88)lodine 123, iodine 125 or iodine 131 as sodium iodide in quantities greater (a) than 30 microcuries (1.11 megabecquerels): R2 Involving the wrong individual or wrong radiopharmaceutical; or 1. 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. A therapeutic radiopharmaceutical dosage other than iodine 123, (b) 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. A gamma stereotactic radiosurgery radiation dose: (c) 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. A teletherapy, particle accelerator or therapeutic x-ray machine radiation (d) 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:
  - 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:
  - 1. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
  - 2. When the dose to the individual exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.
- (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 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.
- (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.
- (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.

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R8 (194) "Nationally tracked source" means a sealed source containing a quantity equal to R8 or greater than Category 1 or Category 2 levels of any radioactive material listed in Rule 64E-5.351, F.A.C. In this context a sealed source is defined as R8 R8 radioactive material that is sealed in a capsule or closely bonded, in a solid form, R8 and which is not exempt from regulatory control. It does not mean material R8 encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked R8 R8 sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those R8 R8 containing radioactive material at a quantity equal to or greater than the Category R8 2 threshold but less than the Category 1 threshold. (Pursuant to 120.54(6)) R8 Florida Statutes, 64E-5.101(194) is substantively identical to 10 CFR 20.1003 published on 01/01/2007.) R8

- 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.
- (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 radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released as specified in Rule 64E-5.622, F.A.C., from voluntary participation in medical research programs, or as a member of the public.
- R4 (97) "Offshore" means within the territorial waters of the State of Florida as specified in Article II, Section 1 of the Constitution of the State of Florida.
- R4 (98) "Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.
- R4 (99) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

- R8 (100) "Package" means that as defined in 49 C.F.R. 173.403. (Pursuant to 120.54(6) Florida Statutes, 64E-5.101(100) is substantively identical to 49 CFR 173.403 published on 10/01/2007.)
- R4 (101) "Packaging" means, for radioactive materials, the assembly of components necessary to ensure compliance with the packaging requirements of the U.S. Nuclear Regulatory Commission and the U.S. Department of Transportation. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The conveyance, tie-down system, and auxiliary equipment may sometimes be designated as part of the packaging.
- R4 (102) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.
- R4 (103) "Permanent radiographic installation" means an enclosed shielded room, cell, or vault, as specified in Rule 64E-5.431, F.A.C., in which industrial radiography is performed.
- R4 (104) "Permit" means the written authorization issued by the department for the transportation of radioactive waste as described in Rule 64E-5.1509.
- R4 (105) "Personal supervision" means supervision in which the radiographer or logging supervisor is physically present at the site where sources of radiation and associated equipment are being used, watching the performance of the radiographer's assistant or supervised individual and in such proximity that immediate assistance can be given if required.
- R4 (106) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.
- R4 (107) "Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:
  - (a) In a written directive; or
  - (b) Either in the diagnostic clinical procedures manual or in any appropriate record as specified in the directions of the authorized user for diagnostic procedures.

R4 (108) "Prescribed dose" means:

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- (a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
- (b) For brachytherapy, either the total source strength and exposure time or the total dose as documented in the written directive; or
- (c) For teletherapy, particle accelerator or therapeutic x-ray machine, the total dose and dose per fraction as documented in the written directive.
- R4 (109) "Primary beam" means the radiation which passes through an aperture of the source housing in a direct path from the x-ray tube located in the radiation source housing.
  - (175) "Principal activities" means activities authorized by the license that are essential to achieve the purpose for which the department issued or amended the license. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.
  - "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive materials released by a licensee or registrant, or to any other sources of radiation under the control of the licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released as specified in Rule 64E-5.622, F.A.C., or from voluntary participation in medical research programs.
- R4 (111) "Quality factor" (Q) means the modifying factor listed in the tables in 64E-5.106(3) and (4) used to derive dose equivalent from absorbed dose.
- R4 (112) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee or registrant of approximately 13 consecutive weeks. The beginning of the first quarter in a year shall coincide with the starting date of the year and no day shall be omitted or duplicated in consecutive quarters.
- R4 (113) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).
- R4 (114) "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, "ionizing radiation" is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radio waves or microwaves, visible, infrared, or ultraviolet light.
- R4 (115) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual's receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.
- R4 (116) "Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

- R4 (117) "Radiation Safety Officer or RSO" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules.
- R4 (118) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.
- R4 (119) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.
- R4 (120) "Radiographer" means any individual who has completed successfully the training and testing requirements specified in Rule 64E-5.434(2), F.A.C., performs or personally supervises radiographic operations and is responsible to the licensee or registrant for assuring compliance with the requirements of these rules and all license or certificate of registration conditions.
  - (121) "Radiographer's assistant or assistant radiographer" means any individual who has completed successfully the training and testing requirements specified in Rule 64E-5.434(1), F.A.C., and who, under the personal supervision of a radiographer, conducts radiographic operations.
  - (122) "Radiographic exposure device" means any instrument containing a sealed source, fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed from a shielded position to an unshielded position for the purpose of making a radiographic exposure. It also is known as a camera or a projector. (Pursuant to 120.54(6) Florida Statutes, 64E-5.101(122) is substantively identical to 10 CFR 34.3 published on 01/01/2007.)
- R4 (123) "Recordable event" means the administration of:

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- (a) A radiopharmaceutical or radiation without a written directive where a written directive is required;
- (b) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;
- (c) Iodine 123, iodine 125 or iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels) when:
  - 1. The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage; and
  - 2. The difference between the administered dosage and the prescribed dosage exceeds 15 microcuries.
- (d) A therapeutic administration of a radiopharmaceutical other than iodine 123, iodine 125 or iodine 131 as sodium iodide, when the administered dosage differs from the prescribed dosage by more than 10 percent from the prescribed dosage;
- (e) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose; or

- (f) A teletherapy, particle accelerator or therapeutic x-ray machine radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.
- R4 (124) "Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics can be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."
- R4 (125) "Registrant" means any person who is registered with the department and is legally obliged to register with the department pursuant to these rules and the Act.
- R4 (126) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR, Parts 100-189.
- R4 (127) "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).
- R4 (128) "Research and development" means:

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- (a) Theoretical analysis, exploration or experimentation; or
- (b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.
- R4 (129) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.
  - (179) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee but excludes background radiation. It also includes radioactive material as a result of routine or accidental releases of radioactive material at the site and previous burials at the site even if those burial sites were made as specified in Part III of this Chapter.
- R4 (130) "Restricted area" means an area, access to which is limited by the licensee or registrant to protect individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building can be set apart as a restricted area.
- R4 (131) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58 x 10<sup>-4</sup> coulombs per kilogram of air.

(132) "Sanitary sewerage" means a system of public sewers for carrying off waste R4 water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant. R8 (133) "Sealed source" means radioactive material that is encased in a capsule designed to prevent release or escape of the radioactive material. (Pursuant to R8 120.54(6) Florida Statutes, 64E-5.101(133) is substantively identical to 10 CFR R8 30.4 published on 01/01/2007.) R8 (185) "Self-contained breathing apparatus" or "SCBA" means an atmosphere-supplying R6 respirator for which the breathing air source is designed to be carried by the user. R6 R6 (190) Semiannual or Semiannually means an interval not to exceed six months. R6 R4 (134) "Shallow dose equivalent" (H<sub>s</sub>), which applies to the external exposure of the skin R6 of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm<sup>2</sup>). R6 R4 (135) "Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from R4 R4 movement by manufacturer's design. R6 (136) "Shipping paper" means a shipping order, bill of lading, manifest or other shipping document serving a similar purpose and containing the information required by 49 CFR, Parts 172.202, 172.203 and 172.204. R6 (137) "SI" means an abbreviation of the International System of Units. R6 (138) "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem). (139)R6 "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources. R6 (140) "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations. R6 "Source material" means: (a) Uranium or thorium, or any combination thereof, in any physical or chemical form: or

Source material does not include special nuclear material.

Ores which contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium.

(b)

- R6 (142) "Source material milling" means any activity that results in the production of byproduct material as defined by 64E-5.101.
- R6 (143) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.
- R6 (144) "Special form" means radioactive material which satisfies all of the following conditions:
  - (a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
  - (b) The piece or capsule has at least one dimension not less than 5 millimeters; and
  - (c) It satisfies the test requirements of 49 CFR, Part 173.469. Special form encapsulations designed in accordance with the requirements of 49 CFR, Part 173.389 in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. Special form encapsulations either designed or constructed after June 30, 1985, must meet the requirements of this part.
- "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:
  - <u>175 (grams contained U-235)</u> + <u>50 (grams U-233)</u> + <u>50 (grams Pu)</u> = 1 350 200 200
- R6 (146) "Specific activity" means the activity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the activity per unit mass of the material.
- "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For the purposes of these rules, "probabilistic effect" is an equivalent term.

- \*\*To weight the external whole body dose to add it to the internal dose, a single weighting factor, W<sub>T</sub> = 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
- (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<sup>5</sup> 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;

- 64E-5.102
- (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 R1 (175) added alphabetically May 18, 1998. Authorized Nuclear Pharmacist (176) added August 8, 2001 R6 (177) Critical Group, (178) Distinguishable from background, (179) Residual radioactivity added alphabetically December 19, 2001, and renumbered as above September 28, 2006) The following R6 definitions have been alphabetized effective, September 28, 2006. ((189) Annual or Annually, (180) R6 "Assigned protection factor" or "APF", (181) "Atmosphere-supplying respirator", (191) Daily, (182) R6 "Energy compensation source" or "ECS, (183) "Fit factor", (184) "Fit test", (185) "Self-contained R6 breathing apparatus" or "SCBA", (190) Semiannual or Semiannually, (186) "Supplied-air respirator" or R6 "air-line respirator", (187) "Tritium neutron generator target source", (188) "User seal check" or "fit R6 R7 check added and alphabetized effective August 16, 2007 (192) "Mobile C-arm", (193) "C-arm system" R8 February 28, 2008 (194) "Nationally Tracked Source:) Specific Authority: 404.051, 404.061, F.S.

R7 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,
R2 Amended May 15, 1996, Formerly 10D-91.102, Amended May 18, 1998, Amended October 8, 2000.,

R3,R4,R5,R6 Amended August 6, 2001, Amended September 11, 2001, Amended December 19, 200, Amended September 28, 2006, R7,R8 Amended August 16, 2007, Amended February 28, 2008.

#### 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;

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- Shall transfer or dispose of such depleted uranium only by transfer 3. in accordance with the provisions of 64E-5.215. In the case where the transferee receives the depleted uranium pursuant to the general license established by (4)(a), above, the transferor shall furnish the transferee a copy of this regulation and a copy of the "Registration Certificate - Use of Depleted Uranium Under General License". In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to (4)(a), above, the transferor shall furnish the transferee a copy of this regulation and a copy of the "Registration" Certificate - Use of Depleted Uranium Under General License" accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as in this regulation;
- 4. Within 30 days of any transfer, shall report in writing to the department the name and address of the person receiving the depleted uranium pursuant to such transfer; and
- 5. Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.
- (e) Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by (4)(a), above, is exempt from the requirements of Parts III and IX with respect to the depleted uranium covered by that general license.

Specific Authority: 404.051, 404.061, 404.081, 404.141, F.S. Law Implemented: 404.022, 404.051(1),(4),(6),(8),(9),(10), 404.061(2), 404.081(1), 404.141, F.S. History: New July 17, 1985, Formerly 10D-91.305.

#### 64E-5.206 General Licenses - Radioactive Material Other Than Source Material.

(1) Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, owns, possess and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of 64E-5.103 through 64E-5.104, 64E-5.203(1)(b), 64E-5.214, 64E-5.215, Part III, Part IX and Part XV.

- (a) Static Elimination Devices. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBg) of polonium 210 per device; and
- (b) Ion Generating Tubes. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBg) of polonium 210 per device or a total of not more than 50 millicuries (1.85 GBg) of tritium per device.
- (2) Reserved
- (3)Reserved

(b)<mark>1.</mark>

(4) Certain Measuring, Gauging and Controlling Devices.

published on 01/01/2007.)

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A general license is hereby issued to commercial and industrial firms and (a) to research, educational and medical institutions, individuals in the conduct of their businesses, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of (4)(b), (c) and (d), below, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

The general license in (4)(a), above, applies only to radioactive material

accordance with the specifications contained in a specific license issued

license issued by the department pursuant to 64E-5.210(4) or in

by the NRC, or an agreement state, which authorizes distribution of

devices to persons granted a general license by the U.S. NRC, or an agreement state. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in

contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific

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(b)2. The devices must have been received from one of the specific licenses described in (b)1., above or through a transfer made under subparagraph 6E-5.206(4)(c)8., F.A.C.

Section 179.21 of 21 CFR Part 179. (Pursuant to 120.54(6) Florida

Statutes, 64E-5.206(4)(b)1. is substantively identical to 10 CFR 31.5(b)(1)

Any person who owns, receives, acquires, possesses, uses, or transfers (c) radioactive material in a device pursuant to the general license in (4)(a), above:

- Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;
- 2. Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label. However,
  - a. Devices containing only krypton need not be tested for leakage of radioactive material; and
  - Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- or gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
- 3. Shall assure that other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed:
  - a. In accordance with the instructions provided by the labels, or
  - By a person holding an applicable specific license from the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to perform such activities;
- 4. Shall maintain records showing compliance with the requirements of (4)(c)2. and 3., above. The records shall show the results of tests. The records also shall show the dates of performance of. and the names of persons performing testing, installation, servicing and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by (4)(c)2., above, shall be maintained for at least three years after the next required leak test is performed or until the transfer or disposal of the sealed source. Records of tests of the on-off mechanism and indicator required by (4)(c)2., above, shall be maintained for at least three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by (4)(c)3., above, shall be maintained for a period of at least three years from the date of the recorded event or until the transfer or disposal of the device; (Pursuant to 120.54(6) Florida Statutes, 64E-5.206(4)(c)4. is substantively identical to 10 CFR 31.5(c)(4)i published on 01/01/2007.)

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- 5. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days. furnish to the department a report containing a brief description of the event and the remedial action taken; and in the case of removable radioactive materials or failure of or damage to a source likely to result in contamination of the premises or the environment. a plan for ensuring the premise and environment are acceptable for unrestricted use using the criteria described in Rule 64E-5.222, F.A.C.
- 6. Shall not abandon the device containing radioactive material;
- 7. Except as provided in (4)(c)8., below, shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph 15 below, transfer to a specific licensee of the department, the NRC, or an agreement state, whose specific license authorizes him to receive the device, and within 30 days after transfer of a device to a specific licensee, shall furnish to the department a report containing identification of the device by manufacturer's or initial transferor's name and model number and serial number, the name, address, license number, where applicable, of the person receiving the device and the date of the transfer:
- 8. Shall transfer the device by export as provided by paragraph 15 below, or to another general licensee only:
  - a. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section, a copy of Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C., and any safety documents identified in the label on the device and within 30 days of the transfer, report to the department the manufacturer's or initial transferor's name and model number and serial number of device transferred, the transferor's name and mailing address for the location of use, and the name title, and phone number of the responsible individual identified by the transferee in accordance with paragraph 64E-5.206(4)(c) and subsection (11), F.A.C., to have knowledge of and authority to take actions to ensure compliance with these regulations; or

- b. Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and
- 9. Shall comply with the provisions of 64E-5.343 and 64E-5.344 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Parts III and IX.
- 10. Shall be required to obtain written Department authorization before transferring the device to any other specific license not specifically identified in subparagraph 64E-5.206(4)(c)7, F.A.C. The Department authorization is granted provided the specific license identifies the device.
- 11. Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with the appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in the regard.
- 12. a. Shall register, in accordance with sub-subparagraphs 64E-5.206(4)(c)12.b., and 64E-5.206(4)(c)12.c., F.A.C., all devices except exit signs containing tritium. Each address for a location of use as described in sub-subparagraph 64E-5.206(4)(c)12.c.(IV), F.A.C., represents a separate general license and requires a separate registration.
  - b. Shall annually register with the Department the possession of a device meeting the criteria in sub-subparagraph 64E-5.206(4)(c)12.a., F.A.C. Registration must be done by verifying, correcting or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, the general licensee holding devices that meet the criteria of sub-subparagraph 64E-5.206(4)(c)12.a., F.A.C., is subject to the bankruptcy notification requirements in subsection 64E-5.213(3), F.A.C.
  - c. Shall provide the following information and any other information requested by the Department:
    - Name and mailing address of the general licensee;
    - (II) For each device, the manufacturer's name or initial transferor name, model number, serial number, the radioisotope and activity as identified on the label;

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- (III) Name, title, and telephone number of the responsible person designated a representative of the general licensee under paragraph 64E-5.206(4)(c) and subsection (11), F.A.C.;
- (IV) Address or location at which the device(s) are used or stored. For portable devices, the address of the primary place of storage;
- (V) Certification by the responsible representative of the general licensee that the information concerning the devices(s) have been verified through a physical inventory and checking the label information; and
- (VI) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.
- d. Persons generally licensed by other Agreement States, Licensing States, or the U.S. Nuclear Regulatory Commission with respect to devices meeting the criteria in 10 CFR 31.5(c)(13)(i) are not subject to registration requirements if the devices are used in areas subject to the Department jurisdiction for less than 180 days in any calendar year. The Department will not request registration from such licensees.
- 13. Shall report to the Department changes in the general licensee name and the mailing address for each location of use within 30 days of the effective date of the change. For a portable device, a report of address change is required for a change in the device's primary place of storage.
- 14. Shall not hold devices that are not in use longer than 2 years. If the devices with shutters are not being used, the shutters must be locked in the closed position. The testing required by subparagraph 64E-5.206(4)(c)2., F.A.C., need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two year time limit if the general licensee performs physical inventories at intervals not to exceed three months while they are in standby. (Pursuant to 120.54(6) Florida Statutes, 64E-5.206(4)(c)14. is substantively identical to 10 CFR 31.5(c)(15) published on 01/01/2007.)
- 15. Shall not export the device containing radioactive material except in accordance with 10 C.F.R. Part 110;

R8 16. Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Department, a written justification for the request for extension of time. (Pursuant to 120.54(6) Florida Statutes, 64E-5.206(4)(c)(16) is substantively identical to 10 CFR 31.5(c)(11) published on 01/01/2007.)

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- (9) Ice Detection Devices.
  - (a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium 90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium 90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the department or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.
  - (b) Persons who own, receive, acquire, possess, use or transfer strontium 90 contained in ice detection devices pursuant to the general license in (9)(a), above;
    - Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 64E-5.328;
    - 2. Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and
    - 3. Are exempt from the requirements of Parts III and IX except that such persons shall comply with the provisions of 64E-5.328, 64E-5.343 and 64E-5.344.
  - (c) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium 90 in ice detection devices.
  - (d) This general license is subject to the provisions of 64E-5.103 through 64E-5.104, 64E-5.213, 64E-5.215 and Part XV.
- (10) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S Law Implemented: 404.022, 404.051(1),(4),(6),(8),(9),(10),(11), 404.061(2), 404.071(1),(3), 404.081(1), 404.141, F.S. History: New July 17, 1985, amended April 4, 1989, Amended January 1, 1994, Formerly 10D-91.306, Amended September 28, 2006, Amended February 28, 2008.

# SUBPART C SPECIFIC LICENSES

# 64E-5.207 Filing Application for Specific Licenses.

- (1) Application for specific licenses, license renewals, and license amendments shall be filed with the department in triplicate on Application for Radioactive Materials License Non-Human Use, DH Form 1054 Dec 86 or Application for Radioactive Materials Human Use, DH Form 1322 Oct 92, in accordance with Regulatory Guide 1.30 dated October 1992, which are herein incorporated by reference.
- (2) The department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the department to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- (3) An existing license shall not expire until final action by the department if a licensee has filed an application for renewal in proper form not less than 30 days before expiration of his existing license or for a new license authorizing the same activities.
- (4) Applications for license amendments are not required to be submitted on DOH forms but shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.141, F.S. Law Implemented: 404.022, 404.051(1),(4),(6),(9),(10),(11), 404.061(2), 404.141, F.S. History: New July 17, 1985, Amended April 4, 1989, Amended May 12, 1993, Amended, May 15, 1996, Formerly 10D-91.307.

**64E-5.208** General Requirements for the Issuance of Specific Licenses. A license application for a new, amended, or renewed license\_will be approved if the department determines that:

- (1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property;
- (2) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property.

Specific Authority: 404.051, 404.061, 404.071, 404.141, F.S. Law Implemented: 404.022, 404.051(1),(4),(6),(10),(11), 404.061(2), 404.141, F.S. History: New July 17, 1985, Amended May 12, 1993, Amended, May 15, 1996, Formerly 10D-91.308.

- (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.
- (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:
  - 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;
  - 2. A copy of Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C.;
  - 3. A list of services that can only be performed by a specific licensee;
  - Information on acceptable disposal options including costs of disposal; and
  - An indication that department policy is to issue high civil penalties for improper disposal.
- (e) If a device containing radioactive material is transferred for use under an equivalent general license of an Agreement State or the NRC, 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:

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- 1. Report all transfers of devices to persons for use under the general license in an Agreement State or the NRC, that are equivalent to subsection 64E-5.206(4), F.A.C., and all receipts of devices from persons licensed under a general license in Agreement State or the NRC jurisdiction to the responsible Agreement State, or the NRC agency. This report must contain all of the information described in "Transfers of Industrial Devices Report 04/2007."
- 2. The report must be clear and legible and contain the following data:
  - 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:
  - 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;
  - c. The date of transfer;

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- The type, model number, and serial number of the device transferred; and
- e. The quantity and type of radioactive materials contained in the device.
- 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).
- 4. For devices received from a 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.
- 5. If the licensee makes changes to the device possessed by a 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.
- 6. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

- 7. If no transfers have been made to or from a particular Agreement State or the NRC during the reporting period, this information shall be reported to the responsible Agreement State or the NRC agency upon request of the agency.
- 8. The report must cover each calendar quarter and must be filed within 30 days of the end of the calendar quarter and must clearly indicate the period covered by the report.
- (j) The persons shall maintain all information concerning transfers and receipts of devices that supports the reports required by subsection 64E-5.210(4), F.A.C. Records and reports described in subsection 64E-5.210(4), F.A.C., shall be maintained for inspection by the department for a period of 3 years following the date of the recorded event.
- (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:

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

- 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.
- 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 Byproduct 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.
- (15) Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters. (Pursuant to 120.54(6) Florida Statutes, 64E-5.210(15) is substantively identical to 10 CFR 32.201 published on 01/01/2007.)

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 Amended February 28, 2008.
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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

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- (2) receive title to, receive, possess and use source material for milling or byproduct 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.

(5) Shipment and transport of radioactive material shall be in accordance with the provisions of Part XV.

Specific Authority: 404.051, 404.061, 404.081, 404.141, 404.20, F.S Law Implemented: 404.022, 404.051(1),(2),(4),(11), 404.061(2), 404.081(1), 404.20(1), F.S. History: New July 17, 1985, Formerly 10D-91.319.

# SUBPART D RECIPROCITY

64E-5.216 Reciprocal Recognition of Licenses for By-product, Source, Naturally Occurring and Accelerator Produced Radioactive Material, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

- (1) Subject to these regulations, any person who holds a specific license from the NRC, or an agreement state and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, will be granted a general license by the department to conduct the activities authorized in such licensing document within the State of Florida, except for areas of exclusive federal jurisdiction, for a period not in excess of 365 consecutive days provided that:
  - (a) The out-of-state license document does not limit the performance of the function authorized by such document to specified installations or locations;
  - (b) The out-of-state licensee notifies the department in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner.
  - (c) The out-of-state licensee complies with these applicable regulations and with all the terms and conditions of the licensing document, except any such terms and conditions that are inconsistent with these applicable regulations; and
  - (d) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person:
    - Specifically licensed by the department, by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to receive such material, or
    - 2. Exempt from the requirements for a license for such material under Rule 64E-5.203(1)(a), F.A.C.

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- (e) Shall not possess or use radioactive materials or engage in activities authorized in 64E-5.216(1) above for more than a period in excess of 180 days in any calendar year. (Pursuant to 120.54(6) Florida Statutes, 64E-5.216(1)(e) is substantively identical to 10 CFR 150.20(b)(4) published on 01/01/2007.)
- (2) Notwithstanding the provisions of (1), above, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a Licensing State authorizing the holder to manufacture, transfer, install or service a device described in 64E-5.206(4)(a) within areas subject to the jurisdiction of the licensing body may be granted a general license by the department to install, transfer, demonstrate or service such a device in this State provided that:
  - (a) Such person shall file a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of radioactive material contained in the device;
  - (b) The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State;
  - (c) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
  - (d) The holder of the specific license shall furnish to each general licensee to whom he transfers such device, or on whose premises he installs such device, a copy of the general license contained in 64E-5.206(4) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.
- (3) The department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health, safety or property.

Specific Authority: 404.051(4),(11) 404.061(2), 404.081(1), 404.141, F.S. Law Implemented: 404.051(1),(2),(4),(6),(11), 404.061(2), 404.081(1), F.S.

History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.321, Amended October 8, 2000, Amended February 28, 2008.

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R8	64E-5	.350	Reports of Transactions Involving Nationally Tracked Sources. Each
			ufactures, transfers, receives, disassembles, or disposes of a nationally
R8			all complete and submit to the NRC a National Source Tracking Transaction
R8			d in paragraphs (1) through (5) of this section for each type of transaction.
R8			64(6) Florida Statutes, 64E-5.350, except 64E-5.350(8) as noted below, is
R8	substantively	/ ident	tical to 10 CFR 20.2207 effective 02/06/2007.)
Do	(4)	Гоор	licenses who manufactures a nationally tracked course shall complete and
R8 R8	(1)		licensee who manufactures a nationally tracked source shall complete and
R8			nit a National Source Tracking Transaction Report. The report must include ollowing information:
NO		נווכ ונ	moving information.
R8		(a)	The name, address, and license number of the reporting licensee;
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R8		(b)	The name of the individual preparing the report;
R8		(c)	The manufacturer, model, and serial number of the source;
R8		(d)	The radioactive material in the source;
110		(u)	The radioactive material in the source,
R8		(e)	The initial source strength in becquerels (curies) at the time of
R8		,	manufacture; and
R8		(f)	The manufacture date of the source.
R8	(2)	Each	licensee that transfers a nationally tracked source to another person shall
R8	(2)		blete and submit a National Source Tracking Transaction Report. The report
R8		•	include the following information:
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R8			
<b>D</b> •		(a)	The name, address, and license number of the reporting licensee;
$\Box$ 0		` /	
R8		(a) (b)	The name, address, and license number of the reporting licensee;  The name of the individual preparing the report;
R8 R8		` /	
		(b)	The name of the individual preparing the report;
R8 R8		(b)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;
R8 R8		(b)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not
R8 R8		(b)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;
R8 R8		(b)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not
R8 R8 R8 R8		(b) (c) (d)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;  The radioactive material in the source;
R8 R8 R8 R8		(b) (c)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
R8 R8 R8 R8 R8		(b) (c) (d) (e) (f)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;  The radioactive material in the source;  The initial or current source strength in becquerels (curies);
R8 R8 R8 R8 R8 R8		(b) (c) (d) (e) (f) (g)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;  The radioactive material in the source;  The initial or current source strength in becquerels (curies);  The date for which the source strength is reported;
R8 R8 R8 R8 R8		(b) (c) (d) (e) (f)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;  The radioactive material in the source;  The initial or current source strength in becquerels (curies);
R8 R8 R8 R8 R8 R8		(b) (c) (d) (e) (f) (g) (h)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;  The radioactive material in the source;  The initial or current source strength in becquerels (curies);  The date for which the source strength is reported;  The shipping date;
R8 R8 R8 R8 R8 R8 R8		(b) (c) (d) (e) (f) (g) (h)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;  The radioactive material in the source;  The initial or current source strength in becquerels (curies);  The date for which the source strength is reported;
R8 R8 R8 R8 R8 R8 R8 R8		(b) (c) (d) (e) (f) (g) (h)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;  The radioactive material in the source;  The initial or current source strength in becquerels (curies);  The date for which the source strength is reported;  The shipping date;  The estimated arrival date; and  For nationally tracked sources transferred as waste under a Uniform Low-
R8 R8 R8 R8 R8 R8 R8 R8 R8		(b) (c) (d) (e) (f) (g) (h)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;  The radioactive material in the source;  The initial or current source strength in becquerels (curies);  The date for which the source strength is reported;  The shipping date;  The estimated arrival date; and  For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the
R8 R8 R8 R8 R8 R8 R8 R8		(b) (c) (d) (e) (f) (g) (h)	The name of the individual preparing the report;  The name and license number of the recipient facility and the shipping address;  The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;  The radioactive material in the source;  The initial or current source strength in becquerels (curies);  The date for which the source strength is reported;  The shipping date;  The estimated arrival date; and  For nationally tracked sources transferred as waste under a Uniform Low-

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The initial or current source strength in becquerels (curies);

The date for which the source strength is reported;

The disassemble date of the source.

R8 Each licensee who disposes of a nationally tracked source shall complete and (5)R8 submit a National Source Tracking Transaction Report. The report must include the following information: R8 R8 The name, address, and license number of the reporting licensee: (a) R8 (b) The name of the individual preparing the report; R8 (c) The waste manifest number; R8 The container identification with the nationally tracked source; (d) R8 The date of disposal; and (e) R8 (f) The method of disposal. R8 (6) The National Source Tracking Transaction Report discussed in subsections (1) R8 through (5) of this section must be submitted to the NRC by the close of the next business day after the transaction. A single report may be submitted for multiple R8 sources and transactions. The reports must be submitted to the National Source R8 Tracking System by using: R8 R8 The on-line National Source Tracking System; (a) R8 (b) Electronically using a computer-readable format; R8 By facsimile; (C) R8 (d) By mail to the address on the NRC Form 748 National Source Tracking R8 Transaction Report Form; or R8 By telephone with followup by facsimile or mail. (e) (7) R8 Each licensee shall correct any error in previously filed reports or file a (a) new report for any missed transaction within 5 business days of the R8 discovery of the error or missed transaction. Such errors may be detected R8 by a variety of methods such as administrative reviews or by physical R8 R8 inventories required by regulation. R8 (b) In addition, every year each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that R8 R8 licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The R8 R8 reconciliation process must include resolving any discrepancies between R8 the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (1) through (5) of this section. In order to R8 R8 reconcile each transaction, the licensee shall file a report for missed R8 transactions or file a corrected report for previously submitted reports R8 containing inaccuracies. By January 31 of each year, each licensee must R8 submit to the National Source Tracking System confirmation that the data

in the National Source Tracking System is correct.

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R8 R8 R8 R8 R8 R8 R8 R8 R8	(8)	Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009 or as specified in 10 C.F.R. 20.2207(h), whichever is the latest. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009 or as specified in 10 C.F.R. 20.2207(h), whichever is the latest. The information may be submitted by using any of the methods identified by paragraph (6)(a) through (6)(e) of this section. The initial inventory report must include the following information: (Pursuant to 120.54(6) Florida Statutes, 64E-5.350(8) is substantively identical to 10 CFR 20.2207(h) effective 10/19/2007.)
R8		(a) The name, address, and license number of the reporting licensee;
R8		(b) The name of the individual preparing the report;
R8 R8 R8		(c) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;
R8		(d) The radioactive material in the sealed source;
		(e) The initial or current source strength in becquerels (curies); and
R8		(f) The date for which the source strength is reported.

R8 Specific Authority: 404.051, 404.081, F.S.

R8 Law Implemented: 404.022, 404.051, 404.081, F.S.

R8 History: New February 28, 2008.

R8 thresholds are listed in table 1 below with the Terabecquerel (TBq) values as the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion. (Pursuant to 120.54(6) Florida Statutes, 64E-5.351 is substantively identical to Appendix E to 10 CFR Part 20 effective 02/06/2007.

R8 Table 1

R8	Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
R8 R8	Actinium-227	20	540	0.2	5.4
R8	Americium-241	60	1,600	0.6	16
R8	Americium-241/Be	60	1,600	0.6	16
R8	Californium-252	20	540	0.2	5.4
R8	Cobalt-60	30	810	0.3	8.1
R8 R8	Curium-244	50	1,400	0.5	14
R8	Cesium-137	100	2,700	1	27
R8	Gadolinium-153	1,000	27,000	10	270
R8	Iridium-192	80	2,200	0.8	22
R8	Plutonium-238	60	1,600	0.6	16
R8	Plutonium-239/Be	60	1,600	0.6	16
R8 R8	Polonium-210	60	1,600	0.6	16
R8	Promethium-147	40,000	1,100,000	400	11,000
R8	Radium-226	40	1,100	0.4	11
R8	Selenium-75	200	5,400	2	54
R8	Strontium-90	1,000	27,000	10	270
R8 R8	Thorium-228	20	540	0.2	5.4
R8	Thorium-229	20	540	0.2	5.4
R8	Thulium-170	20,000	540,000	200	5,400
R8	Ytterbium-169	300	8,100	3	81

R8 Specific Authority: 404.051, 404.081, F.S.
R8 Law Implemented: 404.022, 404.051, 404.081, F.S.
R8 History: New February 28, 2008.

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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

R4	64E-5.423	DefinitionsIV-1
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R4	64E-5.424	Requirements for Industrial Radiography Equipment Using Sealed SourcesIV-3
R4	64E-5.425	Locking of Sources of Radiation, Storage Precautions, and SurveillanceIV-5
R4	64E-5.426	Radiation Survey Instruments
R6	64E-5.427	Leak Testing, Repairing, Tagging, Opening,
		Modifying and Replacing Sealed Sources and Devices
R4	64E-5.428	Quarterly Inventory
R6	64E-5.429	Source Movement Logs, Daily Survey Reports, and Individual Dosimeter LogsIV-8
R8	64E-5.430	Inspection and MaintenanceIV-9
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		E RADIATION SAFETY REQUIREMENTS (Formerly Subpart B)
	64E-5.432	Radiation Protection Program
	64E-5.433	Radiation Safety Officer
_	64E-5.434	Training, Testing, Certification, and Audits
	64E-5.435	Conducting Industrial Radiographic Operations
	64E-5.436	Operating and Emergency Procedures
R4	64E-5.437	Personnel MonitoringIV-18
R4	SUBPART F	PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS (Formerly Subpart C)
	64E-5.438	Radiation SurveysIV-20
	64E-5.439	PostingIV-21
	64E-5.440	RecordsIV-21
R8	64E-5.441	Reporting Requirements IV-23

- R4 (h) Evidence of performance of the equipment checks described in 64E-5.430(1), F.A.C.; R4 R4 (i) The results of the survey of the posted perimeter in mR/hr (mSv/hr) and R4 feet (meters); R4 (j) The total exposure time; and R4 (k) The start, end, and total pocket dosimeter readings for all radiographic R4 personnel. R4 (3)Radiographic personnel shall maintain an individual log of their daily dosimeter R4 totals. Each individual shall record the doses measured by his or her dosimeter R4 at the end of each day of radiographic operations and total the recorded doses at R4 the end of each week and at the end of each month. Copies of the individual R4 dosimeter logs shall be provided to the radiation safety officer (RSO) or the R4 RSO's designee no later than 7 days after each month. The RSO or the RSO's R4 designee shall review the logs within 7 days of receipt and shall date and sign or initial the logs at the time of the review. Each log shall include the following R4 information: R4 R4 The name of the individual: (a) R4 The dates of the monitoring periods; (b) R4 (c) The daily, weekly, and monthly individual radiation dose totals as R4 measured by the dosimeter; and
  - R4 Specific Authority: 404.051, F.S.

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- R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.
- R6 History: New September 11, 2001, Amended September 28, 2006.

# 64E-5.430 Inspection and Maintenance.

(1) Each licensee or registrant shall perform visual and operability checks on survey instruments, radiation machines, radiographic exposure devices, associated equipment, transport containers, storage containers, and source changers before use on each day the equipment is to be used to ensure the equipment is in good working condition, the sources are shielded adequately, and required labeling is present. All appropriate parts shall be maintained in accordance with the manufacturer's specifications. Each radiation survey instrument shall be visually inspected, have its batteries checked, and have its operability checked with a radiation source at the beginning of each day of use and at the beginning of each work shift. If equipment problems are found, the equipment shall be removed from service until repaired.

signature or initials of the RSO or the RSO's designee.

The date the log was reviewed by the RSO or the RSO's designee and the

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- R8 (2) Each licensee or registrant shall have written procedures and perform equipment inspection and maintenance as described below. (Pursuant to 120.54(6) Florida Statutes, 64E-5.430(2) is substantively identical to 10 CFR 34.31(b) published on 01/01/2007.)
  - (a) Inspection and maintenance of survey instruments, radiation machines, radiographic exposure devices, associated equipment, source changers, storage containers, and transport containers shall be performed quarterly to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with the manufacturer's specifications. Verification of compliance with radiation limits specified in 64E-5.424(4), F.A.C., shall be included in each quarterly inspection. If equipment problems are found, the equipment shall be labeled as defective and removed from service until repaired. Replacement components shall meet manufacturer's specifications.
  - (b) Inspection and maintenance of Type B packages used to transport radioactive materials shall be performed quarterly in accordance with each package's certificate of compliance or other approval.
- R4 Specific Authority: 404.051, F.S.
- R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.
- R8 History: New September 11, 2001, Amended February 28, 2008.

# 64E-5.431 Permanent Radiographic Installations.

- (1) Each entrance used for personnel access to a high radiation area in a permanent radiographic installation shall have either:
  - (a) An entrance control that reduces the radiation level to below the level at which an individual might receive a deep dose equivalent of 0.1 rem (1 millisievert) in 1 hour at 30 centimeters from the source of radiation from any surface the radiation penetrates, or
  - (b) Conspicuous visible and audible signals to warn of the presence of radiation. The visible signal shall be actuated by radiation. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed or the radiation machine is activated.
- (2) The alarm system shall be tested for proper operation with a radiation source each day before radiographic operations. The test shall include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry shall be tested monthly. If an entrance control device or an alarm is operating improperly, it shall be labeled immediately as defective and repaired within 7 days. The installation can continue to be used by an unaccompanied radiographer during this 7-day period if the continuous surveillance requirements of 64E-5.425(6), F.A.C., are implemented and an alarming ratemeter is used.
- R4 Specific Authority: 404.051, F.S.
- R4 Law Implemented: 404.022, 404.051(1), (4), F.S..
- R4 History: New September 11, 2001.

R4 **64E-5.439 Posting.** In addition to the posting requirements specified in R4 64E-5.901, F.A.C., the licensee or registrant shall comply with the requirements described R4 below.

- R4 (1) Radiation areas and high radiation areas created by radiographic operations shall be posted conspicuously as specified in 64E-5.323(1) and (2), F.A.C. Areas or rooms in which licensed material is used or stored shall be posted as specified in 64E-5.323(5), F.A.C. The exceptions to posting specified in 64E-5.324(1), F.A.C., do not apply to industrial radiography.
- R4 (2) Source movement logs specified in 64E-5.429, F.A.C., that document the current location of each source of radiation and source movements for the previous 30 days shall be posted conspicuously adjacent to the area where the source of radiation is stored.
- R4 Specific Authority: 404.051, F.S.

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- R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), 404.20, F.S.
- R4 History: New September 11, 2001.

# R4 **64E-5.440** Records.

- (1) Each licensee or registrant shall maintain the following records for 3 years after the event at the location specified in 64E-5.432, F.A.C., for inspection by the department:
  - (a) Survey instrument, dosimeter, and alarm ratemeter calibrations specified in 64E-5.426 and 64E-5.437(5) (6), F.A.C.;
  - (b) Leak test results specified in 64E-5.427, F.A.C., which shall contain the manufacturer's name, model, and serial number of each sealed source or device tested, including the device the source was stored in, the identity of each radionuclide, the estimated activity of each sealed source, the measured activity of each test sample expressed in microcuries (becquerels), the date of the test, and the signature or initials of the RSO or the RSO's designee;
  - (c) Quarterly inventories specified in 64E-5.428, F.A.C., which shall include the name of the person conducting the inventory, the radionuclide, number of curies (becquerels) or mass in each device, location of each sealed source, device, and machine, the manufacturer, model, and serial number of each sealed source, device, and machine, the date of the inventory, and the signature or initials of the RSO or the RSO's designee;
  - (d) Source movement logs and daily survey reports specified in 64E-5.429, F.A.C.
  - (e) Quarterly equipment inspection and maintenance specified in 64E-5.430(2), F.A.C., including the date of the inspection, the name of inspector, the equipment involved, any problems found, and what repair or maintenance was done;

:			
R4 R4		(f)	Operation tests on permanent radiographic installation entrance controls and audible and visual alarms specified in 64E-5.431, F.A.C.;
R4 R4		(g)	Records of internal audits specified in 64E-5.434(8), F.A.C., including lists of audit items checked and any violations observed;
R4 R4 R4 R4 R4		(h)	Records showing receipts and transfers of sealed sources and devices using DU for shielding, including the date, the name of the individual making the record, radionuclide, number of curies (becquerels) or mass, manufacturer, model, and serial number of each sealed source and device, as appropriate.
R6 R6		(i)	Records of annual ALARA audits specified in paragraph 64E-5.432(4)(c), F.A.C.
R4 R4	(2)		licensee or registrant shall maintain the following records until the rtment terminates the license or registration requiring the record:
R4		(a)	Individual dosimeter logs specified in 64E-5.429, F.A.C.;
R4 R4 R4 R4		(b)	Initial and refresher radiation safety training specified in 64E-5.434, F.A.C., including lists of the topics discussed, dates the training was conducted, names of the instructors and attendees, and written and practical examinations;
R4		(c)	Verification of previous radiography experience;
R4 R8		(d)	Radiographer certification documents specified in 64E-5.434(2)(d), F.A.C., and verification of certification status;
R4 R4 R4 R4 R4		(e)	Records of personnel exposure investigations specified in 64E-5.432(4)(b), F.A.C., including the names of the individuals involved, the exposures received, the dates the exposures were received, a description of the cause of the exposures, the corrective actions taken, and the signature of the RSO;
R4 R4 R4 R4		(f)	Records of estimates of exposures as a result of off-scale dosimeters or lost or damaged personnel monitoring badges, including records of surveys used to determine an individual's exposure and reports submitted to the department as specified in 64E-5.437(3), F.A.C.;
R6 R6		(g)	Personnel monitoring badge records from the accredited NVLAP processor as specified in subsection 64E-5.437(2), F.A.C.; and
R6 R6 R6		(h)	Operating and emergency procedures. Licensees shall retain superseded material for 3 years after making changes to operating or emergency procedures.
R4 R4 R4	(3)	site s	licensee or registrant conducting industrial radiography at a temporary job shall have the following records available at that site for inspection by the orthography:

Florida Administrative Code

64E-5.440

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- R4 (a) Appropriate license or registration; R4 (b) Certification by a certifying entity; R4 (c) Operating and emergency procedures; R4 (d) Rules contained in Chapter 64E-5, Parts I – IV, IX, and XV, F.A.C.; R4 (e) Calibration records for the survey instruments, pocket dosimeters, and alarm ratemeters used at the site or calibration tags or labels that are R4 R4 affixed to the devices: R4 (f) Records of the latest leak test results for the specific devices in use at the site or leak test tags or labels that are affixed to the devices; and R4 R4 Source movement logs and daily survey reports for the period of operation (g) R4 at the site.
- R4 Specific Authority: 404.051, F.S.

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- R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), 404.20, F.S.
- R8 History: New September 11, 2001, Amended September 28, 2006, Amended February 28, 2008.

# 64E-5.441 Reporting Requirements.

- (1) In addition to the reporting requirements specified in rules contained in Chapter 64E-5, Parts III and IX, F.A.C., and other sections of this part, each licensee shall provide a written report to the department within 30 days of the occurrence of any of the incidents involving radiographic equipment described below. Such reports shall be mailed to the Bureau of Radiation Control, Radioactive Materials Section, Bin C21, 4052 Bald Cypress Way, Tallahassee, Florida 32399-1741 for incidents involving radioactive materials or to the Bureau of Radiation Control, Radiation Machine Section, 705 Wells Road, Suite 300, Orange Park, Florida 32073 for incidents involving radiation machines.
  - (a) Unintentional disconnection of the source assembly from the control cable.
  - (b) Inability to retract and secure the source assembly to the fully shielded position.
    - (c) Failure of any component critical to safe operation of the device to perform its intended function properly.
- (2) The licensee shall include the information described below in each report submitted as specified in this section.
- R4 (a) A description of the equipment problem.
- R4 (b) Cause of each incident if known.
- R4 (c) Manufacturer name and model number of the equipment involved in the incident.

=	64E-5	Florida Administrative Code	64E-5.441
R4		(d) Place, time, and date of the incident.	
R4		(e) Actions taken to establish normal operations.	
R4		(f) Corrective actions taken or planned to prevent recurrence.	
R4		(g) Qualifications of the personnel involved in the incident.	
R4 R4 R4	(3)	Reports of overexposures submitted as specified in rules contained Chapter 64E-5, F.A.C., that involve failure of safety components of equipment also must include the information specified in 64E-5.4410	adiography
R8 R8 R8 R8	(4)	Any licensee conducting radiographic operations or storing radioaction any location not listed on the license for a period in excess of 180 dacalendar year, shall notify the Department prior to exceeding the 180 (Pursuant to 120.54(6) Florida Statutes, 64E-5.441(4) is substantive 10 CFR 34.101(c) published on 01/01/2007.)	ays in a 0 days.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.

R8 History: New September 11, 2001, September 28, 2006, Amended February 28, 2008.

	PART X ENVIRONMENTAL RADIATION STANDARDS	
	SUBPART A RADIATION STANDARDS FOR BUILDINGS	
	64E-5.1001 Standards	X-1
	SUBPART B ENVIRONMENTAL MONITORING	
	64E-5.1002 Monitoring Requirements	X-1
R8	64E-5.1003. Monitoring Fees	X-2

# PART X

# **ENVIRONMENTAL RADIATION STANDARDS**

# Subpart A

## **ENVIRONMENTAL RADIATION STANDARDS**

## 64E-5.1001 Standards.

- (1) Radiation exposure to the public from naturally occurring radioactive materials shall be maintained as low as reasonably achievable. For the purposes of this part, the normal background level of gamma radiation in buildings is 6 microroentgens (1.55 nC/kg) per hour and the normal background radon decay product concentration in buildings is 0.004 Working Level (WL).
- (2) The mean gamma exposure rate in a building shall not exceed 20 microroentgens (5.16 nC/kg) per hour, including background, and the annual average radon decay product concentration shall not exceed 0.02 WL, including background.

Specific Authority: 404.051, 404.056, F.S.

Law Implemented: 404.022(2), 404.051(4), 404.056, F.S.

History: New February 16, 1986, Amended January 3, 1989, Formerly 10D-91.1104.

# Subpart B

### **ENVIRONMENTAL MONITORING**

**64E-5.1002 Monitoring Requirements**. The department will perform the following tests both prior to phosphate mining and subsequent to reclamation:

- (1) Gamma radiation exposure measurements.
- (2) Soil characterization measurements consisting of
  - (a) Radon emanation determinations.
  - (b) Soil radium determinations.
- (3) Air monitoring determinations.
- (4) Surface and ground water monitoring of such water that is potentially affected by mining activities unless existing test data is available.

Specific Authority: 404.051, 404.056, F.S.

Law Implemented: 404.022(2), 404.051(4), 404.056, F.S.

History: New November 13, 1985, Amended September 26, 1991, Amended May 15, 1996, Formerly 10D-91.1003

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# 64E-5.1003 Monitoring Fees.

- (1) The costs incurred by the department and the subsequent fees associated with the monitoring program shall be annually prorated on the basis of the total number of measurements to be made on land proposed to be mined and land proposed to be reclaimed, excluding bodies of water.
- (2) The annual fees paid by the mining companies shall be calculated by the following method:
  - (a) Gamma radiation exposure measurements will be made at the rate of one per acre. An annual fee of \$11.63 per measurement shall be assessed the mining company by the department.
  - (b) Soil characterization measurements will be made at the rate of one per 20 acres. An annual fee of \$496.00 per each 20 acres measured shall be assessed the mining company by the department.
  - (c) Air monitoring measurements will be assessed at the rate of \$255.75 per measurement. The department shall prorate the cost of air monitoring measurements among the mining companies based on their share of the total acreage to be mined and reclaimed each year. The department will conduct no more than 272 air monitoring measurements per year for all mining companies for which a fee will be assessed.
  - (d) Surface and ground water monitoring measurements will be assessed at the rate of \$300.00 per measurement. The department shall prorate the cost of water monitoring among the mining companies based on their share of the total acreage to be mined and reclaimed each year. The department will analyze no more than 160 water samples per year for all mining companies for which a fee will be assessed.
- (3) The department shall bill each affected company by March for activities which are planned for the following July through December time period. The department shall bill each affected company by September for activities which are planned for the following January through June time period. Each mining company shall remit the fee to the department within 60 days of the billing date.
- (4) Overpayments or underpayments from an affected company will be reconciled by the department on an annual basis.

Specific Authority: 404.022, 404.051, 404.056, 404.131, F.S. Law Implemented: 404.022(2), 404.051(4), 404.131(5), F.S.

History: New November 13, 1985, Amended September 26, 1991, Amended February 28, 2008, Formerly 10D-91.1112.

	PART XI RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE	E OPERATIONS
R1	64E-5.1101Prohibitions	XI-1
	SUBPART A EQUIPMENT CONTROL	
	64E-5.1102Storage and Transportation Precautions	XI-2
R2	64E-5.1103Radiation Survey Instruments	XI-2
R6	64E-5.1104Leak Testing of Sealed Sources	
	64E-5.1105Quarterly Inventory	
	64E-5.1106Utilization Records	
R6	64E-5.1107Design, Performance and Certification Criteria for Sealed Source	
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R6	64E-5.11071Uranium Sinker Bars	XI-5
R8	64E-5/11072Energy Compensation Source	XI-6
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R6 History: New September 28, 2006

- (1) For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is subject only to the requirements specified in Rules 64E-5.1104, 64E-5.1105, and 64E-5.1106, F.A.C., above.
- For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is subject only to the requirements specified in Rules 64E-5.1101, 64E-1104, 64E-5.1105, 64E-5.1106, 64E-5.1119(5), and 64E-5.343 through 64E-5.349, F.A.C.
- R6 Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S.
- R6 Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.071(1), 404.081(1), F.S.
- R8 History: New September 28, 2006, Amended February 28, 2008.

# 64E-5.11073 Tritium Neutron Generator Target Source.

- (1) Use of a tritium neutron generator target source containing quantities not exceeding 30 curies (1,110 MBq) and in a well with a surface casing to protect fresh water aquifers is not subject to the requirements specified in Rules 64E-5.1101, 64E-5.1107, 64E-5.1119(5), and 64E-5.343 through 64E-5.349, F.A.C.
- (2) Use of a tritium neutron generator target source containing more than 30 curies (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers is not subject to the requirements specified in Rule 64E-5.1107, F.A.C.
- R6 Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S.
- R6 Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.071(1), 404.081(1), F.S.
- R6 History: New September 28, 2006

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# 64E-5.1108 Labeling.

(1) Each source, source holder or logging tool containing radioactive material shall bear a durable, legible and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol as described and illustrated in 64E-5.322, without the conventional color requirement, and the following wording:

# DANGER (OR "CAUTION") RADIOACTIVE

This label shall be on the smallest component transported as a separate piece of equipment.

(2) Each transport container shall have permanently attached to it a durable, legible and clearly visible label which has, as a minimum, the standard radiation caution symbol as described and illustrated in 64E-5.322 and the following wording:

# DANGER (OR "CAUTION") RADIOACTIVE NOTIFY CIVIL AUTHORITIES IF FOUND

Specific Authority: 404.051, 404.061, 404.081, 404.20, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.081(1), 404.20(1), F.S. History: New July 17, 1985, Amended <u>January 1, 1994</u>, Formerly 10D-91.1209.

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# **PART XV**

# TRANSPORTATION OF RADIOACTIVE MATERIALS

#### **R8** 64E-5.1501 Purpose and Scope.

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- (1) The packaging and transportation of radioactive material are also subject to the requirements of other agencies such as the U.S. Department of Transportation. the U.S. Nuclear Regulatory Commission and the U.S. Postal Service. The requirements of this part are in addition to, and not in substitution for, other requirements.
- (2) Determinations and listings of A<sub>1</sub> and A<sub>2</sub> values are found in 10 CFR Part 71, Appendix A as published on 01/01/2007.
- (3)The regulations in this part apply to any licensee authorized by specific or general license issued by the Department to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the license, or transports that material on public highways. No provision of this part authorizes possession of licensed material.
- (4) Definition of terms used in this part are those listed in 49 C.F.R. and 10 C.F.R. 71.4, except that whenever a definition refers to evaluation or approval by the U.S. Department of Transportation or NRC, and such evaluation or approval is within the jurisdiction of the State of Florida as an Agreement State. the Department shall perform the evaluation or approval.

Specific Authority: 404.051, 404.20, F.S. Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.20(1), F.S.

R8 History: New July 17, 1985, Amended May 15, 1996, Formerly 10D-91.2001, Amended February 28, 2008.

#### 64E-5.1502 Transportation of Radioactive Material.

- (1) No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general license or specific license issued by the department or as exempted in 64E-5.1503.
- (2) Each licensee who transports radioactive material outside of the confines of his facility or other place of use, or who offers radioactive material to a carrier for transport shall:
  - (a) Comply with the current applicable requirements, appropriate to the mode of transport, of 49 CFR Parts 107, 171-180, 383, 390-397 published on 10/01/2007, and 10 C.F.R. Part 71 published on 01/01/2007.
  - (b) Establish procedures for safely opening and closing packages in which radioactive material is transported and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport;
  - (c) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

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R8 R8	(d)		icensee shall comply with U.S. Department of Transportation and regulations in the following areas:
R8		1.	Packaging, 49 C.F.R. part 173, subparts A, B, and I;
R8 R8		2.	Marking and labeling, 49 C.F.R. part 172, subpart D, §§172.400 through 172.407, §§172.436 through 172.441 of subpart E;
R8 R8		3.	Placarding, 49 C.F.R. part 172, subpart F, especially §§172.500 through 172.519 and 172.556, and appendices B and C;
R8		4.	Accident reporting, 49 C.F.R. part 171, §§171.15 and 171.16;
R8 R8		5.	Shipping papers and emergency information, 49 C.F.R. part 172, subparts C and G;
R8 R8		6.	Hazardous material employee training, 49 C.F.R. part 172, subpart H;
R8		7.	Security plans, 49 C.F.R. part 172, subpart I;
R8 R8		8.	Hazardous material shipper/carrier registration, 49 C.F.R. part 107, subpart G;
R8		9.	Definitions, 10 C.F.R. 71.4;
R8		10.	Transportation of licensed material, 10 C.F.R. 71.5;
R8		11.	Exemptions for low level material, 10 C.F.R. 71.14(a);
R8		12.	General license, NRC-approved package, 10 C.F.R. 71.17;
R8		13.	Previously approved package, 10 C.F.R. 71.19(a) and (b);
R8 R8		14.	General license, U.S. Department of Transportation specification container material, 10 C.F.R. 71.20;
R8 R8		15.	General license, Use of foreign approved package, 10 C.F.R. 71.21;
R8		16.	General license, Fissile material, 10 C.F.R. 71.22;
R8		17.	External radiation standards for all packages, 10 C.F.R. 71.47;
R8		18.	Assumptions as to unknown properties, 10 C.F.R. 71.83;
R8		19.	Preliminary determinations, 10 C.F.R. 71.85;
R8		20.	Routine determinations, 10 C.F.R. 71.87;
R8		21.	Air transportation of plutonium, 10 C.F.R. 71.88;

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R8		22.	Opening instructions, 10 C.F.R. 71.89;
R8 R8		23.	Advance notification of shipment of irradiated reactor fuel and nuclear waste, 10 C.F.R. 71.97
R8 R8		24.	Quality assurance requirements, 10 C.F.R. 71.101(a), (b), (c), (f) and (g);
R8		25.	Quality assurance organization, 10 C.F.R. 71.103;
R8		26.	Quality assurance program, 10 C.F.R. 71.105;
R8		27.	Exemption of physicians, 10 C.F.R. 71.13;
R8		28.	Handling storage and shipping control, 10 C.F.R. 71.127;
R8		29.	Inspection tests and operating status, 10 C.F.R. 71.129;
R8		30.	Nonconforming materials parts or components, 10 C.F.R. 71.131;
R8		31.	Corrective action, 10 C.F.R. 71.13;
R8		32.	Quality assurances records, 10 C.F.R. 71.135;
R8		33.	Audits, 10 C.F.R. 71.137;
R8		34.	Appendix A to Part 71; and
R8		35.	General license plutonium beryllium special form material.
R8 R8	(e)		censee shall also comply with U.S. Department of Transportation ations pertaining to the following modes of transportation:
R8		1.	Rail, 49 C.F.R. part 174, subparts A through D and K;
R8		2.	Air, 49 C.F.R. part 175;
R8		3.	Vessel, 49 C.F.R. part 176, subparts A through F and M; and
R8		4.	Public Highway, 49 C.F.R. part 177 and parts 390 through 397.
R8 R8 R8 R8 R8 R8 R8	of lice requir of this subject modifi	nsed nements section to U. cation.	rtment of Transportation regulations are not applicable to a shipment naterial, the licensee shall conform to the standards and s of the U.S. Department of Transportation specified in paragraph (2) in to the same extent as if the shipment or transportation were S. Department of Transportation regulations. A request for waiver, or exemption from those requirements, and any notification those requirements, must be filed with, or made to, the Department.

Specific Authority: 404.051, 404.061, 404.141, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.061(2), 404.141, 404.20(1), F.S.

R8 History: New July 17, 1985, Formerly 10D-91.2003, Amended October 8, 2000, Amended September 28, 2006, Amended February 28, 2008.

# 64E-5.1503 Exemptions.

- (1) Common and contract carriers, freight forwarders, and warehousemen who are subject to the requirements of the U.S. Department of Transportation in 49 CFR Parts 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR Part 111.1 (1974), are exempt from these regulations to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 64E-5.1501 and other applicable sections of these regulations.
- (2) Any licensee is exempt from the requirements of this part to the extent that he delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 0.002 microcurie (74 Bq) per gram.

Specific Authority: 404.051, 404.061, 404.141, 404.20, F.S. Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.061(2), 404.141, 404.20(1), F.S. History: New July 17, 1985, Formerly 10D-91.2004.

# 64E-5.1504 General Licenses for Carriers.

- (1) A general license is hereby issued to any common or contract carrier not exempt under 64E-5.1503 to receive, possess, transport and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in these U.S. Department of Transportation requirements shall also be filed with, or made to, the department.
- (2) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in these U.S. Department of Transportation requirements shall be filed with, or made to, the department.
- (3) Persons who transport radioactive material pursuant to the general license in 64E-5.1504(1) or (2) are exempt from the requirements of Parts III and IX to the extent that they transport radioactive material.

Specific Authority: 404.051, 404.061, 404.141, 404.20, F.S. Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.061(2), 404.141, 404.20(1), F.S. History: New July 17, 1985, Formerly 10D-91.2005.