

February 2008

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

Revision 8 Filing Instructions: Changes to Chapter 64E-5, Florida Administrative Code (F.A.C.)

Changes to "Control of Radiation Hazard Regulations," Chapter 64E-5, F.A.C., became effective February 28, 2008. The requirements for nationally tracking certain radioactive sources described in Sections 64E-5.350 and 64E-5.351 does not become effective until January 31, 2009. These changes are indicated as Revision 8 or (R8) in the margin.

These instructions apply to the complete version (brown cover) of Chapter 64E-5, F.A.C. Be sure that Revisions 1, 2, 3, 4, 5, 6 and 7 changes have been inserted before making these changes. This may be verified by checking page ii of the index. **Visit our website at** <u>www.doh.state.fl.us/environment/radiation/</u> to download R8 pages to replace.

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

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

- Part I: Definitions to support the terms National Source Tracking requirements added to Part III and minor changes to definitions of radiographic exposure device, sealed source, low specific activity material (LSA), and package to remain compatible with U.S. Nuclear Regulatory Commission (NRC).
- Part II: Minor changes to the general license device requirements to remain compatible with the NRC such as longer record keeping requirements and following NRC regulations to export devices. Requires manufacturers of general licensed devices to use unique serial numbers for the tracking these devices. As required by NRC, reciprocity licensees may be in Florida no more than 180 days in a calendar year.

Part III: Adds reporting requirements to the NRC to track the movements of sealed sources of certain isotopes above quantities of concern. This reporting requirement does not become effective until January 31, 2009 or later if authorized by 10 CFR 20.2207(h). SEE RULE TEXT FOR DETAILS.

- Part IV Requires industrial radiography licensees to have "written procedures" for inspection and maintenance of equipment. It also requires licensees to notify the department if they are conducting radiographic operations more than 180 days at a location not listed on the license.
- Part X Increases the fees for environmental radiological testing for pre- and post mining.
- Part XI Corrects a reference regarding the use of energy compensation sources and protection of fresh water aquifers as required to be compatible with the NRC.
- Part XV Transportation regulations updated to reflect the current regulations required by the U.S. Department of Transportation and the U.S. Nuclear Regulatory Commission.

Visit our website at <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, F.A.C.

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



CONTROL OF RADIATION HAZARD REGULATIONS



Chapter 64E-5 Florida Administrative Code

Effective Date July 3, 1997 Includes

Revision 1	(May 18, 2000);
Revision 2	(October 8, 2000);
Revision 3	(August 6, 2001);
Revision 4	(September 11, 2001;
Revision 5	(December 19, 2001)
Revision 6	(September 28, 2006);
Revision 7	(August 16, 2007) and
Revision 8	(February 28, 2008)



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

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

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This is an "unofficial" copy that has been re-formatted for ease of use and to provide attachments. Electronic versions of these regulations are posted on the Bureau's website: <u>http://www.doh.state.fl.us/environment/radiation</u>. Chapter 64E-5 and all other Florida Administrative Codes are available at <u>https://www.flrules.org/</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, Transfers of Industrial Devices Report 10-2003
R7	August 16, 2007	64E-5.101, 64E-5.204, 64E-5.210, 64E-5.502, 64E-5.504, 64E-5.506, 64E-5.511, 64E-5.1508, Transfers of Industrial Devices Report 04/2007, Radiation Machine Facility Registration DH 03/2007
R8	February 28, 2008	64E05.101, 64E-5.206, 64E-5.206, 64E-5.210, 64E-5.216, New 64E-5.350, New 64E-5.351, 64E-5.430, 64E-5.440, 64E-5.441, 64E-5.1003, 64E-5.11702, 64E-5.1501, 64E-5.1502

PART I GENERAL PROVISIONS

R8	64E-5.101	Definitions	I-1
	64E-5.102	Exemptions	. I-22
	64E-5.103	Records	. I-23
		. Tests	
		Prohibited Use	
	64E-5.106	Units of Exposure and Dose	. I-24
	PART II	LICENSING OF RADIOACTIVE MATERIALS	
R2		Licensing of Radioactive Material	
		Source Material - Exemptions	
R2	64E-5.203	Radioactive Material Other than Source Material - Exemptions	<mark> II-4</mark>
	SUBPART A	LICENSE TYPES AND FEES	
R8	64E-5.204	. Types of Licenses	II-10
	SUBPART B	GENERAL LICENSES	
	64E-5.205	. General Licenses - Source Material	ll-15
R6		General Licenses - Radioactive Material Other Than Source Material	
	SUBPART C	SPECIFIC LICENSES	
	64E-5.207	Filing Application for Specific Licenses	. II-30
		General Requirements for the Issuance of Specific Licenses	
		Special Requirements for Specific Licenses of Broad Scope	. II-31
R8	64E-5.210	Special Requirements for a Specific License to Manufacture, Assemble,	
		Repair or Distribute Commodities, Products or Devices which	
	045 5 044	Contain Radioactive Material	II-35
	64E-5.211	Special Requirements for Issuance of Specific Licenses for	11 5 4
	615 5 212	Source Material Milling Issuance of Specific Licenses	
R6		Specific Terms and Conditions of Licenses	
R5		Expiration and Termination of Licenses and Decommissioning of Buildings	11-50
	012 0.211	and Outdoor Areas	II-60
	64E-5.215	Transfer of Material	
	SUBPART D	RECIPROCITY	
R8		Reciprocal Recognition of Licenses for By-product, Source, Naturally	
		Occurring and Accelerator Produced Radioactive Material, and	
		Special Nuclear Material in Quantities not Sufficient to Form a Critical Mass	II-65
	SUBPART E	BONDING	
		. Bonding of Persons Licensed Pursuant to Subpart C	. II-67
	SUBPART F	INSPECTION AND ENFORCEMENT	
	64E-5.218	Performance of Inspections	. II-70
		Emergency Planning	
		. Radioactive Quantities	

	SUBPART G	ng of Radioactive Materials (continued) RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION	
R5 R5 R5	64E-5.222	Radiological Criteria for License TerminationI Radiological Criteria for Unrestricted UseI Radiological Criteria for License Termination Under Restricted ConditionsI	<mark>ll-78a</mark>
R5 R5	64E-5.223	Alternate Criteria for License Termination	1-70a 11-78c
R5		Public Notification and Public Participation	
R5		Minimizing Contamination	
	Schedule A	Exempt Concentrations	11-79
		Exempt Quantities	
		Limits for Broad License	
	PART III	STANDARDS FOR PROTECTION	
	SUBPART A	GENERAL PROVISIONS	
R2		Standards for Protection Against Radiation	
	64E-5.302	Implementation	. 111-1
		RADIATION PROTECTION PROGRAMS	
R2	64E-5.303	Radiation Protection Programs	<mark>. III-2</mark>
	SUBPART C	OCCUPATIONAL DOSE LIMITS	
R6	64E-5.304	Occupational Dose Limits for Adults	<mark>. III-2</mark>
	64E-5.305	Compliance with Requirements for Summation of External and Internal Doses	111.2
	64E-5 306	Determination of External Dose from Airborne Radioactive Material	
		Determination of Internal Exposure	
		Determination of Prior Occupational Dose	
R2	64E-5.309	Planned Special Exposures	<mark> III-8</mark>
	64E-5.310	Occupation Dose Limits for Minors	. III-9
R2	64E-5.311	Dose to an Embryo Fetus	<mark>. -9</mark>
		RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC	
R2		Dose Limits for Individual Members of the Public.	
	64E-5.313	Compliance with Dose Limits for Individual Members of the Public	111-11
	SUBPART E	SURVEYS AND MONITORING	
R2		General	<mark>III-12</mark>
R2	64E-5.315	Conditions Requiring Individual Monitoring of External and Internal Occupational Dose	111 12
			III-13
	SUBPART F	CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS	
	64E-5.316	Control of Access to High Radiation Areas	III-14
		Control of Access to Very High Radiation Areas	

	Part III Standards for Protection (continued)		
	SUBPART G	RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS	
R6		Use of Process or Other Engineering Controls	
R6	64E-5.319	Use of Individual Respiratory Protection Equipment	<mark> III-16</mark>
	SUBPART H	STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION Security of Stored Sources of Radiation	III_18
	64E-5.320	Control of Sources of Radiation Not in Storage	111-18
	SUBPART I	PRECAUTIONARY PROCEDURES	
	64E-5.322	Caution Signs	III-19
R2	64E-5.323	Posting Requirements	<mark> III-20</mark>
	64E-5.324	Exceptions to Posting Requirements	III-20
	64E-5.325	Labeling Containers and Radiation Machines	III-21
R2	64E-5.326	Exemptions to Labeling Requirements	III-21
	64E-5.327	Procedures for Receiving and Opening Packages	111-22
	SUBPART J	WASTE MANAGEMENT	
	64E-5.328	General Requirements	III-23
	64E-5.329	Method of Obtaining Approval of Proposed Disposal Procedures	III-24
	64E-5.330	Discharge by Release into Sanitary Sewerage	111-24
	64E-5.331	Disposal of Specific Wastes	III-25
R1		Transfer for Disposal and Manifests	III-26a
R1	64E-5.333	Classification and Characteristics of Low Level Radioactive Waste	
		for Near-Surface Land Disposal, Labeling and Manifest Requirements	111-27
	SUBPART K	for Near-Surface Land Disposal, Labeling and Manifest Requirements	III-27
R2	64E-5.334	RECORDS General Provisions	<mark> III-36</mark>
R2	<mark>64E-5.334</mark> 64E-5.335	RECORDS General Provisions Records of Radiation Protection Programs	<mark> -36</mark> -36
<mark>R2</mark>	64E-5.334 64E-5.335 64E-5.336	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys	<mark> -36</mark> -36 -36a
<mark>R2</mark>	64E-5.334 64E-5.335 64E-5.336 64E-5.337	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources	<mark> -36</mark> -36 -36a -36a
	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures	<mark> -36</mark> -36 -36a -36a -37
	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results	<mark> -36</mark> -36 -36a -37 -37
	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340	RECORDS General Provisions	<mark> -36</mark> -36 -36a -37 -37 -38
	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Waste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas	-36 -36a -36a -37 -37 -38 -38
	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341	RECORDS General Provisions	-36 -36a -36a -37 -37 -38 -38
	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Waste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas	-36 -36a -36a -37 -37 -38 -38
	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341 64E-5.342 SUBPART L	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records Reports Reports of Stolen, Lost, or Missing Licensed or	-36 -36a -36a -37 -37 -38 -38 -39
R2	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341 64E-5.342 64E-5.342 64E-5.343	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation	111-36 111-36a 111-36a 111-37 111-37 111-38 111-38 111-39
R2 R2	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341 64E-5.342 SUBPART L 64E-5.343 64E-5.344	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Waste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records REPORTS Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation Notification of Incidents	111-36 111-36a 111-36a 111-37 111-37 111-38 111-38 111-39
R2	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341 64E-5.342 SUBPART L 64E-5.343 64E-5.344	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Waste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation Notification of Incidents Reports of Exposure, Radiation Levels, Concentrations of	-36 -36a -36a -37 -37 -38 -38 -39 -39
R2 R2	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341 64E-5.342 64E-5.343 64E-5.343 64E-5.343 64E-5.343 64E-5.343 64E-5.343	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Waste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation Notification of Incidents Reports of Exposure, Radiation Levels, Concentrations of Radioactive Material Exceeding the Limits, and Misadministrations	-36 -36a -36a -37 -37 -38 -38 -39 -39 -40
R2 R2 R2	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341 64E-5.342 64E-5.343 64E-5.343 64E-5.343 64E-5.343 64E-5.343 64E-5.344 64E-5.345 64E-5.346	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Vaste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation Notification of Incidents Reports of Exposure, Radiation Levels, Concentrations of Radioactive Material Exceeding the Limits, and Misadministrations Reports of Planned Special Exposures	-36 -36a -36a -37 -37 -38 -38 -39 -39 -40 -43 -43
R2 R2	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.340 64E-5.341 64E-5.342 SUBPART L 64E-5.343 64E-5.344 64E-5.345 64E-5.346 64E-5.347	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Waste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records Reports Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation Notification of Incidents Reports of Exposure, Radiation Levels, Concentrations of Radioactive Material Exceeding the Limits, and Misadministrations Reports of Planned Special Exposures Notifications and Reports to Individuals	111-36 111-36a 111-36a 111-37 111-37 111-38 111-38 111-38 111-39 111-40 111-43 111-46 111-46
R2 R2 R2	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341 64E-5.342 64E-5.343 64E-5.343 64E-5.343 64E-5.343 64E-5.343 64E-5.344 64E-5.345 64E-5.346 64E-5.347 64E-5.348	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Waste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records REPORTS Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation Notification of Incidents Reports of Exposure, Radiation Levels, Concentrations of Radioactive Material Exceeding the Limits, and Misadministrations Reports of Planned Special Exposures Notifications and Reports to Individuals Reports of Leaking or Contaminated Sealed Sources	III-36 III-36a III-36a III-37 III-37 III-38 III-38 III-38 III-38 III-39 III-40 III-46 III-46 III-46
R2 R2 R1	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.340 64E-5.341 64E-5.342 64E-5.342 64E-5.343 64E-5.343 64E-5.343 64E-5.344 64E-5.345 64E-5.345 64E-5.347 64E-5.348 64E-5.349	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Waste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records REPORTS Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation Notification of Incidents Reports of Exposure, Radiation Levels, Concentrations of Radioactive Material Exceeding the Limits, and Misadministrations Reports of Planned Special Exposures Notifications and Reports to Individuals Reports of Leaking or Contaminated Sealed Sources Vacating Premises	III-36 III-36a III-36a III-37 III-37 III-37 III-38 III-38 III-38 III-39 III-39 III-40 III-46 III-46 III-46 III-46
R2 R2 R2	64E-5.334 64E-5.335 64E-5.336 64E-5.337 64E-5.338 64E-5.339 64E-5.340 64E-5.341 64E-5.342 64E-5.343 64E-5.343 64E-5.343 64E-5.343 64E-5.343 64E-5.343 64E-5.344 64E-5.345 64E-5.346 64E-5.347 64E-5.349 64E-5.349 64E-5.350	RECORDS General Provisions Records of Radiation Protection Programs Records of Surveys Records of Tests for Leakage or Contamination of Sealed Sources Records of Planned Special Exposures Records of Individual Monitoring Results Records of Waste Disposal or Transfers Records of Testing Entry Control Devices for Very High Radiation Areas Form of Records REPORTS Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation Notification of Incidents Reports of Exposure, Radiation Levels, Concentrations of Radioactive Material Exceeding the Limits, and Misadministrations Reports of Planned Special Exposures Notifications and Reports to Individuals Reports of Leaking or Contaminated Sealed Sources	III-36 III-36a III-36a III-37 III-37 III-38 III-38 III-38 III-39 III-39 III-40 III-40 III-46 III-46 III-46 III-46 III-46

PART IV RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

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

R4	64E-5.423	. Definitions	IV-1
R4	SUBPART D	EQUIPMENT CONTROL (formerly Subpart A)	
R4		Requirements for Industrial Radiography Equipment Using Sealed Sources	
R4		Locking of Sources of Radiation, Storage Precautions, and Surveillance	
R4	64E-5.426	. Radiation Survey Instruments	IV-6
R6	64E-5.427	Leak Testing, Repairing, Tagging, Opening,	
		Modifying and Replacing Sealed Sources and Devices	IV-6
R4	64E-5.428	Quarterly Inventory	IV-7
R6	64E-5.429	Source Movement Logs, Daily Survey Reports, and Individual Dosimeter Logs	<mark> IV-8</mark>
R8	64E-5.430	. Inspection and Maintenance	IV-9
R4	64E-5.431	. Inspection and Maintenance	<mark> IV-10</mark>
R4	SUBPART E	RADIATION SAFETY REQUIREMENTS (formerly Subpart B)	
R4	64E-5.432	Radiation Protection Program	IV-11
R4		Radiation Safety Officer	
R6		Training, Testing, Certification, and Audits	
R4		Conducting Industrial Radiographic Operations	
R4		Operating and Emergency Procedures	
R4		Personnel Monitoring	
R4	SUBPART F	PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS (formerly Subpart C)	
R4	64E-5.438	. Radiation Surveys	IV-20
R4	64E-5.439	Posting	
R8		Records	
R8		Reporting Requirements	
	PART V	X-RAYS IN THE HEALING ARTS	
	64E-5.501	Definitions	V-1
R7	64E-5.502	General Requirements	V-10
	64E-5.503	General Requirements for all Diagnostic X-ray Systems	V-17
R7	64E-5.504	Fluoroscopic X-ray Systems	V-23
R2			
		Diagnostic Radiography Systems, Other than Fluoroscopic,	
	64E-5.505	Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems	V-30
R7	64E-5.505 64E-5.506	Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems Intraoral Dental Radiographic Systems	<mark> V-30</mark> V-34
	64E-5.505 64E-5.506 64E-5.507	Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems Intraoral Dental Radiographic Systems Therapeutic X-ray Systems of Less Than 1 MeV	<mark> V-30</mark> V-34 V-36
	64E-5.505 64E-5.506 64E-5.507 64E-5.508	Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems Intraoral Dental Radiographic Systems Therapeutic X-ray Systems of Less Than 1 MeV X-ray and Electron Therapy Systems with Energies of 1 MeV and Above	V-30 V-34 V-36 V-43
R7	64E-5.505 64E-5.506 64E-5.507 64E-5.508 64E-5.509	Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems Intraoral Dental Radiographic Systems Therapeutic X-ray Systems of Less Than 1 MeV X-ray and Electron Therapy Systems with Energies of 1 MeV and Above Veterinary Medicine X-ray Operations	V-30 V-34 V-36 V-43 V-57
	64E-5.505 64E-5.506 64E-5.507 64E-5.508 64E-5.509 64E-5.510	Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems Intraoral Dental Radiographic Systems Therapeutic X-ray Systems of Less Than 1 MeV X-ray and Electron Therapy Systems with Energies of 1 MeV and Above	V-30 V-34 V-36 V-43 V-57 V-59

	PART VI	USE OF RADIONUCLIDES IN THE HEALING ARTS	
R3	64E-5.601	. License RequiredVI	-1
	64E-5.602	. License Amendments	-1
R3	64E-5.603	. NotificationVI	<mark>-2</mark>
	SUBPART A	GENERAL ADMINISTRATIVE REQUIREMENTS	
		. ALARA Program VI	
		. Radiation Safety OfficerVI	
R3		. Radiation Safety CommitteeVI	
		. Authority and Responsibilities	
		. Supervision	
		Visiting Authorized User	
		. Mobile Nuclear Medicine Service Requirements	-8
	64E-5.611	. Quality Management Program and Notifications, Records and	~
		Reports of Misadministrations.	
	64E-5.612	. SuppliersVI-1	1
	SUBPART B	GENERAL TECHNICAL REQUIREMENTS	
	64E-5.613	. Quality Control of Diagnostic InstrumentationVI-1	2
		. Possession, Use, Calibration, and Check of Dose Calibrators	
		. Calibration and Check of Survey Instruments	
		. Assay of Radiopharmaceutical Dosages	
R1		. Authorization for Calibration and Reference Sources	
		. Requirements for Possession of Sealed Sources and	-
		Brachytherapy Sources	6
	64E-5.619	. Syringe Shields and LabelsVI-1	
		. Vial Shields and LabelsVI-1	
	64E-5.621	. Surveys for Contamination and Ambient Radiation Dose Rate	9
R2	64E-5.622	. Release of Patients Containing Radiopharmaceuticals or	
		Permanent ImplantsVI-2	<mark>20</mark>
		. Storage of Volatiles and Gases VI-20	
	64E-5.624	. Decay in Storage)a
R2	64E-5.625	. Safety Instruction and Precautions for Radiopharmaceutical Therapy, Brachytherapy, and TeletherapyVI-2	
		Brachytherapy, and TeletherapyVI-2	<u>21</u>
	SUBPART C	UPTAKE, DILUTION, AND EXCRETION	
D 0			
R3	64E-5.626	. Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies	<mark>:4</mark>
	SUBPART D	IMAGING AND LOCALIZATION	
R3	04E-0.027	. Use of Radiopharmaceuticals, Generators, and Reagent Kits for	<mark>) /</mark>
	645 5 629	Imaging and Localization Studies	.4 >7
	64E-5.020	. Control of Aerosols and GasesVI-2	.4)5
	04E-0.029	. CUTITION OF ACTUSUIS ATTU GASES	.0
	SUBPART E	RADIOPHARMACEUTICALS FOR THERAPY	
R3	64E-5.630	. Use of Radiopharmaceuticals for TherapyVI-2	<mark>26</mark>
	SUBPART F	SEALED SOURCES FOR DIAGNOSIS	
	64E-5.631	. Use of Sealed Sources for Diagnosis VI-2	26

SUBPART G SOURCES FOR BRACHYTHERAPY

64E-5.632 Use of Sources for Brachytherapy	VI-26
64E-5.633 Brachytherapy Sources Inventory	VI-27

SUBPART H TELETHERAPY

	64E-5.634 Use of Sealed Source in a Teletherapy Unit	VI-28
	64E-5.635 Maintenance and Repair Restrictions.	VI-28
	64E-5.636 Amendments	
	64E-5.637 Doors, Interlocks, and Warning Systems	
	64E-5.638 Radiation Monitoring Devices	
	64E-5.639 Viewing Systems	
	64E-5.640 Dosimetry Equipment	
	64E-5.641 Full Calibration Measurements	
	64E-5.642 Periodic Spot-Checks	VI-33
R2	64E-5.643 Radiation Surveys for Teletherapy Facilities	VI-35
	64E-5.644 Safety Spot-Checks for Teletherapy Facilities	
R2	64E-5.645 Modification of Teletherapy Unit or Room Before Beginning a	
	Treatment Program	VI-36
	64E-5.646 Reports of Teletherapy Surveys, Checks, Tests, and Measurements.	
	64E-5.647 Five Year Inspection	VI-37

SUBPART I TRAINING AND EXPERIENCE REQUIREMENTS

64E-5.648 Radiation Safety Officer	VI-37
64E-5.649 Training for Uptake, Dilution, or Excretion Studies	
64E-5.650 Training for Imaging and Localization Studies	VI-39
64E-5.651 Training for Therapeutic Use of Radiopharmaceuticals	VI-41
64E-5.652 Training for Therapeutic Use of Brachytherapy Sources	VI-42
64E-5.653 Training for Ophthalmic Use of Strontium 90	VI-44
64E-5.654 Training for Use of Sealed Sources for Diagnosis	VI-45
64E-5.655 Training for Teletherapy	VI-45
64E-5.656 Training for Teletherapy Physicist	VI-47
64E-5.657 Training for Experienced Authorized Users	VI-47
64E-5.658 Recentness of Training	VI-48

PART VII RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

64E-5.701	Equipment Requirements	VII-1
64E-5.702	Area Requirements	VII-2
64E-5.703	Operating Requirements	VII-3
	Personnel Requirements	

PART VIII RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL PARTICLE ACCELERATORS

SUBPART A REGISTRATION PROCEDURE

64E-5.801	Registration Requirements	VIII-1
	General Requirements for the Issuance of a Registration Certificate for	
	Particle Accelerators	VIII-1
64E-5.803	Particle Accelerators for Therapeutic Use on Humans	VIII-2

SUBPART B RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

64E-5.804 Limitations	VIII-3
64E-5.805 Shielding and Safety Design Requirements	VIII-3
64E-5.806 Particle Accelerator Controls and Interlock Systems	
64E-5.807 Warning Devices	
64E-5.808 Operating Procedures	VIII-5
64E-5.809 Radiation Monitoring Requirements	
64E-5.810 Ventilation Systems	VIII-6

PART IX NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

R5	64E-5.901 Posting of Notices to Workers	IX-1
	64E-5.902 Instructions to Workers	
	64E-5.903 Notification and Reports to Individuals	IX-3
	64E-5.904 Presence of Representatives of Licensees or Registrants and	
	Workers During Inspection	IX-4
	64E-5.905 Consultation with Workers During Inspections	IX-5
	64E-5.906 Request by Workers for Inspections	IX-5
	64E-5.907 Inspections Not Warranted; Informal Review	IX-6

PART X ENVIRONMENTAL RADIATION STANDARDS

SUBPART A	RADIATION STANDARDS FOR BUILDINGS
64E-5.1001	StandardsX-1
SUBPART B	ENVIRONMENTAL MONITORING

64E-5.1002..... Monitoring Requirements.....X-1 R8 64E-5.1003..... Monitoring Fees.....X-2

PART XI RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

64E-5.1101 ProhibitionsXI-1

	SUBPART A	EQUIPMENT CONTROL	
	64E-5.1102	Storage and Transportation Precautions	.XI-2
R2	64E-5.1103	Radiation Survey Instruments	. XI-2
R6	64E-5.1104	Leak Testing of Sealed Sources	. XI-3
		Quarterly Inventory	
	64E-5.1106	Utilization Records	XI-4
R6	64E-5.1107	Design, Performance and Certification Criteria for Sealed Sources	
		Used in Downhole Operations	.XI-4
R6	64E-5.11071	Uranium Sinker Bars.	. XI-5
R8	64E-5.11072	Energy Compensation Sources	. XI-6
R6		Tritium Neutron Generator Target Source	
		Labeling	
		Inspection and Maintenance	

	SUBPART B	REQUIREMENTS FOR PERSONNEL SAFETY	
		. Training Requirements . Operating and Emergency Procedures	
R6		Personnel Monitoring	
	SUBPART C	PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER OPERATIONS	
	64E-5.1114	. Security . Handling Tools . Subsurface Tracer Studies	XI-9
	SUBPART D	RADIATION SURVEYS AND RECORDS . Radiation Surveys	XI-10
		. Documents and Records Required at Field Stations	
		. Documents and Records Required at Temporary Job Sites	
	SUBPART E	NOTIFICATION	
R6	64E-5.1119	. Notification of Incidents, Abandonment and Lost Sources	.XI-12
R6		. Subjects to be Included in Training Courses for Logging Supervisors	
	PART XII	RADON REQUIREMENTS (text of these regulations not included in this printing)	
	PART XIII	RADIATION SAFETY REQUIREMENTS FOR POSSESSION AND USE OF SEALED OR UNSEALED SOURCES OF	
		RADIOACTIVE MATERIALS	
	C4E E 1201	Sealed or Unsealed Sources of Radioactive Materials	
	04E-5.1501		. ^111- 1
	SUBPART A	GENERAL REQUIREMENTS	
	64E-5.1302	. Operating and Emergency Procedures	.XIII-1
	64E-5.1303	. Leak Test Requirements for Possession of Sealed Sources	. XIII-2
		Inventory Requirements	. XIII-3
	64E-5.1305	. Training Requirements, Authority, Duties and Responsibilities of the Radiation Safety Officer	XIII_4
	64E-5.1306	. Opening Sealed Sources	
		. Training Requirements for Authorized Users	
	64E-5.1308	. Additional Requirements for General Licenses	. XIII-6
	64E-5.1309	. Training for Current Authorized Users	XIII-6
R2	64E-5.1310	Personnel Monitoring	. XIII-6
	SUBPART B	REQUIREMENTS FOR THE POSSESSION AND USE OF SEALED SOURCES IN PORTABLE DEVICES	
R6	64E-5.1311	. Storage, Security and Transportation Precautions	. XIII-7
		. Training and User Requirements	
	SUBPART C	REQUIREMENTS FOR THE POSSESSION AND USE OF SEALED SOURCES IN FIXED DEVICES	
		. Training and User Requirements	
		Possession of Survey Instruments	
	04⊏-0.1315	Additional Requirements	. XIII-9

	SUBPART D	REQUIREMENTS FOR THE POSSESSION AND USE OF UNSEALED SOURCES OF RADIOACTIVE MATERIALS	
	64E-5.1316	. General Rules for the Safe Use of Unsealed Sources of	
		Radioactive Material	XIII-9
	64E-5.1317	. Storage and Control of Volatiles and Gases	XIII-10
	64E-5.1318	. Instrumentation	XIII-10
	64E-5.1319	. Contamination Control Program	XIII-11
	PART XIV	LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS	
	SUBPART A	GENERAL PROVISIONS	
		. Irradiators	
	64E-5.1402	. Definitions	XIV-1
	SUBPART B	SPECIFIC LICENSE FOR LARGE IRRADIATORS	
	64E-5.1403	. Specific License for Large Irradiators	XIV-3
		. Start of Construction	
	SUBPART C	DESIGN AND PERFORMANCE REQUIREMENTS FOR LARGE	RRADIATORS
	64E-5.1405	. Performance Criteria for Sealed Sources	XIV-5
R2	64E-5.1406	. Access Control	XIV-6
		. Shielding	
		. Fire Protection	
		. Radiation Monitors	
		. Control of Source Movement	
		. Irradiator Pools	
		. Source Rack Protection	
		. Power Failures	
	64E-5.1414	. Design Requirements	XIV-11
	64E-5.1415	. Construction Control	XIV-14
	SUBPART D	OPERATION OF IRRADIATORS	
		. Training	
		. Operating and Emergency Procedures	
R2	64E-5.1418	. Personnel Monitoring	XIV-18
		. Radiation Surveys	
		. Detection of Leaking or Contaminated Sources	
	64E-5.1421	. Inspection and Maintenance	XIV-21
		. Pool Water Purity	
	64E-5.1423	. Attendance During Operation	XIV-22
		. Entering and Leaving the Radiation Room	
	64E-5.1425	. Irradiation of Explosive or Highly Flammable Materials	XIV-23
	SUBPART E	RECORDS AND REPORTS	
			X/IV / 0.4

64E-5.1426 Records and Retention Periods	XIV-24
64E-5.1427 Reports and Notifications	XIV-26

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

R8	64E-5.1501 Purpose and Scope	XV-1a
R8	64E-5.1502 Transportation of Radioactive Material	XV-1a
	64E-5.1503 Exemptions	
	64E-5.1504 General Licenses for Carriers	
	64E-5.1505 Routine Determinations	XV-3
	64E-5.1506 Advance Notification of Shipment of Certain Quantities of Radioactive Waste.	XV-3
	64E-5.1507 Designation of Routes for Shipment of Radioactive Waste	
	Requiring Advanced Notification	XV-5
R7	64E-5.1508 Inspection of Low-Level Radioactive Waste Shipments	
	64E-5.1509 Permit Requirements	XV-7
	64E-5.1510 Air Transport of Plutonium	XV-9
	64E-5.1511 Notification in the Event of Suspected or Real Breach of Containment	XV-9
	64E-5.1512 Inspections	XV-10
R2	64E-5.1513 Communications	
	Appendix A Appendix A to 10 CFR Part 71 Determination of A1 and A2 Values	XV-11
	Table A-1 A1 and A2 Values for Radionuclides	XV-13
	Table A-2 Relationship Between A1 and Emax for Beta Emitters	XV-30
	Table A-3 Relationship Between A ₃ for Alpha Emitters and the	
	Atomic Number of the Radionuclide	XV-30
	Table A-4 Activity - Mass Relationships for Uranium/Thorium	XV-31

ATTACHMENTS

ALIS, DACs, and Effluent Concentrations July 1993

- R6 Protection Factors for Respirators May 2006
- R2 Radioactive Material Requiring Labeling May 2000

Occupational Exposure Record for a Monitoring Period Form DH-1622 Edition 05/1997

Cumulative Occupational Exposure History Form DH-1623 Edition 05/1997

Certificate - Disposition of Radioactive Materials Form DH-1059 Edition 05/1997

Radioactive Materials License Application -- Non-Human Use Form DH-1054 Edition 05/1997

- 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
- R3 Authorized Nuclear Pharmacist Training Requirements
- R4 State of Florida Boundaries (map) State Constitution Article II, Section 1 (Exact boundaries)
- R7 Transfers of Industrial Devices Report 04/2007
- R7 Radiation Machine Facility Registration 1107 DH 03/07

PART I GENERAL PROVISIONS

64E-5.101	Definitions	I-1
64E-5.102	Exemptions	. I- 22
64E-5.103	Records	. I-23
64E-5.104	Tests	. I-23
64E-5.105	Prohibited Use	. I-23
64E-5.106	Units of Exposure and Dose	. I- 24
	64E-5.102 64E-5.103 64E-5.104 64E-5.105	64E-5.103 Records 64E-5.104 Tests 64E-5.105 Prohibited Use

- R4 (72) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the department.
- R4 (73) "Licensee" means any person who is licensed by the department in accordance with these rules and the Act.
- R4 (74) "Licensing State" means any state with rules equivalent to the Suggested State Regulations for Control of Radiation for the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.
- R4 (75) "Local components" means parts of an analytical x-ray system and includes areas that are struck by x-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but does not include power supplies, transformers, amplifiers, readout devices and control panels.
- R4 (76) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.
- R4 (77) "Logging tool" means a device used subsurface to perform well-logging.
- R4 (78) "Lost or missing licensed material" means licensed material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.
- R8(79)"Low specific activity material (LSA)" means that as defined in 49 C.F.R.R8173.403. (Pursuant to 120.54(6) Florida Statutes, 64E-5.101(79) is substantivelyR8identical to 49 CFR 173.403 published on 10/01/2007.)
- R4 (80) "Lung class" (see "Class").
- R4 (81) "Major processor" means a user processing, handling or manufacturing radioactive material exceeding 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):
- R2

R2

- 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:
 - 1. Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
 - 2. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.
- (c) A gamma stereotactic radiosurgery radiation dose:
 - 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
 - 4. When the calculated administered dose differs from the prescribed dose by more than 20 percent from the prescribed dose.
- (f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of iodine 123, iodine 125 or iodine 131 as sodium iodide, both:
 - 1. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
 - 2. When the dose to the individual exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.
- R7 (192) "Mobile C-arm" means a mobile fluoroscopic machine that is designed for and
 R7 used without a patient support device such as a radiographic table, cradle or
 R7 radiolucent stretcher. This would include machines moved from room to room to
 R7 assist in surgical procedures. Measurements of patient entrance exposure for
 R7 this type of system will be measured in accordance with paragraph
 R7 64E-5.504(3)(e) 2, 3, and 4.
- R4 (89) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, radiation monitoring and radiation protection monitoring are equivalent terms.
- R4 (90) "NARM" means any naturally occurring or accelerator-produced radioactive material. To meet the definition of licensing state, NARM only refers to discrete sources of NARM. Diffuse sources of NARM, which are large in volume and low in activity, are excluded from consideration by the Conference of Radiation Control Program Directors, Inc., for licensing state designation purposes.

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R8 R8 R8 R8 R8 R8 R8 R8 R8 R8 R8 R8 R8 R	(194)	"Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Rule 64E-5.351, F.A.C. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form, and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to 120.54(6) Florida Statutes, 64E-5.101(194) is substantively identical to 10 CFR 20.1003
R8		published on 01/01/2007.)
R4	<mark>(91)</mark>	"Natural radioactivity" means radioactivity of naturally occurring nuclides.
R4	<mark>(92)</mark>	"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	<mark>(93)</mark>	"Normal form" means radioactive material which has not been demonstrated to qualify as "special form"; also referred to as "nonspecial form."
R4	<mark>(94)</mark>	"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	<mark>(95)</mark>	"Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.
R4	<mark>(96)</mark>	"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 R2 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	<mark>(97)</mark>	"Offshore" means within the territorial waters of the State of Florida as specified
R4 R4	(97)	in Article II, Section 1 of the Constitution of the State of Florida.
R4	<mark>(98)</mark>	"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	<mark>(99)</mark>	"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

- R8(100)"Package" means that as defined in 49 C.F.R. 173.403. (Pursuant to 120.54(6)R8Florida Statutes, 64E-5.101(100) is substantively identical to 49 CFR 173.403R8published on 10/01/2007.)
- R4 (101) "Packaging" means, for radioactive materials, the assembly of components necessary to ensure compliance with the packaging requirements of the U.S. Nuclear Regulatory Commission and the U.S. Department of Transportation. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The conveyance, tie-down system, and auxiliary equipment may sometimes be designated as part of the packaging.
- R4 (102) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.
- R4(103) "Permanent radiographic installation" means an enclosed shielded room, cell, 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 direction orientation.
- R4 (119) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.
- R4 (120) "Radiographer" means any individual who has completed successfully the rraining 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.
- R8 (122) "Radiographic exposure device" means any instrument containing a sealed
 R8 source, fastened or contained therein, in which the sealed source or shielding
 R8 thereof may be moved, or otherwise changed from a shielded position to an
 R8 unshielded position for the purpose of making a radiographic exposure. It also is
 R8 known as a camera or a projector. (Pursuant to 120.54(6) Florida Statutes, 64ER8 5.101(122) is substantively identical to 10 CFR 34.3 published on 01/01/2007.)
- R4 (123) "Recordable event" means the administration of:
 - (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 v	therapy, particle accelerator or therape when the calculated weekly administer he weekly prescribed dose.		
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.			
R4	<mark>(127)</mark>	"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).			
R4	<mark>(128)</mark>	"Research and development" means:			
		(a) Theore	retical analysis, exploration or experime	entation; or	
		techni demor of moo develo	extension of investigative findings and the ical nature into practical application for nstration purposes, including the exper- dels, devices, equipment, materials and opment does not include the internal or ion or radioactive material to human be	experimental and imental production and testing d processes. Research and rexternal administration of	
R4	<mark>(129)</mark>		protective equipment" means an appa ce an individual's intake of airborne rac		
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>	"Roentgen" n 2.58 x 10 ⁻⁴ co	means the special unit of exposure. Or oulombs 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.
- R8 (133) "Sealed source" means radioactive material that is encased in a capsule
 R8 designed to prevent release or escape of the radioactive material. (Pursuant to 120.54(6) Florida Statutes, 64E-5.101(133) is substantively identical to 10 CFR
 R8 30.4 published on 01/01/2007.)
- 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:

- (a) 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.
- 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.

*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 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 R6 definitions have been alphabetized effective, September 28, 2006. ((189) Annual or Annually, (180) R6 "Assigned protection factor" or "APF", (181) "Atmosphere-supplying respirator", (191) Daily, (182) R6 "Energy compensation source" or "ECS, (183) "Fit factor", (184) "Fit test", (185) "Self-contained R6 breathing apparatus" or "SCBA", (190) Semiannual or Semiannually, (186) "Supplied-air respirator" or R6 "air-line respirator", (187) "Tritium neutron generator target source", (188) "User seal check" or "fit R6 R7 check"added and alphabetized effective August 16, 2007 (192) "Mobile C-arm", (193) "C-arm system" R8 February 28, 2008 (194) "Nationally Tracked Source:) Specific Authority: 404.051, 404.061, F.S. R7 Law Implemented: 404.031, 404.061, 404.20, 404.22, 404.30, F.S. History: New July 17, 1985, Amended April 4, 1989, Amended May 12, 1993, Amended January 1, 1994,

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

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

64E-5.102 Exemptions.

- (1) The department may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property or the environment.
- (2) Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, transports or acquires sources of radiation:
 - (a) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

R2	64E-5.201Licensing of Radioactive MaterialII-1		
	64E-5.202 Source Material - ExemptionsII-2		
R2	64E-5.203 Radioactive Material Other than Source Material - ExemptionsII-4		
	SUBPART A LICENSE TYPES AND FEES		
R8	64E-5.204Types of LicensesII-10		
	SUBPART B GENERAL LICENSES		
	64E-5.205General Licenses - Source Material		
<mark>R6</mark>	64E-5.206General Licenses - Radioactive Material Other Than Source MaterialII-17		
	SUBPART C SPECIFIC LICENSES		
	64E-5.207Filing Application for Specific Licenses		
	64E-5.208General Requirements for the Issuance of Specific Licenses		
R8	64E-5.209Special Requirements for a Specific License to Manufacture,		
IX0	Assemble, Repair or Distribute Commodities, Products or Devices		
	which Contain Radioactive Material		
	64E-5.211 Special Requirements for Issuance of Specific Licenses for		
	Source Material Milling.		
	64E-5.212 Issuance of Specific LicensesII-57		
<mark>R6</mark>	64E-5.213 Specific Terms and Conditions of LicensesII-58		
<mark>R5</mark>	64E-5.214 Expiration and Termination of Licenses and DecommissioningII-60		
	of Building Outdoor Areas		
	64E-5.215Transfer of MaterialII-63		
	SUBPART D RECIPROCITY		
R8	64E-5.216Reciprocal Recognition of Licenses for By-product, Source, Naturally		
	Occurring and Accelerator Produced Radioactive Material, and		
	Special Nuclear Material In Quantities Not Sufficient to Form a		
	Critical MassII-65		
	SUBPART E BONDING		
	64E-5.217Bonding of Persons Licensed Pursuant to Subpart C		
	SUBPART F INSPECTION AND ENFORCEMENT		
	64E-5.218Performance of InspectionsII-70		
	64E-5.219Emergency PlanningII-71		
	64E-5.220Radioactive QuantitiesII-75		

SUBPART G RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

R5	64E-5.221Radiological Criteria for License Termination	ll-78a
R5	64E-5.222Radiological Criteria for Unrestricted Use	II-78a
R5	64E-5.223Radiological Criteria for License	
	Termination Under Restricted Conditions	II-78a
R5	64E-5.224Alternate Criteria for License Termination	II-78c
R5	64E-5.225Public Notification and Public Participation	II-78d
R5	64E-5.226Minimizing Contamination	II-78d
	Schedule AExempt Concentrations	II-79
	Schedule BExempt Quantities	
	Schedule DLimits for Broad License	

64E-5 Florida Administrative Code 64E-5.206

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

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

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

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

- (a) Static Elimination Devices. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 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 or initially transferred 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 NRC, or an agreement state, which authorizes distribution of devices to persons granted a general license by the U.S. NRC, or an agreement state. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of 21 CFR Part 179. (Pursuant to 120.54(6) Florida Statutes, 64E-5.206(4)(b)1. is substantively identical to 10 CFR 31.5(b)(1) published on 01/01/2007.)
 - (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;

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- 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
 - By a person holding an applicable specific license from the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to perform such activities;
- 4. Shall maintain records showing compliance with the requirements of (4)(c)2. and 3., above. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing testing, installation, servicing and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by (4)(c)2., above, shall be maintained for at least three years after the next required leak test is performed or until the transfer or disposal of the sealed source. Records of tests of the on-off mechanism and indicator required by (4)(c)2. above, shall be maintained for at least three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by (4)(c)3, above, shall be maintained for a period of at least three years from the date of the recorded event or until the transfer or disposal of the device; (Pursuant to 120.54(6) Florida Statutes, 64E-5.206(4)(c)4. is substantively identical to 10 CFR 31.5(c)(4)i published on 01/01/2007.)

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64E-5 Florida Administrative Code 64E-5.206

5.	Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the department a report containing a brief description of the event and the remedial action taken; and in the case of removable radioactive materials or failure of or damage to a source likely to result in contamination of the premises or the environment, a plan for ensuring the premise and environment are acceptable for unrestricted use using the criteria described in Rule 64E-5.222, F.A.C.	
6.	Shall not abandon the device containing radioactive material;	
7.	Except as provided in (4)(c)8., below, shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph 15 below, transfer to a specific licensee of the department, the NRC, or an agreement state, whose specific license authorizes him to receive the device, and within 30 days after transfer of a device to a specific licensee, shall furnish to the department a report containing identification of the device by manufacturer's or initial transferor's name and model number and serial number, the name, address, license number, where applicable, of the person receiving the device and the date of the transfer;	
8.	Shall transfer the device <mark>by export as provided by paragraph 15</mark> below, or to another general licensee only:	
	a. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section, a copy of Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C., and any safety documents identified in the label on the device and within 30 days of the transfer, report to the department the manufacturer's or initial transferor's name and model number and serial number of device transferred, the transferor's name and mailing address for the location of use, and the name title, and phone number of the responsible individual identified by the transferee in accordance with paragraph 64E-5.206(4)(c) and subsection (11), F.A.C., to have knowledge of and authority to take actions to ensure compliance with these	
	6. 7.	
		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
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	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.
R6 R6 R6 R6 R6	10.	Shall be required to obtain written Department authorization before transferring the device to any other specific license not specifically identified in subparagraph 64E-5.206(4)(c)7, F.A.C. The Department authorization is granted provided the specific license identifies the device.
R6 R6 R6 R6 R6	<mark>11.</mark>	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.
R6 R6 R6 R6 R6 R6	<mark>12.</mark>	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.
R6 R6 R6 R6 R6 R6 R6 R6 R6 R6 R6 R6 R6		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.
R6 R6		c. Shall provide the following information and any other information requested by the Department:
R6		(I) Name and mailing address of the general licensee;
R6 R6 R6		(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;

Florida Administrative Code

64E-5.206

64E-5

R6 R6 R6 R6		(111)	Name, title, and telephone number of the responsible person designated a representative of the general licensee under paragraph 64E-5.206(4)(c) and subsection (11), F.A.C.;
R6 R6 R6		<mark>(IV)</mark>	Address or location at which the device(s) are used or stored. For portable devices, the address of the primary place of storage;
R6 R6 R6 R6		(V) 	Certification by the responsible representative of the general licensee that the information concerning the devices(s) have been verified through a physical inventory and checking the label information; and
R6 R6 R6		(VI)	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 R6	10	Licens Comn 10 CF requir Depar calenc from s	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 <mark>R8</mark> R6 R6 R6	<mark>13.</mark>	name and th 30 days of th report of add	to the Department changes in the general licensee be mailing address for each location of use within the effective date of the change. For a portable device, a dress change is required for a change in the device's e of storage.
R8 R6 R6 R6 R6 R8 R8 R8 R8 R8 R8 R8 R8 R8 R8 R8 R8 R8	<mark>14.</mark>	devices with locked in the 64E-5.206(4 of storage or transferred to required test transfer and for future use general licen exceed three 120.54(6) Fit	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 for leakage before use or the shutter tested before use. Devices kept in standby e are excluded from the two year time limit if the neee performs physical inventories at intervals not to e months while they are in standby. (Pursuant to orida Statutes, 64E-5.206(4)(c)14. is substantively 0 CFR 31.5(c)(15) published on 01/01/2007.)
R8 R8	15.		port the device containing radioactive material except in with 10 C.F.R. Part 110;

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

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

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

Law Implemented: 404.022, 404.051(1),(4),(6),(8),(9),(10),(11), 404.061(2), 404.071(1),(3), 404.081(1), 404.141, F.S.

R6 History: New July 17, 1985, amended April 4, 1989, Amended January 1, 1994, Formerly 10D-91.306, Amended September
 28, 2006, Amended February 28, 2008.

SUBPART C SPECIFIC LICENSES

64E-5.207 Filing Application for Specific Licenses.

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

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

64E-5 Florida Administrative Code 64E-5.210

	(c)	In the event the applicant desires that the general licensee under 64E-5.206 or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the limits specified in 64E-5.304.
R6	(d)	If a device containing radioactive material is transferred for use under the
R6 R6 R6 R6 R6 R6 R6 R6 R6		general license described in subsection 64E-5.206(4), F.A.C., each person that is licensed under subsection 64E-5.210(4), F.A.C., shall provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to the initial transfer to the intermediate person. The required information includes the following:
R6 R6 R6 R6		 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;
R8		2. A copy of Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C.;
R6		3. 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		 An indication that department policy is to issue high civil penalties for improper disposal.
R6	(e)	If a device containing radioactive material is transferred for use under an
R8		<mark>equivalent general license of an Agreement State or the NRC</mark> , each
R6		person that is licensed under subsection 64E-5.210(4), F.A.C., shall
R6		provide the information specified in this section to each person to whom a
R6		device is to be transferred. This information must be provided before the
R6 R6		device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended
R6		user prior to the initial transfer to the intermediate person. The required
R6		information includes the following:

R8 R8 R6 R6 R6 R6 R6		 A copy of the Agreement State or NRC equivalent to Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C. If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the Agreement State's 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 R6	<mark>(f)</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 R7 R6 R7	<mark>(g)</mark>	If a notification of bankruptcy has been made under subsection 64E-5.213(3), F.A.C., or the license is to be terminated, each person licensed under subsection 64E-5.210(4), F.A.C., shall provide, upon request, to the department, U.S. Nuclear Regulatory Commission and to any appropriate Agreement State, records of final disposition required under paragraph 64E-5.210(4)(j), F.A.C.
R7 R6	<mark>(h)</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 R7 R6 R6 R7 R7 R7		1. Report all transfers of devices to persons for use under the general license described in subsection 64E-5.206(4), F.A.C., and all receipts of devices from persons licensed under subsection 64E-5.206(4), F.A.C., to the department. This report must be submitted at intervals not to exceed 3 months and contain all of the information described in "Transfers of Industrial Devices Report 04/2007" herein incorporated by reference and is available at the address listed in paragraph 64E-5.204(2)(b) or at http://www.doh.state.fl.us/environment/radiation/.
R6 R6		 This 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		 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		 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	<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	<mark>6.</mark>	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 report must so indicate.
R6 R6 R6 <mark>R8</mark>	comp	person licensed under subsection 64E-5.210(4), F.A.C., shall ly with the following additional reporting and record keeping ements for transfers and receipt of devices to Agreement States or RC.

R6	1.	Report all transfers of devices to persons for use under the general
R8		license in an Agreement State or the NRC, that are equivalent to
R6		subsection 64E-5.206(4), F.A.C., and all receipts of devices from
R8		persons licensed under a general license in Agreement State or the
R8		NRC jurisdiction to the responsible Agreement State, or the NRC
R6		agency. This report must contain all of the information described in
R7		"Transfers of Industrial Devices Report 04/2007."
R6	2.	The report must be clear and legible and contain the following data:
R6		a. The identity of each general licensee by name and mailing
R6		address for the location of use; if no mailing address for the
R6		location of use, an alternative address for the general
R6		licensee shall be submitted along with information on the
R6		actual location of use;
R6		b. The name, title, and phone number of the person identified
R6		by the general licensee as having knowledge of and
R6		authority to take required actions to ensure compliance with
R6		the appropriate regulations and requirements;
R6		c. The date of transfer;
R6		d. The type, model number, and serial number of the device
R6		transferred; and
R6		e. The quantity and type of radioactive materials contained in
R6		the device.
R6	3.	If one or more intermediate persons will temporarily possess the
R6	0.	device at the intended place of use before its possession by the
R6		user, the report must include the same information for both the
R6		intended user and each intermediate person and clearly designate
R6		the intermediate person(s).
R6	4.	For devices received from a general licensee, the report must
R6		include the identity of the general licensee by name and address,
R6		the type, model number, and serial numbers of the device received,
R6		the date of receipt, and, in the case of devices not initially
R6		transferred by the reporting licensee, the name of the manufacturer
R6		or initial transferor.
R6	5.	If the licensee makes changes to the device possessed by a
R6		general licensee, such that the label must be changed to update
R6		required information, this report must identify the general licensee,
R6		the device, and the changes to information on the device label.
		the device, and the changes to information on the device label.
R6	<mark>6.</mark>	The report must clearly identify the specific licensee submitting the
R6		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 or the NRC during the reporting period, this information shall be reported to the responsible Agreement State or the NRC agency upon request of the agency.
 - 8. The report must cover each calendar quarter and must be filed within 30 days of the end of the calendar quarter and must clearly indicate the period covered by the report.
- (j) The persons shall maintain all information concerning transfers and receipts of devices that supports the reports required by subsection 64E-5.210(4), F.A.C. Records and reports described in subsection 64E-5.210(4), F.A.C., shall be maintained for inspection by the department for a period of 3 years following the date of the recorded event.
- (5) Special Requirements for the Manufacture, Assembly or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium 147 for use in aircraft, for distribution to general licensees under 64E-5.206(5) will be approved if the requirements of Sections 32.53, 32.54, 32.55, 32.56 and 32.101 of 10 CFR Part 32, or their equivalent and the general requirements specified in 64E-5.208 are satisfied.
- (6) Special Requirements for License to Manufacture Calibration Sources Containing Americium 241, Plutonium or Radium 226 for Distribution to Persons Generally Licensed Under 64E-5.206(6). An application for a specific license to manufacture calibration and reference sources containing americium 241, plutonium or radium 226 to general licensees under 64E-5.206(6) will be approved if the requirements of Sections 32.57, 32.58, 32.59 and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70, or their equivalent and the general requirements of 64E-5.208 are satisfied.
- (7) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In addition to requirements set forth in 64E-5.208, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in 64E-5.206(7) will be issued if
 - (a) The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biological product issued by the Secretary, U.S. department of Health and Human Services; and
 - (b) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:

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

Name of Manufacturer

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

Name of Manufacturer

- 1. U. S. department of Health and Human Services Publication FDA 81-8025 June 1981, Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM), which is herein incorporated by reference and which is available from the department.
- U. S. Nuclear Regulatory Commission Regulatory Guide 10.10 March 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations and Registration of Devices Containing Byproduct Material, which is herein incorporated by reference and which is available from the department
- 3. U. S. Nuclear Regulatory Commission Regulatory Guide 10.11 June 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations of Sealed Sources Containing By-product Material, which is herein incorporated by reference and which is available from the department.
- 4. American National Standards Institute Standard N538, Classification of Industrial Ionizing Radiation Gauging Devices October 1979, which is herein incorporated by reference and which is available from the department.
- 5. American National Standards Institute Standard N540, Classification of Radioactive Self-Luminous Light Sources January 1976, which is herein incorporated by reference and which is available from the department.
- 6. American National Standards Institute Standard N432, Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography January 1980, which is herein incorporated by reference and which is available from the department.
- 7. American National Standards Institute Standard N542, Sealed Radioactive Sources Classification July 1978, which is herein incorporated by reference and which is available from the department.
- (d) The licensee or applicant shall not distribute devices or products containing sealed sources unless the devices or sealed sources are manufactured and distributed in accordance with the registration and as authorized by a specific radioactive materials license issued by the department for such manufacture or distribution.

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

R8 (15) Each licensee who manufactures a nationally tracked source after February 6,
R8 2007 shall assign a unique serial number to each nationally tracked source.
R8 Serial numbers must be composed only of alpha-numeric characters. (Pursuant to 120.54(6) Florida Statutes, 64E-5.210(15) is substantively identical to 10 CFR
R8 32.201 published on 01/01/2007.)

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

- R7 Law Implemented: 404.022, 404.051, 404.061, 404.081, 404.141, F.S.
- History: New July 17, 1985, Amended August 25, 1991, Amended May 12, 1993, Amended January 1, 1994,

R6 Amended May 15, 1996, Formerly 10D-91.311, Amended August 6, 2001., Amended September 28, 2006,

R7 Amended August 16, 2007 Amended February 28, 2008.

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64E-5.211 Special Requirements for Issuance of Specific Licenses for Source

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

- (1) An application for a license to
- (2) receive title to, receive, possess and use source material for milling or byproduct material as defined in Part I shall address the following:
 - (a) Description of the proposed project or action;
 - (b) Area or site characteristics including geology, topography, hydrology and meteorology;
 - (c) Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;
 - (d) Environmental effects of accidents;
 - (e) Long-term impacts including decommissioning, decontamination and reclamation; and
 - (f) Site and project alternatives.
- (2) The applicant shall not commence construction of the project until the department has weighed the environmental, economic, technical and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.
- (3) At least 1 full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential longterm effects.
- (4) Prior to issuance of the license, the applicant shall establish financial surety arrangements consistent with the requirements of 64E-5.217.

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

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

SUBPART D RECIPROCITY

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

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(1) Subject to these regulations, any person who holds a specific license from the NRC, or an agreement state and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, will be granted a general license by the department to conduct the activities authorized in such licensing document within the State of Florida, except for areas of exclusive federal jurisdiction, for a period not in excess of 365 consecutive days provided that:

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

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

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

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

R8 History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.321, Amended October 8, 2000, Amended February 28, 2008.

	PART III STANDARDS FOR PROTECTION
	SUBPART A GENERAL PROVISIONS
R2	64E-5.301 Standards for Protection Against RadiationIII-1
	64E-5.302. ImplementationIII-1
	SUBPART B RADIATION PROTECTION PROGRAMS
R2	64E-5.303 Radiation Protection ProgramsIII-2
	SUBPART C OCCUPATIONAL DOSE LIMITS
R6	64E-5.304. Occupational Dose Limits for AdultsIII-2
	64E-5.305 Compliance with Requirements for Summation of External and Internal DosesIII-3
	64E-5.306 Determination of External Dose from Airborne Radioactive Material
	64E-5.307. Determination of Internal Exposure
R2	64E-5.308. Determination of Prior Occupational Dose
	64E-5.310 Occupation Dose Limits for MinorsIII-9
R2	64E-5.311. Dose to an Embryo FetusIII-9
	SUBPART DRADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC
R2	64E-5.312 Dose Limits for Individual Members of the Public
	SUBPART E SURVEYS AND MONITORING
R2 R2	64E-5.314. GeneralIII-12 64E-5.315 Conditions Requiring Individual Monitoring of External and
	Internal Occupational Dose
	SUBPART F CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS
	64E-5.316 Control of Access to High Radiation Areas
	SUBPART G RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS
R6 R6	64E-5.318. Use of Process or Other Engineering Controls
	SUBPART H STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION
	64E-5.320 Security of Stored Sources of RadiationIII-18 64E-5.321 Control of Sources of Radiation Not in StorageIII-18

SUBPART I PRECAUTIONARY PROCEDURES

	64E-5.322. Caution Signs	III-19
R2	64E-5.323. Posting Requirements	
	64E-5.324. Exceptions to Posting Requirements	
	64E-5.325. Labeling Containers and Radiation Machines	III-21
R2	64E-5.326. Exemptions to Labeling Requirements	<mark>.III-21</mark>
	64E-5.327 Procedures for Receiving and Opening Packages	.III-22

SUBPART J WASTE MANAGEMENT

	64E-5.328. General Requirements	III-23
	64E-5.329. Method of Obtaining Approval of Proposed Disposal Procedures	
	64E-5.330. Discharge by Release into Sanitary Sewerage	III-24
	64E-5.331. Disposal of Specific Wastes	III-25
R1	64E-5.332 Transfer for Disposal and Manifests	III-26a
R1	64E-5.333. Classification and Characteristics of Low Level Radioactive Waste	
	for Near-Surface Land Disposal, Labeling and Manifest Requirements.	III-27

SUBPART K RECORDS

R2	64E-5.334. General Provisions	Ill-36
	64E-5.335 Records of Radiation Protection Programs	III-36
	64E-5.336 Records of Surveys	III-36a
	64E-5.337 Records of Tests for Leakage or Contamination of Sealed Sources	III-36a
	64E-5.338 Records of Planned Special Exposures	III-37
R2	64E-5.339 Records of Individual Monitoring Results	Ill-37
	64E-5.340 Records of Waste Disposal or Transfers	III-38
	64E-5.341 Records of Testing Entry Control Devices for Very High Radiation Are	eas III-38
	64E-5.342 Form of Records	III-39

SUBPART L REPORTS

	64E-5.343 Reports of Stolen, Lost, or Missing Licensed or	
	Registered Sources of Radiation	.111-39
R2	64E-5.344. Notification of Incidents	<mark>.III-40</mark>
R2	64E-5.345 Reports of Exposure, Radiation Levels, Concentrations of	
	Radioactive Material Exceeding the Limits, and Misadministrations	<mark>.III-43</mark>
	64E-5.346 Reports of Planned Special Exposures	.111-46
R1	64E-5.347. Notifications and Reports to Individuals	.111-46
	64E-5.348 Reports of Leaking or Contaminated Sealed Sources	.111-46
	64E-5.349. Vacating Premises	.111-46
R8	64E-5.350 Reports of Transactions Involving Nationally Tracked Sources	. 111-47
R8	64E-5.351 Nationally Tracked Source Thresholds	. III-50

R8 R8 R8 R8 R8 R8	tracked sour Report as sp (Pursuant to	o manu ce sha pecified 120.5	Reports of Transactions Involving Nationally Tracked Sources. Each ifactures, transfers, receives, disassembles, or disposes of a nationally ill complete and submit to the NRC a National Source Tracking Transaction d in paragraphs (1) through (5) of this section for each type of transaction. 4(6) Florida Statutes, 64E-5.350, except 64E-5.350(8) as noted below, is ical to 10 CFR 20.2207 effective 02/06/2007.)
R8 R8 R8	(1)	subm	licensee who manufactures a nationally tracked source shall complete and it a National Source Tracking Transaction Report. The report must include plowing information:
R8		(a)	The name, address, and license number of the reporting licensee;
R8		(b)	The name of the individual preparing the report;
R8		(C)	The manufacturer, model, and serial number of the source;
R8		(d)	The radioactive material in the source;
R8 R8		(e)	The initial source strength in becquerels (curies) at the time of manufacture; and
R8		(f)	The manufacture date of the source.
R8 R8 R8	(2)	comp	licensee that transfers a nationally tracked source to another person shall lete and submit a National Source Tracking Transaction Report. The report include the following information:
R8		(a)	The name, address, and license number of the reporting licensee;
R8		(b)	The name of the individual preparing the report;
R8 R8		(C)	The name and license number of the recipient facility and the shipping address;
R8 R8		(d)	The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
R8		(e)	The radioactive material in the source;
R8		(f)	The initial or current source strength in becquerels (curies);
R8		(g)	The date for which the source strength is reported;
R8		(h)	The shipping date;
R8		(i)	The estimated arrival date; and
R8 R8 R8		(j)	For nationally tracked sources transferred as waste under a Uniform Low- Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

- R8 (3) Each licensee that receives a nationally tracked source shall complete and
 R8 submit a National Source Tracking Transaction Report. The report must include
 R8 the following information:
- R8 (a) The name, address, and license number of the reporting licensee;
- R8 (b) The name of the individual preparing the report;
- R8(c)The name, address, and license number of the person that provided the
source;R8source;
- R8(d)The manufacturer, model, and serial number of the source or, if notR8available, other information to uniquely identify the source;
- R8 (e) The radioactive material in the source;
- R8 (f) The initial or current source strength in becquerels (curies);
 - (g) The date for which the source strength is reported;
- R8 (h) The date of receipt; and

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- (i) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.
- (4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:
- R8 (a) The name, address, and license number of the reporting licensee;
 - (b) The name of the individual preparing the report;
- R8 (c) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- R8 (d) The radioactive material in the source;
- R8 (e) The initial or current source strength in becquerels (curies);
- R8 (f) The date for which the source strength is reported;
- R8 (g) The disassemble date of the source.

- R8(5)Each licensee who disposes of a nationally tracked source shall complete andR8submit a National Source Tracking Transaction Report. The report must includeR8the following information:
- R8 (a) The name, address, and license number of the reporting licensee;
- R8 (b) The name of the individual preparing the report;
- R8 (c) The waste manifest number;
- R8 (d) The container identification with the nationally tracked source;
- R8 (e) The date of disposal; and
- R8 (f) The method of disposal.
- R8 (6) The National Source Tracking Transaction Report discussed in subsections (1)
 R8 through (5) of this section must be submitted to the NRC by the close of the next
 B8 business day after the transaction. A single report may be submitted for multiple
 R8 sources and transactions. The reports must be submitted to the National Source
 R8 Tracking System by using:
- R8 (a) The on-line National Source Tracking System;
- R8 (b) Electronically using a computer-readable format;
 - (c) By facsimile;

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- (d) By mail to the address on the NRC Form 748 National Source Tracking Transaction Report Form; or
 - (e) By telephone with followup by facsimile or mail.
- (7) (a) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation.
- R8 (b) In addition, every year each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that **R8 R8** licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The R8 **R8** reconciliation process must include resolving any discrepancies between R8 the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (1) through (5) of this section. In order to R8 **R8** reconcile each transaction, the licensee shall file a report for missed R8 transactions or file a corrected report for previously submitted reports R8 containing inaccuracies. By January 31 of each year, each licensee must R8 submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct. **R8**

(8)	its ini Source 20.22 natio tracke as sp may throu follow	licensee that possesses Category 1 nationally tracked sources shall report tial inventory of Category 1 nationally tracked sources to the National ce Tracking System by January 31, 2009 or as specified in 10 C.F.R. 207(h), whichever is the latest. Each licensee that possesses Category 2 nally tracked sources shall report its initial inventory of Category 2 nationally ed sources to the National Source Tracking System by January 31, 2009 or becified in 10 C.F.R. 20.2207(h), whichever is the latest. The information be submitted by using any of the methods identified by paragraph (6)(a) gh (6)(e) of this section. The initial inventory report must include the ving information: (Pursuant to 120.54(6) Florida Statutes, 64E-5.350(8) is tantively identical to 10 CFR 20.2207(h) effective 10/19/2007.)
	(a)	The name, address, and license number of the reporting licensee;
	(b)	The name of the individual preparing the report;
	(C)	The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;
	(d)	The radioactive material in the sealed source;
	(e)	The initial or current source strength in becquerels (curies); and
	(f)	The date for which the source strength is reported.
Law Implemented	d: 404.0	22, 404.051, 404.081, F.S.
thresholds ar	re liste	Nationally Tracked Source Thresholds. The nationally tracked source ed in table 1 below with the Terabecquerel (TBq) values as the regulatory
	Specific Authority Law Implemente History: New Fet 64E-5 thresholds a	its ini Sourd 20.22 natio track as sp may throu follov subsi (a) (b) (c) (d) (c) (d) (e) (f) Specific Authority: 404.09 Law Implemented: 404.0 History: New February 28 64E-5.351 thresholds are lister

R8 standard. The curie (Ci) values specified are obtained by converting from the TBq value. The
 R8 curie values are provided for practical usefulness only and are rounded after conversion.

R8 (Pursuant to 120.54(6) Florida Statutes, 64E-5.351 is substantively identical to Appendix E to
 R8 10 CFR Part 20 effective 02/06/2007.

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

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

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PART IV

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

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

R4	64E-5.423	Definitions	IV-1
R4	SUBPART I	D EQUIPMENT CONTROL (Formerly Subpart A)	
<mark>R4</mark>	64E-5.424	Requirements for Industrial Radiography Equipment Using Sealed Sources	IV-3
<mark>R4</mark>	64E-5.425	Locking of Sources of Radiation, Storage Precautions, and Surveillance	
<mark>R4</mark>	64E-5.426	Radiation Survey Instruments	IV-6
<mark>R6</mark>	64E-5.427	Leak Testing, Repairing, Tagging, Opening,	
		Modifying and Replacing Sealed Sources and Devices	IV-6
<mark>R4</mark>	64E-5.428	Quarterly Inventory	<u>1V-7</u>
R6	64E-5.429	Source Movement Logs, Daily Survey Reports, and Individual Dosimeter Logs	
	64E-5.430	Inspection and Maintenance	
R4	64E-5.431	Permanent Radiographic Installations	<mark>V-10</mark>
R4	SUBPART	E RADIATION SAFETY REQUIREMENTS (Formerly Subpart B)	
R4			
	64E-5.432	Radiation Protection Program	
R4	64E-5.433	Radiation Safety Officer	<mark>V-13</mark>
R6	64E-5.433 64E-5.434	Radiation Safety Officer	V-13 V-14
R6 R4	64E-5.433 64E-5.434 64E-5.435	Radiation Safety Officer I Training, Testing, Certification, and Audits I Conducting Industrial Radiographic Operations I	V-13 V-14 V-17
R6 R4 R4	64E-5.433 64E-5.434 64E-5.435 64E-5.436	Radiation Safety Officer I Training, Testing, Certification, and Audits I Conducting Industrial Radiographic Operations I Operating and Emergency Procedures I	V-13 V-14 V-17 V-17
R6 R4 R4	64E-5.433 64E-5.434 64E-5.435	Radiation Safety Officer I Training, Testing, Certification, and Audits I Conducting Industrial Radiographic Operations I	V-13 V-14 V-17 V-17
R6 R4 R4 R4 R4	64E-5.433 64E-5.434 64E-5.435 64E-5.436 64E-5.437	Radiation Safety Officer I Training, Testing, Certification, and Audits. I Conducting Industrial Radiographic Operations I Operating and Emergency Procedures I Personnel Monitoring I	V-13 V-14 V-17 V-17 V-18
R6 R4 R4 R4 R4	64E-5.433 64E-5.434 64E-5.435 64E-5.436 64E-5.437	Radiation Safety Officer I Training, Testing, Certification, and Audits I Conducting Industrial Radiographic Operations I Operating and Emergency Procedures I	V-13 V-14 V-17 V-17 V-18
R6 R4 R4 R4 R4	64E-5.433 64E-5.434 64E-5.435 64E-5.436 64E-5.437	Radiation Safety Officer I Training, Testing, Certification, and Audits I Conducting Industrial Radiographic Operations I Operating and Emergency Procedures I Personnel Monitoring I PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS (Formerly Subplacement)	V-13 V-14 V-17 V-17 V-18 Dart C)
R6 R4 R4 R4 R4	64E-5.433 64E-5.434 64E-5.435 64E-5.436 64E-5.437 SUBPART F	Radiation Safety Officer I Training, Testing, Certification, and Audits. I Conducting Industrial Radiographic Operations I Operating and Emergency Procedures I Personnel Monitoring I PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS (Formerly Subpliced Subpl	V-13 V-14 V-17 V-17 V-18 Dart C) V-20
R6 R4 R4 R4 R4 R4	64E-5.433 64E-5.434 64E-5.435 64E-5.436 64E-5.437 SUBPART F 64E-5.438	Radiation Safety Officer I Training, Testing, Certification, and Audits I Conducting Industrial Radiographic Operations I Operating and Emergency Procedures I Personnel Monitoring I PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS (Formerly Subplacement)	V-13 V-14 V-17 V-17 V-18 Dart C) V-20 V-21

	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.;	bed in 64E-
R4 R4		(i)	The results of the survey of the posted perimeter in mR/hi feet (meters);	r (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 d s. Each individual shall record the doses measured by his o 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 t meter logs shall be provided to the radiation safety officer (R 's designee no later than 7 days after each month. The RS gnee shall review the logs within 7 days of receipt and shall I the logs at the time of the review. Each log shall include th mation:	r her dosimeter ecorded doses at he individual SO) or the O 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	otals as
R4		ed: 404.0	22, 404.05 <mark>1(1), (4), 404.081(1), F.S.</mark>	designee and the
R6 R4	-	eptember 5.430	11, 2001, <u>Amended September 28, 2006.</u> Inspection and Maintenance.	
R/	(1)		licensee or registrant shall perform visual and operability of	backs on survov

R4 Each licensee or registrant shall perform visual and operability checks on survey (1) instruments, radiation machines, radiographic exposure devices, associated R4 R4 equipment, transport containers, storage containers, and source changers before use on each day the equipment is to be used to ensure the equipment is in good 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

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

R4 Specific Authority: 404.051, F.S.

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

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

R4 64E-5.431 Permanent Radiographic Installations.

- R4 (1) Each entrance used for personnel access to a high radiation area in a permanent radiographic installation shall have either:
- R4(a)An entrance control that reduces the radiation level to below the level atR4which an individual might receive a deep dose equivalent of 0.1 rem (1R4millisievert) in 1 hour at 30 centimeters from the source of radiation fromR4any surface the radiation penetrates, or
- R4 (b) Conspicuous visible and audible signals to warn of the presence of
 R4 radiation. The visible signal shall be actuated by radiation. The audible
 R4 signal shall be actuated when an attempt is made to enter the installation
 R4 while 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 and repaired within 7 days. The installation can continue to be used by an R4 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 September 11, 2001.

R4 64E-5.439 Posting. In addition to the posting requirements specified in

R4 64E-5.901, F.A.C., the licensee or registrant shall comply with the requirements described R4 below.

- R4 (1) Radiation areas and high radiation areas created by radiographic operations shall be posted conspicuously as specified in 64E-5.323(1) and (2), F.A.C. Areas or rooms in which licensed material is used or stored shall be posted as specified in 64E-5.323(5), F.A.C. The exceptions to posting specified in 64E-5.324(1), 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
 R4 location of each source of radiation and source movements for the previous 30
 R4 days shall be posted conspicuously adjacent to the area where the source of
 R4 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 ir making the record, radionuclide, number of curies (becquere manufacturer, model, and serial number of each sealed sou device, as appropriate.	ndividual els) or mass,
R6 R6		<mark>(i)</mark>	Records of annual ALARA audits specified in paragraph 64E F.A.C.	E-5.432(4)(c),
R4 R4	(2)		I licensee or registrant shall maintain the following records unti- rtment 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 pra examinations;	s conducted,
R4		(c)	Verification of previous radiography experience;	
R4 <mark>R8</mark>		(d)	Radiographer certification documents specified in 64E-5.434(2)(d), F.A.C., and verification of certification statu	IS;
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 individuation the exposures received, the dates the exposures were received description of the cause of the exposures, the corrective act and the signature of the RSO;	ved, a
R4 R4 R4 R4		(f)	Records of estimates of exposures as a result of off-scale de 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.;	ords of
R6 R6		(g)	Personnel monitoring badge records from the accredited NV 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 en procedures.	
R4 R4 R4	(3)	site s	I licensee or registrant conducting industrial radiography at a to shall have the following records available at that site for inspec artment:	

	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.	iod of operation
R4		d: 404.0	51, F.S. 22, 404.051(1), (4), 404.081(1), 404.20, F.S. 11, 2001, Amended September 28, 2006 <u>, Amended February 28, 2008.</u>	
R4	64E-{	5.441	Reporting Requirements.	
R4 R6 R4 R4 R4 R4 R4 R4	(1)	64E- provi of the shall Bin C invol Mach	dition to the reporting requirements specified in rules contain 5, Parts III and IX, F.A.C., and other sections of this part, eac 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 C21, 4052 Bald Cypress Way, Tallahassee, Florida 32399-17 ving radioactive materials or to the Bureau of Radiation Cont hine Section, 705 Wells Road, Suite 300, Orange Park, Florid ents involving radiation machines.	ch licensee shall ccurrence of any v. Such reports aterials Section, 41 for incidents rol, Radiation
R4 R4		(a)	Unintentional disconnection of the source assembly from the	ne control cable.
R4 R4		(b)	Inability to retract and secure the source assembly to the fup osition.	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)		licensee shall include the information described below in eac nitted as specified in this section.	h report
R4		(a)	A description of the equipment problem.	
R4		(b)	Cause of each incident if known.	

R4 (c) Manufacturer name and model number of the equipment involved in the incident.

	64E-5	Florida Administrative Code	64E-5.441
R4		(d) Place, time, and date of the incident.	
R4		(e) Actions taken to establish normal operations.	
R4		(f) Corrective actions taken or planned to prevent recurrence.	
R4		(g) Qualifications of the personnel involved in the incident.	
R4 R4 R4	(3)	Reports of overexposures submitted as specified in rules containe Chapter 64E-5, F.A.C., that involve failure of safety components o equipment also must include the information specified in 64E-5.44	f radiography
R8 R8 R8 R8 R8	(4)	Any licensee conducting radiographic operations or storing radioa any location not listed on the license for a period in excess of 180 calendar year, shall notify the Department prior to exceeding the 1 (Pursuant to 120.54(6) Florida Statutes, 64E-5.441(4) is substantin 10 CFR 34.101(c) published on 01/01/2007.)	days in a 80 days.
R4	Specific Authori	ty: 404.051, F.S.	

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.
R8 History: New September 11, 2001, September 28, 2006, <u>Amended February 28, 2008.</u>

PART	X ENVIRONMENTAL RADIATION STANDARDS	
SUBP	ART A RADIATION STANDARDS FOR BUILDINGS	
64E-5.	1001StandardsX-	1

SUBPART B ENVIRONMENTAL MONITORING

	64E-5.1002 Monitoring Requirements λ	X-1
R8	64E-5.1003 Monitoring Fees	K-2

PART X

ENVIRONMENTAL RADIATION STANDARDS

Subpart A

ENVIRONMENTAL RADIATION STANDARDS

64E-5.1001 Standards.

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

Specific Authority: 404.051, 404.056, F.S. Law Implemented: 404.022(2), 404.051(4), 404.056, F.S. History: New February 16, 1986, Amended <u>January 3, 1989</u>, Formerly 10D-91.1104.

Subpart B

ENVIRONMENTAL MONITORING

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

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

Specific Authority: 404.051, 404.056, F.S.

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

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

64E-5.1003 Monitoring Fees.

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

R8

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	PART XI RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE	OPERATIONS
R1	64E-5.1101Prohibitions	XI-1
	SUBPART A EQUIPMENT CONTROL	
	64E-5.1102Storage and Transportation Precautions	XI-2
R2	64E-5.1103Radiation Survey Instruments	XI-2
R6	64E-5.1104Leak Testing of Sealed Sources	XI-3
	64E-5.1105Quarterly Inventory	XI-4
R6	64E-5.1106Utilization Records 64E-5.1107Design, Performance and Certification Criteria for Sealed Sources	
	Used in Downhole Operations	
R6	64E-5.11071Uranium Sinker Bars	
R8	64E-5/11072Energy Compensation Source	XI-6
R6	64E-5/11072Energy Compensation Source 64E-5.11073Tritium Neutron Generator Target Source	XI-6
	64E-5.1108Labeling	XI-6
	64E-5.1109Inspection and Maintenance	XI-7
	SUBPART B REQUIREMENTS FOR PERSONNEL SAFETY	
	64E-5.1110Training Requirements	XI-7
	64E-5.1111Operating and Emergency Procedures	XI-8
R6	64E-5.1112Personnel Monitoring	<mark>XI-9</mark>
	SUBPART C PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER OPERATIONS	
	64E-5.1113Security	XI-9
	64E-5.1114Handling Tools	
	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	
	64E-5.1118Documents and Records Required at Temporary Jobsites	XI-11
	SUBPART E NOTIFICATION	
R6	64E-5.1119Notification of Incidents, Abandonment and Lost Sources	XI-12
R6	64E-5.1120Subjects To Be Included in Training Courses For Logging	
	Supervisors	XI-14

- R6 (2) A licensee can use a sealed source manufactured on or before July 14, 1989, in 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 1. Temperature. The test source is held at -40° C for 20 minutes, R6 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 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 (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

64E-5 Florida Administrative Code 64E-5.11072

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

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.

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

R8	64E-5.1501Purpose and Scope	XV-1a
R8	64E-5.1502Transportation of Radioactive Material	XV-1a
	64E-5.1503Exemptions	
	64E-5.1504General Licenses for Carriers	
	64E-5.1505Routine Determinations	XV-3
	64E-5.1506 Advance Notification of Shipment of	
	Certain Quantities of Radioactive Waste	XV-3
	64E-5.1507Designation of Routes for Shipment of Radioactive Wast	e
	Requiring Advanced Notification	
R7	64E-5.1508Inspection of Low-Level Radioactive Waste Shipments	XV-6
	64E-5.1509Permit Requirements	
	64E-5.1510Air Transport of Plutonium	
	64E-5.1511Notification in the Event of Suspected or Real Breach of	Containment XV-9
	64E-5.1512Inspections	XV-10
R2	64E-5.1513Communications	XV-10
	APPENDIX A.To 10 CFR Part 71 Determination of A ₁ , and A ₂ Values.	XV-11
	TABLE A-1 A1 and A2 Values for Radionuclides	XV-13
	TABLE A-2 Relationship Between A1 and Emax for Beta Emitters	XV-31
	TABLE A-3Relationship Between A ₃ for Alpha Emitters and the	
	Atomic Number of the Radionuclide	XV-31
	TABLE A-4 Activity - Mass Relationships for Uranium/Thorium	XV-32
	ATTACHMENTS	
	ALIs, DACs, and Effluent Concentrations May 2006	Attachments Page-1
<mark>R6</mark>	Protection Factors for Respirators May 1006	Attachments Page-63
R2	Radioactive Material Requiring Labeling May 2000	Attachments Page-68
	Occupational Exposure Record for a Monitoring Period	
	DH Form 1622 Edition 05/1997	Attachments Page-81
	Cumulative Occupational Exposure History DH Form 1623 Edition 05/1997	Attachmonts Page-84
	Certificate - Disposition of Radioactive Materials	Allachinenis Page-04
	Certificate - Disposition of Radioactive Materials DH Form 1059 Edition 05/1997	Attachments Page-87
	Radioactive Materials License Application Non-Human Use	
	DH Form 1054 Edition 05/1997	
R5	Notice to Employees DH Form 1081 3/01	Attachments Page 93
R1	Requirements for Transfers of Low-Level Radioactive Waste Intended	
R1	for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997	Attachments page 95
R7	Transfers of Industrial Devices Report 04/2007	

R7 Radiation Machine Facility Registration DH 1107 03/07

PART XV

TRANSPORTATION OF RADIOACTIVE MATERIALS

R8 64E-5.1501 Purpose and Scope.

- (1) The packaging and transportation of radioactive material are also subject to the requirements of other agencies such as the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission and the U.S. Postal Service. The requirements of this part are in addition to, and not in substitution for, other requirements.
- (2) Determinations and listings of A_1 and A_2 values are found in 10 CFR Part 71, Appendix A as published on 01/01/2007.
- R8 (3) The regulations in this part apply to any licensee authorized by specific or
 R8 general license issued by the Department to receive, possess, use, or transfer
 R8 licensed material, if the licensee delivers that material to a carrier for transport,
 R8 transports the material outside the site of usage as specified in the license, or
 R8 transports that material on public highways. No provision of this part authorizes
 R8 possession of licensed material.
- R8 (4) Definition of terms used in this part are those listed in 49 C.F.R. and
 R8 10 C.F.R. 71.4, except that whenever a definition refers to evaluation or approval
 B8 by the U.S. Department of Transportation or NRC, and such evaluation or
 R8 approval is within the jurisdiction of the State of Florida as an Agreement State,
 R8 the Department shall perform the evaluation or approval.

Specific Authority: 404.051, 404.20, F.S.

R8

R6

R8

R8

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

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

64E-5.1502 Transportation of Radioactive Material.

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

XV - 1a

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

		64E-5	Florida Administrative Code 64E-5.1502	
R8		22.	Opening instructions, 10 C.F.R. 71.89;	
R8 R8		23.	Advance notification of shipment of irradiated reactor fuel and nuclear waste, 10 C.F.R. 71.97	
R8 R8		24.	Quality assurance requirements, 10 C.F.R. 71.101(a), (b), (c), (f) and (g);	
R8		25.	Quality assurance organization, 10 C.F.R. 71.103;	
R8		26.	Quality assurance program, 10 C.F.R. 71.105;	
R8		27.	Exemption of physicians, 10 C.F.R. 71.13;	
R8		28.	Handling storage and shipping control, 10 C.F.R. 71.127;	
R8		29.	Inspection tests and operating status, 10 C.F.R. 71.129;	
R8		30.	Nonconforming materials parts or components, 10 C.F.R. 71.131;	
R8		31.	Corrective action, 10 C.F.R. 71.13;	
R8		32.	Quality assurances records, 10 C.F.R. 71.135;	
R8		33.	Audits, 10 C.F.R. 71.137;	
R8		34.	Appendix A to Part 71; and	
R8		35.	General license plutonium beryllium special form material.	
R8 R8	((licensee shall also comply with U.S. Department of Transportation lations pertaining to the following modes of transportation:	
R8		1.	Rail, 49 C.F.R. part 174, subparts A through D and K;	
R8		2.	Air, 49 C.F.R. part 175;	
R8		3.	Vessel, 49 C.F.R. part 176, subparts A through F and M; and	
R8		4.	Public Highway, 49 C.F.R. part 177 and parts 390 through 397.	
R8 R8 R8 R8 R8 R8 R8 R8 R8 R8	o ru o s n ru	of licensed equirement of this section subject to L nodification	partment of Transportation regulations are not applicable to a shipment d material, the licensee shall conform to the standards and nts of the U.S. Department of Transportation specified in paragraph (2) tion to the same extent as if the shipment or transportation were U.S. Department of Transportation regulations. A request for on, waiver, or exemption from those requirements, and any notification o in those requirements, must be filed with, or made to, the Department.	

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

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.061(2), 404.141, 404.20(1), F.S. R8 History: New July 17, 1985, Formerly 10D-91.2003, Amended October 8, 2000, Amended September 28, 2006, Amended February 28, 2008.

64E-5.1503 Exemptions.

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

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

64E-5.1504 General Licenses for Carriers.

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

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