

January 2007

Bureau of Radiation Control RADIOACTIVE MATERIALS SECTION Information Notice 2007-01

Revision 6 Filing Instructions: Changes to Chapter 64E-5, Florida Administrative Code (F.A.C.)

Changes were made to "Control of Radiation Hazard Regulations," Chapter 64E-5, F.A.C., which became effective September 28, 2006. These changes are indicated as Revision 6 or (R6) 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, and 5 changes have been made before making these changes. This can be verified by checking page ii of the index. **Visit our website at**

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
	Page Number	Page Number
Index	i through xii	i through xii
I General Provisions	Part I Index I-1 through I-24	Part I Index I-1 through I-24
II Licensing of Radioactive Materials	Part II Index 9c/10, 15/16, 17/18,19/20 29/30, 39/40, 41/42 43/44 57/58, 59/60	Part II Index 9c/10, 15/16, 17/18,19/20 New pages 20a/20b 29/30, 39/40, 41/42 43/43a New Pages 43b/43c, 43d/44 57/58, 59/60
III Standards for Protection	Part III Index 1/2, 3/4, 15/16, 17/18	Part III Index 1/2, 3/4, 15/16, 17/18
IV Radiation Safety Requirements for Industrial Radiographic Operations	Part IV Index 7/8, 9/10, 13/14, 15/16, 21/22, 23/24	Part IV Index 7/8, 9/10, 13/14, 15/16, 21/22, 23/24
XI Radiation Safety Requirements for Wireline Service Operations	Part XI Index 3 through14	Part XI Index 3 through14 New Pages 15/16
XIII Radiation Safety Requirements for Possession and Use of Sealed or Unsealed Sources of Radioactive Materials	Part XIII Index 7/8	Part XIII Index 7/8

www.doh.state.fl.us/environment/radiation/ to download R6 pages to replace.

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
	Page Number	Page Number
XV Transportation of Radioactive Materials	Part XV Index 1/2	Part XV Index 1/2
Attachment 2 – Protection Factors for Respirators	63 through 67 (all pages)	63 through 66 (page 67 removed)
New Attachment - Transfers of Industrial Devices Report 10- 2003		1 through 7 at end of attachments

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

- Part I: Definitions to support the terms used in part XI and Attachment 2 added and the rest of the definitions renumbered.
- Part II: Substantial changes to general licensees possessing devices containing radioactive materials, manufacturers and distributors that require information to be submitted when a device is received or transferred, An additional information notice will be sent describing these changes.
- Part III: Shallow dose equivalent determination modified and respiratory protection (respirators) used to limit intake of radioactive materials substantially changed to meet current federal standards.
- Part IV: Source movement logs must now include the dates removed and returned to storage and identity of the radiographer.
- Part XI: Substantial changes to wireline service operation rules to allow the use of uranium sinker bars, energy compensation sources and tritium neutron generator target sources as currently allowed under federal standards.
- Part XIII: Substantial change in the security of portable gauges that takes effect January 1, 2007. After this date each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee. This is in accordance with current federal standards. An additional information notice will be developed.
- Part XV Licensee must now comply with current federal transportation regulations when they go into effect. This change removes the potential conflict that Florida regulations could have with current federal regulations (49 CFR).

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

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

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 P.O. Box 210 Jacksonville, FL 32231 Telephone: (904) 359-6363 Fax: (904) 359-6362

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

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

	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,		

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- R5 Notice to Employees 3/01
- R1 Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997
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PART I

GENERAL PROVISIONS

64E-5.101 Definitions. As used in these rules, these terms have the definitions set forth below. Additional definitions used only in a certain part are defined in that respective part.

- (1) "A₁" means the maximum activity of special form radioactive material permitted in a Type A package.
- (2) "A₂" means the maximum activity of radioactive material, other than special form or low specific activity radioactive material, permitted in a Type A package.
- (3) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.
- (4) "Accelerator-produced material" means any material made radioactive by a particle accelerator.
- (5) "Act" means the Florida Radiation Protection Act, Chapter 404, Florida Statutes.
- (6) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).
- (7) "Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, used, or stored.
- (8) "Adult" means an individual 18 or more years of age.
- (9) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors or gases.
- (10) "Airborne radioactivity area" means a room, enclosure or operating area in which airborne radioactive materials exist in concentrations:
 - (a) In excess of the derived air concentrations (DACs) specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, which is herein incorporated by reference and which is available from the department, or
 - (b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

- (11) "ALARA" means as low as reasonably acheivable making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to use of nuclear energy and licensed or registered sources of radiation in the public interest.
- (12) "Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.
- (13) "Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

(189) Annual or Annually means an interval not to exceed 12 months.

- (14) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by Reference Man that would result in a committed effective dose equivalent of 5 rem (0.05 sievert) or a committed dose equivalent of 50 rem (0.5 sievert) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Columns 1 and 2.
- (15) "Area of use" means a portion of a physical structure that has been set aside to receive, use, or store radioactive material.
- R6 (180) "Assigned protection factor" or "APF" means the expected workplace level of
 R6 respiratory protection provided by a properly functioning respirator or a class of
 R6 respirators to properly fitted and trained users. Operationally, the inhaled
 R6 concentration can be estimated by dividing the ambient airborne concentration by
 R6 the APF.
 - (176) "Authorized nuclear pharmacist" means a pharmacist who is actively licensed as a nuclear pharmacist by the Board of Pharmacy as specified in Rule 64B16-28.903, F.A.C., and is authorized on a radioactive materials license by the department.
 - (181) "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators and self-contained breathing apparatus units.
 - (16) "Authorized user" means a physician, dentist or podiatrist who is identified as an authorized user on a department, U.S. Nuclear Regulatory Commission, agreement state, or licensing state license that authorizes the medical use of radioactive material.

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- (17) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation. Background radiation does not include sources of radiation from radioactive materials regulated by the department.
- R4(18) "Baggage x-ray system" means a cabinet x-ray system with a maximum energyR4less than 120 kVp that produces only fluoroscopic images and that is used forR4packages or carry-on baggage.
- R4 (19) "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (s^{-1}).
- R4 (20) "Bioassay" means the determination of kinds, quantities or concentrations, and in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.
- R4 (21) "Brachytherapy" means a method of radiation therapy in which sealed sources are used to deliver a radiation dose by surface, intracavitary, or interstitial application.
- R4 (22) "Byproduct material" means:
 - (a) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and
 - (b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface waste resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute byproduct material within this definition.
- (<mark>23</mark>) R4 "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an R4 enclosure or cabinet that, independently of existing architectural structures except the floor on which it is placed, is intended to contain at least the portion of R4 the material being irradiated, to provide radiation attenuation, and to exclude R4 R4 persons from its interior during generation of x-radiation. An x-ray tube used R4 within a shielded part of a building or x-ray equipment that temporarily or R4 occasionally incorporates portable shielding is not considered a cabinet x-ray R4 system.

- R4 (24) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin on January 1 and subsequent calendar quarters shall be arranged so that no day is included in more than 1 calendar quarter, no calendar quarter, or part thereof, is included in more than 1 calendar year, and no day in any 1 year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him to determine calendar quarters for purposes of these rules except at the beginning of a calendar year.
- R4 (25) "Calibration" means:
 - (a) The determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
 - (b) The determination of the strength of a source of radiation relative to a standard.
- R4 (26) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier or by civil aircraft.
- R4 (27) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.
- R4 (28) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.
- R4 (29) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.
- R4 (30) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).
- R4(31) "Constraint" or "dose constraint" means a value above which specified licenseeR2actions are required.
- R6 (177) "Critical Group" means the group of individuals reasonably expected to receive R5 the greatest exposure to residual radioactivity for any applicable set of circumstances.
- R4 (32) "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7 x 10¹⁰ transformations per second (tps).

R6 (191) Daily means an interval not to exceed a consecutive 24 hour period or once R6 every calendar day worked. R4 (33) "Declared pregnant woman" means a woman who has voluntarily informed her employer in writing of her pregnancy and the estimated date of conception. R2 The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant. R2 R4 <mark>(34)</mark> "Dedicated check source" means a radioactive source that is used to assure the consistent operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes. "Deep dose equivalent" (H_d), which applies to external whole body exposure, R4 (35) means the dose equivalent at a tissue depth of 1 centimeter $(1,000 \text{ mg/cm}^2)$. R4 <mark>(36)</mark> "Decommission" means to remove a facility safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license or release of the property under R5 restricted conditions and the termination of the license. R5 R4 (37) "Depleted uranium" means the source material uranium in which the isotope uranium 235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material. R4 (38) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3. R4 "Derived air concentration-hour" (DAC-hour) means the product of the (39)concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee can take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rem (0.05 sievert). "Diagnostic clinical procedures manual" means a collection of written procedures R4 <mark>(40)</mark> that describes each method and other instructions and precautions by which the licensee shall perform diagnostic clinical procedures. Each diagnostic clinical procedure shall be approved by the authorized user and shall include the radiopharmaceutical, dosage, and route of administration. (178) "Distinguishable from background" means that the detectable concentration of a R6 radionuclide is statistically different from the background concentrations of that R5 R5 radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical R5 techniques.

R4 (41)"Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. For the purposes of these rules, "radiation dose " is an equivalent term. R4 <mark>(42)</mark> "Dose equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem. R4 <mark>(43)</mark> "Dose limits" means the permissible upper bounds of radiation doses established as specified in these rules. For the purpose of these rules, "limits" is an equivalent term. R4 <mark>(44)</mark> "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices to determine the radiation dose delivered to the monitoring devices. R4 <mark>(45)</mark> "Effective dose equivalent" (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_F = \Sigma W_T H_T$). R4 (46) "Embryo" or "fetus" means the developing human organism from conception until birth. (182) "Energy compensation source" or "ECS" means a small sealed source with an R6 activity not exceeding 100 microcuries (3.7 MBg) used within a logging tool or R6 R6 other tool components to provide a reference standard to maintain the tool's calibration when in use. R6 R4 <mark>(47)</mark> "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use. R4 (48) "Exposure", when used as a noun, means the quotient of dQ by dm, where "dQ" is the absolute value of the total charge of the ions of 1 sign produced in air when all the electrons, negatrons and positrons, liberated by photons in a volume element of air having mass "dm" are completely stopped in air. "Exposure", when used as a verb, means being exposed to ionizing radiation or to radioactive material. The special unit of exposure is the roentgen (R). See 64E-5.106 for the SI equivalent. R4 (49) "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour. R4 (50)"External dose" means that portion of the dose equivalent received from any source of radiation outside the body. R4 (51) "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

- R4 (52) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm²).
- R4 (53) "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.
- R4 (54) "Field station" means a temporary or portable facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.
- R6 (183) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.
- R6 (184) "Fit test" means the use of a protocol to evaluate qualitatively or quantitatively R6 the fit of a respirator on an individual.
- R4 (55) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.
- R4 (56) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.
- R4 (57) "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
- R4 (58) "Healing arts" means professions concerned with diagnosis or treatment of human and animal maladies, including the practice of medicine, dentistry, veterinary medicine, osteopathy, chiropractic, podiatry and naturopathy.
- R4 (59) "High radiation area" means an area, accessible to individuals, in which radiation R2 levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates. For purposes of these rules, rooms or areas in which diagnostic xray systems are used for healing arts purposes are not considered high radiation areas.
- R4 (60) "Human use" means the internal or external administration of radiation or radioactive material to human beings.
- R4 (61) "Individual" means any human being.

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R4 <mark>(62)</mark>		"Individual monitoring" means the assessment of:		
		(a)	Dose equivalent by the use of individual monitoring devices or by the use of survey data; or	
		(b)	Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed.	
R4 R2 R2 R2 R2	<mark>(63)</mark>	"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters, pocket ionization chambers, and personal or lapel air sampling devices. For purposes of these rules, individual monitoring equipment and personnel monitoring equipment are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), optically stimulated luminescent devices (OSLDs), pocket ionization chambers, and personal air sampling devices.		
R4	<mark>(64)</mark>		strial radiography" means nondestructive testing using ionizing radiation to radiographic images or radiographs to detect flaws in objects.	
R4	<mark>(65)</mark>	"Inhal	ation class" (see "Class").	
R4	<mark>(66)</mark>	"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.		
R4	<mark>(67)</mark>	event	lock" means a device arranged or connected such that the occurrence of an or condition is required before a second event or condition can occur or nue to occur.	
R4	<mark>(68)</mark>		nal dose" means that portion of the dose equivalent received from active material taken into the body.	
R4	<mark>(69)</mark>	500 re source source not ac radiol	e irradiator" means an irradiator where radiation dose rates exceeding em (5 sieverts) per hour exist at 1 meter from the sealed radioactive es in air or in water. This does not include irradiators in which both sealed e and the area subject to irradiation are contained within a device and are ccessible to personnel, or to radioactive materials used for medical ogy, teletherapy, industrial radiography, gauging, calibration of radiation tion instruments, or open-field agricultural irradiations.	
R4 R2 R2	<mark>(70)</mark>	<mark>eye a</mark>	dose equivalent (LDE)" applies to the external exposure of the lens of the nd is taken as the dose equivalent at the tissue depth of 0.3 centimeter ng/cm ²).	
R4	<mark>(71)</mark>	"Licer	nse" means a license issued by the department in accordance with the rules	

 (71) "License" means a license issued by the department in accordance with the rules adopted by the department.

- 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.
- R4 (79) "Low specific activity material (LSA)" means any of the following:
 - Uranium or thorium ores and physical or chemical concentrates of these ores;
 - (b) Unirradiated natural or depleted uranium or unirradiated natural thorium;
 - (c) Tritium oxide in aqueous solutions provided the concentration does not exceed 5.0 millicuries (185 MBq) per milliliter;
 - (d) Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration of contents does not exceed:
 - 1. 0.0001 millicurie (3.7 kBq) per gram of radionuclides for which the A₂ quantity is not more than 0.05 curie (1.85 GBq);
 - 0.005 millicurie (185 kBq) per gram of radionuclides for which the A₂ quantity is more than 0.05 curie (1.85 GBq), but not more than 1 curie (37 GBq); or
 - 3. 0.3 millicurie (11.1 MBq) per gram of radionuclides for which the A_2 quantity is more than 1 curie (37 GBq).

- (e) Objects externally contaminated with radioactive material, provided that the radioactive material is not readily dispersible and the surface contamination, when averaged over an area of 1 square meter, does not exceed 0.0001 millicurie (3.7 kBq) per square centimeter for radionuclides of which the A₂ quantity in Appendix A is not more than 0.05 curie (1.85 GBq), or, for all other radionuclides, 0.001 millicurie (37 kBq) per square centimeter.
- R4 (80) "Lung class" (see "Class").
- R4 (81) "Major processor" means a user processing, handling or manufacturing radioactive material exceeding A₂ quantities as unsealed sources or material, or exceeding 4 times A₁ quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. A₁ and A₂ 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 (84) "Medical use" means the intentional internal or external administration of 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.
- R4 (87) "Minor" means an individual less than 18 years of age.
- R4 (88) "Misadministration" means the administration of:

- (a) Iodine 123, iodine 125 or iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels):
 - 1. Involving the wrong individual or wrong radiopharmaceutical; or

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

- (b) A therapeutic radiopharmaceutical dosage other than iodine 123, iodine 125 or iodine 131 as sodium iodide:
 - Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
 - 2. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.
- (c) A gamma stereotactic radiosurgery radiation dose:
 - 1. Involving the wrong individual or wrong treatment site; or
 - 2. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.
- (d) A teletherapy, particle accelerator or therapeutic x-ray machine radiation dose:
 - 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

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

- R4 (90) "NARM" means any naturally occurring or accelerator-produced radioactive material. To meet the definition of licensing state, NARM only refers to discrete sources of NARM. Diffuse sources of NARM, which are large in volume and low in activity, are excluded from consideration by the Conference of Radiation Control Program Directors, Inc., for licensing state designation purposes.
- R4 (91) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
- R4 (92) "Nonstochastic effect" means a health effect the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.
- R4 (93) "Normal form" means radioactive material which has not been demonstrated to qualify as "special form"; also referred to as "nonspecial form."
- R4 (94) "Normal operating procedures" means operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.
- R4 (95) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.
- R4 (96) "Occupational dose" means the dose received by an individual in the course of employment which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background
 R2 radiation, from any medical administration the individual has received, from 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 specifiedR4in 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.
- R4 (100) "Package" means the packaging, together with its radioactive contents, as presented for transport.
- 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, orR4vault, as specified in Rule 64E-5.431, F.A.C., in which industrial radiography isR4performed.
- 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:
 - (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.
- R6 (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.
 R1 Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.
- R4 (110) "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
- 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 raining 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.
- R4(121)"Radiographer's assistant or assistant radiographer" means any individual whoR4has completed successfully the training and testing requirements specified inR4Rule 64E-5.434(1), F.A.C., and who, under the personal supervision of aR4radiographer, conducts radiographic operations.
- R4 (122) "Radiographic exposure device" means any instrument containing a sealed
 R4 source that is used to make a radiographic exposure. It also is known as a
 R4 camera or a projector.
- R4 (123) "Recordable event" means the administration of:

direction orientation.

- (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

-		64E-5	Florida Administrative Code	64E-5.101	
		dose	etherapy, particle accelerator or therap when the calculated weekly administe the weekly prescribed dose.	5	
R4	<mark>(124)</mark>	"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	<mark>(125)</mark>	"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	<mark>(126)</mark>	"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR, Parts 100-189.		tion" means the regulations in	
R4	<mark>(127)</mark>	equivalent.	ns the special unit of any of the quantit The dose equivalent in rem is equal to y the quality factor (1 rem = 0.01 siever	the absorbed dose in rad	
R4	<mark>(128)</mark>	"Research a	and development" means:		
		(a) Theo	retical analysis, exploration or experim	entation; or	
		techn demo of mo devel	extension of investigative findings and the initial nature into practical application for ponstration purposes, including the expendeds, devices, equipment, materials are lopment does not include the internal of tion or radioactive material to human be	r experimental and rimental production and testing nd processes. Research and r external administration of	
R4	<mark>(129)</mark>		y protective equipment" means an appa uce an individual's intake of airborne ra	· · · · · · · · · · · · · · · · · · ·	
R6 R5 R5 R5 R5 R5 R5	<mark>(179)</mark>	"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	<mark>(130)</mark>	"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	<mark>(131)</mark>		means the special unit of exposure. C coulombs per kilogram of air.	ne roentgen (R) equals	

- R4 (132) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.
- R4 (133) "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.
- R6(185) "Self-contained breathing apparatus" or "SCBA" means an atmosphere-supplyingR6respirator for which the breathing air source is designed to be carried by the user.
- R6 (190) Semiannual or Semiannually means an interval not to exceed six months.
- R4(134)"Shallow dose equivalent" (H_s), which applies to the external exposure of the skinR6of the whole body or the skin of an extremity, means the dose equivalent at aR6tissue depth of 0.007 centimeter (7 mg/cm²).
- R4(135)"Shielded position" means the location within the radiographic exposure device orR4source changer where the sealed source is secured and restricted fromR4movement 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).
- R6 (139) "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 (141) "Source material" means:

- Uranium or thorium, or any combination thereof, in any physical or chemical form; or
- (b) 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. Source material does not include special nuclear material.

- 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.
- R6 (145) "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:

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.

R1

R6 (147) "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.

R6 (148) "Storage area" means any location, facility, or vehicle which is used to store, transport, or secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source. R6 "Storage container" means a container in which sealed sources are secured and (149)stored. (150) "Subsurface tracer study" means the release of a substance tagged with R6 radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation. (186) "Supplied-air respirator" or "air-line respirator" means an atmosphere-supplying R6 respirator for which the source of breathing air is not designed to be carried by R6 the user. **R6** R6 (151) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal or presence of sources of radiation. When appropriate, such evaluation includes tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present. **R6** (152) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body. R6 (153) "Teletherapy physicist" means an individual identified as the gualified teletherapy physicist on a department license. R6 (154)"Temporary job site" means a site, base or facility that is created and maintained to support a single job lasting for less than 2 years. (155) "Test" means the process of verifying compliance with an applicable rule. R6 (187) "Tritium neutron generator target source" means a tritium source used within a R6 neutron generator tube to produce neutrons for use in well logging applications. R6 R6 "Total effective dose equivalent" means the sum of the deep dose equivalent for (156)external exposures and the committed effective dose equivalent for internal exposures. R6 (157) "Type B packaging" means a packaging designed to retain the integrity of containment and shielding required by U.S. Nuclear Regulatory Commission and U.S. Department of Transportation regulations when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR, Part 71. R6 (158) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating or refining.

- R6 (159) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.
- R6 (160) "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof as specified in sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy as specified in section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)
- R6 (188) "User seal check" or "fit check" means an action conducted by the respirator
 R6 user to determine if the respirator is seated to the face properly. Examples
 R6 include negative pressure check, positive pressure check, irritant smoke check,
 R6 and isoamyl acetate check.
- R6 (161) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess to 500 rad (5 gray) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.
- R6 (162) "Visiting authorized user" means an authorized user who is not identified on the license.
- R6 (163) "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.
- R6 (164) "Weighting factor" (W_T) for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

ORGAN DOSE WEIGHTING FACTORS					
ORGAN OR TISSUE	WT				
Gonads	0.25				
Breasts	0.15				
Red Bone Marrow	0.12				
Lung	0.12				
Thyroid	0.03				
Bone Surfaces	0.03				
Remainder	0.30*				
Whole Body	1.00**				

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

- **To weight the external whole body dose to add it to the internal dose, a single weighting factor, W_T = 1.0, has been specified. The department will consider the use of other weighting factors for external exposure.
- R6 (165) "Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed
- R6 (166) "Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.
- R6 (167) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.
- R6 (168) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.
- R6 (169) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.
- R6 (170) "Worker" means an individual engaged in work in a restricted area under the authority of a license or registration issued by the department.
- R6 (171) "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3 x 10⁵ MeV of potential alpha particle energy. The short-lived radon daughters are:
 - (a) For radon 222: polonium 218, lead 214, bismuth 214, and polonium 214;
 - (b) For radon 220: polonium 216, lead 212, bismuth 212, and polonium 212.
- R6 (172) "Working level month" (WLM) means an exposure to 1 working level for 170 hours. Two thousand working hours per year divided by 12 months per year is approximately equal to 170 hours per month.
- R6 (173) "Written directive" means a written order for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, which shall contain the following information:
 - (a) For a therapeutic administration of a radiopharmaceutical other than iodine 123, iodine 125 or iodine 131 as sodium iodide, the radiopharmaceutical, dosage, and route of administration;
 - (b) For any administration of iodine 123, iodine 125 or iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels), the dosage;
 - (c) For gamma stereotactic radiosurgery, target coordinates, collimator size, plug pattern, and total dose;
 - (d) For teletherapy, particle accelerator or therapeutic x-ray machine, the total dose, dose per fraction, treatment site, and overall treatment period;

- (e) For high dose rate remote afterloading brachytherapy, the radioisotope, treatment site, and total dose; and
- (f) For all other brachytherapy,
 - 1. Prior to implantation, the radioisotope, number of sources, and source strengths; and
 - 2. After implantation but prior to completion of the procedure, the radioisotope, treatment site, total source strength and exposure time or total dose.
- R6 (174) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant can change the starting date of the year used to determine compliance by the licensee or registrant if the change is made at the beginning of the year and if no day is omitted or duplicated in consecutive years.

Editor's Note: Definitions have been alphabetized effective, May 15, 1996. (Principal activity R1 (175) added alphabetically May 18, 1998. Authorized Nuclear Pharmacist (176) added August 8, 2001

^{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

R6 alphabetically December 19, 2001. and renumbered as above September 28, 2006) The following

 R_{DC}^{R} 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 check")

Specific Authority: 404.051, 404.061, F.S.

Law Implemented: 404.031, 404.061(2), 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, December 19, 200, Amended September 28, 2006

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;

- (b) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;
- (c) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and
- (d) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine:
 - 1. That the exemption of the prime contractor or subcontractor is authorized by law; and
 - 2. That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health, safety and environment.

Specific Authority: 404.051, 404.061, F.S. Law Implemented: 404.051(10), 404.061(4), 404.111(3), 404.121(1), 404.20, F.S. History: New July 17, 1985, Amended <u>May 12, 1993</u>, Formerly 10D-91.103.

64E-5.103 Records. Each licensee and registrant shall maintain records showing the receipt, transfer and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these regulations.

Specific Authority: 404.051, 404.061, 404.081, F.S. Law Implemented: 404.022, 404.061(2), 404.081, 404.20(2), 404.22(2), F.S. History: New <u>July 17, 1985</u>, Formerly 10D-91.104.

64E-5.104 Tests. Each licensee and registrant shall perform upon instructions from the department, and shall permit the department to perform, such reasonable tests as the department deems appropriate and necessary, including tests of:

- (1) Sources of radiation;
- (2) Facilities wherein sources of radiation are used or stored;
- (3) Radiation detection and monitoring instruments; and
- (4) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

Specific Authority: 404.051, 404.061, F.S. Law Implemented: 404.022, 404.051(1)(7), 404.061(2), 404.22(1), F.S. History: New July 17, 1985, Formerly 10D-91.106.

64E-5.105 Prohibited Uses.

- (1) A hand-held fluoroscopic screen shall not be used unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.
- (2) A shoe-fitting fluoroscopic device shall not be used.

Specific Authority: 404.051, 404.061, 404.141, F.S. Law Implemented: 404.022, 404.051, 404.061(2), 404.141, 404.22(3), F.S. History: New July 17, 1985, Amended <u>January 1, 1994</u>, Formerly 10D-91.110.

64E-5.106 Units of Exposure and Dose.

- (1) As used in these regulations, the unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58 x 10⁻⁴ coulomb per kilogram of air.
- (2) As used in these regulations, the units of dose are:
 - (a) Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
 - (b) Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).
 - (c) Rem is 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 Sv).
 - Sievert is 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).
- (3) As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown below:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES					
TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent ^a			
X, gamma, or beta radiation and high-speed electrons	1	1			
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05			
Neutrons of unknown energy	10	0.1			
High-energy protons	10	0.1			

^a Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 Sv.

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SUBPART A LICENSE TYPES AND FEES

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

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- (1) Some general licenses provided in this part may be effective without the filing of applications with the department or the issuance of licensing documents to the particular persons, although the filing of a certificate with the department for general licenses pursuant to 64E-5.206(7) or (8) shall be required of the particular general licensee prior to the receipt of radioactive material and the Department requires registration of certain general licenses described in subsection 64E-5.206(4), F.A.C.. The payment of a fee is also required by all persons possessing general licensed material described in (1)(c), below. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.
 - (a) The annual registration fee set forth in this section for general licenses shall be payable every July 1, for as long as the license remains in effect.
 - (b) The annual fee for a general license set forth in 64E-5.216 under reciprocal agreement shall be paid before the first entrance into the State and on each anniversary date thereafter, if applicable. Manufacturers, manufacturer's representatives, distributors, and waste treatment, storage or disposal companies servicing Florida radioactive materials license applicants or licensees are exempt from this fee.
 - (c) Payment of the indicated annual fee pursuant to (1)(a), above, is required for the following types of devices held or activities performed under a general license:

1.	Static elimination devices as described in 64E-5.206(1)(a)\$25.00 per unit.
2.	Measuring, gauging, and control devices as described in 64E-5.206(4)\$25.00 per unit.
3.	<i>In Vivo</i> testing as described in 64E-5.206(7)\$125.00 per license.
4.	<i>In Vitro</i> testing as described in 64E-5.206(8)\$125.00 per license.
5.	Depleted uranium as described in 64E-5.205(4)\$125.00 per license.

			APPLICATION FEE	ANNUAL FEE
	7.	DEVICE, PRODUCT, OR SEALED SOURCE SAFETY EVALUATION		
R1	a.	Device evaluation, per device;	\$1,208	NONE
R1	b.	Sealed source design, per source	\$528	NONE

Specific Authority: 404.051, 404.061, 404.131, F.S.

R1 Law Implemented: 404/032, 404.061, 404.051(1)(4)(10), 404.131(1), F.S.

History: New July 17, 1985, amended April 4, 1989, Amended September 9, 1990, Amended August 25, 1991,

R1 Amended May 12, 1993, Amended November 6, 1994, Formerly 10D-91.304, Amended May 18, 1998.

R6 Amended September 28, 2008

SUBPART B GENERAL LICENSES

64E-5.205 General Licenses - Source Material.

- (1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local governmental agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any given time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any calendar year.
- (2) Persons who receive, possess, use or transfer source material pursuant to the general license issued in (1), above, are exempt from the provisions of Parts III and IX to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.
- (3) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.
- (4) Depleted Uranium in Industrial Products and Devices.
 - (a) A general license is hereby issued to receive, acquire, possess, use or transfer, in accordance with the provisions of (4)(b), (c), (d) and (e), below, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

- (b) The general license in (4)(a), above, applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 64E-5.210, or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to general licensees of the U.S. Nuclear Regulatory Commission or an agreement state.
- (c) 1. Persons who receive, acquire, possess or use depleted uranium pursuant to the general license established by (4)(a), above, shall submit the information requested on DH Form 1619, entitled "General License for Depleted Uranium", which is herein incorporated by reference effective July 17, 1985, with the department. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall submit a fee as required in 64E-5.204(1)(c).
 - 2. The registrant possessing or using depleted uranium under the general license established by (4)(a), above, shall report in writing to the department any changes in information furnished by him in the "Registration Certificate Use of Depleted Uranium Under General License" form. The report shall be submitted within 30 days after the effective date of such change.
- (d) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by (4)(a), above:
 - 1. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;
 - 2. Shall not abandon such depleted uranium;

64E-5 Florida Administrative Code 64E-5.206

- 3. Shall transfer or dispose of such depleted uranium only by transfer 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 MBq) 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 MBq) of polonium 210 per device or a total of not more than 50 millicuries (1.85 GBq) of tritium per device.
- (2) Reserved
- (3) Reserved
- (4) Certain Measuring, Gauging and Controlling Devices.
 - (a) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their businesses, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of (4)(b), (c) and (d), below, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.
 - (b)1. The general license in (4)(a), above, applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to 64E-5.210(4) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State, which authorizes distribution of devices to persons granted a general license by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State. Regulatory Commission, an agreement state or a Licensing State. Regulatory Commission, an agreement state or a Licensing State. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of 21 CFR Part 179.
 - (b)2. The devices must have been received from one of the specific licenses described in (b)1., above or through a transfer made under subparagraph 6E-5.206(4)(c)8., F.A.C.
 - Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in (4)(a), above;

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

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- 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 Bg) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days. furnish to the department a report containing a brief description of the event and the remedial action taken; and in the case of removable radioactive materials or failure of or damage to a source likely to result in contamination of the premises or the environment. a plan for ensuring the premise and environment are acceptable for unrestricted use using the criteria described in Rule 64E-5.222, F.A.C.
- 6. Shall not abandon the device containing radioactive material;
- 7. Except as provided in (4)(c)8., below, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State, whose specific license authorizes him to receive the device, and within 30 days after transfer of a device to a specific licensee, shall furnish to the department a report containing identification of the device by manufacturer's or initial transferor's name and model number and serial number, the name, address, license number, where applicable, of the person receiving the device and the date of the transfer;
- 8. Shall transfer the device to another general licensee only:
 - a. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section, a copy of Rules 64E-5.103, 64E-5.328, and 64E-5.329, F.A.C., and any safety documents identified in the label on the device and within 30 days of the transfer, report to the department the manufacturer's or initial transferor's name and model number and serial number of device transferred, the transferor's name and mailing address for the location of use, and the name title, and phone number of the responsible individual identified by the transferee in accordance with paragraph 64E-5.206(4)(c) and subsection (11), F.A.C., to have knowledge of and authority to take actions to ensure compliance with these regulations;or

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

R6 R6 R6		<mark>(III)</mark>	Name, title, and telephone number of the responsible person designated a representative of the general licensee under paragraph 64E-5.206(4)(c) and
R6 R6 R6		(IV)	subsection (11), F.A.C.; Address or location at which the device(s) are used or stored. For portable devices, the address of the
R6 R6 R6 R6 R6		<mark>(V)</mark>	primary place of storage; 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
R6 R6 R6		<mark>(VI)</mark>	Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.
R6 R6 R6 R6 R6 R6 R6	ζ	Licens Comn 10 CF requir Depar calend	ons generally licensed by other Agreement States, sing States, or the U.S. Nuclear Regulatory nission with respect to devices meeting the criteria in FR 31.5(c)(13)(i) are not subject to registration rements if the devices are used in areas subject to the rtment jurisdiction for less than 180 days in any dar year. The Department will not request registration such licensees.
R6 R6 R6 R6 R6	r	name and th 30 days of th report of add	to the Department changes in the general licensee le mailing address for each location or use within ne effective date of the change. For a portable device, a lress change is required for a change in the device's e of storage.
R6 R6 R6 R6 R6 R6 R6 R6 R6 R6 R6	c l c t t t	devices with ocked in the 64E-5.206(4 of storage or transferred to required test n standby fo the general I	d devices that are not in use longer than 2 years. If the shutters are not being used, the shutters must be closed position. The testing required by subparagraph)(c)2., F.A.C., need not be performed during the period nly. However, when devices are put back into service or o another person, and have not been tested within the t interval, they must be tested before use. Devices kept or future use are excluded from the two year time limit if icensee performs physical inventories at intervals not ree months while they are in standby.

- (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.
 - 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;
 - 1. 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.

R6 <u>28, 2006</u>.

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. R6 History: New July 17, 1985, amended April 4, 1989, Amended January 1, 1994, Formerly 10D-91.306, <u>Amended September</u>

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, <u>May 15, 1996</u>, 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.

- Instructions and precautions necessary to assure safe installation, operation and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information.
- b. The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and
- c. The information called for in one of the following statements, as appropriate, in the same or substantially similar form. The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device;
 - (I) The receipt, possession, use and transfer of this device, model _____, serial no. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

(II) The receipt, possession, use and transfer of this device, model _____, serial no. _____, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

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- 4. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the radioisotope and quantity, the words "Caution Radioactive Materials," the radiation symbol described in Rule 64E-5.322, F.A.C., the name of the manufacturer or initial distributor.
 - 5. Each device containing at least 10 millicuries (370 MBq) of cesium-137, 0.1 millicuries (3.7 MBq) of strontium-90, 1 millicurie (37 MBq) of cobalt-60, or 1 millicurie (37 MBq) of americium-241 or any other element with atomic numbers greater than 92, based on the activity indicated on the label, must bear a permanent label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words "Caution Radioactive Materials," and if practical, the radiation symbol described in Rule 64E-5.322, F.A.C. Example of a permanent label include labels that are embossed, etched, stamped or engraved to the source housing or device as applicable.
 - (b) In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider the following information:
 - 1. Primary containment or source capsule;
 - 2. Protection of primary containment;
 - 3. Method of sealing containment;
 - 4. Containment construction material;
 - 5. Form of contained radioactive material;
 - 6. Maximum temperature withstood during prototype tests;
 - 7. Maximum pressure withstood during prototype tests;
 - 8. Maximum quantity of contained radioactive material;
 - 9. Radiotoxicity of contained radioactive material; and
 - 10. Operating experience with identical devices or similarly designed and constructed devices.

64E-5 Florida Administrative Code 64E-5.210

	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:
	 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-5.328, and 64E-5.329, F.A.C.;
	 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.
	If a device containing radioactive material is transferred for use under an equivalent general license of an Agreement State or the U.S. Nuclear Regulatory Commission, each person that is licensed under subsection 64E-5.210(4), F.A.C., shall provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to the initial transfer to the intermediate person. The required information includes the following:
	d) e)

64E-5 Florida Administrative Code 64E-5.210

R6 R6 R6 R6 R6 R6 R6 R6		1. A copy of the Agreement States or U.S. Nuclear Regulatory Commission equivalent to Rules 64E-5.103, 64E-5.328, and 64E-5.329, F.A.C. If a copy of the U.S. Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement States regulations, it shall be accompanied by a note explaining that the use of the device is regulated by the Agreement State. If certain parts of the regulations do not apply to the particular device, those regulations may be omitted;
R6		 A list of services that can only be performed by a specific licensee;
R6 R6		 Information on acceptable disposal options including costs of disposal; and
R6 R6 R6 R6		4. The name or title, address, and phone number of the contact at the Agreement State regulatory agency or U.S. Nuclear Regulatory Commission, as applicable, from which additional information may be obtained.
R6	<mark>(f)</mark>	Reserved
R6 R6	<mark>(g)</mark>	Each device that is transferred must meet the labeling requirements in subparagraphs 64E-5.210(4)(d)3. through 5., F.A.C.
R6 R6 R6 R6 R6 R6	(h)	If a notification of bankruptcy has been made under subsection 64E-5.213(3), F.A.C., or the license is to be terminated, each person licensed under subsection 64E-5.210(4), F.A.C., shall provide, upon request, to the Department, U.S. Nuclear Regulatory Commission and to any appropriate Agreement State, records of final disposition required under paragraph 64E-5.210(4)(k), F.A.C.
R6 R6	<mark>(i)</mark>	Each person licensed under subsection 64E-5.210(4), F.A.C., shall comply with the following reporting and record keeping requirements.
R6 R6 R6 R6 R6 R6 R6		1. Report all transfers of devices to persons for use under the general license described in subsection 64E-5.206(4), F.A.C., and all receipts of devices from persons licensed under subsection 64E-5.206(4), F.A.C., to the Department. This report must be submitted at intervals not to exceed 3 months and contain all of the information described in "Transfers of Industrial Devices Report 10/2003" herein incorporated by reference.
R6 R6		2. This report must be clear and legible and contain the following data:

R6 R6 R6 R6 R6		 The identity of each general licensee by name and mailing address for the location of use; if no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;
R6 R6 R6 R6		 b. The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
R6		c. The date of transfer;
R6 R6		 The type, model number, and serial number of the device transferred; and
R6 R6		e. The quantity and type of radioactive materials contained in the device.
R6 R6 R6 R6 R6	<mark>3.</mark>	If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person and clearly designate the intermediate person(s).
R6 R6 R6 R6 R6 R6	<mark>4.</mark>	For devices received from a subsection 64E-5.206(4), F.A.C., general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial numbers of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
R6 R6 R6 R6 R6	5.	If the licensee makes changes to the device possessed by a subsection 64E-5.206(4), F.A.C., general licensee, such that the label must be changed to update required information, this report must identify the general licensee, the device, and the changes to information on the device label.
R6 R6	6.	The report must clearly identify the specific licensee submitting the report and include the licenses number of the specific licensee.
R6 R6 R6	7.	If no transfers have been made to or from persons generally licensed under subsection 64E-5.206(4), F.A.C., during the reporting period, the report must so indicate.
R6 R6 R6	compl	person licensed under subsection 64E-5.210(4), F.A.C., shall y with the following additional reporting and record keeping ements for transfers and receipt of devices to Agreement States.

R6 R6 R6 R6 R6 R6 R6	1.	Report all transfers of devices to persons for use under the general license in an Agreement State 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 jurisdiction to the responsible Agreement State agency. This report must contain all of the information described in "Transfers of Industrial Devices Report 10/2003."
R6	2.	The report must be clear and legible and contain the following data:
R6 R6 R6 R6 R6		a. The identity of each general licensee by name and mailing address for the location of use; if no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;
R6 R6 R6 R6		 b. The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
R6		c. The date of transfer;
R6 R6		 The type, model number, and serial number of the device transferred; and
R6 R6		e. The quantity and type of radioactive materials contained in the device.
R6 R6 R6 R6 R6	3.	If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person and clearly designate the intermediate person(s).
R6 R6 R6 R6 R6 R6	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.
R6 R6 R6 R6	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.
R6 R6	<mark>6.</mark>	The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

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- 7. If no transfers have been made to or from a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State 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.
- (k) 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:

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

Name of Manufacturer

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

Name of Manufacturer

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- (8) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 64E-5.206(8) will be approved if:
 - (a) The applicant satisfies the general requirements specified in 64E-5.208.
 - (b) The radioactive material is to be prepared for distribution in prepackaged units of:
 - 1. Carbon 14 in units not exceeding 10 microcuries (370 kBq) each.
 - 2. Cobalt 57 in units not exceeding 10 microcuries (370 kBq) each.
 - 3. Hydrogen 3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.
 - 4. Iodine 125 in units not exceeding 10 microcuries (370 kBq) each.
 - 5. Mock iodine 125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine 129 and 0.005 microcurie (185 Bq) of americium 241 each
 - 6. Iodine 131 in units not exceeding 10 microcuries (370 kBq) each.
 - 7. Iron 59 in units not exceeding 20 microcuries (740 kBq) each.
 - 8. Selenium 75 in units not exceeding 10 microcuries (370 kBq) each.
 - (c) Each prepackaged unit bears a durable, clearly visible label:
 - Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine 125, iodine 131, carbon 14, cobalt 57 or selenium 75; 50 microcuries (1.85 MBq) of hydrogen 3 (tritium); 20 microcuries (740 kBq) of iron 59; or mock iodine 125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine 129 and 0.005 microcurie (185 Bq) of americium 241 each; and
 - 2. Displaying the radiation caution symbol described in 64E-5.322(1) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".
 - (d) 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 a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

- (a) The final disposition of tailings or wastes at source material milling sites should be such that the need for ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections shall be conducted by the government agency retaining ultimate custody of the site where tailings or wastes are stored to confirm the integrity of the stabilized tailings or waste systems and to determine the need, if any, for maintenance and monitoring. Results of the inspection shall be reported to the U.S. Nuclear Regulatory Commission within 60 days following each inspection. The U.S. Nuclear Regulatory Commission may require more frequent site inspections, if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.
- (b) A minimum charge of \$405,000 to cover the costs of long-term surveillance shall be paid by each mill operator to the department prior to the termination of a uranium or thorium mill license. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in (6)(a), above, additional funding requirements may be specified by the department. The total charge to cover the cost of longterm surveillance shall be such that, with an assumed 1 percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The charge will be assessed quarterly and will be reviewed annually by the department to recognize or adjust for inflation.

Specific Authority: 404.051, 404.061, 404.062, 404.071, 404.081, 404.111, 404.141, F.S. Law Implemented: 404.022, 404.051(1),(4),(5),(7),(8),(11), 404.061(2), 404.071(1), 404.081(1), 404.111,404.141, F.S. History: New July 17, 1985, Formerly 10D-91.312.

64E-5.212 Issuance of Specific Licenses.

- (1) Upon a determination that an application meets the requirements of Chapter 404, Florida Statutes, and these regulations, the department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.
- (2) The department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:
 - (a) Minimize danger to public health and safety or property;
 - (b) Require reports and the keeping of records, and to provide for inspections of activities under the license; and
 - (c) Prevent loss or theft of material subject to this part.

(3) The department shall issue an expiration date authorizing each license to be valid for a period not to exceed 5 years from the last day of the issuance month. The department shall indicate the expiration date on each license. The licensee shall be granted a 90 day extension of the expiration date if written justification is submitted and approved by the department.

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.141, F.S. Law Implemented: 404.022, 404.051(1)(4)(8), 404.081(1), 404.141, F.S. History: New July 17, 1985, Amended <u>May 12, 1993</u>, Formerly 10D-91.313.

64E-5.213 Specific Terms and Conditions of License.

- (1) Each license issued pursuant to this part shall be subject to all the provisions of the applicable laws, now or hereafter in effect, and to all rules of the department.
- (2) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control to any person unless the department, after securing a completed specific license application and application fee from the transferee, has issued a proper license in accordance with the provisions of the Act.
- (3) (a) Each specific or general licensee shall notify the department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code (U.S.C.) by or against:
 - 1. The licensee;
 - 2. An entity, as that term is defined in 11 U.S.C. 101(14), controlling the licensee or listing the license or licensee as property of the estate; or
 - 3. An affiliate, as that term is defined in 11 U.S.C. 101(2), of the licensee.
 - (b) This notification shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition for bankruptcy.
 - (4) Each person licensed by the department pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.
 - (5) A separate license is required for the following:
 - (a) Each activity as designated by license category in 64E-5.204(2)(e).

		(b)	Facilities for which one or more of the following applies:		
			1. The facilities are not contiguous;		
			2. The facilities are not under a single radiation safety program; or		
			3. The facilities are not under the same management.		
		(C)	Each facility operated by an out-of-state licensee under reciprocity as specified in 64E-5.216 and does not meet the definition of a temporary job site.		
		(d)	Each large irradiator as defined in 64E-5.101.		
	(6)		parate license is not required for temporary job sites or for each facility that thorized under a broad scope license.		
R1 R1 R1	(7)		ensee shall notify the department in writing within 30 days after a radiation y officer permanently discontinues performance of radiation safety officer s.		
R1	(8)	A lice	ensee shall apply and receive a license amendment or department approval:		
R1 R1		(a)	Before using radioactive material for a method or type of use not permitted by the license;		
R1 R1		(b)	Before permitting anyone to use radioactive material as an authorized user as authorized by the license;		
R1		(C)	Before changing the radiation safety officer		
R1 R1		(d)	Before ordering or receiving radioactive materials in excess of the amount authorized on the license		
R1 R1		(e)	Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and		
R1 R1		(f)	Before changing statements, representations, and procedures which are incorporated into the license.		
R1	Specific Authority: 404.051, 404.061, F.S.				

- R1 Specific Authority: 404.051, 404.061, F.S.
 R1 Law Implemented: 404.051(1)(4), 404.061(2)(3), F.S. History: New July 17, 1985, Amended April 4, 1989 Amended May 12, 1993, Amended August 29, 1994,
 R6 Formerly 10D-91.314, Amended May 18, 1998., Amended September 28, 2006

R1 64E-5.214 Expiration and Termination of Licenses and Decommissioning of R1 Sites and Separate Buildings or Outdoor Areas.

- (1) Except as provided in Part II, each specific license shall expire at the end of the specified day in the month and year stated therein. Each specific license
 R1 revoked by the department expires at the end of the day on the date of the department's final order revoking the license or on the expiration date stated in the final order.
- **R1** (2) (a) Each licensee shall notify the department in writing within 60 days of the occurrence of any of the following and either begin decommissioning its **R1 R1** site or any separate building or outdoor area that contains residual **R1** radioactivity so that the building or outdoor area is suitable for release as specified in these rules or send a notice of a decommissioning plan within **R1** 12 months as specified in (4)(c) below and begin decommissioning upon **R1 R1** approval of that plan.
- R1 1. The license has expired as specified in (1), above.

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- R12.The licensee has ceased principal activities permanently at the
entire site or in any separate building or outdoor area.
 - The licensee has conducted no principal activities under the license for 24 months.
 - 4. The licensee has conducted no principal activities for 24 months in any separate building or outdoor area that contains residual radioactivity to the extent that the building or outdoor area is unsuitable for release as specified in these rules.
- R1 (b) The notification and request for termination of the license shall include the reports and information specified in (4)(a)4. and 5., below.
 - (3) No less than 30 days before the expiration date specified in the license, the licensee shall either:
 - (a) Submit an application for license renewal on the same form used for the initial application under Part II, or
 - (b) Notify the department, in writing, if the licensee decides not to apply for license renewal.
 - (4) (a) If a licensee does not submit an application for license renewal under Part II, the licensee shall, on or before the expiration date specified in the license:

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PART III

STANDARDS FOR PROTECTION AGAINST RADIATION

SUBPART A GENERAL PROVISIONS

64E-5.301 Standards for Protection Against Radiation.

- (1) The rules in this part control the receipt, possession, use, disposal, and transfer of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this part. However, nothing in this part shall be construed to limit actions necessary to protect health and safety.
- (2) Except as specifically provided in other parts of these rules, this part applies to persons licensed or registered by the department to receive, possess, use, or transfer sources of radiation. The limits in this part do not apply to doses from background radiation, to exposure of patients to radiation for medical diagnosis or therapy, to exposure from individuals administered radioactive material and released as specified in Rule 64E-5.622, F.A.C., or to voluntary participation in medical research programs.

Specific Authority: 404.051(1), F.S.

R2 Law Implemented: 404.022, 404.051(1)(4), 404.181(1)(b) F.S.

R2 History: New January 1, 1994, Amended May 15, 1996, Formerly 10D-91.431, Amended October 8, 2000.

64E-5.302 Implementation.

- (1) Any existing license or registration condition that is more restrictive than Part III remains in force until there is an amendment or renewal of the license or registration.
- (2) If a license or registration condition exempts a licensee or registrant from a provision of the part in effect on or before the effective date of this rule, it also exempts the licensee or registrant from the corresponding provisions of this part.
- (3) If a license or registration condition cites provisions of this part in effect prior to the effective date of this rule which do not correspond to any provisions of this part, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

Specific Authority: 404.051, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S. History: New <u>January 1, 1994</u>, Formerly 10D-91.433.

R2 R2

SUBPART B-- RADIATION PROTECTION PROGRAMS

64E-5.303 Radiation Protection Programs.

- (1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this part. See 64E-5.335 for recordkeeping requirements relating to these programs.
- R2 (2) The licensee or registrant shall use to the extent practical procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as reasonably achievable.
 - (3) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.
 - (4) Dental and podiatry registrants are exempt from (1) and (3), above.
- R2 To implement the ALARA requirements of Rule 64E-5.303(2), F.A.C., and (5) R2 notwithstanding the requirements of Rule 64E-5.312, F.A.C., of this part, licensees shall establish constraints on air emissions of radioactive material, R2 excluding radon 222 and its daughters, to the environment so that individual R2 R2 members of the public who are likely to receive the highest doses are not expected to receive a total effective dose equivalent in excess of 10 millirems R2 R2 (0.10 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the R2 occurrence as specified in Rule 64E-5.345, F.A.C., and promptly take corrective R2 action to ensure against recurrence.

R2 Specific Authority: 404.051(4), 404.081(1), F.S.

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

R2 History: New January 1, 1994, Amended November 20, 1994, Formerly 10D-91.434, Amended October 8, 2000.

SUBPART C -- OCCUPATIONAL DOSE LIMITS

64E-5.304 Occupational Dose Limits for Adults.

- (1) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures as specified in Rule 64E-5.309, F.A.C., to the following dose limits:
 - (a) An annual limit, which is the more limiting of:
 - 1. The total effective dose equivalent equal to 5 rem (0.05 sievert); or
 - 2. The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye equal to 50 rem (0.5 sievert).
- R6(b)The annual limits to the lens of the eye, to the skin of the whole body, andR6to the skin of the extremities which are:
 - 1. An lens dose equivalent of 15 rem (0.15 sievert), and
- R62.A shallow dose equivalent of 50 rem (0.5 sievert) to the skin of the
whole body or to skin of any extremity.

- (2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual could receive during the current year and during the individual's lifetime as specified in Rule R2 64E-5.309(5)(a) and (b), F.A.C.
- R6 (3) The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements to demonstrate compliance with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable.
 - (4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, and can be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 64E-5.339.
 - (5) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993.
 - (6) The licensee or registrant shall reduce the dose that an individual can be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 64E-5.308(5).

(Specific Authority: 404.051, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S. R2,R6 History: New January 1, 1994, Formerly 10D-91.435, Amended October 8, 2000, <u>Amended September 28, 2006.</u>

64E-5.305 Compliance with Requirements for Summation of External and Internal Doses.

- (1) If the licensee is required to monitor as specified in both 64E-5.515(1) and (2), the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only as specified in 64E-5.315(1) or only as specified in 64E-5.315(2), then summation is not required to demonstrate compliance with the dose limits. The licensee can demonstrate compliance with the requirements for summation of external and internal doses as specified in 64E-5.305(2),(3) and (4). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.
- (2) Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit and one of the following does not exceed unity:

- (a) The sum of the fractions of the inhalation ALI for each radionuclide;
- (b) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or
- (c) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is considered significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50} , or $W_T H_{T,50}$, per unit intake for any organ or tissue.
- (3) Intake by Oral Ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.
- (4) Intake through Wounds or Absorption through Skin. The licensee shall evaluate and to the extent practical account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen 3 and does not need to be evaluated or accounted for as specified in this subsection.

Specific Authority: 404.051, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S. History: New January 1, 1994, Formerly 10D-91.436.

64E-5.306 Determination of External Dose from Airborne Radioactive Material.

- (1) Licensees shall include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud when determining the dose from airborne radioactive material. See State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, footnotes 1 and 2.
- (2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

Specific Authority: 404.051, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S. History: New <u>January 1, 1994</u>, Formerly 10D-91.437. (7) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 64E-5.316 if the registrant has met all the specific requirements for access and control specified in other applicable parts of these rules, such as Part IV for industrial radiographic operations, Part V for x-rays in the healing arts, and Part VIII for particle accelerators.

Specific Authority: 404.051, 404.081, F.S Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S. History: New <u>January 1, 1994</u>, Formerly 10D-91.447.

64E-5.317 Control of Access to Very High Radiation Areas.

- (1) In addition to the requirements in 64E-5.316, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 gray) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation or to non-self-shielded irradiators.
- (2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 64E-5.317(1) if the registrant has met all the specific requirements for access and control specified in other applicable parts of these rules, such as Part IV for industrial radiographic operations, Part V for x-rays in the healing arts, and Part VIII for particle accelerators.

Specific Authority: 404.051, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S. History: New <u>January 1, 1994</u>, Formerly 10D-91.448.

SUBPART G

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

64E-5.318 Use of Process or Other Engineering Controls. The licensee shall use R6 to the extent practical process or other engineering controls such as containment, R6 decontamination, or ventilation to control the concentrations of radioactive material in air.

- R6 (1) When it is not practical to apply process or other engineering controls, to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:
- R6 (a) Control of access;
- R6 (b) Limitation of exposure time;
- R6 (c) Use of respiratory protection equipment; or
- R6 (d) Other controls.
- R6(2)If the licensee performs an ALARA analysis to determine whether or not to useR6respirators, the licensee can consider safety factors other than radiologicalR6factors. The licensee also should consider the impact of respirator use onR6workers' industrial health and safety.

64E-5 Florida Administrative Code 64E-5.319

Specific Authority: 404.051, F.S.

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

R6 History: New January 1, 1994, Amended May 15, 199, Formerly 10D-91.450, Amended September 28, 2006.

64E-5.319 Use of Individual Respiratory Protection Equipment.

- (1) If the licensee uses respiratory protection equipment to limit intakes as specified in 64E-5.318:
 - (a) The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety, except as provided in 64E-5.319(1)(b).
 - (b) If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use demonstrated by testing or on the basis of reliable test information.
 - (c) The licensee shall implement and maintain a respiratory protection program that includes:
 - 1. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;
 - 2. Surveys and bioassays as needed to evaluate actual intakes;
 - Testing of respirators for operability including user seal checks for face sealing devices and functional checks for other devices immediately before to each use;
 - 4. Written procedures regarding supervision and training of respirator users; monitoring, including air sampling and bioassays; fit testing; respirator selection; breathing air quality; inventory and control; storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment; limitations on periods of respirator use and relief from respirator use; and recordkeeping;
 - 5. Determination by a physician before initial fitting of face sealing respirators, before the first field use of non-face sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician that the individual user is medically fit to use respiratory protection equipment; and
 - 6. Fit testing before the first field use of tight fitting face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year with fit factor ≥ 10 times the APF for negative pressure devices and a fit factor ≥ 500 for any positive pressure, continuous flow, and pressure-demand devices. Fit testing shall be performed with the facepiece operating in the negative pressure mode.

- R6 (d) The licensee shall advise each respirator user that the user can leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.
- R6(e)The licensee also shall consider limitations appropriate to the type andR6mode of use. When selecting respiratory devices, the licensee shallR6provide for vision correction, adequate communication, low temperatureR6work environments, and the concurrent use of other safety or radiologicalR6protection equipment. The licensee shall use equipment in such a way asR6not to interfere with the proper operation of the respirator.
 - (f) Standby rescue persons are required whenever one-piece atmospheresupplying suits or any combination of supplied-air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. Standby persons shall be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers through visual, voice, signal line, telephone, radio, or other suitable means and be available immediately to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons shall be available immediately to assist all users of this type of equipment and to provide effective emergency rescue if needed.
- R6(g)Atmosphere-supplying respirators shall be supplied with respirable air ofR6grade D quality or better as defined by the Compressed Gas AssociationR6in publication G-7.1, "Commodity Specification for Air," 1997, which isR6herein incorporated by reference and, available from the Compressed GasR6Association, Inc., and included in the regulations of the OccupationalR6Safety and Health Administration. Grade D quality air criteria include:
 - 1. Oxygen content (v/v) of 19.5 23.5%; cubic meter of air or less;
 - Condensed hydrocarbon content of 5 milligrams per
 - Carbon monoxide content of 10 ppm or less;
 - Carbon dioxide content of 1,000 ppm or less; and
 - 5. Lack of noticeable odor.

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R6(h)The licensee shall ensure that no objects, materials, or substances suchR6as facial hair, or any conditions that interfere with the face-to-facepieceR6seal or valve function and that are under the control of the respiratorR6wearer are between the skin of the wearer's face and the sealing surfaceR6of a tight-fitting respirator facepiece.

- R6(2)When estimating the dose to individuals from airborne radioactive materials, the
concentration of radioactive material in the air that is inhaled when respirators
are worn is assumed initially to be the ambient concentration in air without
respiratory protection divided by the assigned protection factor. If the dose later
is found to be greater than the estimated dose, the corrected value shall be used.R6If the dose later is found to be less than the estimated dose, the corrected value
can be used.
- R6(a)Licensees shall take actions to limit doses to individuals from intakes ofR6airborne radioactive materials to maintain total effective dose equivalentR6ALARA, which could include using process or other engineering controlsR6and limiting the use of respiratory protection equipment.
- R6(b)The licensee shall obtain authorization from the department before usingR6assigned protection factors in excess of those specified in State of FloridaR6Bureau of Radiation Control Protection Factors for Respirators, May 2006.
The department can authorize a licensee to use higher protection factors
on receipt of an application that:
 - 1. Describes the situation for which a need exists for higher protection factors; and
 - 2. Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

Specific Authority: 404.051, 404.081, F.S.

- R1 Law Implemented: 404.051(1)(4), 404.081, F.S.
- R6 History: New January 1, 1994, Formerly 10D-91.452, Amended May 18, 1998, Amended September 28, 2006.

SUBPART H

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

64E-5.320 Security of Stored Sources of Radiation. The licensee shall secure from unauthorized removal or access licensed sources of radiation that are stored in restricted or unrestricted areas.

Specific Authority: 404.051, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S. History: New January 1, 1994, Formerly 10D-91.453.

64E-5.321 Control of Sources of Radiation Not in Storage.

- (1) The licensee shall control and maintain constant surveillance of licensed radioactive material that is in an unrestricted area and that is not in storage or in a patient.
- (2) The registrant shall maintain control of radiation machines that are in a restricted or unrestricted area and that are not in storage.

Specific Authority: 404.051, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S. History: New <u>January 1, 1994</u>, Formerly 10D-91.454.

SUBPART I PRECAUTIONARY PROCEDURES

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PART IV

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

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	64E-5	Florida Administrative Code	64E-5.428
R4 R4 R4 R4 R4 R4 R4	(2)	Each sealed source shall be tested for radioactive contamination intervals not to exceed 6 months. In the absence of a certificate indicating that a test has been made within the 6 months before t sealed source shall not be used until tested. Sealed sources that department license for storage only do not require leak testing du shall be tested before use or transfer to another person if the inter exceeds 6 months.	from a transferor he transfer, the t are listed in a ring storage but
R4 R4 R4 R4 R4 R4	(3)	Each exposure device using depleted uranium (DU) shielding and configuration shall be tested for DU contamination at intervals nor months. DU shielded devices do not have to be tested for DU co while in storage and not in use. However, the DU devices shall be contamination before use or transfer if the interval of storage exce Licensees must comply with the DU leak testing requirements of within 6 months after the effective date of this rule.	t to exceed 12 ntamination e tested for DU eeds 12 months.
R4 R4 R4 R6	(4)	Leak testing as specified in 64E-5.427(2) and (3), F.A.C., shall be detecting the presence of 0.005 microcurie (185 Bq) of removable on the test sample. The wipe sample shall be taken from the nea point to the sealed source where contamination could accumulate	e contamination arest accessible
R4 R4 R6 R6 R4 R4 R4 R4 R4 R4 R4 R4	(5)	If any test conducted pursuant to this section reveals the present microcurie (185 Bq) or more of removable radioactive material, the immediately shall withdraw the equipment from use and cause it decontaminated and repaired or disposed of in accordance with F 5.1303, F.A.C., and the applicable sections of rules contained in F of Chapter 64E-5, F.A.C. If DU leak testing reveals the presence microcurie (185 Bq) or more of removable DU contamination, the device shall be removed from use until an evaluation of the wear has been made. If the evaluation reveals that the S-tube is worn device shall not be used. The licensee shall file a report with the describing the equipment involved, the test results, and the corre taken within 5 days after obtaining results of the test.	e licensee to be Rule 64E- Parts III and XV of 0.005 exposure on the S-tube through, the department
R4	Specific Authori	ity: 404.051, F.S.	

R4 Specific Autofity. 404.051, F.S. R4 Law Implemented: 404.022, 404.051(1), (4), (6), F.S.

R6 History: New September 11, 2001, <u>Amended September 28, 2006</u>.

R4 64E-5.428 Quarterly Inventory. Each licensee or registrant shall conduct a quarterly
 R4 physical inventory to account for all sources of radiation received or possessed during the
 R4 quarter. The inventory shall cover all sources of radiation requiring licensure or registration by
 R4 the department, including sealed sources, radiation machines, radiographic exposure devices,
 R4 and source changers containing DU.

R4 Specific Authority: 404.051, F.S.

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

R4 History: New September 11, 2001.

R464E-5.429Source Movement Logs, Daily Survey Reports, and IndividualR4Dosimeter Logs.

- R4 (1) Each time a radiation source is removed from storage, the licensee or registrant
 R4 shall complete and maintain source movement logs for each radiation source with
 R4 the following information, as applicable:
- R4 (a) The locations where used, the names of the jobs or clients, and the dates R6 of use including the dates removed and returned to storage ;
- R4 (b) The manufacturer's name, model, and serial number of the radiographic exposure device, source changer, or radiation machine used;
- R4(c)The sealed source manufacturer's name, model, and serial number,
activity in curies (becquerels) on the date of receipt and each date of use,
and the due date of the next leak test;
- R4 (d) The results of the reference survey of the radiographic exposure device or source changer performed upon removal and return to storage; and
- R6 (e) The identity and signature or initials of the radiographer to whom the radiation source has been assigned.
- R4 (2) Before performing industrial radiography, leak tests, source exchanges, or
 R4 quarterly inspection and maintenance of radiographic equipment, the licensee or
 R4 registrant shall prepare and maintain a daily survey report for each radiation
 R4 source with the information described below as it becomes available:
- R4 (a) The location where used, the name of the job or client, and the date of use;
- R4 (b) The manufacturer's name, model, and serial number of the radiographic exposure device, source changer, or radiation machine used;
- R4(c)The sealed source manufacturer's name, model, and serial number and
activity in curies (becquerels) for the date of use;
- R4(d)The names and titles of the radiographic personnel working with the
radiation source;
- R4 (e) The serial number of the personnel monitoring badge, pocket dosimeter, R4 and alarm ratemeter used by each of the radiography crew members;
- R4 (f) The manufacturer's name, model, serial number, and date of calibration or calibration due date for each survey meter used;
- R4(g)The results of the reference survey performed when the radiographicR4exposure device or source changer is removed from or returned toR4storage;

	64E-5		Florida Administrative Code	64E-5.430
R4 R4		(h)	Evidence of performance of the equipment checks describ 5.430(1), F.A.C.;	ed in 64E-
R4 R4		(i)	The results of the survey of the posted perimeter in mR/hr feet (meters);	(mSv/hr) and
R4		(j)	The total exposure time; and	
R4 R4		(k)	The start, end, and total pocket dosimeter readings for all personnel.	radiographic
R4 R4 R4 R4 R4 R4 R4 R4	(3)	totals at the the e dosir RSO desig initia	ographic personnel shall maintain an individual log of their days. Each individual shall record the doses measured by his or e end of each day of radiographic operations and total the re end of each week and at the end of each month. Copies of the meter logs shall be provided to the radiation safety officer (Radia 's designee no later than 7 days after each month. The RSC gnee shall review the logs within 7 days of receipt and shall of the logs at the time of the review. Each log shall include the mation:	her dosimeter corded doses at ne individual SO) or the D or the RSO's date and sign or
R4		(a)	The name of the individual;	
R4		(b)	The dates of the monitoring periods;	
R4 R4		(c)	The daily, weekly, and monthly individual radiation dose to measured by the dosimeter; and	tals as
R4 R4		(d)	The date the log was reviewed by the RSO or the RSO's or signature or initials of the RSO or the RSO's designee.	lesignee and the
R4	Specific Authori Law Implemente History: New Se	d: 404.0	51, F.S. 22, 404.051(1), (4), 404.081(1), F.S. 11, 2001, <mark>Amended September 28, 2006.</mark>	
R4	64E-	5.430	Inspection and Maintenance.	
R4 R4	(1)		n licensee or registrant shall perform visual and operability ch uments, radiation machines, radiographic exposure devices,	•

instruments, radiation machines, radiographic exposure devices, associated K4 equipment, transport containers, storage containers, and source changers before R4 use on each day the equipment is to be used to ensure the equipment is in good R4 working condition, the sources are shielded adequately, and required labeling is R4 present. All appropriate parts shall be maintained in accordance with the R4 manufacturer's specifications. Each radiation survey instrument shall be visually R4 inspected, have its batteries checked, and have its operability checked with a R4 radiation source at the beginning of each day of use and at the beginning of each R4 work shift. If equipment problems are found, the equipment shall be removed R4 from service until repaired. R4

- R4 (2) Each licensee or registrant shall perform equipment inspection and maintenance R4 as described below.
- R4 (a) Inspection and maintenance of survey instruments, radiation machines,
- R4 radiographic exposure devices, associated equipment, source changers, R4 storage containers, and transport containers shall be performed guarterly
- R4 to assure proper functioning of components important to safety. All
- R4 appropriate parts shall be maintained in accordance with the
- R4manufacturer's specifications. Verification of compliance with radiationR4limits specified in 64E-5.424(4), F.A.C., shall be included in each quarterlyR4inspection. If equipment problems are found, the equipment shall beR4labeled as defective and removed from service until repaired.
- R4 Replacement components shall meet manufacturer's specifications.
- R4(b)Inspection and maintenance of Type B packages used to transportR4radioactive materials shall be performed quarterly in accordance with eachR4package'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.

R4 History: New September 11, 2001.

R4 64E-5.431 Permanent Radiographic Installations.

- R4 (1) Each entrance used for personnel access to a high radiation area in a permanent R4 radiographic installation shall have either:
- R4(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 (1R4millisievert) in 1 hour at 30 centimeters from the source of radiation from
any surface the radiation penetrates, or
- R4(b)Conspicuous visible and audible signals to warn of the presence ofR4radiation. The visible signal shall be actuated by radiation. The audibleR4signal shall be actuated when an attempt is made to enter the installationR4while the source is exposed or the radiation machine is activated.
- R4 (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 R4 R4 the visible and audible signals. Entrance control devices that reduce the R4 radiation level upon entry shall be tested monthly. If an entrance control device R4 or an alarm is operating improperly, it shall be labeled immediately as defective R4 and repaired within 7 days. The installation can continue to be used by an R4 unaccompanied radiographer during this 7-day period if the continuous R4 surveillance requirements of 64E-5.425(6), F.A.C., are implemented and an R4 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 <u>September 11, 2001</u>.

	64E-5		Florida Administrative Code	64E-5.433
R4	64E-5	5.433	Radiation Safety Officer.	
R4 R4 R4 R4	(1)	need	icensee or registrant shall appoint an RSO and delegate the a ed to fulfill the duties of the position. Except as specified in 6 C., below, the minimum qualifications, training, and experience be:	4E-5.433(2),
R4 R4		(a)	One year of documented industrial radiography experience radiographer; and	as a
R4 R4 R4 R4 R4 R4		(b)	Sixteen hours of formal instruction in the establishment and of a radiation protection program, including training to perfo audits and mitigation of radiological incidents. Individuals in RSO on an industrial radiography license or registration bef effective date of this rule are not required to comply with the requirements of this paragraph.	rm internal lentified as an fore the
R4 R4 R4 R4	(2)	opera radia	valent alternative radiation and safety training and experience ations and formal training in the establishment and maintenan tion protection program can substitute for the requirements sp 8(1)(a) and (b), F.A.C., above.	ce of a
R4	(3)	In ad	dition to other duties specified in this part, the RSO shall:	
R4 R4 R4		(a)	Ensure compliance with all components of the licensee's or radiation protection program as specified in 64E-5.432, F.A and conditions of the license, and this rule;	•
R4 R4		(b)	Investigate incidents and direct corrective actions, including operations when necessary;	halting
R4		(c)	Serve as the licensee's or registrant's contact with the depa	irtment; and
R4 R4 R4		(d)	Ensure that radiation safety activities are performed using a procedures and requirements in Chapter 64E-5, F.A.C., in t operation of the licensee's program.	
R4	Specific Authorit	y: 404.05	51, 404.061, F.S.	

R4 Law Implemented: 404.022, 404.051(1), (4), 404.061(2), F.S. R4 History: New <u>September 11, 2001</u>.

R4	64E-5	.434	Train	ing, Testing, Certification, and Audits.
R4 R4	(1)			or registrant shall not permit any individual to act as a 's assistant until such individual:
R4 R4		(a)		ves a copy of the licensee's or registrant's operating and emergency dures;
R4 R4 R4 R4 R4		(b)	regist instru relate	eletes 8 hours of training, including instruction in the licensee's or rant's operating and emergency procedures and supervised ction in use of the licensee's or registrant's radiographic equipment, d handling tools, radiation survey instruments, and personnel oring devices during a special training session; and
R4 R4 R4 R4 R4 R4		(c)	licens practi to der radiog	essfully completes a closed-book, written examination on the ee's or registrant's operating and emergency procedures and a cal examination that is not conducted during production radiography nonstrate competence in the use of the licensee's or registrant's graphic equipment, related handling tools, radiation survey ments, and personnel monitoring devices.
R4 R4 R4 R4 R4	(2)	and te radiog	esting s graphy rant sh	nd registrants can allow individuals who have completed the training specified in $64E-5.434(2)(a) - (d)$, F.A.C., below, to perform industrial for 12 months after the effective date of these rules. The licensee or all not permit any individual to act as a radiographer until such
R4 R4 R4 R4		(a)	XV, F certifi	ves copies of rules contained in Chapter 64E-5, Parts I – IV, IX and .A.C., applicable USDOT regulations, the appropriate license or cate of registration, and the licensee's or registrant's operating and gency procedures;
R4 R4 R4 R4		(b)	1.	For radioactive material radiographic operations, completes 320 hours of on-the-job training in industrial radiography, excluding hours as specified in 64E-5.434(2)(b)2., F.A.C., below, as a radiographer's assistant using radioactive material; or
R4 R4			2.	For machine produced radiographic operations, completes 200 hours of on-the-job training using radiation machines;
R4 R4 R4 R4 R4		(C)	64E-5 sessio radioo	ves 40 hours of formal instruction in the subjects outlined in 6.434(6), F.A.C., and supervised instruction during a special training on in the inspection and use of the licensee's or registrant's graphic equipment, related handling tools, radiation survey ments, and personnel monitoring devices;
R4 R6 R4 R4		(d)	outlin demo	essfully completes a closed-book, written examination on the subjects ed in subsection 64E-5.434(6), F.A.C., and a practical examination to nstrate competence in the use of the licensee's or registrant's graphic and safety equipment; and
R4		(e)	ls cer	tified by a certifying entity.

	64E-5		Florida Administrative Code	64E-5.434
R4 R4 R4 R4	(3)	reciprocal r the state if	ners who work for an out-of-state radioactive materials l recognition are authorized to conduct radiographic oper they have a valid certification from a certifying entity for ucted before entering the state.	ations within
R4 R4 R4 R4 R4 R4 R4 R4 R4	(4)	F.A.C., abc complete 4 operations. registrant's during a sp radiograph completion 5.434(1)(c)	ual who has completed all requirements specified in 64 ove, and begins work for a different Florida licensee or r hours of additional training and testing before conducti The training shall consist of instructions in the license operating and emergency procedures and supervised becial training session in the use of the licensee's or reg ic and safety equipment. The testing shall consist of su of the written and practical examinations described in 6 , F.A.C. The RSO shall document how the prior radiati was verified.	egistrant shall ng radiographic e's or instruction istrant's iccessful 54E-
R4 R4	(5)		using industrial cabinet x-ray systems for industrial radion 6 hours of training and testing as described below:	ography shall
R4 R4		(a) Ten	hours of training and testing as described in 64E-5.434	(6), F.A.C.; and
R4 R4 R4 R4 R4 R4 R4 R4 R4		proc ray s sess relat mon exar equi the u	hours of instruction in the registrant's operating and en redures pertaining to industrial radiography using indust systems, 2 hours of supervised instruction during a spe sion in the use of the registrant's industrial cabinet x-ray red handling tools, radiation survey instruments, and pe itoring devices, and 2 hours of testing, which shall const mination covering operating and emergency procedures pment use and a practical examination to demonstrate use of the registrant's industrial cabinet x-ray system ar pment.	rial cabinet x- cial training system, rsonnel sist of a written and competence in
R4	(6)	The subjec	ts to be covered during the instruction of radiographers	shall include:
R4 R4 R4 R4 R4		units	damentals of radiation safety, including characteristics of s of radiation dose, quantities of radioactivity, hazards of osure, radiation protection standards, radiation levels fro ation, and methods of minimizing radiation dose.	f radiation
R4		(b) Rad	iation detection instruments, including:	
R4 R4		1.	Use, operation, calibration, and limitations of radiation instruments;	n survey
R4		2.	Survey techniques; and	
R4		3.	Use of personnel monitoring equipment.	

-	64E-5			Florida Administrative Code	64E-5.434
R4		(c)	Equip	oment to be used, including, as applicable:	
R4 R4 R4 R4			1.	Operation and control of radiation machines, radiogr equipment, remote handling equipment, source char containers, and transport containers, including pictur source assemblies;	ngers, storage
R4			2.	Storage, control, and disposal of licensed material; a	Ind
R4			3.	Inspection and maintenance of equipment.	
R4 R4		(d)		applicable requirements of these rules and NRC and U ations.	SDOT
R4		(e)	The I	icensee's or registrant's operating and emergency pro-	cedures.
R4		(f)	Case	histories of industrial radiography accidents.	
R6 R4 R4	(7)		y traini	ee or registrant shall provide 8 hours of <mark>refresher</mark> annung to all radiographic personnel, which can be conduct	
R4 R4 R4 R4 R4 R4 R4 R4 R4	(8)	radio regul emer perfo radio radio for m licens radio	graphe ations, gency graphic graphe ore tha see's o graphic	the RSO's designee shall audit the job performance of and radiographer's assistant to ensure that the depa license requirements, and the licensee's or registrant's procedures are followed. The audits shall include obs e of each radiographer or radiographer's assistant duri c operation at intervals not to exceed 6 months. Radio or's assistants who have not participated in a radiograp in 6 months since the last audit shall demonstrate know r registrant's operating and emergency procedures and c and related equipment by a practical examination befor in a radiographic operation. Audits of the RSO are not	rtment's s operating and ervation of the ng an actual graphers or hic operation wledge of the d safe use of fore
R4 R4	(9)			conducting internal radiation safety training or audits sl ialifications specified in 64E-5.433(1), F.A.C., for the F	

R4 Specific Authority: 404.051404.061, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.061(2), F.S.
R6 History: New September 11, 2001, <u>Amended September 28, 2006.</u>

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), R4
 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.

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**.

- R4 (1) Each licensee or registrant shall maintain the following records for 3 years after R4 the event at the location specified in 64E-5.432, F.A.C., for inspection by the R4 department:
- R4(a)Survey instrument, dosimeter, and alarm ratemeter calibrations specifiedR4in 64E-5.426 and 64E-5.437(5) (6), F.A.C.;
- R4(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;
- R4(c)Quarterly inventories specified in 64E-5.428, F.A.C., which shall includeR4the name of the person conducting the inventory, the radionuclide, numberR4of curies (becquerels) or mass in each device, location of each sealedR4source, device, and machine, the manufacturer, model, and serial numberR4of each sealed source, device, and machine, the date of the inventory, andR4the signature or initials of the RSO or the RSO's designee;
- R4(d)Source movement logs and daily survey reports specified in 64E-5.429,R4F.A.C.
- R4(e)Quarterly equipment inspection and maintenance specified in 64E-R45.430(2), F.A.C., including the date of the inspection, the name ofR4inspector, the equipment involved, any problems found, and what repair orR4maintenance was done;

	64E-5		Florida Administrative Code	64E-5.440
R4 R4		(f)	Operation tests on permanent radiographic installation entra 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., of audit items checked and any violations observed;	, including lists
R4 R4 R4 R4 R4		(h)	Records showing receipts and transfers of sealed sources a using DU for shielding, including the date, the name of the in making the record, radionuclide, number of curies (becquere manufacturer, model, and serial number of each sealed sour device, as appropriate.	ndividual els) or mass,
R6 R6		<mark>(i)</mark>	Records of annual ALARA audits specified in paragraph 64I F.A.C.	E-5.432(4)(c),
R4 R4	(2)		n licensee or registrant shall maintain the following records unt Irtment terminates the license or registration requiring the reco	
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 including lists of the topics discussed, dates the training was names of the instructors and attendees, and written and praexaminations;	s conducted,
R4		(C)	Verification of previous radiography experience;	
R4 R4		(d)	Radiographer certification documents specified in 64E-5.434(2)(e) – (f), 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 individu the exposures received, the dates the exposures were rece description of the cause of the exposures, the corrective act and the signature of the RSO;	ived, a
R4 R4 R4 R4		(f)	Records of estimates of exposures as a result of off-scale d lost or damaged personnel monitoring badges, including rec surveys used to determine an individual's exposure and rep to the department as specified in 64E-5.437(3), F.A.C.;	cords of
R6 R6		(g)	Personnel monitoring badge records from the accredited NN processor as specified in subsection 64E-5.437(2), F.A.C.;	
R6 R6 R6		(h)	Operating and emergency procedures. Licensees shall reta material for 3 years after making changes to operating or er procedures.	
R4 R4 R4	(3)	site s	n licensee or registrant conducting industrial radiography at a t shall have the following records available at that site for inspec ortment:	

	64E-5		Florida Administrative Code	64E-5.441
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 R4 R4		(e)	Calibration records for the survey instruments, pocket dosi alarm ratemeters used at the site or calibration tags or labe affixed to the devices;	
R4 R4		(f)	Records of the latest leak test results for the specific devic site or leak test tags or labels that are affixed to the device	
R4 R4		(g)	Source movement logs and daily survey reports for the per at the site.	riod of operation
R4	Law Implemente	d: 404.0	51, F.S. 22, 404.051(1), (4), 404.081(1), 404.20, F.S. 11, 2001, <mark>Amended September 28, 2006</mark> .	
R4	64E-5	.441	Reporting Requirements.	
R4 R6 R4 R4 R4 R4 R4 R4	(1)	64E- provie of the shall Bin C involv Mach	dition to the reporting requirements specified in rules contain 5, Parts III and IX, F.A.C., and other sections of this part, each de a written report to the department within 30 days of the or e incidents involving radiographic equipment described below be mailed to the Bureau of Radiation Control, Radioactive M 221, 4052 Bald Cypress Way, Tallahassee, Florida 32399-17 ving radioactive materials or to the Bureau of Radiation Control hine Section, P. O. Box 210, Jacksonville, Florida 32231 for i ving radiation machines.	ch licensee shall ccurrence of any v. Such reports laterials Section, 41 for incidents rol, Radiation
R4 R4		(a)	Unintentional disconnection of the source assembly from the source asse	ne control cable.
R4 R4		(b)	Inability to retract and secure the source assembly to the fip position.	ully shielded
R4 R4		(C)	Failure of any component critical to safe operation of the d its intended function properly.	evice to perform
R4 R4	(2)		icensee shall include the information described below in eac hitted as specified in this section.	h report
R4		(a)	A description of the equipment problem.	
R4		(b)	Cause of each incident if known.	
R4 R4		(C)	Manufacturer name and model number of the equipment in incident.	nvolved in the
			IV - 23	

	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 R4	(3)	Chap	orts of overexposures submitted as specified in rules contained oter 64E-5, F.A.C., that involve failure of safety components of oment also must include the information specified in 64E-5.441	radiography
	Specific Author	,	51, F.S. 22, 404, 051(1), (4), 404, 081(1), E.S.	

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S. R4 History: New September 11, 2001, <u>Amended September 28, 2006</u>..

	PART XI RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OF	PERATIONS
R1	64E-5.1101Prohibitions	XI-1
	SUBPART A EQUIPMENT CONTROL	
	64E-5.1102Storage and Transportation Precautions	
R2	64E-5.1103Radiation Survey Instruments	
<mark>R6</mark>	64E-5.1104Leak Testing of Sealed Sources	
	64E-5.1105Quarterly Inventory 64E-5.1106Utilization Records	
<mark>R6</mark>	64E-5.1107Design, Performance and Certification Criteria for Sealed Sources	
	Used in Downhole Operations <mark>64E-5.11071Uranium Sinker Bars</mark>	XI-4
R6	64E-5.11071. Uranium Sinker Bars	XI-5
R6	64E-5/11072. Energy Compensation Source	XI-6
R6	64E-5.11073 Tritium Neutron Generator Target Source	
	64E-5.1108Labeling 64E-5.1109Inspection and Maintenance	
	•	
	SUBPART B REQUIREMENTS FOR PERSONNEL SAFETY	
	64E-5.1110Training Requirements	
	64E-5.1111Operating and Emergency Procedures	
<mark>R6</mark>	64E-5.1112Personnel Monitoring	XI-9
	SUBPART C PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER OPERATIONS	
	64E-5.1113Security	XI-9
	64E-5.1114Handling Tools	XI-9
	64E-5.1115Subsurface Tracer Studies	XI-9
	SUBPART D RADIATION SURVEYS AND RECORDS	
	64E-5.1116Radiation Surveys	XI-10
	64E-5.1117Documents and Records Required at Field Stations	XI-11
	64E-5.1118Documents and Records Required at Temporary Jobsites	XI-11
	SUBPART E NOTIFICATION	
<mark>R6</mark> R6	64E-5.1119Notification of Incidents, Abandonment and Lost Sources	XI-12
	Supervisors	XI-14

64E-5.1104 Leak Testing of Sealed Sources.

- (1) Requirements. Each licensee using sealed sources containing radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department for 3 years after the leak test is performed or until transfer or disposal of the sealed source.
- (2) Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state using a leak test kit or method approved by the department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The test sample shall be taken from the nearest accessible point to the sealed source where contamination might accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.
- R6 (3) Test frequency.

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- (a) Each sealed source except an energy compensation source or ECS containing radioactive material shall be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within the 6 months before the transfer, the sealed source shall not be used until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.
- R6(b)Each ECS that is not exempt from testing as specified in subsection 64E-R65.1104(5), F.A.C., below, shall be tested at intervals not to exceed 3R6years. In the absence of a certificate from a transferor that a test has beenR6made within the 3 years before transfer, the ECS shall not be used untilR6tested.
- R6 (4) Removal of Leaking or Contaminated Sources from service. If the test specified R6 in subsection (3), above, reveals the presence of 0.005 microcurie (185 Bg) or R6 more of removable radioactive material, the licensee shall remove the sealed R6 source from service immediately and shall cause it to be decontaminated, R6 repaired, or disposed of by a person licensed by the department, the U.S. R6 Nuclear Regulatory Commission, an Agreement State, or a Licensing State to R6 perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination, and if contaminated, have it decontaminated or disposed of in accordance with these regulations. A report describing the equipment involved, the test results, any contamination which resulted from the leaking source, and corrective action taken shall be filed with the department within 5 days of receiving the test results.
 - (5) Exemptions. The following sources are exempted from the periodic leak test requirements of 64E-5.1104(1) through (4):
 - (a) Hydrogen 3 sources;

- (b) Sources containing radioactive material with a half-life of 30 days or less;
- (c) Sealed sources containing radioactive material in gaseous form;
- (d) Sources of beta-emitting or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and
- (e) Sources of alpha-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

Specific Authority: 404.022, 404.051(1)(4), 404.061, 404.081(1), F.S. Law Implemented: 404.022, 404.051(1)(5), 404.061(2), F.S.

R6 History: New April 4, 1989, Formerly 10D-91.12051, Amended September 28, 2006.

64E-5.1105 Quarterly Inventory. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for 2 years from the date of the inventory for inspection by the department and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory and the name of the individual conducting the inventory.

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.22, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), 404.081(1), 404.22(1), F.S. History: New July 17, 1985, Formerly 10D-91.1206.

64E-5.1106 Utilization Records. Each licensee using radioactive materials shall maintain utilization records, which shall be kept available for inspection by the department for 2 years from the date of the recorded event, showing the following information for each source of radiation:

- (1) Make, model number and a serial number or a description of each source of radiation used;
- (2) The identity of the well logging supervisor or field unit to whom assigned;
- (3) Locations where used and dates of use; and
- (4) In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

Specific Authority: 404.051, 404.061, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.081(1), F.S. History: New July 17, 1985, Formerly 10D-91.1207.

64E-5.1107 Design, Performance and Certification Criteria for Sealed Sources Used in Downhole Operations.

R6 (1) A licensee can use a sealed source in well logging applications if:
R6 (a) The sealed source is doubly encapsulated;
R6 (b) The sealed source contains radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and
R6 (c) The sealed source meets the requirements specified in (2), (3), or (4), below.

- R6 A licensee can use a sealed source manufactured on or before July 14, 1989, in (2) R6 well logging applications if it meets the requirements of USASI N5.10 – 1968. R6 "Classification of Sealed Radioactive Sources", which is herein incorporated by R6 reference and available from the Department, or the requirements specified in R6 subsections (3) and (4), below. R6 (3) A licensee can use a sealed source manufactured after July 14, 1989, in well R6 logging applications if it meets the oil-well logging requirements specified in R6 ANSI/HPS N43.6 – 1997, "Sealed Radioactive Sources – Classification", which is R6 herein incorporated by reference and available from the Department. R6 A licensee can use a sealed source manufactured after July 14, 1989, in well (4) R6 logging applications if: R6 The sealed source's prototype has been tested and found to maintain its (a) R6 integrity after each of the following tests: R6 Temperature. The test source is held at -40° C for 20 minutes, 1. **R**6 600° C for 1 hour, and then subjected to a thermal shock test with a temperature drop from 600° C to 20° C within 15 seconds. R6 Impact test. A 5 kg steel hammer 2.5 cm in diameter is dropped 2. R6 from a height of 1 m onto the test source. R6 3. Vibration test. The test source is subjected to a vibration from R6 25 Hz to 500 Hz at 5 g amplitude for 30 minutes. R6 Puncture test. A 1 gram hammer and 0.3 cm diameter pin is 4. R6 dropped from a height of 1 m onto the test source. R6 5. Pressure test. The test source is subjected to an external pressure R6 of 24,600 pounds per square inch absolute (1,695 x 107 pascals). R6 (5) The requirements of subsection (1) through (4), above, do not apply to sealed R6 sources that contain licensed material in gaseous form. R6 (6) The requirements of subsections (1) through (4), above, do not apply to ECSs. R6 ECSs shall be registered with the department as specified in subsection R6 64E-5.210(14), F.A.C., the U.S. Nuclear Regulatory Commission, an Agreement R6 State, or a Licensing State Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.071(1), 404.081(1), F.S. R6 History: New July 17, 1985, Formerly 10D-91.1208m Amended September 28, 2006
- R6
 64E-5.11071
 Uranium sinker bars. The licensee can use a uranium sinker bar
 R6 in well logging applications only if it is legibly impressed with the words
- ^{R6} "CAUTION RADIOACTIVE DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES
 ^{R6} (OR COMPANY NAME) IF FOUND.

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

R6 R6 R6	is contained v	.11072 Energy Compensation Source. The licensee can use an ECS that within a logging tool or other tool components only if the ECS contains 100 3.7 MBq) or less of licensed material					
R6 R6 R6	<mark>(1)</mark>	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-5.1107, and 64E-5.1106, F.A.C., above.					
R6 R6 R6 R6	aquifers, use of the ECS is subject only to the requirements specified in F 64E-5.1101, 64E-1104, 64E-5.1105, 64E-5.1106, 64E-5.1119(5), and 64						
R6 R6 R6	Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.071(1), 404.081(1), F.S. History <u>: New September 28, 2006</u>						
R6	64E-5	.11073 Tritium Neutron Generator Target Source.					
R6 R6 R6 R6 R6	(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.					
R6 R6 R6	(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 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

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.

64E-5.1109 Inspection and Maintenance.

- (1) Each licensee possessing radioactive material shall conduct, at intervals not to exceed 6 months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of 2 years for inspection by the department.
- (2) If any inspection conducted pursuant to this section reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.
- (3) The repair, opening or modification of any sealed source device shall be performed only by persons specifically authorized to do so by the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state.

Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.071(1), 404.081(1), F.S. History: New July 17, 1985, Formerly 10D-91.1210.

SUBPART B REQUIREMENTS FOR PERSONNEL SAFETY

64E-5.1110 Training Requirements.

- (1) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this part until such individual has:
 - (a) Received, in a course taught by an individual who has been licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, instruction in the subjects outlined in this part and demonstrated an understanding thereof;
 - (b) Read and received instruction in the regulations contained in this part and the applicable sections of Parts I, III and IX, or their equivalent, conditions of the appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and
 - (c) Demonstrated competence to use sources of radiation, related handling tools and radiation survey instruments which will be used on the job.
- (2) No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:
 - (a) Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and

- (b) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools and radiation survey instruments which will be used on the job.
- (3) The licensee or registrant shall maintain employee training records for inspection by the department for 2 years following termination of employment.

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.22, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), 404.081(1), 404.22(1), F.S. History: New <u>July 17, 1985</u>, Formerly 10D-91.1211.

64E-5.1111 Operating and Emergency Procedures. The licensee's or registrant's operating and emergency procedures shall include appropriate instructions in at least the following:

- Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Part III;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods and occasions for locking and securing sources of radiation;
- (4) Personnel monitoring and the use of personnel monitoring equipment;
- (5) As applicable, the transportation of radioactive sources to temporary job sites and field stations, including the packaging and placing of such sources in vehicles, placarding of vehicles and securing the sources during transportation;
- (6) Minimizing exposure of individuals in the event of an accident;
- (7) Procedure for notifying proper personnel in the event of an accident;
- (8) Maintenance of records;
- (9) As applicable, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers and injection tools;
- (10) As applicable, procedures to be followed in the event a sealed source is lodged downhole; and
- (11) As applicable, procedures to be used for picking up, receiving and opening packages containing radioactive material.

Specific Authority: 404.051, 404.061, 404.081, 404.20, 404.22, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.081(1), 404.20(1), 404.22, F.S. History: New July 17, 1985, Formerly 10D-91.1212.

64E-5.1112 Personnel Monitoring. No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the use of sources of radiation unless
 R2 such individual wears a film badge, optically stimulated luminescent device (OSLD), or a
 R6 thermoluminescent dosimeter (TLD) that is processed and evaluated by an accredited NVLAP
 Processor. Each film badge, OSLD or TLD shall be assigned to and worn by only one
 R6 individual. Film badges shall be replaced at least monthly and OSLDs and TLDs shall be
 R6 replaced at least quarterly. Each film badge, OSLD, and TLD shall be processed promptly after
 R6 replacement. The licensee shall retain records of personnel dosimeters and bioassay results
 until the Department terminates each pertinent license or registration requiring the records.

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

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

R6 History: New July 17, 1985, Amended May 15, 1996, Formerly 10D-91.1213, Amended October 8, 2000, <u>Amended September</u>
 R6 <u>28, 2006.</u>

SUBPART C PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER OPERATIONS

64E-5.1113 Security. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in 64E-5.101.

Specific Authority: 404.051, 404.061, F.S. Law Implemented: 404.022, 404.031, 404.051(1)(4), 404.061(2), F.S. History: New July 17, 1985, Amended <u>August 29, 1994</u>, Formerly 10D-91.1214.

64E-5.1114 Handling Tools. The licensee shall provide and require the use of tools that will assure remote handling of sealed sources except for low-activity calibration sources that result in a gamma exposure rate at contact of less than 100 milliroentgens $(2.58 \times 10^{-5} \mu C \text{ per kg})$ per hour.

Specific Authority: 404.051, 404.061, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.061(2), F.S. History: New July 17, 1985, Formerly 10D-91.1215.

64E-5.1115 Subsurface Tracer Studies.

- (1) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.
- (2) No licensee shall intentionally inject radioactive material into any fresh water aquifers unless the Department of Health and the Department of Environmental Regulation determine that such injection will not endanger the public health, safety and welfare.
- (3) No licensee shall inject radioactive material into any well unless it can be demonstrated to the department that the procedure will not result in any liquids or gases distributed to the public exceeding the following criteria:

- (a) For gases, the air concentration in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table II, Column 2, shall apply.
- (b) For liquids, the water concentration values in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table II, Column 2, shall apply.

Specific Authority: 404.051, 404.061, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4), 404.061(2), F.S. History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.1216.

SUBPART D RADIATION SURVEYS AND RECORDS

64E-5.1116 Radiation Surveys.

- (1) Radiation surveys and personnel exposure calculations shall be made and recorded for each area where radioactive materials are stored.
- (2) Radiation surveys and personnel exposure calculations shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys and calculations shall include each source of radiation or combination of sources to be transported in the vehicle.
- (3) After removal of the sealed source from the logging tool and before departing the job site, a survey meter shall be used to assure that the logging tool is free of contamination.
- (4) Radiation surveys shall be made and recorded at the job site or well-head for each tracer operation, except those using tritium, carbon 14 and sulfur 35. These surveys shall include measurements of radiation levels before and after the operation. If radiation levels, post operation, exceed twice background, the area shall be decontaminated or restricted until radiation levels reach twice background.
- (5) Records required pursuant to this section shall include the dates, the identification of individuals making the survey, the identification of survey instruments used and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the department for 2 years after completion of the survey.

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.20, F.S. Law Implemented: 404.022, 404.051(1)(4)(6), 404.071(1), 404.081(1), 404.20(1), F.S. History: New July 17, 1985, Formerly 10D-91.1217. 64E-5.1117 Documents and Records Required at Field Stations. Each licensee or registrant shall maintain, for inspection by the department, the following documents and records for the specific devices and sources used at the field station:

- (1) Appropriate license or certificate of registration;
- (2) Operating and emergency procedures;
- (3) A copy of these regulations;
- (4) Records of the latest survey instrument calibrations pursuant to 64E-5.1103 and Part III;
- (5) Records of the latest leak test results pursuant to license conditions;
- (6) Quarterly inventories required pursuant to 64E-5.1105;
- (7) Utilization records required pursuant to 64E-5.1106;
- (8) Records of inspection and maintenance required pursuant to 64E-5.1109; and
- (9) Survey records required pursuant to 64E-5.1116.

Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), 404.081(1), F.S. History: New July 17, 1985, Formerly 10D-91.1218.

64E-5.1118 Temporary Job sites. Each licensee or registrant conducting operations at a temporary job site, which is a location to which radioactive materials have been dispatched to perform wireline service operations or subsurface tracer studies, shall have the following documents and records available at that site for inspection by the department:

- (1) Operating and emergency procedures;
- (2) Survey records required pursuant to 64E-5.1116 for the period of operation at the site;
- (3) Evidence of current calibration for the radiation survey instruments in use at the site; and
- (4) When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration or equivalent documents.

Specific Authority: 404.051, 404.061, 404.081, 404.22, F.S. Law Implemented: 404.022, 404.051(1)(4)(11), 404.061(2), 404.081(1), 404.22, F.S. History: New July 17, 1985, Amended <u>May 15, 1996</u>, Formerly 10D-91.1219.

SUBPART E NOTIFICATION

64E-5.1119 Notification of Incidents, Abandonment and Lost Sources.

- (1) Notification shall be made of radiation incidents and radioactive sources lost in other than downhole logging operations in accordance with appropriate provisions of Part III.
- (2) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:
 - Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and
 - (b) Notify the department immediately by telephone or telegraph if radioactive contamination is detected at the surface or if the source appears to be damaged.
- (3) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:
 - (a) Advise the well-operator and the department of an appropriate method of abandonment, which shall include:
 - 1. The immobilization and sealing in place of the radioactive source with a cement plug;
 - 2. The setting of a whipstock or other deflection device; and
 - 3. The mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by this section;
- R6(b)Notify the department by telephone of the circumstances that resulted in
the inability to retrieve the source and obtain the Department's approval to
implement abandonment procedures or notify the Department that the
licensee implemented abandonment before receiving Department
approval because the licensee believed there was an immediate threat to
public health and safety
 - (c) File a written report with the department within 30 days of the abandonment, setting forth the following information:
 - 1. Date of occurrence and a brief description of attempts to recover the source;
 - 2. A description of the radioactive source involved, including radionuclide, quantity and chemical and physical form;

		6	4E-5	Florida Administrative Code 64E-5.1119
			3.	Surface location and identification of well;
			4.	Results of efforts to immobilize and set the source in place;
			5.	Depth of the lodged radioactive source;
			6.	Depth of the top of the cement plug;
R6			7.	Depth of the well;
R6			8.	Information contained on the permanent identification plaque; and
R6 R6 R6			<mark>9.</mark>	he immediate threat to public health and safety that justified abandonment before Department approval as specified in paragraph (3)(b), above; and
R6 R6 R6		(d) Develop and implement a means to prevent inadvertent intrusion on the source unless the source is not accessible to any subsequent drilling operations.		
R6 R6 R6	(4)	Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque, as described below, for posting the well or well-bore at the surface of the well unless the mounting of the plaque is not practical. The size of the plaque shall be at least 7 inches (17 cm) square and 1/8 inch (3 mm) thick. This plaque shall:		
R6 R6		 Be constructed of long-lasting material, such as stainless steel, brass, bronze, or monel, and 		
		(b) Contain the following information engraved on its face:		
			1.	The word "CAUTION";
			2.	The radiation symbol without the conventional color requirement;
			3.	The date of abandonment;
			4.	The name of the well operator or well owner;
			5.	The well name and well identification numbers or other designation;
			6.	The sealed sources by radionuclide and quantity of activity;
			7.	The source depth and the depth to the top of the plug; and
			8.	An appropriate warning, depending on the specific circumstances of each abandonment which may include:
				a. "Do not drill below plug-back depth";
				b. "Do not enlarge casing"; or
				c. "Do not reenter the hole," followed by the words, "before contacting the Department of Health."
				YI- 13

(5) The licensee shall immediately notify the department by telephone or telegraph, and subsequently by confirming letter, if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss and explain efforts planned or being taken to mitigate these consequences.

Specific Authority: 404.051, 404.061, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.081(1), F.S.
R6 History: New July 17, 1985, Formerly 10D-91.1220., <u>Amended September 28, 2006.</u>

64E-5.1120 Subjects To Be Included In Training Courses For Logging Supervisors. The following subjects must be included in training courses for logging supervisors.

- (1) Fundamentals of radiation safety, including:
 - (a) Characteristics of radiation;
 - (b) Units of radiation dose and, if appropriate, quantity of radioactivity;
 - (c) Significance of radiation dose, including:
 - 1. Radiation protection standards; and
 - 2. Biological effects of radiation dose;
 - (d) Levels of radiation from sources of radiation; and
 - (e) Methods of minimizing radiation dose, including:
 - 1. Working time;
 - 2. Working distances; and
 - 3. Shielding.
- (2) Radiation detection instrumentation to be used, including:
 - (a) Use of radiation survey instruments, including operation, calibration and limitations;
 - (b) Survey techniques; and
 - (c) Use of personnel monitoring equipment;

- (3) Equipment to be used, including:
 - (a) Handling equipment, if appropriate;
 - (b) Sources of radiation;
 - (c) Storage precautions, if appropriate, and control of equipment; and
 - (d) Operation and control of equipment.
- (4) The requirements of these regulations.
- (5) The licensee's or registrant's written operating and emergency procedures.
- (6) The licensee's or registrant's record keeping procedures.

Specific Authority: 404.051, 404.061, 404.081, F.S. Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.081(1), 404.22, F.S. History: New July 17, 1985, Formerly 10D-91.1221. Page Intentionally left Blank

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

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- R2 (4) A whole body film badge , OSLD, or TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of any gamma-emitting isotope with a gamma ray energy greater than 50 kiloelectron volts or the use of any beta-emitting isotope with a maximum beta energy of 300 kiloelectron volts or more.
- R2 (5) An extremity film badge or, OSLD, TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of 1,000 microcuries (37 MBq) or more of beta-emitting isotopes with a maximum beta energy of 1,000 kiloelectron volts or more in any month or by any individual who receives a dose of 40 millirem (400 μSv) or more on a whole body film R2
 R2 badge, OSLD, or TLD for 2 consecutive months.
- R2(6)Each film, OSLD, and TLD badge shall be assigned to and worn by only oneR2individual. Film badges and extremity OSLDs and TLDs must be replacedR2monthly. Whole body OSLDs and TLDs must be replaced quarterly. AfterR2replacement, each film badge, OSLD, and TLD must be promptly processed.

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

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

R2 History--New May 15, 1996, Formerly 10D-91.1411, Amended October 8, 2000.

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

64E-5.1311 Storage, Security and Transportation Precautions

- (1) Each sealed source of radioactive material shall be provided with a storage or transport container. The container shall be equipped with a lock or tamper seal to prevent unauthorized removal of or exposure to the source of radiation.
- (2) All portable gauge licensees must comply with either paragraph (2)(a) or (2)(b) below. Effective January 1, 2007, portable gauge licensees must comply only with paragraph (2)(b).
- (a) Sealed sources must have a minimum of two locks between the device and the public when being transported or stored.
- R6(b)Each portable gauge licensee shall use a minimum of two independentR6physical controls that form tangible barriers to secure portable gaugesR6from unauthorized removal, whenever portable gauges are not under theR6control and constant surveillance of the licensee.
 - (3) Transport containers shall be physically secured in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal. The sealed source shall be transported as far away from occupied areas of the vehicle as possible.
 - (4) Sealed sources not in storage or being transported must be under the constant surveillance and immediate control of the licensee.

64E-5.1312 Training and User Requirements.

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

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S. Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S. History: New <u>May 12, 1993</u>, Formerly 10D-91.1415.

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

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

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

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

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PART XV

TRANSPORTATION OF RADIOACTIVE MATERIALS

64E-5.1501 Transportation of Radioactive Material.

- (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 A₁ and A₂ values are found in 10 CFR Part 71, Appendix A, which is herein incorporated by reference and which is available from the department.

Specific Authority: 404.051, 404.20, F.S. Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.20(1), F.S. History: New July 17, 1985, Amended <u>May 15, 1996</u>, Formerly 10D-91.2001.

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 171-173, 177, 383, and 390-397.
 - (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; and
 - (c) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

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.

R6 History: New July 17, 1985, Formerly 10D-91.2003, Amended October 8, 2000, Amended September 28, 2006.

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 <u>July 17, 1985</u>, Formerly 10D-91.2005.

STATE OF FLORIDA

BUREAU OF RADIATION CONTROL

PROTECTION FACTORS FOR RESPIRATORS

May 2006

PROTECTION FACTORS FOR RESPIRATORS(^a)

The following definitions apply:

"Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

"Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

"Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator and a disposable escape-only self-contained breathing apparatus.

"Filtering facepiece" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium and not equipped with elastomeric sealing surfaces and adjustable straps.

"Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

"Hood" means a respiratory inlet covering that completely covers the head and neck and also can cover portions of the shoulders and torso.

"Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

"Negative pressure respirator" or "tight-fitting respirator" means a respirator in which the air pressure inside the facepiece is lower than the ambient air pressure outside the respirator during inhalation.

"Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering is higher than the ambient air pressure outside the respirator.

"Powered air-purifying respirator" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

"Qualitative fit test" means a pass or fail test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

"Quantitative fit test" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

	Operating Mode	Assigned Protection Factors
I. Air Purifying Respirators (Particulate ^b only) ^c		
Filtering facepiece disposable ^d	Negative Pressure	(^d)
Facepiece, half ^e	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25

II. Atmosphere supplying respirators (particulate,					
gases, and vapors ^f)					
1. Air-line respirator:					
Facepiece, half	Demand	10			
Facepiece, half	Continuous Flow	50			
Facepiece, half	Pressure Demand	50			
Facepiece, full	Demand	100			
Facepiece, full	Continuous Flow	1000			
Facepiece, full	Pressure Demand	1000			
Helmet/hood	Continuous Flow	1000			
Facepiece, loose-fitting	Continuous Flow	25			
Suit	Continuous Flow	(^g)			
2. Self-contained breathing Apparatus (SCBA)					
Facepiece, full	Demand	^h 100			
Facepiece, full	Pressure Demand	ⁱ 10,000			
Facepiece, full	Demand, Recirculating	^h 100			
Facepiece, full	Positive Pressure Recirculating	ⁱ 10,000			
III. Combination Respirators					
Any combination of air-purifying and	Assigned protection factor for type and mode of				
atmosphere-supplying respirators operating as listed above.					

^aThese assigned protection factors apply only in a respiratory protection program that meets the requirements of this part. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of or in addition to radioactive hazards. Selection and use of respirators for such circumstances also must comply with U.S. Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of State of Florida Bureau of Radiation Control ALI's. DAC's, and Effluent Concentrations, July 1993 are based on internal dose due to inhalation could also present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

^bAir purifying respirators with APF <100 must be equipped with particulate filters that are at least 95% efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99% efficient. Air purifying respirators with APFs >100 must be equipped with particulate filters that are at least 99.97% efficient.

^cThe licensee can apply to the department for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors such as radioiodine.

^dLicensees can permit individuals who have not been medically screened or fit tested on the device to use this type of respirator if no credit is taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in Rule 64E-5.319, F.A.C., apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 can be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated qualitative or quantitative fit test.

^eUnder-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece such as disposable or reusable disposable respirators. Both types are acceptable if the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95% efficient, and all other requirements of this part are met.

^fThe assigned protection factors for gases and vapors are not applicable to radioactive

contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard and protective actions for these contaminants should be based on external or submersion dose considerations.

^gNo NIOSH approval schedule currently is available for atmosphere supplying suits. This equipment can be used in an acceptable respiratory protection program if all the other minimum program requirements except fit testing are met.

^hThe licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health.

ⁱThis type of respirator can be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device cannot be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

Editors Note: Page 67 deleted Next attachment Page is Page 68

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Transfers of Industrial 64F-5.210(4)	Devices Report 10/20	003 Continued	REAU OF RADIATION CO	EPORT (FROM GENERAL LICENSEES)							
For eac	For each "licensee" from whom a device(s) has been received during the reporting period, supply the following:										
			GENERAL LICENSEE	E INFORMATION							
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Transfers of Industrial	I Devices Report 10/20	2003 Continued	REAU OF RADIATION CO	ONTROL EPORT (FROM GENERAL LICENSEES)							
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	Devices Report 10/2003 C	continued	EAU OF RADIATION		RT (LABEL C	HANGES)	
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