

Josie Piccone, Deputy Director
February 4, 2002
Page 2

A current copy of Florida regulations is enclosed. Revision 3 (blue pages) became effective 8/6/2001, Revision 4, IR, (also blue pages) became effective 9/11/2001 and Revision 5 (purple pages) became effective 12/19/2001. The page margin lists the revision number where the change occurred and the changes are shaded for easy identification.

If you have any questions, please contact me.

Sincerely,



Michael N. Stephens
Environmental Administrator

Enclosures: Fred Combs 2/8/2001 letter with Florida's RATS data
Current version of Florida Regulations Revision 3, 4 (Blue pages), and Revision 5
(Purple pages)
Revision 3 Selected Sections Identified as RATS ID 1995-1
Revision 4 Comparison Table 10 CFR Part 34 to 64E-5, Part IV, FAC (IR Rule)
Revision 5 Comparison Table 10 CFR Part 20, Subpart E to Applicable Sections
64E-5, Part II, FAC (License Termination Rule)

cc: William Passetti, Chief Bureau of Radiation Control

Richard Woodruff, Regional State Agreements Officer
U.S. Nuclear Regulatory Commission
Sam Nunn Atlanta Federal Center, 23 T 85
61 Forscyth Street SW
Atlanta, GA 30303-3415



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20535-0001

February 8, 2001

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DEPT OF HEALTH
BUREAU OF
RADIATION CONTROL

Mr. William A. Passetti, Chief
Bureau of Radiation Control
Department of Health
4052 Bald Cypress Way, Bin #C21
Tallahassee, FL 32399-1741

Dear Mr. Passetti:

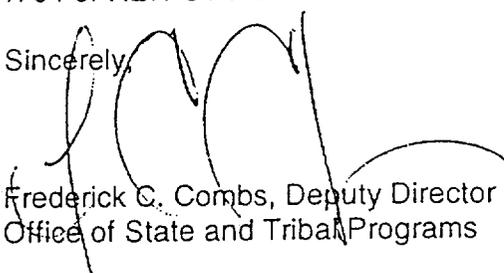
We have reviewed the final Florida regulations Control of Radiation Hazard Regulations, Chapter 64E-5, Florida Administrative Code, which became effective in October 8, 2000. The regulations were sent on January 10, 2001. The final regulations are in response to the 10 amendments identified in the enclosed Regulations Assessment Tracking System (RATS) Data Sheet. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 20, 30, 35, 61, 70, 71, and 150. In addition, we reviewed our November 8, 2000 letter to you that addressed the proposed regulations. We also discussed our review of the regulations with Mr. Michael N. Stephens on January 25, 2001.

As a result of the NRC review, we have determined that the Florida regulations, as adopted, meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

We have also summarized on the RATS Data Sheet our knowledge of the status of other Florida regulations. Please let us know if you note any inaccuracies or have any comments on the information contained in the RATS Data Sheet.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me or Richard L. Woodruff, Region II, at 404-562-4704 or RLW@NRC.GOV.

Sincerely,


Frederick C. Combs, Deputy Director
Office of State and Tribal Programs

Enclosure:
As stated

REGULATION ASSESSMENT TRACKING SYSTEM
RATS DATA SHEET

State: Florida

Tracking Ticket Number: 1-13

[10 final amendments dated October 8, 2000 identified by a
★ at the beginning of each equivalent NRC regulation.]

Date: February 8, 2001

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed/ Final- Comment (Y/N) ¹	NRC Review Date	Final State Regulation ² (Effective Date)
★Standards for Protection Against Radiation-Part 20	56 FR 23360 56 FR 61352 57 FR 38588 57 FR 57877 58 FR 67657 59 FR 41641 60 FR 20183 (1/1/94)	1991-3	F-N (see note 5)	2/8/01	10/8/00
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843 (1/10/94)	1991-1	F-N	11/8/00	1/1/94
ASNT Certification of Radiographers-Part 34	56 FR 11504 (none)	1991-2			Not required ³
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980 (10/15/94)	1991-4	F-N	11/8/00	1/1/94
Quality Management Program and Misadministrations-Part 35	56 FR 34104 (1/27/95)	1992-1	F-N	11/8/00	1/1/94
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566 (none)	1992-2			Not required ³
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715 (7/1/96)	1993-2	F-N	11/8/00	8/14/96
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886 (7/22/96)	1993-3			Not applicable SECY-95-112 ⁴
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628 (10/25/96)	1993-1	F-N	11/8/00	8/14/96
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726 59 FR 1618 (none)	1994-1			Not required ³
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220 (7/1/97)	1994-2			Not applicable to Florida
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026 (8/15/97)	1994-3	F-N	11/8/00	5/18/98
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767 59 FR 65243 60 FR 322 (1/1/98)	1995-1			
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900 (3/13/98)	1995-2	F-N	11/8/00	5/18/98

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed/ Final- Comment (Y/N) ¹	NRC Review Date	Final State Regulation ² (Effective Date)
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649 60 FR 25983 (3/1/98)	1995-3	F-N	11/8/00	5/18/98
Performance Requirements for Radiography Equipment- Part 34	60 FR 28323 (6/30/98)	1995-4	F-N	11/8/00	5/18/98
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038 (8/14/98)	1995-5	F-N	11/8/00	5/18/98
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235 (11/24/98)	1995-6	F-N	11/8/00	5/18/98
*Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623 (10/20/98)	1995-7	F-N	2/8/01	10/8/00
*10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248 61 FR 28723 (4/1/99)	1996-1	F-N	2/8/01	10/8/00
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109 (none)	1996-2			Not required ³
*Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669 (6/17/99)	1996-3	F-N	2/8/01	10/8/00
*Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120 (1/9/00)	1997-1	F-N	2/8/01	10/8/00
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907 (none)	1997-4			Not required ³
*Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662 (2/27/00)	1997-2	F-N	2/8/01	10/8/00
*Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120 (5/29/00)	1997-3	F-N	2/8/01	10/8/00
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28948 (6/27/00)	1997-5			
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39058 (8/20/00)	1997-6			
*Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634 (1/02/01)	1997-7	F-N	2/8/01	10/8/00
*Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 150	63 FR 1890 63 FR 13773 (2/12/01)	1998-1	F-N	2/8/01	10/8/00
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees-Parts 30, 40, 70	63 FR 29535 (none)	1998-2			Not required ³
License Term for Medical Use Licenses- Part 35	63 FR 31604 (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059 (7/9/01)	1998-4			

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed/ Final- Comment (Y/N) ¹	NRC Review Date	Final State Regulation ² (Effective Date)
*Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477 63 FR 45393 (10/26/01)	1998-5	F-N	2/8/01	10/8/00
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127 (11/20/01)	1998-6			
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506 (6/11/02)	1999-1			
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269 (none)	1999-2			Not required ³
Respiratory Protection and Controls to Restrict Internal Exposure - Part 20	64 FR 54543 64 FR 55525 (2/2/03)	1999-3			
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications - Part 39	65 FR 20337 (5/17/03)	2000-1			

1. (Y/N) Y means "Yes," there are comments in the review letter that the State needs to address. N means "No," there are no comments in the review letter.
2. Or other generic Legally Binding Requirement.
3. Not required means these regulations are not required for purposes of compatibility.
4. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. Proposed modifications were made to be compatible with Part 20 as requested in NRC letter dated 11/24/97.

Stephens, Mike N

From: Stephen Salomon [SNS@nrc.gov]
Sent: Thursday, November 30, 2000 1:50 PM
To: Stephens, Mike N
Cc: BGU@nrc.gov; RLW@nrc.gov
Subject: Error in 11/8/00 letter to William Passetti

Mike,

The NRC Review date of 11/8/00 was omitted in the RATS Data Sheet for RATS ID 1995-6. Also, there should be an "x" in front of the NRC regulation, "Clarification of Decommissioning Funding Requirements- Parts 30, 40, 70."

Also, the head of the Data sheet should read Six final (5/18/98) and in the second paragraph, the third line of the letter should read "six amendments" instead of "five amendments".

Please make these corrections.

Sorry for the error.

Steve Salomon
State and Tribal Programs, NRC
301-415-2368

Stephens, Mike N

From: Passetti, Bill A
Sent: Monday, April 09, 2001 10:40 AM
To: Stephens, Mike N
Subject: FW: Change of RATS Data Sheet to State Regulation Status in 2/8/01 letter

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-----Original Message-----

From: Stephen Salomon [SMTP:SNS@nrc.gov]
Sent: Wednesday, April 04, 2001 9:37 AM
To: Passetti, Bill A
Subject: Change of RATS Data Sheet to State Regulation Status in 2/8/01 letter

Bill Passetti,

FYI

In our 2/8/01 letter to you posted at the STP website we used the State Regulation Status instead of the RATS Data Sheet that was mailed to you with that letter.

Steve Salomon
301-415-2368

Revision 3: RATS ID 1995-1 Selected Sections.

This rule change was driven by a request from the Florida Pharmacy Association. No future changes to Florida's medical regulations are planned at this time.

The following change to our definitions to 64E-5, Part I, F.A.C.

- Authorized Nuclear Pharmacist (ANP) added to definitions 64E-5.101(177). This definition incorporates training requirements specified by the Board of Pharmacy. These training requirements are listed as an attachment to the regulations and are similar to those currently in place in 10 CFR Part 35.980.

The following changes to our medical regulations 64E-5, Part VI, F.A.C., were made in connection to an Authorized Nuclear Pharmacist.

- An ANP may be added as an authorized user 64E-5.601(4)(a). Equivalent to 35.11(b)
- Notification of ANP changes 64E-5.603. Equivalent to 35.14(1)
- RSC approval of ANP 64E-5.606(6). Equivalent to 35.22(b)(2)(i)
- Removed the requirement of FDA approved IND or NDA for medical use.
64E-5.626. Equivalent to 34.100(a) and (b).
64E-5.627. Equivalent to 34.200(a) and (b).
64E-5.630. Equivalent to 34.300(a) and (b).

10 CFR Part 32.72(a) and (a)(4) has been added as described in 64E-5.210(10)(b) and (d). The wording is very similar.

Also similar language to 32.72(c) was added in 64E-5.210(10)(e).

Cover Sheet for Revision 4. 64E-5, Part IV comparison to 10 CFR Part 34.

We have moved several of the Part 34 sections to topic specific Florida sections. The conversion table lists the cross-references to Part 34.

Please note that we have identified the following errors that require minor technical corrections. We will wait until NRC's review before fixing these errors.

64E-5.440(2)(d) refers to radiographer certification documents specified in .434(2)(e) - (f). There is no 64E-5.434(2)(f). This error will be corrected during next rule revision.

64E-5.440(2)(g) referenced records of ALARA audits specified in 64E-5.432(3)(c). The reference 64E-5.432(3)(c) does not exist. The correct reference is 64E-5.432(4)(c).

Major deviances from 10 CFR Part 34.

The concept of "Field Station" as listed in 10 CFR Part 34 is not permitted by Florida regulations due to our definition of "temporary job site" and was not adopted. The definition of "temporary job sites (TJS)" as listed in 10 CFR Part 34 is not adopted.

Florida's temporary job site definition that was adopted in 1993 applies to all licensees' not just industrial radiography. This definition is "a site, base or facility that is created and maintained to support a single job lasting for less than 2 years," Florida regulations also requires a separate license for sites that do not meet our definition of temporary job site (64E-5.213(6)). As mentioned this definition has been in place since 1993 to recover the Bureau's programs costs and it addresses health and safety issues that come with extended use of radioactive material of all licensees at job sites.

Florida regulations require NRC-defined field stations to have a separate FL license; multiple field stations under one license are not authorized in Florida.

Comparison Table – 10 CFR Part 34 & Part IV of 64E-5, FAC

10CFR	Title	Compatibility	64E-5	Title	Comments
34.1	Purpose and scope	D	N/A	N/A	Not adopted
34.3	Definitions	Multiple	.101 & .423	.101: Definitions .423: Definitions	Definitions applicable to IR are found in both Part I (.101) & Part IV (.423)
	ALARA	[A]	.101(11)	ALARA	No change from previous compatible status with NRC
	Annual refresher safety training	C	---	---	Not defined; term is self-descriptive when used in appropriate section.
	Associated equipment	B	.432(1)	Associated equipment	Worded slightly differently, but essentially identical to NRC. Florida is not allowed to use parentheses or example like this in rules; NRC definition ends with an example but FL cannot use examples
	Becquerel	[A]	.101(19)	Becquerel	No change from previous compatible status with NRC
	Certifying entity	B	.423(2)	Certifying entity	NRC definition only applies to CEs for RAM radiography; CE defined as independent certifying organization meeting Part 34 App. A requirements; FL definition is split into subsections (a) & (b); (a) addresses RAM CE & is compatible with NRC definition; (b) addresses x-ray CE; defines x-ray CE as any Agreement State or organization approved by CRCPD (i.e., ASNT)
	Collimator	B	.432(3)	Collimator	Wording is identical to NRC language
	Control (drive) cable	B	.432(4)	Control cable	Worded slightly differently, but essentially identical to NRC
	Control drive mechanism	B	.432(5)	Control drive mechanism	Worded slightly differently; NRC: "to and from the exposure device"; FL: "to and from the shielded position"; FL adds "also known as a crank assembly"
	Control tube	B	.432(6)	Control tube	Wording is identical to NRC language
	Exposure head	B	.432(7)	Exposure head	Worded slightly differently; NRC: "locates the gamma radiography sealed source in the selected working position"; FL: "locates the sealed source in the selected position"
	Field station	C	.101(54)	Field station	Not adopted; FL regulations require NRC-defined field station to have a separate FL license; multiple field stations under one license are not authorized in FL; FL adopted requirement for separate licenses for temporary job sites in 1993 and considers it a health and safety issue
	Gray	[A]	.101(57)	Gray	No change from previous compatible status with NRC
	Guide tube (projection sheath)	B	.432(3)	Guide tube	Worded slightly different, but essentially identical to NRC; FL adds "also known as a projection sheath or source tube"
	Hands-on experience	C	---	---	Not defined; term is self-descriptive when used in appropriate section.
	Independent certifying organization	B	---	---	Not adopted. The only place this term is used in the definition of certifying entity, which incorporates Part 34 Appendix A by reference; the term is not used nor needed in Part IV because FL's definition of CE references Part 34 App. A.
	Industrial radiography (radiography)	B	.101(64)	Industrial radiography	Similar wording w/ same meaning as NRC language
	Lay-barge radiography	B	.432(10)	Lay-barge radiography	Wording is identical to NRC language
	Offshore platform radiography	B	.432(11)	Platform radiography	Wording is similar but FL adds separate definition for <i>offshore</i> in Part I (see definition of <i>offshore</i> listed below)

Comparison Table – 10 CFR Part 34 & Part IV of 64E-5, FAC

10CFR	Title	Compatibility	64E-5	Title	Comments
34.3	Definitions	Multiple	.101 & .423	.101: Definitions .423: Definitions	Definitions applicable to IR are found in both Part I (.101) & Part IV (.423)
	Permanent radiographic installation	C	.101(103)	Permanent radiographic installation	Wording similar to NRC, but FL adds reference to .431 (req. for PRIs) and deletes prohibition for PRIs at TJS
	Practical examination	C	---	---	Not defined; term is self-descriptive when used in appropriate section.
	Radiation safety officer for ind. radiography	C	.101(117)	Radiation safety officer	FL has a generic definition applicable to all licensees/registrants: "a person who has the knowledge and responsibility to apply appropriate radiation protection rules"; IR RSO requirements are specified in .433; IR RSO is also named on license
	Radiographer	C	.101(120)	Radiographer	FL adds reference to training/testing req. in .434(2) & expands definition to include x-ray, but otherwise matches NRC language
	Radiographer certification	B	.432(12)	Radiographer certification	Slightly different wording, but essentially identical to NRC
	Radiographer's assistant	B	.101(121)	Radiographer's assistant	FL adds reference to training/testing req. in .434(1), expands definition to include x-ray, & adds reference to radiographic operations rather than the list of activities in the NRC definition, but meaning matches NRC language
	Radiographic exposure device	B	.101(122)	Radiographic exposure device	FL language is more simplistic but is essentially same as NRC
	Radiographic operations	C	.432(13)	Radiographic operations	FL expands definition to include x-ray radiography & contracts NRC's verbiage
	S-tube	B	.432(16)	S-tube	Wording is identical to NRC language
	Sealed source	[A]	.101(133)	Sealed source	No change from previous compatible status with NRC
	Shielded position	C	.101(135)	Shielded position	Wording is identical to NRC language, but adds "by manufacturer's design"
	Sievert	[A]	.101(139)	Sievert	No change from previous compatible status with NRC
	Source assembly	B	.432(17)	Source assembly	Wording similar to NRC, but FL adds acronym "pigtail"
	Source changer	B	.101(140)	Source changer	Wording almost identical to NRC language
	Storage area	D	.101(149)	Storage area	Wording is identical to NRC language
	Storage container	B	.101(150)	Storage container	Wording is almost identical to NRC language
	Temporary jobsite	B	.101(155)	Temporary job site	FL definition applies to all licensees and has been in effect since 1993. "a site, base or facility that is created and maintained to support a single job lasting for less than 2 years"; FL requires a separate license for sites operated > 2 yrs. or that are used to serve multiple contracts; definition addresses health and safety issues that come with extended use of radioactive material at a job sites and to recover program costs.
	Underwater radiography	B	.432(20)	Underwater radiography	Wording identical to NRC language, except FL includes x-ray machines
	---	---	.101(18)	Baggage x-ray system	For x-ray use only; FL: "a cabinet x-ray system with a maximum energy less than 120 kVp that produces only fluoroscopic images and that is used for packages or carry-on baggage"

Comparison Table – 10 CFR Part 34 & Part IV of 64E-5, FAC

10CFR	Title	Compatibility	64E-5	Title	Comments
34.3	Definitions	Multiple	.101 & .423	.101: Definitions .423: Definitions	Definitions applicable to IR are found in both Part I (.101) & Part IV (.423)
	---	---	.101(23)	Cabinet x-ray system	For x-ray use only; FL: "an x-ray system with the x-ray tube installed in an enclosure or cabinet that, independently of existing architectural structures except the floor on which it is placed, is intended to contain at least the portion of the material being irradiated, to provide radiation attenuation, and to exclude persons from its interior during generation of x-radiation. An x-ray tube used within a shielded part of a building or x-ray equipment that temporarily or occasionally incorporates portable shielding is not considered a cabinet x-ray system"
	---	---	.432(9)	Industrial cabinet x-ray system	For x-ray use only; FL: "a cabinet x-ray system used to perform industrial radiography excluding baggage x-ray systems"
	---	---	.101(97)	Offshore	FL: "within the territorial waters of the State of Florida as specified in Article II, Section I of the Constitution of the State of Florida"
	---	---	.101(105)	Personal supervision	FL: "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."; applies to both IR & well logging
	---	---	.432(14)	Radiographic personnel	FL: "radiographers and radiographer's assistants"; added to replace references to radiographers and assistants in Part IV
	---	---	.432(15)	Reference survey	FL: "a survey made with a radiation survey instrument within 6 inches (15 cm) of the surface of a radiographic exposure device or source changer at a location established by the licensee; reference survey is used to verify that the sealed source is located properly in the shielded position and to establish a radiation level for reference before, during, and after radiographic operations"; definition added to address requirement for performance of uniform radiation surveys
	---	---	.432(18)	Special training session	FL: "training not conducted during production radiography" definition added to address prohibition on conducting initial training during production radiography
	---	---	.432(19)	Transport container	FL: "a package that is designed to provide radiation safety and security when sealed sources are transported and that meets all applicable requirements of the U.S. Department of Transportation (USDOT)"; definition added to harmonize rule with CRCPD SSRRCR Part E
34.5	Interpretations	D	---	---	Not included because there is no equivalent language in FL regs
34.8	Info. collection req.: OMB approval	D	---	---	Not included because there is no equivalent language in FL regs
34.11	Application for a specific license	D	---	---	Covered in Part II (.207 & .208)

Comparison Table – 10 CFR Part 34 & Part IV of 64E-5, FAC

10CFR	Title	Compatibility	64E-5	Title	Comments
34.13	Specific license for industrial radiography	C	.432	Radiation Protection Program	First paragraph – .208 34.13(a) – omitted; covered by .208 34.13(b) = .432(2) 34.13(b)(1) – omitted; FL requires submittal of training program descriptions 34.13(b)(2) – omitted; FL requires submittal of training program descriptions 34.13(c) = .432(3); rad. cert. procedures 34.13(d) = .432(6); O&E procedures 34.13(e) = .432(5); internal audit procedures 34.13(f) = .432(1); organizational structure 34.13(g) = .432(1); name/qualifications of RSO; combined with description of organization structure 34.13(h) = .432(7); leak testing procedures 34.13(i) = .432(8); survey meter calibrations; additional language on alarm ratemeter calibration procedures added * .432(10) – new language on procedures for pocket dosimeter calibrations 34.13(j) & (k) – omitted; covered by .208 * .432(9) – new language on procedures for quarterly equipment inspection and maintenance
34.20	Performance requirements for IR equipment	B	.424	Requirements for IR Equipment	34.20(a)(1) = .424(1)(a) 34.20(a)(2) = .424(1)(a) 34.20(b) = .424(2) 34.20(b)(1) = .424(2)(a)(i) – (iv) 34.20(b)(2) = Required in 64E-5, Part XV, to follow all applicable 49 CFR requirements. 34.20(b)(3) = .424(2)(c) 34.20(c) = .424(3) 34.20(c)(1) = .424(3)(a) 34.20(c)(2) = .424(3)(b) 34.20(c)(3) = .424(3)(c) 34.20(c)(4) = .424(3)(d) 34.20(c)(5) = .424(3)(e) 34.20(c)(6) = .424(3)(f) 34.20(c)(7) = .424(3)(g) 34.20(c)(8) = .424(3)(h) 34.20(c)(9) = .424(3)(i) 34.20(d) = omitted; grace period from 1996 not applicable 34.20(e) = .424(1)(b)
34.21	Limits on external radiation levels from storage containers and source changers	B	.421	Requirements for IR Equipment	34.21 = .424(4); rad. limits are just additional requirements for rad. equipment, so they don't need to have a separate section

Comparison Table – 10 CFR Part 34 & Part IV of 64E-5, FAC

10CFR	Title	Compatibility	64E-5	Title	Comments
34.23	Locking of radiation exposure devices, storage containers and source changers	B	.424 & .425	.424: Requirements for IR Equipment .425: Storage Precautions and Locking of Sources of Radiation	34.23(a) = .424(5) & .425(1), (2), (4) & (6); the requirement for REDs to be equipped with a lock or outer locked container falls within the subject of .424 (IR equipment requirements), so it was included in that section instead of .425, which discusses security procedures 34.23(b) = .424(5) & .425(1) & (2); same logic applied here as was used for 34.23(a); the requirement for storage containers and source changers to be equipped with a lock or outer locked container falls within the subject of .424 (IR equipment requirements), so it was included in that section instead of .425 * .425(2) adds requirement for keys to be maintained in the possession of the radiographer/assistant responsible for the equipment, in a manner that prevents access by unauthorized personnel; language was added to address the potential for a key being left in a lock, making theft of the source more dangerous * .425(5) adds requirement for locking and securing transport containers in the transport vehicle
34.25	Radiation survey instruments	C	.426 (& .440)	Radiation Survey Instruments	34.25(a) = .426(1) 34.25(b) = .426(2) 34.25(b)(1) = .426(2)(a) * .426(2)(b) adds the requirement: "At appropriate energies for use" 34.25(b)(2) = .426(2)(d) 34.25(b)(3) = .426(2)(c) * .426(2)(e) adds the requirement: "By a person licensed by the department, another agreement state, or the NRC" 34.25(c) = .440(1)(a))
34.27	Leak testing and replacement of sealed sources	C	.427	Leak Testing, Repair, Tagging, Opening, Modification and Replacement of Sealed Sources and Devices	34.27(a) = .4275(1) 34.27(b) = .427(1); (a) & (b) combined into one subsection 34.27(c)(1) = .427(1), (2) and (4) 34.27(c)(2) = .440(1)(b) 34.27(c)(3) = .427(2) 34.27(d) = .427(5) 34.27(e) = .427(1), (3), (4) and (5)
34.29	Quarterly inventory	C	.428 (& .440)	Quarterly Inventory	34.29(a) = .428; new language adds requirement to inventory radiation machines and empty REDs containing DU 34.29(b) = .440(1)(c); new language specifies the information required for inventory records
34.31	Inspection and maintenance of REDs, transport and storage containers	C	.430 (& .440)	Inspection and Maintenance	34.31(a) = .430(1) 34.31(b) = .430(2); requirement for written I&M procedures: .436(7) 34.31(b)(1) = .430(2)(a) 34.31(b)(2) = .430(2)(b) 34.31(c) = .440(1)(e)

Comparison Table – 10 CFR Part 34 & Part IV of 64E-5, FAC

10CFR	Title	Compatibility	64E-5	Title	Comments
34.33	Permanent radiographic installations	D/H&S	.431 (& .440)	Permanent Radiographic Installations	34.33(a) = .431(1) 34.33(a)(1) = .431(1)(a) 34.33(a)(2) = .431(1)(b) 34.33(b) = .431(2) and .440(1)(f)
34.35	Labeling, storage, and transportation	B	.424, .425 & .436(6)	.424: Requirements for IR Equipment .425: Storage Precautions and Locking of Sources of Radiation .436: O&E Procedures	34.35(a) = .424(2)(b); this is an IR equipment req., so it was moved to the section addressing that topic - .424 34.35(b) = .436(6) 34.35(c) = .425(3) 34.35(d) = .425(5)
34.41	Conducting radiographic operations	B	.432 & .435	Conducting Radiographic Operations	34.41(a) = .435(1) 34.41(b) = .435(3) 34.41(c) = .432(11) 34.41(d) = omitted; grace period not applicable
34.42	RSO for industrial radiography	D	.433	Radiation Safety Officer	34.42 = .433(3)(a) 34.42(a) = .433(1)(a); Note: certification is not specified as a requirement to be RSO 34.42(b) = .433(1)(2); Note: FL's IR RSO min. qualifications differ from NRC; rather than 2000 hrs of experience, Part IV requires min. of 1 yr of documented radiography experience as a radiographer 34.42(c) = .433(3); Note: BRC version is abbreviated
34.43	Training	B; (a)(2) is D	.434	Training, Testing, Certification and Audits	34.43(a)(1) = .434(2), (2)(b)(c) & (e); FL requires 320 hrs. OJT rather than NRC's 2 mths.; FL has no equivalent to Part 34 App. A because FL defines certifying entities as Agreement States or organizations approved by the NRC or CRCPD 34.43(a)(2) = .434(2); FL requires rad. cert. 12 mths. after effective date of rule (9/01) 34.43(b)(1) = .434(2)(a) & (c); FL requires min. of 40 hrs. formal training and specifies that practical training must be conducted in special training sessions, not during production radiography 34.43(b)(2) = .434(2)(d); FL requires a closed-book exam covering .434(6) subjects 34.43(b)(3) = .434(2)(c) 34.43(b)(4) = .434(2)(d) 34.43(c)(1) = .434(1)(a) & (b) 34.43(c)(2) = .434(1)(b) 34.43(c)(3) = .434(1)(c); FL requires closed-book exam, and practical exam taken as special training session 34.43(d) = .434(7); FL requires min. of 8 hrs. refresher training, which can be broken up into multiple sessions 34.43(e)(1) = .434(8) 34.43(e)(2) = .434(8) 34.43(e)(3) = .434(8); FL exempts RSOs from internal audits; such audits are unnecessary, have no objectivity and thus no value 34.43(e)(4) = .434(8); FL exempts RSOs from internal audits

Comparison Table – 10 CFR Part 34 & Part IV of 64E-5, FAC

10CFR	Title	Compatibility	64E-5	Title	Comments
34.43 (contd.)	Training	B; (a)(2) is D	.434	Training, Testing, Certification and Audits	34.43(f) = .440(2)(b), (c) & (d); note: .440(2)(d) refers to radiographer certification documents specified in .434(2)(e) - (f), but there is no .434(2)(f); error will be corrected during next rule revision 34.43(g) = .434(6) 34.43(g)(1) = .434(6)(a) 34.43(g)(2) = .434(6)(b) 34.43(g)(3) = .434(6)(c) 34.43(g)(4) = .434(6)(d) 34.43(g)(5) = .434(6)(f) 34.43(h) = omitted; requirement for provision of training reference materials became effective with effective date of rule (9/11/01) 34.43(i) = .434(2) & .440(2)(d)
34.45	Operating and emergency procedures	C; (a)(9), (b) are D	.436	Operating and Emergency Procedures	34.45(a)(1) = .436(1) 34.45(a)(2) = .436(2) 34.45(a)(3) = .436(3) 34.45(a)(4) = .436(4); FL refers to sources of radiation, which encompasses radiographic exposure devices, transport and storage containers and sealed sources 34.45(a)(5) = .436(5); FL adds "including steps to be taken immediately by radiography personnel when a pocket dosimeter is found off-scale, an alarm ratemeter alarms unexpectedly, or a personnel monitoring badge is damaged or lost" 34.45(a)(6) = .436(6); FL language slightly different but equivalent 34.45(a)(7) = .436(7); FL includes procedures for leak testing, inventories and disposal 34.45(a)(8) = .436(5) 34.45(a)(9) = .436(11) 34.45(a)(10) = .436(10) 34.45(a)(11) = .436(10) 34.45(a)(12) = .436(10) 34.45(a)(13) = .436(12) 34.45(b) = .440(2)(h) & .440(3)(c)
34.46	Supervision of radiographer's assistants	B	.435	Conducting Rad. Operations	34.46(a) = .435(1) & (2), & .101(105) – definition of <i>personal supervision</i> 34.46(b) = .435(1) & (2), & .101(105) – definition of <i>personal supervision</i> 34.46(c) = .435(1) & (2), & .101(105) – definition of <i>personal supervision</i>
34.47	Personnel monitoring	C	.437 (& .440)	Personnel Monitoring	34.47(a) = .437(1); FL allows use of OSLDs for PM badges 34.47(a)(1) = .437(3); FL adds requirement to recharge dosimeters when 75% of full scale is reached, and requires initial, final and total dosimeter readings to be recorded at the start and end of each shift; .437(1)(b) references use of electronic dosimeters in place of ion chamber pocket dosimeters 34.47(a)(2) = .437(2) 34.47(a)(3) = .437(2); FL requires all PM badges to be exchanged monthly 34.47(a)(4) = .437(2) 34.47(b) = .437(3); FL requires initial, final and total dosimeter readings to be recorded at the start and end of each shift

Comparison Table – 10 CFR Part 34 & Part IV of 64E-5, FAC

10CFR	Title	Compatibility	64E-5	Title	Comments
34.47 (contd.)	Personnel monitoring	C	.437 (& .440)	Personnel Monitoring	34.47(c) = .437(6) & .440(1)(a); FL requires dosimeter calibration to include a drift check and a leakage check 34.47(d) = .437(4) & .440(2)(f); FL requires results of the determination of the individual's radiation exposure to be reported within 30 days 34.47(e) = .437(2) & .440(2)(f) 34.47(f) = .339 & .440(2)(f) 34.47(g) = .437(5) 34.47(g)(1) = .437(5)(a); 34.47(g)(2) = .437(5)(b) & .437(6) 34.47(g)(3) = .437(5)(c) 34.47(g)(4) = .437(6) & .440(1)(a)
34.49	Radiation surveys	C; (d) is D	.438	Radiation Surveys	34.49(a) = .438(1) 34.49(b) = .438(2)(c); FL refers to performance of reference survey (.423(15)) 34.49(c) = .440(2)(d) and (e) 34.49(d) = .440(1)(d); survey results must be recorded in SMLs and DSRs * .438(2)(a) adds a requirement to perform a reference survey when initially removing a source from storage * .438(2)(b) adds a requirement to perform an area survey during the initial exposure to verify proper posting and dose limits
34.51	Surveillance	C	.435	Locking of Sources of Radiation, Storage Precautions, and Surveillance	34.51 = .425(6) * .425(7) addresses surveillance of industrial cabinet x-ray systems
34.53	Posting	C	.439	Posting	34.53 = .439(1) * .439(2) adds requirement to conspicuously post, in the area where the source is stored, source movement logs documenting the current location of the source and source movements for the previous 30 days
34.61	Records of the specific license for ind. rad.	D	.901	Posting of Notices to Workers	34.61 = .901(1)(b); the requirement for licensees to post a copy of their license, amendments and documents incorporated into the license serves as a requirement to maintain those documents until license termination, thereby negating the need for a separate rule requiring maintenance of such documents
34.63	Records of the receipt and transfer of sealed sources	C	.440	Records	34.63(a) = .440(1)(h) 34.63(b) = .440(1)(h)
34.65	Records of radiation survey instruments	C	.440	Records	34.65 = .440(1)(a)
34.67	Records of leak testing of sealed sources and devices containing DU	C	.440	Records	34.67 = .440(1)(b)
34.69	Records of quarterly inventory	C	.440	Records	34.69 = .440(1)(c)

Comparison Table – 10 CFR Part 34 & Part IV of 64E-5, FAC

10CFR	Title	Compatibility	64E-5	Title	Comments
34.71	Utilization logs	B	.429 (& .440)	Source Movement Logs Daily Survey Reports, and Individual Dosimeter Logs	34.71 = .429; NRC utilization logs are equivalent to FL source movement logs 34.71(a)(1) = .429(1)(b) 34.71(a)(2) = .429(1)(e); FL requires signature or initials of radiographer 34.71(a)(3) = .429(1)(a) 34.71(b) = .440(1)(d)
34.73	Records of inspection and maintenance of REDs, transport and storage containers, assoc. equipment, SCs, and survey instruments	C	.429, .430 & .440	.429: SMLs, DSRs, and IDLs .430: Inspection and Maintenance .440: Records	34.73(a) = .429(2)(h), .440(1)(d) & .440(1)(e) 34.73(b) = .429(2)(h), .440(1)(d) & .440(1)(e)
34.75	Records of alarm system and entrance control checks at PRIs	D	.440	Records	34.75 = .440(1)(f)
34.79	Records of training and certification	C	.440	Records	34.79(a) = .440(2)(b), (c) & (d); FL requires records to be kept until lic. termination 34.79(b) = .440(1)(g), .440(2)(b), (c) & (d); FL requires of internal audits to be maintained for 3 yrs. and records of refresher training to be kept until lic. termination
34.81	Copies of O&E procedures	C	.440	Records	34.81 = .440(2)(h)
34.83	Records of personnel monitoring procedures	C	.440 (& .339)	Records	34.83(a) = .440(1)(d) & (2)(a) for dosimeter readings, and .440(1)(a) for dosimeter calibration records 34.83(b) = .440(1)(a) 34.83(c) = .339(5) 34.83(d) = .440(2)(f)
34.85	Records of radiation surveys	D	.440	Records	34.85 = .440(1)(d); survey is recorded on both the SML and DSR
34.87	Form of records	C	.342	Form of Records	34.87 = .342
34.89	Location of documents and records	C	.440	Records	34.89(a) = .212(2)(b); incorporated as part of the license document 34.89(b) = .440(3)
34.101	Notifications	C	.441	Reporting Requirements	34.101(a) = .441(1) 34.101(b) = .441(2) 34.101(c) = omitted; covered by Part II, Subpart D (Reciprocity)
34.111	Applications for exemptions	D	N/A	N/A	Not included in Part IV; covered in .102 (Exemptions)
34.121	Violations	D	N/A	N/A	No equivalent rule in Part IV
34.123	Criminal penalties	D	N/A	N/A	No equivalent rule in Part IV
App. A	Radiographer Certification	B	N/A	N/A	Incorporated by reference via definition of certifying entity in .423(2)(a); FL defines CEs as organizations approved by the NRC (isotope radiographers) or the CRCPD (x-ray radiographers)

Cover sheet for Revision 5 and a comparison of 10 CFR Subpart E and selected section of 64E-5, FAC.

The major deviation from NRC rules and Florida rules on the license termination rule is:

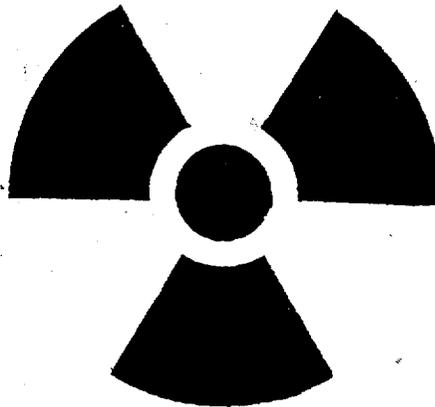
- Florida has removed all language allowing the 500 millirem/year TEDE option as allowed by the compatibility C designation.
- The public participation is required when plans allow above 50 millirem/year TEDE instead of as determined by the Bureau.

This rule also includes changes to notice to employee regulations.

Section 64E-5.901(2) was changed to make a technical correction and to clearly indicate that posting of notices of violations are required. This language is similar to 10 CFR 19.11(a)(4). We also revised our "Notice to Employee" document to reflect the Bureau's current address and phone numbers. Please be advised that the "Notice to Employee" document does not include the discrimination information referenced in section 19.20 that is designated as compatibility D.



CONTROL OF RADIATION HAZARD REGULATIONS



Chapter 64E-5 Florida Administrative Code

July 3, 1997

**Includes Revision 1 (May 18, 2000) and
Revision 2 (October 8, 2000)**

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

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

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

Department of Health
Bureau of Radiation Control
Radiation Machine Section
P.O. Box 210
Jacksonville, FL 32231
Telephone: (904) 359-6363 Fax: (904) 359-6362

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

Department of Health
Bureau of Radiation Control
Radioactive Materials Section
Bin #C21
4052 Bald Cypress Way
Tallahassee, FL 32399-1741
Telephone: (850) 245-4545 Fax: (850) 921-6364

PARTS X and XII

Department of Health
Bureau of Facilities Program
Radon and Indoor Air Quality Section
Bin #C22
4052 Bald Cypress Way
Tallahassee, FL 32399-1742
Telephone: (850) 245-4277 Fax: (850) 487-0864

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Chronology of Rule Revisions

Revision	Effective Date	Sections Affected
R1	May 18, 1998	64E-5.101, 64E-5.204, 64E-5.213, 64E-5.214, 64E-5.319, 64E-5.332 64E-5.333, 64E-5.334, 64E-5.347, 64E-5.402, 64E-5.422, 64E-5.502 64E-5.504, 64E-5.510, 64E-5.617, 64E-5.902, 64E-5.1513, Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997.
R2	October 8, 2000	64E-5.101, 64E-5.201, 64E-5.203, 64E-5.204, 64E-5.214, 64E-5.216 64E-5.301, 64E-5.303, 64E-5.304, 64E-5.309, 64E-5.311, 64E-5.312 64E-5.314, 64E-5.315, 64E-5.323, 64E-5.326, 64E-5.334, 64E-5.339 64E-5.344, 64E-5.345, 64E-5.414, 64E-5.420, 64E-5.422, 64E-5.505 64E-5.622, 64E-5.625, 64E-5.643, 64E-5.645, 64E-5.1103, 64E-5.1112, 64E-5.1310, 64E-5.1406, 64E-5.1418, 64E-5.1502, 64E-5.1513 Radioactive Material Requiring Labeling, May 2000
R3	August 6, 2001	64E-5.101, 64E-5.201, 64E-5.603, 64E-5.606. 64E-5.626, 64E-5.627 64E-5.630
R4	September 11, 2001	64E-5.401 - 64E-5.422 repealed and replaced with sections 64E-5.423, 64E-5.424, 64E-5.425, 64E-5.426, 64E-5.427, 64E-5.428 64E-5.429, 64E-5.430, 64E-5.431, 64E-5.432, 64E-5.433, 64E-5.434 64E-5.435, 64E-5.436, 64E-5.437, 64E-5.438, 64E-5.439, 64E-5.440 64E-5.441
R5	December 19, 2001	64E-5.101, 64E-5.214, 64E-5.221, 64E-5.222, 64E-5.223, 64E-5.224, 64E-5.225, 64E-5.226, 64E-5.901, Notice to Employees 3/01

PART I GENERAL PROVISIONS

R5	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

PART II LICENSING OF RADIOACTIVE MATERIALS

R2	64E-5.201	Licensing of Radioactive Material	II-1
	64E-5.202	Source Material - Exemptions	II-2
R2	64E-5.203	Radioactive Material Other than Source Material - Exemptions	II-4

SUBPART A LICENSE TYPES AND FEES

R2	64E-5.204	Types of Licenses	II-10
----	-----------	-------------------	-------

SUBPART B GENERAL LICENSES

	64E-5.205	General Licenses - Source Material	II-15
	64E-5.206	General Licenses - Radioactive Material Other Than Source Material	II-17

SUBPART C SPECIFIC LICENSES

	64E-5.207	Filing Application for Specific Licenses	II-30
	64E-5.208	General Requirements for the Issuance of Specific Licenses	II-30
	64E-5.209	Special Requirements for Specific Licenses of Broad Scope	II-31
R3	64E-5.210	Special Requirements for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices which Contain Radioactive Material	II-35
	64E-5.211	Special Requirements for Issuance of Specific Licenses for Source Material Milling	II-54
	64E-5.212	Issuance of Specific Licenses	II-57
R1	64E-5.213	Specific Terms and Conditions of Licenses	II-58
R5	64E-5.214	Expiration and Termination of Licenses and Decommissioning of Buildings and Outdoor Areas	II-60
	64E-5.215	Transfer of Material	II-64

SUBPART D RECIPROACITY

R2	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	II-65
----	-----------	---	-------

SUBPART E BONDING

	64E-5.217	Bonding of Persons Licensed Pursuant to Subpart C	II-67
--	-----------	---	-------

SUBPART F INSPECTION AND ENFORCEMENT

	64E-5.218	Performance of Inspections	II-70
	64E-5.219	Emergency Planning	II-71
	64E-5.220	Radioactive Quantities	II-75

Part II Licensing of Radioactive Materials (continued)

SUBPART G RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

R5 64E-5.221 Radiological Criteria for License Termination..... II-78a
R5 64E-5.222 Radiological Criteria for Unrestricted Use II-78a
R5 64E-5.223 Radiological Criteria for License Termination Under Restricted Conditions..... II-78a
R5 64E-5.224 Alternate Criteria for License Termination..... II-78c
R5 64E-5.225 Public Notification and Public Participation II-78d
R5 64E-5.226 Minimizing Contamination II-78d

Schedule A..... Exempt Concentrations..... II-79
Schedule B..... Exempt Quantities..... II-84
Schedule D Limits for Broad License II-90

PART III STANDARDS FOR PROTECTION

SUBPART A GENERAL PROVISIONS

R2 64E-5.301 Standards for Protection Against Radiation III-1
64E-5.302 Implementation III-1

SUBPART B RADIATION PROTECTION PROGRAMS

R2 64E-5.303 Radiation Protection Programs III-2

SUBPART C OCCUPATIONAL DOSE LIMITS

R2 64E-5.304 Occupational Dose Limits for Adults III-2
64E-5.305 Compliance with Requirements for Summation of
External and Internal Doses..... III-3
64E-5.306 Determination of External Dose from Airborne Radioactive Material..... III-4
64E-5.307 Determination of Internal Exposure..... III-5
64E-5.308 Determination of Prior Occupational Dose III-6
R2 64E-5.309 Planned Special Exposures III-8
64E-5.310 Occupation Dose Limits for Minors III-9
R2 64E-5.311 Dose to an Embryo Fetus III-9

SUBPART D RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

R2 64E-5.312 Dose Limits for Individual Members of the Public..... III-10
64E-5.313 Compliance with Dose Limits for Individual Members of the Public..... III-11

SUBPART E SURVEYS AND MONITORING

R2 64E-5.314 General..... III-12
R2 64E-5.315 Conditions Requiring Individual Monitoring of External and
Internal Occupational Dose..... 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
64E-5.317 Control of Access to Very High Radiation Areas III-15

Part III Standards for Protection (continued)

SUBPART G RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

R1 64E-5.318 Use of Process or Other Engineering Controls III-15
 R1 64E-5.319 Use of Individual Respiratory Protection Equipment III-16

SUBPART H STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

64E-5.320 Security of Stored Sources of Radiation III-18
 64E-5.321 Control of Sources of Radiation Not in Storage III-18

SUBPART I PRECAUTIONARY PROCEDURES

R2 64E-5.322 Caution Signs III-19
 R2 64E-5.323 Posting Requirements III-20
 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 III-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 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 III-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 III-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 Areas 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 III-39
 R2 64E-5.344 Notification of Incidents III-40
 R2 64E-5.345 Reports of Exposure, Radiation Levels, Concentrations of
 Radioactive Material Exceeding the Limits, and Misadministrations III-43
 64E-5.346 Reports of Planned Special Exposures III-46
 R1 64E-5.347 Notifications and Reports to Individuals III-46
 64E-5.348 Reports of Leaking or Contaminated Sealed Sources III-46
 64E-5.349 Vacating Premises 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 64E-5.424 Requirements for Industrial Radiography Equipment Using Sealed Sources IV-3

R4 64E-5.425 Locking of Sources of Radiation, Storage Precautions, and Surveillance IV-5

R4 64E-5.426 Radiation Survey Instruments IV-6

R4 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

R4 64E-5.429 Source Movement Logs, Daily Survey Reports, and Individual Dosimeter Logs IV-8

R4 64E-5.430 Inspection and Maintenance IV-9

R4 64E-5.431 Permanent Radiographic Installations IV-10

R4 **SUBPART E RADIATION SAFETY REQUIREMENTS** (formerly Subpart B)

R4 64E-5.432 Radiation Protection Program IV-11

R4 64E-5.433 Radiation Safety Officer IV-13

R4 64E-5.434 Training, Testing, Certification, and Audits IV-14

R4 64E-5.435 Conducting Industrial Radiographic Operations IV-17

R4 64E-5.436 Operating and Emergency Procedures IV-17

R4 64E-5.437 Personnel Monitoring IV-18

R4 **SUBPART F PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS**
(formerly Subpart C)

R4 64E-5.438 Radiation Surveys IV-20

R4 64E-5.439 Posting IV-21

R4 64E-5.440 Records IV-21

R4 64E-5.441 Reporting Requirements IV-23

PART V X-RAYS IN THE HEALING ARTS

64E-5.501 Definitions V-1

R1 64E-5.502 General Requirements V-10

64E-5.503 General Requirements for all Diagnostic X-ray Systems V-17

R1 64E-5.504 Fluoroscopic X-ray Systems V-23

R2 64E-5.505 Diagnostic Radiography Systems, Other than Fluoroscopic,
Mammographic, Dental Intraoral or Veterinary Systems V-30

64E-5.506 Intraoral Dental Radiographic Systems V-34

64E-5.507 Therapeutic X-ray Systems of Less Than 1 MeV V-36

64E-5.508 X-ray and Electron Therapy Systems with Energies of 1 MeV and Above V-43

64E-5.509 Veterinary Medicine X-ray Operations V-57

R1 64E-5.510 Mammographic Systems V-59

64E-5.511 Registration of Radiation Machines V-68

PART VI USE OF RADIONUCLIDES IN THE HEALING ARTS

R3	64E-5.601	License Required	VI-1
	64E-5.602	License Amendments	VI-1
R3	64E-5.603	Notification	VI-2
SUBPART A GENERAL ADMINISTRATIVE REQUIREMENTS			
	64E-5.604	ALARA Program	VI-2
	64E-5.605	Radiation Safety Officer	VI-3
R3	64E-5.606	Radiation Safety Committee	VI-4
	64E-5.607	Authority and Responsibilities	VI-6
	64E-5.608	Supervision	VI-6
	64E-5.609	Visiting Authorized User	VI-7
	64E-5.610	Mobile Nuclear Medicine Service Requirements	VI-8
	64E-5.611	Quality Management Program and Notifications, Records and Reports of Misadministrations	VI-9
	64E-5.612	Suppliers	VI-11
SUBPART B GENERAL TECHNICAL REQUIREMENTS			
	64E-5.613	Quality Control of Diagnostic Instrumentation	VI-12
	64E-5.614	Possession, Use, Calibration, and Check of Dose Calibrators	VI-12
	64E-5.615	Calibration and Check of Survey Instruments	VI-14
	64E-5.616	Assay of Radiopharmaceutical Dosages	VI-15
R1	64E-5.617	Authorization for Calibration and Reference Sources	VI-16
	64E-5.618	Requirements for Possession of Sealed Sources and Brachytherapy Sources	VI-16
	64E-5.619	Syringe Shields and Labels	VI-18
	64E-5.620	Vial Shields and Labels	VI-18
	64E-5.621	Surveys for Contamination and Ambient Radiation Dose Rate	VI-19
R2	64E-5.622	Release of Patients Containing Radiopharmaceuticals or Permanent Implants	VI-20
	64E-5.623	Storage of Volatiles and Gases	VI-20a
	64E-5.624	Decay in Storage	VI-20a
R2	64E-5.625	Safety Instruction and Precautions for Radiopharmaceutical Therapy, Brachytherapy, and Teletherapy	VI-21
SUBPART C UPTAKE, DILUTION, AND EXCRETION			
R3	64E-5.626	Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies	VI-24
SUBPART D IMAGING AND LOCALIZATION			
R3	64E-5.627	Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies	VI-24
	64E-5.628	Permissible Molybdenum 99 Concentration	VI-24
	64E-5.629	Control of Aerosols and Gases	VI-25
SUBPART E RADIOPHARMACEUTICALS FOR THERAPY			
R3	64E-5.630	Use of Radiopharmaceuticals for Therapy	VI-26
SUBPART F SEALED SOURCES FOR DIAGNOSIS			
	64E-5.631	Use of Sealed Sources for Diagnosis	VI-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 VI-28
 64E-5.637 Doors, Interlocks, and Warning Systems VI-28
 64E-5.638 Radiation Monitoring Devices VI-29
 64E-5.639 Viewing Systems VI-30
 64E-5.640 Dosimetry Equipment VI-30
 64E-5.641 Full Calibration Measurements VI-31
 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 VI-36
 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 VI-36
 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 VI-38
 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
 64E-5.704 Personnel Requirements VII-4

PART VIII RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL PARTICLE ACCELERATORS

SUBPART A REGISTRATION PROCEDURE

64E-5.801 Registration Requirements VIII-1
 64E-5.802 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 VIII-3
 64E-5.807 Warning Devices VIII-4
 64E-5.808 Operating Procedures VIII-5
 64E-5.809 Radiation Monitoring Requirements VIII-5
 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
 R1 64E-5.902 Instructions to Workers IX-2
 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 Standards X-1

SUBPART B ENVIRONMENTAL MONITORING

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

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

64E-5.1101 Prohibitions XI-1

SUBPART A EQUIPMENT CONTROL

R2 64E-5.1102 Storage and Transportation Precautions XI-2
 64E-5.1103 Radiation Survey Instruments XI-2
 64E-5.1104 Leak Testing of Sealed Sources XI-3
 64E-5.1105 Quarterly Inventory XI-4
 64E-5.1106 Utilization Records XI-4
 64E-5.1107 Design, Performance and Certification Criteria for Sealed Sources
 Used in Downhole Operations XI-4
 64E-5.1108 Labeling XI-5
 64E-5.1109 Inspection and Maintenance XI-6

SUBPART B REQUIREMENTS FOR PERSONNEL SAFETY

R2 64E-5.1110 Training Requirements XI-6
 64E-5.1111 Operating and Emergency Procedures XI-7
 64E-5.1112 Personnel Monitoring XI-8

**SUBPART C PRECAUTIONARY PROCEDURES IN LOGGING AND
SUBSURFACE TRACER OPERATIONS**

64E-5.1113 Security..... XI-8
 64E-5.1114 Handling Tools..... XI-8
 64E-5.1115 Subsurface Tracer Studies..... XI-8

SUBPART D RADIATION SURVEYS AND RECORDS

64E-5.1116 Radiation Surveys..... XI-9
 64E-5.1117 Documents and Records Required at Field Stations..... XI-10
 64E-5.1118 Documents and Records Required at Temporary Job Sites..... XI-10

SUBPART E NOTIFICATION

64E-5.1119 Notification of Incidents, Abandonment and Lost Sources..... XI-11
 64E-5.1120 Subjects to be Included in Training Courses for Logging Supervisors..... XI-13

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**

64E-5.1301 Sealed or Unsealed Sources of Radioactive Materials..... XIII-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
 64E-5.1304 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..... XIII-5
 64E-5.1307 Training Requirements for Authorized Users..... XIII-5
 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**

64E-5.1311 Storage, Security and Transportation Precautions..... XIII-7
 64E-5.1312 Training and User Requirements..... XIII-8

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

64E-5.1313 Training and User Requirements..... XIII-8
 64E-5.1314 Possession of Survey Instruments..... XIII-9
 64E-5.1315 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 GasesXIII-10
 64E-5.1318 InstrumentationXIII-10
 64E-5.1319 Contamination Control Program.....XIII-11

PART XIV LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

SUBPART A GENERAL PROVISIONS

64E-5.1401 Irradiators XIV-1
 64E-5.1402 Definitions XIV-1

SUBPART B SPECIFIC LICENSE FOR LARGE IRRADIATORS

64E-5.1403 Specific License for Large Irradiators..... XIV-3
 64E-5.1404 Start of Construction XIV-5

SUBPART C DESIGN AND PERFORMANCE REQUIREMENTS FOR LARGE IRRADIATORS

R2 64E-5.1405 Performance Criteria for Sealed Sources..... XIV-5
 R2 64E-5.1406 Access Control..... XIV-6
 64E-5.1407 Shielding XIV-8
 64E-5.1408 Fire Protection XIV-8
 64E-5.1409 Radiation Monitors XIV-9
 64E-5.1410 Control of Source Movement XIV-9
 64E-5.1411 Irradiator Pools XIV-10
 64E-5.1412 Source Rack Protection XIV-11
 64E-5.1413 Power Failures XIV-11
 64E-5.1414 Design Requirements XIV-11
 64E-5.1415 Construction Control XIV-14

SUBPART D OPERATION OF IRRADIATORS

R2 64E-5.1416 Training..... XIV-15
 R2 64E-5.1417 Operating and Emergency Procedures XIV-17
 R2 64E-5.1418 Personnel Monitoring XIV-18
 64E-5.1419 Radiation Surveys XIV-19
 64E-5.1420 Detection of Leaking or Contaminated Sources XIV-20
 64E-5.1421 Inspection and Maintenance XIV-21
 64E-5.1422 Pool Water Purity XIV-22
 64E-5.1423 Attendance During Operation..... XIV-22
 64E-5.1424 Entering and Leaving the Radiation Room..... XIV-23
 64E-5.1425 Irradiation of Explosive or Highly Flammable Materials XIV-23

SUBPART E RECORDS AND REPORTS

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

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

64E-5.1501Transportation of Radioactive Material..... XV-1

R2 64E-5.1502Transportation of Radioactive Material..... XV-1

64E-5.1503 Exemptions XV-2

64E-5.1504 General Licenses for Carriers XV-2

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

64E-5.1508 Inspection of Low-Level Radioactive Waste Shipments XV-6

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 XV-10

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 E_{max} for Beta Emitters..... XV-30

Table A-3 Relationship Between A₃ 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
- Protection Factors for Respirators July 1993
- 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)

PART I**GENERAL PROVISIONS**

R5	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

PART I

GENERAL PROVISIONS

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

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

- (11) "ALARA" means as low as reasonably achievable making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to use of nuclear energy and licensed or registered sources of radiation in the public interest.
- (12) "Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.
- (13) "Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.
- (14) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by Reference Man that would result in a committed effective dose equivalent of 5 rem (0.05 sievert) or a committed dose equivalent of 50 rem (0.5 sievert) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Columns 1 and 2.
- (15) "Area of use" means a portion of a physical structure that has been set aside to receive, use, or store radioactive material.

R3 (177) "Authorized nuclear pharmacist" means a pharmacist who is actively licensed
 R3 as a nuclear pharmacist by the Board of Pharmacy as specified in Rule
 R3 64B16-28.903, F.A.C., and is authorized on a radioactive materials license by
 R3 the department.

(16) "Authorized user" means a physician, dentist or podiatrist who is identified as an authorized user on a department, U.S. Nuclear Regulatory Commission, agreement state, or licensing state license that authorizes the medical use of radioactive material.

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

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

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

- R4 (20) "Bioassay" means the determination of kinds, quantities or concentrations, and in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.
- R4 (21) "Brachytherapy" means a method of radiation therapy in which sealed sources are used to deliver a radiation dose by surface, intracavitary, or interstitial application.
- R4 (22) "Byproduct material" means:
- (a) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and
 - (b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface waste resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute byproduct material within this definition.
- R4 (23) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure or cabinet that, independently of existing architectural structures except the floor on which it is placed, is intended to contain at least the portion of the material being irradiated, to provide radiation attenuation, and to exclude persons from its interior during generation of x-radiation. An x-ray tube used within a shielded part of a building or x-ray equipment that temporarily or occasionally incorporates portable shielding is not considered a cabinet x-ray system.
- R4 (24) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin on January 1 and subsequent calendar quarters shall be arranged so that no day is included in more than 1 calendar quarter, no calendar quarter, or part thereof, is included in more than 1 calendar year, and no day in any 1 year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him to determine calendar quarters for purposes of these rules except at the beginning of a calendar year.
- R4 (25) "Calibration" means:
- (a) The determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
 - (b) The determination of the strength of a source of radiation relative to a standard.

- R4 (26) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier or by civil aircraft.
- R4 (27) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.
- R4 (28) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.
- R4 (29) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.
- R4 (30) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum W_T H_{T,50}$).
- R4 (31) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.
- R2
- R5 (178) "Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.
- R5
- R4 (32) "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps).
- R4 (33) "Declared pregnant woman" means a woman who has voluntarily informed her employer in writing of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.
- R2
- R2
- R4 (34) "Dedicated check source" means a radioactive source that is used to assure the consistent operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.
- R4 (35) "Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter ($1,000 \text{ mg/cm}^2$).
- R4 (36) "Decommission" means to remove a facility safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license or release of the property under restricted conditions and the termination of the license.
- R5
- R5
- R4 (37) "Depleted uranium" means the source material uranium in which the isotope uranium 235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

- R4 (38) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3.
- R4 (39) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee can take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rem (0.05 sievert).
- R4 (40) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method and other instructions and precautions by which the licensee shall perform diagnostic clinical procedures. Each diagnostic clinical procedure shall be approved by the authorized user and shall include the radiopharmaceutical, dosage, and route of administration.
- R5 (179) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentrations of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.
- R4 (41) "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. For the purposes of these rules, "radiation dose" is an equivalent term.
- R4 (42) "Dose equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.
- R4 (43) "Dose limits" means the permissible upper bounds of radiation doses established as specified in these rules. For the purpose of these rules, "limits" is an equivalent term.
- R4 (44) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices to determine the radiation dose delivered to the monitoring devices.
- R4 (45) "Effective dose equivalent" (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$).
- R4 (46) "Embryo" or "fetus" means the developing human organism from conception until birth.

- R4 (47) "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.
- R4 (48) "Exposure", when used as a noun, means the quotient of dQ by dm , where " dQ " is the absolute value of the total charge of the ions of 1 sign produced in air when all the electrons, negatrons and positrons, liberated by photons in a volume element of air having mass " dm " are completely stopped in air. "Exposure", when used as a verb, means being exposed to ionizing radiation or to radioactive material. The special unit of exposure is the roentgen (R). See 64E-5.106 for the SI equivalent.
- R4 (49) "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.
- R4 (50) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.
- R4 (51) "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.
- R4 (52) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).
- R4 (53) "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.
- R4 (54) "Field station" means a temporary or portable facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.
- R4 (55) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.
- R4 (56) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

- R4 (57) "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
- R4 (58) "Healing arts" means professions concerned with diagnosis or treatment of human and animal maladies, including the practice of medicine, dentistry, veterinary medicine, osteopathy, chiropractic, podiatry and naturopathy.
- R4 (59) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates. For purposes of these rules, rooms or areas in which diagnostic x-ray systems are used for healing arts purposes are not considered high radiation areas.
- R2
- R4 (60) "Human use" means the internal or external administration of radiation or radioactive material to human beings.
- R4 (61) "Individual" means any human being.
- R4 (62) "Individual monitoring" means the assessment of:
- (a) Dose equivalent by the use of individual monitoring devices or by the use of survey data; or
 - (b) Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed.
- R4 (63) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters, pocket ionization chambers, and personal or lapel air sampling devices. For purposes of these rules, individual monitoring equipment and personnel monitoring equipment are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), optically stimulated luminescent devices (OSLDs), pocket ionization chambers, and personal air sampling devices.
- R2
- R4 (64) "Industrial radiography" means nondestructive testing using ionizing radiation to make radiographic images or radiographs to detect flaws in objects.
- R4 (65) "Inhalation class" (see "Class").
- R4 (66) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.
- R4 (67) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

- R4 (68) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.
- R4 (69) "Large irradiator" means an irradiator where radiation dose rates exceeding 500 rem (5 sieverts) per hour exist at 1 meter from the sealed radioactive sources in air or in water. This does not include irradiators in which both sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel, or to radioactive materials used for medical radiology, teletherapy, industrial radiography, gauging, calibration of radiation detection instruments, or open-field agricultural irradiations.
- R4 (70) "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at the tissue depth of 0.3 centimeter (300 mg/cm²).
- R2
- R2
- R4 (71) "License" means a license issued by the department in accordance with the rules adopted by the department.
- R4 (72) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the department.
- R4 (73) "Licensee" means any person who is licensed by the department in accordance with these rules and the Act.
- R4 (74) "Licensing State" means any state with rules equivalent to the Suggested State Regulations for Control of Radiation for the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.
- R4 (75) "Local components" means parts of an analytical x-ray system and includes areas that are struck by x-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but does not include power supplies, transformers, amplifiers, readout devices and control panels.
- R4 (76) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.
- R4 (77) "Logging tool" means a device used subsurface to perform well-logging.
- R4 (78) "Lost or missing licensed material" means licensed material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

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- R4 (79) "Low specific activity material (LSA)" means any of the following:
- (a) Uranium or thorium ores and physical or chemical concentrates of these ores;
 - (b) Unirradiated natural or depleted uranium or unirradiated natural thorium;
 - (c) Tritium oxide in aqueous solutions provided the concentration does not exceed 5.0 millicuries (185 MBq) per milliliter;
 - (d) Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration of contents does not exceed:
 - 1. 0.0001 millicurie (3.7 kBq) per gram of radionuclides for which the A_2 quantity is not more than 0.05 curie (1.85 GBq);
 - 2. 0.005 millicurie (185 kBq) per gram of radionuclides for which the A_2 quantity is more than 0.05 curie (1.85 GBq), but not more than 1 curie (37 GBq); or
 - 3. 0.3 millicurie (11.1 MBq) per gram of radionuclides for which the A_2 quantity is more than 1 curie (37 GBq).
 - (e) Objects externally contaminated with radioactive material, provided that the radioactive material is not readily dispersible and the surface contamination, when averaged over an area of 1 square meter, does not exceed 0.0001 millicurie (3.7 kBq) per square centimeter for radionuclides of which the A_2 quantity in Appendix A is not more than 0.05 curie (1.85 GBq), or, for all other radionuclides, 0.001 millicurie (37 kBq) per square centimeter.
- R4 (80) "Lung class" (see "Class").
- R4 (81) "Major processor" means a user processing, handling or manufacturing radioactive material exceeding A_2 quantities as unsealed sources or material, or exceeding 4 times A_1 quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. A_1 and A_2 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 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:
 - R2 1. Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
 - 2. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

- (c) A gamma stereotactic radiosurgery radiation dose:
- R2
1. Involving the wrong individual or wrong treatment site; or
 2. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.
- (d) A teletherapy, particle accelerator or therapeutic x-ray machine radiation dose:
- R2
1. Involving the wrong individual, wrong mode of treatment, or wrong treatment;
 2. When treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
 3. When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
 4. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.
- (e) A brachytherapy radiation dose:
- R2
1. Involving the wrong individual, wrong radioisotope, or wrong treatment site, excluding, for permanent implants, seeds that were implanted in the correct site but which migrated outside the treatment site;
 2. Involving a sealed source that is leaking;
 3. When, for a temporary implant, one or more seeds are not removed upon completion of the procedure; or
 4. When the calculated administered dose differs from the prescribed dose by more than 20 percent from the prescribed dose.

- (f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of iodine 123, iodine 125 or iodine 131 as sodium iodide, both:
- R2 1. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
- R2 2. When the dose to the individual exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.
- R4 (89) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, radiation monitoring and radiation protection monitoring are equivalent terms.
- R4 (90) "NARM" means any naturally occurring or accelerator-produced radioactive material. To meet the definition of licensing state, NARM only refers to discrete sources of NARM. Diffuse sources of NARM, which are large in volume and low in activity, are excluded from consideration by the Conference of Radiation Control Program Directors, Inc., for licensing state designation purposes.
- R4 (91) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
- R4 (92) "Nonstochastic effect" means a health effect the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.
- R4 (93) "Normal form" means radioactive material which has not been demonstrated to qualify as "special form"; also referred to as "nonspecial form."
- R4 (94) "Normal operating procedures" means operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.
- R4 (95) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.
- R4 (96) "Occupational dose" means the dose received by an individual in the course of employment which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background 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.
- R2
- R2
- R2

- R4 (97) "Offshore" means within the territorial waters of the State of Florida as specified
R4 in Article II, Section 1 of the Constitution of the State of Florida.
- R4 (98) "Open-beam configuration" means an analytical x-ray system in which an
individual could accidentally place some part of his body in the primary beam
path during normal operation.
- R4 (99) "Output" means the exposure rate, dose rate, or a quantity related in a known
manner to these rates from a teletherapy unit for a specified set of exposure
conditions.
- R4 (100) "Package" means the packaging, together with its radioactive contents, as
presented for transport.
- R4 (101) "Packaging" means, for radioactive materials, the assembly of components
necessary to ensure compliance with the packaging requirements of the U.S.
Nuclear Regulatory Commission and the U.S. Department of Transportation. It
may consist of one or more receptacles, absorbent materials, spacing structures,
thermal insulation, radiation shielding, and devices for cooling or absorbing
mechanical shocks. The conveyance, tie-down system, and auxiliary equipment
may sometimes be designated as part of the packaging.
- R4 (102) "Particle accelerator" means any machine capable of accelerating electrons,
protons, deuterons, or other charged particles in a vacuum and of discharging
the resultant particulate or other radiation into a medium at energies usually in
excess of 1 MeV.
- R4 (103) "Permanent radiographic installation" means an enclosed shielded room, cell, or
R4 vault, as specified in Rule 64E-5.431, F.A.C., in which industrial radiography is
R4 performed.
- R4 (104) "Permit" means the written authorization issued by the department for the
transportation of radioactive waste as described in Rule 64E-5.1509.
- R4 (105) "Personal supervision" means supervision in which the radiographer or logging
supervisor is physically present at the site where sources of radiation and
associated equipment are being used, watching the performance of the
radiographer's assistant or supervised individual and in such proximity that
immediate assistance can be given if required.
- R4 (106) "Planned special exposure" means an infrequent exposure to radiation, separate
from and in addition to the annual occupational dose limits.
- R4 (107) "Prescribed dosage" means the quantity of radiopharmaceutical activity as
documented:
- (a) In a written directive; or
 - (b) Either in the diagnostic clinical procedures manual or in any appropriate
record as specified in the directions of the authorized user for diagnostic
procedures.

- R4 (108) "Prescribed dose" means:
- (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.
- R2 (176) "Principal activities" means activities authorized by the license that are essential
R1 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
R1 activities incidental to decontamination or decommissioning are not principal
R1 activities.
- R4 (110) "Public dose" means the dose received by a member of the public from exposure
R2 to radiation or radioactive materials released by a licensee or registrant, or to any
R2 other sources of radiation under the control of the licensee or registrant. Public
R2 dose does not include occupational dose or doses received from background
R2 radiation, from any medical administration the individual has received, from
R2 exposure to individuals administered radioactive materials and released as
R2 specified in Rule 64E-5.622, F.A.C., or from voluntary participation in medical
R2 research programs.
- R4 (111) "Quality factor" (Q) means the modifying factor listed in the tables in
64E-5.106(3) and (4) used to derive dose equivalent from absorbed dose.
- R4 (112) "Quarter" means a period of time equal to one-fourth of the year observed by the
licensee or registrant of approximately 13 consecutive weeks. The beginning of
the first quarter in a year shall coincide with the starting date of the year and no
day shall be omitted or duplicated in consecutive quarters.
- R4 (113) "Rad" means the special unit of absorbed dose. One rad is equal to an
absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).
- R4 (114) "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons,
high-speed electrons, high-speed protons, and other particles capable of
producing ions. For purposes of these rules, "ionizing radiation" is an equivalent
term. Radiation, as used in these rules, does not include nonionizing radiation,
such as radio waves or microwaves, visible, infrared, or ultraviolet light.
- R4 (115) "Radiation area" means any area, accessible to individuals, in which radiation
levels could result in an individual's receiving a dose equivalent in excess of 0.05
mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from
any surface that the radiation penetrates.
- R4 (116) "Radiation machine" means any device capable of producing radiation except
those devices with radioactive material as the only source of radiation.

- R4 (117) "Radiation Safety Officer or RSO" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules.
- R4 (118) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.
- R4 (119) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.
- R4 (120) "Radiographer" means any individual who has completed successfully the training and testing requirements specified in Rule 64E-5.434(2), F.A.C., performs or personally supervises radiographic operations and is responsible to the licensee or registrant for assuring compliance with the requirements of these rules and all license or certificate of registration conditions.
- R4 (121) "Radiographer's assistant or assistant radiographer" means any individual who has completed successfully the training and testing requirements specified in Rule 64E-5.434(1), F.A.C., and who, under the personal supervision of a radiographer, conducts radiographic operations.
- R4 (122) "Radiographic exposure device" means any instrument containing a sealed source that is used to make a radiographic exposure. It also is known as a camera or a projector.
- 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

- (f) A teletherapy, particle accelerator or therapeutic x-ray machine radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

- R4 (124) "Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics can be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."
- R4 (125) "Registrant" means any person who is registered with the department and is legally obliged to register with the department pursuant to these rules and the Act.
- R4 (126) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR, Parts 100-189.
- R4 (127) "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).
- R4 (128) "Research and development" means:
- (a) Theoretical analysis, exploration or experimentation; or
 - (b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.
- R4 (129) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.
- R5 (180) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee but excludes background radiation. It also includes radioactive material as a result of routine or accidental releases of radioactive material at the site and previous burials at the site even if those burial sites were made as specified in Part III of this Chapter.
- R4 (130) "Restricted area" means an area, access to which is limited by the licensee or registrant to protect individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building can be set apart as a restricted area.
- R4 (131) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air.

- R4 (132) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.
- R4 (133) "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.
- R4 (134) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.
- R4 (135) "Shielded position" means the location within the radiographic exposure device
R4 or source changer where the sealed source is secured and restricted from
R4 movement by manufacturer's design.
- R4 (136) "Shielded-room radiography" means industrial radiography conducted in a room so shielded that radiation levels at every location on the exterior meet the limitations specified in Part III.
- R4 (137) "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.
- R4 (138) "SI" means an abbreviation of the International System of Units.
- R4 (139) "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 ($1 \text{ Sv} = 100 \text{ rem}$).
- R4 (140) "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.
- R4 (141) "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.
- R4 (142) "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.

R4 (143) "Source material milling" means any activity that results in the production of byproduct material as defined by 64E-5.101.

R4 (144) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

R4 (145) "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.

R4 (146) "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:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

R1

R4 (147) "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.

R4 (148) "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.

- R4 (149) "Storage area" means any location, facility, or vehicle which is used to store, transport, or secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.
- R4 (150) "Storage container" means a container in which sealed sources are secured and stored.
- R4 (151) "Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.
- R4 (152) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal or presence of sources of radiation. When appropriate, such evaluation includes tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.
- R4 (153) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
- R4 (154) "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.
- R4 (155) "Temporary job site" means a site, base or facility that is created and maintained to support a single job lasting for less than 2 years.
- R4 (156) "Test" means the process of verifying compliance with an applicable rule.
- R4 (157) "Total effective dose equivalent" means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.
- R4 (158) "Type B packaging" means a packaging designed to retain the integrity of containment and shielding required by U.S. Nuclear Regulatory Commission and U.S. Department of Transportation regulations when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR, Part 71.
- R4 (159) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating or refining.
- R4 (160) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

- R4 (161) "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof as specified in sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy as specified in section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)
- R4 (162) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess to 500 rad (5 gray) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.
- R4 (163) "Visiting authorized user" means an authorized user who is not identified on the license.
- R4 (164) "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.
- R4 (165) "Weighting factor" (W_T) for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

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

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

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

- R4 (166) "Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed
- R4 (167) "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.
- R4 (168) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.
- R4 (169) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.
- R4 (170) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.
- R4 (171) "Worker" means an individual engaged in work in a restricted area under the authority of a license or registration issued by the department.
- R4 (172) "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy. The short-lived radon daughters are:
- (a) For radon 222: polonium 218, lead 214, bismuth 214, and polonium 214;
 - (b) For radon 220: polonium 216, lead 212, bismuth 212, and polonium 212.
- R4 (173) "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.
- R4 (174) "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.

R4 (175) "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.

R1 Editor's Note: Definitions have been alphabetized effective, May 15, 1996. (Principal activity
 R2 (176) added alphabetically May 18, 1998. Authorized Nuclear Pharmacist (177) added August 8, 2001
 R5 (178) Critical Group, (179) Distinguishable from background, (180) Residual radioactivity added
 R5 alphabetically December 19, 2001.)

Specific Authority: 404.051, 404.061, F.S.

Law Implemented: 404.031, 404.061(2), 404.20, 404.22, 404.30, F.S.

History: New July 17, 1985, Amended April 4, 1989, Amended May 12, 1993, Amended January 1, 1994,

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

33,R4,R5 Amended August 6, 2001, Amended September 11, 2001, December 19, 2001.

64E-5.102 Exemptions.

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

- (d) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine:
1. That the exemption of the prime contractor or subcontractor is authorized by law; and
 2. That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health, safety and environment.

Specific Authority: 404.051, 404.061, F.S.

Law Implemented: 404.051(10), 404.061(4), 404.111(3), 404.121(1), 404.20, F.S.

History: New July 17, 1985, Amended May 12, 1993, Formerly 10D-91.103.

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

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

Law Implemented: 404.022, 404.061(2), 404.081, 404.20(2), 404.22(2), F.S.

History: New July 17, 1985, Formerly 10D-91.104.

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

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

Specific Authority: 404.051, 404.061, F.S.

Law Implemented: 404.022, 404.051(1)(7), 404.061(2), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.106.

64E-5.105 Prohibited Uses.

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

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

Law Implemented: 404.022, 404.051, 404.061(2), 404.141, 404.22(3), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.110.

64E-5.106 Units of Exposure and Dose.

- (1) As used in these regulations, the unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air.
- (2) As used in these regulations, the units of dose are:
- (a) Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
 - (b) Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).
 - (c) Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).
 - (d) Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).
- (3) As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown below:

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

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

- (4) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 64E-5.106, above, 0.01 Sv (1 rem) of neutron radiation of unknown energies can, for purposes of these regulations, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant can use the fluence rate per unit dose equivalent or the appropriate Q value from the table below to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FORM MONOENERGETIC NEUTRONS				
(thermal)	Neutron Energy (MeV)	Quality Factor^a (Q)	Fluence per Unit Dose Equivalent^b (neutrons) (cm⁻² rem⁻¹)	Fluence per Unit Dose Equivalent^b (neutrons) (cm⁻² rem⁻¹)
	2.5×10^{-8}	2	980×10^6	980×10^8
	1.0×10^{-7}	2	980×10^6	980×10^8
	1.0×10^{-6}	2	810×10^6	810×10^8
	1.0×10^{-5}	2	810×10^6	810×10^8
	1.0×10^{-4}	2	840×10^6	840×10^8
	1.0×10^{-3}	2	980×10^6	980×10^8
	1.0×10^{-2}	2.5	1010×10^6	1010×10^8
	1.0×10^{-1}	7.5	170×10^6	170×10^8
	5.0×10^{-1}	11	39×10^6	39×10^8
	1	11	27×10^6	27×10^8
	2.5	9	29×10^6	29×10^8
	5	8	23×10^6	23×10^8
	7	7	24×10^6	24×10^8
	10	6.5	24×10^6	24×10^8
	14	7.5	17×10^6	17×10^8
	20	8	16×10^6	16×10^8
	40	7	14×10^6	14×10^8
	60	5.5	16×10^6	16×10^8
	100	4	20×10^6	20×10^8
	200	3.5	19×10^6	19×10^8
	300	3.5	16×10^6	16×10^8
	400	3.5	14×10^6	14×10^8

- a Value of quality factor at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.
- b Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

Specific Authority: 404.042, 404.051, 404.061, F.S

Law Implemented: 404.022(2), F.S.

History: New January 1, 1994, Formerly 10D-91.113

PART II LICENSING OF RADIOACTIVE MATERIALS

R2 64E-5.201Licensing of Radioactive Material..... II-1
 64E-5.202 Source Material - Exemptions II-2
 R2 64E-5.203Radioactive Material Other than Source Material - Exemptions II-4

SUBPART A LICENSE TYPES AND FEES

R2 64E-5.204 Types of Licenses II-10

SUBPART B GENERAL LICENSES

64E-5.205 General Licenses - Source Material..... II-15
 64E-5.206 General Licenses - Radioactive Material Other Than Source Material II-17

SUBPART C SPECIFIC LICENSES

64E-5.207 Filing Application for Specific Licenses..... II-30
 64E-5.208 General Requirements for the Issuance of Specific Licenses II-30
 64E-5.209 Special Requirements for Specific Licenses of Broad Scope II-31
 R3 64E-5.210 Special Requirements for a Specific License to Manufacture,
 Assemble, Repair or Distribute Commodities, Products or Devices
 which Contain Radioactive Material II-35
 64E-5.211 Special Requirements for Issuance of Specific Licenses for
 Source Material Milling..... II-54
 64E-5.212 Issuance of Specific Licenses II-57
 R1 64E-5.213 Specific Terms and Conditions of Licenses II-58
 R5 64E-5.214 Expiration and Termination of Licenses and Decommissioning II-60
 of Building Outdoor Areas
 64E-5.215 Transfer of Material..... II-63

SUBPART D RECIPROCITY

R2 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 II-65

SUBPART E BONDING

64E-5.217 Bonding of Persons Licensed Pursuant to Subpart C II-67

SUBPART F INSPECTION AND ENFORCEMENT

64E-5.218 Performance of Inspections II-70
 64E-5.219 Emergency Planning..... II-71
 64E-5.220 Radioactive Quantities II-75

SUBPART G RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

R5	64E-5.221..... Radiological Criteria for License Termination	II-78a
R5	64E-5.222..... Radiological Criteria for Unrestricted Use.....	II-78a
R5	64E-5.223..... Radiological Criteria for License Termination Under Restricted Conditions.....	II-78a
R5	64E-5.224..... Alternate Criteria for License Termination	II-78c
R5	64E-5.225..... Public Notification and Public Participation.....	II-78d
R5	64E-5.226..... Minimizing Contamination.....	II-78d
	Schedule A... Exempt Concentrations	II-79
	Schedule B... Exempt Quantities	II-84
	Schedule D... Limits for Broad License	II-90

PART II

LICENSING OF RADIOACTIVE MATERIALS

64E-5.201 Licensing of Radioactive Material.

- (1) This part provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this part or as otherwise provided in this part. Unless otherwise specified in the license or these rules, no licensee shall use radioactive materials:
 - (a) In or on human beings;
 - (b) In field applications where radioactive materials is released to the environment;
 - (c) In products distributed to the public;
 - (d) In animals, plants, or their products which will be used for human consumption; or
 - (e) In plants or animals where their products are released to the environment
- (2) In addition to the requirements of this part, all licensees are subject to the requirements of Parts I, III, IX and XV. Licensees engaged in industrial radiographic operations are also subject to the requirements of Part IV, licensees using radionuclides in the healing arts are subject to the requirements of Part VI and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part XI.
- R2 (3) The Procedures for Radioactive Materials Enforcement Actions, May 2000, which is available from the department and which is herein incorporated by reference, will be used to determine enforcement actions to be taken.
- (4) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the law, or because of conditions revealed by such application or statement of fact on any report, record or inspection or other means which would warrant the department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the law or of the license, a rule, or an order of the department.

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

R1 Law Implemented: 404.022, 404.051(1),(4),(6), 404.061(2), 404.081(1), 404.091, 404.141, 404.161, 401.162, 404.20(1)F.S.

R1 History: New July 17, 1985, Amended August 25, 1991, Amended May 12, 1993,
Amended, May 15, 1996, Formerly 10D-91.301, Amended October 8, 2000.

64E-5.202 Source Material - Exemptions

- (1) Any person is exempt from this part to the extent that such person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of 1 percent of the mixture, compound, solution or alloy.
- (2) Any person is exempt from this part to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.
- (3) Any person is exempt from this part to the extent that such person receives, possesses, uses or transfers:
 - (a) Any quantities of thorium contained in:
 1. Incandescent gas mantles;
 2. Vacuum tubes;
 3. Welding rods;
 4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium;
 5. Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium;
 6. Rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these; or
 7. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
 - (b) Source material contained in the following products:
 1. Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material;
 2. Glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, ceramic tile or other glass, or ceramic used in construction;

3. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or
 4. Piezoelectric ceramic containing not more than 2 percent by weight source material;
- (c) Photographic film, negatives, and prints containing uranium or thorium;
- (d) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;
- (e) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:
1. The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40;
 2. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM" or "CAUTION - RADIOACTIVE MATERIAL - URANIUM" if manufactured prior to December 31, 1969;
 3. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED", unless manufactured prior to December 31, 1969, and impressed with the legend "CAUTION - RADIOACTIVE MATERIAL - URANIUM".
 4. This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;
- (f) Natural or depleted uranium metal used as shielding constituting part of any shipping container provided that the shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2 mm).

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- (g) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:
1. The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alterations of the lens; or
 2. The receipt, possession, use or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;
- (h) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or
- (i) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
1. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria or thorium dioxide; and
 2. The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.
- (4) The exemptions in this section do not authorize the manufacture of any of the products described.

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

Law Implemented: 404.022, 404.051(1)(4), 404.141, F.S.

History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.302

64E-5.203 Radioactive Material Other Than Source Material - Exemptions.

- (1) Exempt Concentrations.
- (a) Except as provided in this section, any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Schedule A.
 - (b) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under (1)(a), above, or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or Licensing State, except in accordance with a specific license issued pursuant to 64E-5.210 or the general license provided in 64E-5.216.
- (2) Exempt Quantities.
- (a) Except as provided in (2)(b) and (c), below, any person is exempt from

these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B.

- (b) This paragraph does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
 - (c) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this section or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to Section 32.18 of 10 CFR Part 32, or by the department, pursuant to 64E-5.210(2), which license states that the radioactive material may be transferred by the licensee to persons exempt under this subsection or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or Licensing State. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C., 20555.
- (3) Exempt Items.
- (a) Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns or acquires the following products. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C., 20555:
 - 1. Timepieces, hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified amount of radioactive material or dose rate, as applicable:
 - a. Twenty-five millicuries (925 MBq) of tritium per timepiece;
 - b. Five millicuries (185 MBq) of tritium per hand;

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- c. Fifteen millicuries (555 MBq) of tritium per dial; bezels when used shall be considered as part of the dial;
 - d. One hundred microcuries (3.7 MBq) of promethium 147 per watch or two hundred microcuries (7.4 MBq) of promethium 147 per any other timepiece;
 - e. Twenty microcuries (0.74 MBq) of promethium 147 per watch hand or 40 microcuries (1.48 MBq) of promethium 147 per other timepiece hand;
 - f. Sixty microcuries (2.22 MBq) of promethium 147 per watch dial or 120 microcuries (4.44 MBq) of promethium 147 per other timepiece dial; bezels, when used, shall be considered as part of the dial; and
 - g. The radiation dose rate from hands and dials containing promethium 147 or radium 226 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
 - (I) For wrist watches, 0.1 millirad (1 μ Gy) per hour at 10 centimeters from any surface;
 - (II) For pocket watches, 0.1 millirad (1 μ Gy) per hour at 1 centimeter from any surface. Radium shall not be used for pocket watches; and
 - (III) For any other timepiece, 0.2 millirad (2 μ Gy) per hour at 10 centimeters from any surface.
 - h. One microcurie (37 kBq) of radium 226 per timepiece in timepieces acquired prior to January 1, 1989.
2. Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than 2 millicuries (74 MBq) of promethium 147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium 147 will not exceed 1 millirad (10 μ Gy) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

3. Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part.
4. Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.
5. Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas.
6. Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat.
7. Electron tubes, including spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents; provided, that the radiation dose rate from each electron tube containing radioactive material shall not exceed 1 millirad (10 μ Gy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber, and that each tube does not contain more than one of the following specified quantities of radioactive material:
 - a. One hundred fifty millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.
 - b. One microcurie (37 kBq) of cobalt 60.
 - c. Five microcuries (185 kBq) of nickel 63.
 - d. Thirty microcuries (1.11 MBq) of krypton 85.
 - e. Five microcuries (185 kBq) of cesium 137.
 - f. Thirty microcuries (1.11 MBq) of promethium 147.
8. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:
 - a. Each source contains no more than one exempt quantity set forth in Schedule B, and

by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR, Part 32; or a Licensing State pursuant to 64E-5.210(3), which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements. Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing by-product material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

2. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under (3)(c)1., above, provided that the device is labeled in accordance with the specific license authorizing distribution of devices under a general license, and provided further that they meet the requirements of 64E-5.210 (3).
 3. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under (3)(c)1., above, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 64E-5.210 (3).
- (d) Resins Containing Scandium 46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium 46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR, Part 32. This exemption does not authorize the manufacture of any resins containing scandium 46.

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- (4) Radioactive drug: capsules containing carbon 14 urea for in vivo diagnostic use for humans.

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- (a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in these regulations if such person receives, possesses, uses, transfers, owns, or acquires capsules containing 1 microcurie (37 kBq) carbon 14 urea each, allowing for nominal variation that can occur during the manufacturing process, for in vivo diagnostic use for humans.

- R2 (b) Any person who desires to use the capsules for research involving human
R2 subjects shall apply for and receive a specific license as specified in these
R2 regulations.
- R2 (c) Any person who desires to manufacture, prepare, process, produce,
R2 package, repackage, or transfer for commercial distribution such capsules
R2 shall apply for and receive a specific license as specified in 10 CFR Part
R2 32, Sec. 32.21.
- R2 (d) Nothing in this section relieves a person from complying with applicable
R2 FDA, other Federal, and State requirements governing receipt,
R2 administration, and use of drugs

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

Law Implemented: 404.022, 404.051(1)(4)(10), 404.141, F.S.

R2 History: New July 17, 1985, Amended April 4, 1989, May 15, 1996, Formerly 10D-91.303, Amended October 8, 2000.

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**SUBPART A
LICENSE TYPES AND FEES**

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

- (1) Some general licenses provided in this part may be effective without the filing of applications with the department or the issuance of licensing documents to the particular persons, although the filing of a certificate with the department for general licenses pursuant to 64E-5.206(7) or (8) shall be required of the particular general licensee prior to the receipt of radioactive material. The payment of a fee is also required by all persons possessing general licensed material described in (1)(c), below. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.
- (a) The annual registration fee set forth in this section for general licenses shall be payable every July 1, for as long as the license remains in effect.
- (b) The annual fee for a general license set forth in 64E-5.216 under reciprocal agreement shall be paid before the first entrance into the State and on each anniversary date thereafter, if applicable. Manufacturers, manufacturer's representatives, distributors, and waste treatment, storage or disposal companies servicing Florida radioactive materials license applicants or licensees are exempt from this fee.
- (c) Payment of the indicated annual fee pursuant to (1)(a), above, is required for the following types of devices held or activities performed under a general license:
1. Static elimination devices
as described in 64E-5.206(1)(a).....\$25.00 per unit.
 2. Measuring, gauging, and control devices
as described in 64E-5.206(4).....\$25.00 per unit.
 3. *In Vivo* testing
as described in 64E-5.206(7)..... \$125.00 per license.
 4. *In Vitro* testing
as described in 64E-5.206(8)..... \$125.00 per license.
 5. Depleted uranium
as described in 64E-5.206(4)..... \$125.00 per license.

- (d) Those persons who hold a specific license from the U.S. Nuclear Regulatory Commission, an agreement state or licensing state and conduct activities under a reciprocal agreement with this State shall meet the requirements of 64E-5.216(1), and pay the annual fee as specified in (2)(e), below.
- (2) Specific licenses require the submission of an application to the department and the issuance of a licensing document by the department. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document. The licensee is subject to the payment of fees as authorized under section 404.131, Florida Statutes and as outlined below:
- (a) The requirements of this part apply to a person who is an applicant for, or holder of a specific radioactive materials license issued pursuant to Subpart III C, and for a special review of safety designs of sealed sources and devices, whether or not in conjunction with a license application on file or which may be filed.
- (b) All communications concerning the requirements of this part should be addressed to or delivered in person to the Department of Health, Bureau of Radiation Control, Bin #C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741.
- (c) No additional fees shall be required for amendments to licenses.
- (d) Payment of fees.
1. Application fees. Each application for a specific license for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. No application will be processed prior to payment of the fee specified herein. The application-fee is not refundable except in those cases where the department has determined that a license is not required. The department will consider any application abandoned if the department does not receive a reply within 90 days to its most recent request for additional information. In such cases, the applicant must submit a new application with the application fee specified herein.
 2. Annual fees. All current specific licenses that were in effect on January 1, 1979, are subject to payment of the annual fee prescribed herein and on every January 1, thereafter, as long as the license remains in effect. All specific licenses issued after January 1, 1979, are subject to payment of the annual fee specified in this section within 60 days of issuance of the license and on each anniversary date thereafter. The annual fee is not refundable except in those cases where the department has determined that the fee is not required.

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

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

		APPLICATION FEE	ANNUAL FEE
	1. SOURCE MATERIAL.		
R1	a. Licenses for concentration of uranium from phosphate ores for the production of uranium as "yellow cake" or powdered solid;	\$6,907	\$11,942
R1	b. License for concentration of uranium from phosphate ores for the production of "green cake" or equivalent, moist or solid;	\$3,768	\$7,439
R1	c. All other specific source material licenses excluding depleted uranium used as shielding and counterweights.	\$544	\$229
	2. SPECIAL NUCLEAR MATERIAL (SNM).		
R1	a. Licenses for use of SNM in sealed sources contained in devices used in measuring systems;	\$653	\$518
R1	b. Licenses for use of SNM not sufficient to form a critical mass, except as in 2.a., above, and 2.c. and 5.e., below	\$1,340	\$1,944
R1	c. Licensed for use of SNM to be used as calibration and reference sources	\$205	\$109
	3. BY-PRODUCT, NATURALLY OCCURRING OR ACCELERATOR PRODUCED MATERIAL		
R1	a. Licenses for processing or manufacturing for commercial distribution or industrial uses;	\$2,923	\$2,802
R1	b. Licenses for processing or manufacturing and distribution of radiopharmaceuticals. This category includes radiopharmacies;	\$2,560	\$3,840
R1	c. Licenses industrial radiography performed only in an approved shielded radiography installation;	\$1,558	\$2,161
R1	d. Licenses for industrial radiography performed only at the address indicated in the license, or at temporary job sites of the licensee;	\$1,643	\$2,657

	3.	BY-PRODUCT, NATURALLY OCCURRING OR ACCELERATOR PRODUCED MATERIAL		
R1	e.	Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials where the source is not removed from the shield and is less than 10,000 curies;	\$605	\$605
R1	f.(I)	Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is not removed from the shield and is greater than 10,000 curies and less than 100,000 curies or where the source is less than 100,000 curies and is removed from the shield;	\$1,414	\$1,630
R1	f.(II)	Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is greater than 100,000 curies and less than 1,000,000 curies;	\$3,659	\$3,961
R1	f.(III)	Licenses for possession and use of radioactive materials in sealed sources for irradiation of materials when the source is greater than 1,000,000 curies;	\$9,780	\$4,398
R1	g.	Licenses issued to distribute items containing radioactive materials to persons under a general license;	\$1,643	\$2,150
R1	h.	Licenses issued to distribute exempt quantities or items containing naturally occurring or accelerator produced material exempt from licensing;	\$1,643	\$2,150
	i.	Well logging		
R1	(I)	Sealed sources or sub-surface tracer studies	\$1,135	\$1,498
R1	(II)	Sub-surface tracer studies and sealed sources	\$1,436	\$1,594
R1	j.	Nuclear Laundry;	\$3,200	\$5,651
R1	k.	Industrial or Medical Research and Development	\$1,184	\$1,474
R1	I.(I)	Fixed and portable gauging devices	\$605	\$966
R1	(II)	In Vitro and clinical laboratory	\$725	\$918
R1	(III)	Academic	\$978	\$1,171
R1	(IV)	Possession of uranium or thorium, or their decay products as a result of mining or processing	\$978	\$870
R1	(V)	All other specific license except otherwise noted	\$725	\$1,002

	3.	BY-PRODUCT, NATURALLY OCCURRING OR ACCELERATOR PRODUCED MATERIAL		
	m.	Licenses of broad scope		
R1	(I)	Academic	\$3,200	\$7,346
R1	(II)	Medical	\$3,200	\$5,474
R1	(III)	Industrial or Research and Development	\$3,200	\$4,568
R1	n.	Gas chromatography devices	\$434	\$314
R1	o.	Reference or calibration sources equal to or less than one millicurie total;	\$314	\$132
R1	p.	Nuclear service licenses, such as, leak testing, instrument calibration, etc.;	\$518	\$410
	4.	WASTE DISPOSAL OR PROCESSING		
R1	a.	Commercial waste disposal or treatment facilities, including burial or incineration	\$275,842	\$250,555
R1	b.	All other commercial facilities involving compaction, repackaging storage or transfer.	\$27,084	\$24,971
R1	c.	Commercial treatment of radioactive materials for release to unrestricted areas	\$5,760	\$5,735
	5.	MEDICAL USE		
R1	a.	Teletherapy or high dose rate remote afterloading devices	\$1,414	\$1,378
R1	b,	Medical institutions, including hospitals, except category 5.a. and 5.e.	\$1,643	\$1,908
R1	c.	Private practice physicians except category 5.a. and 5.d.	\$1,184	\$1,340
R1	d.	Private practice physicians using only strontium 90 eye applicators, materials authorized by 64E-5.631, and materials authorized by 64E-5.630	\$605	\$748
R1	e.	Nuclear powered pacemakers	\$434	\$266
R1	f.	Mobile nuclear medicine services	\$1,414	\$1,625
R1	6.	CIVIL DEFENSE	\$544	\$821

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

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

R1 Law Implemented: 404.032, 404.061, 404.051(1)(4)(10), 404.131(1), F.S.

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

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

SUBPART B GENERAL LICENSES

64E-5.205 General Licenses - Source Material.

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

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

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

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

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

History: New July 17, 1985, Formerly 10D-91.305.

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

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

- (a) Static Elimination Devices. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium 210 per device; and
 - (b) Ion Generating Tubes. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium 210 per device or a total of not more than 50 millicuries (1.85 GBq) of tritium per device.
- (2) Reserved
- (3) Reserved
- (4) Certain Measuring, Gauging and Controlling Devices.
- (a) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their businesses, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of (4)(b), (c) and (d), below, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.
 - (b) The general license in (4)(a), above, applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to 64E-5.210(4) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State, which authorizes distribution of devices to persons granted a general license by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of 21 CFR Part 179.
 - (c) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in (4)(a), above;

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

6. Shall not abandon the device containing radioactive material;
7. Except as provided in (4)(c)8., below, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State, whose specific license authorizes him to receive the device, and within 30 days after transfer of a device to a specific licensee, shall furnish to the department a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;
8. Shall transfer the device to another general licensee only:
 - a. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation 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 name and model number of device transferred, the name and address of the transferee, and the name or position of an individual who may constitute a point of contact between the department and the transferee; or
 - b. Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and
9. Shall comply with the provisions of 64E-5.343 and 64E-5.344 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Parts III and IX.

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

- (e) The general license provided in (4)(a), above, is subject to the provisions of 64E-5.103 through 64E-5.104, 64E-5.213, 64E-5.215 and Part XV.
- (5) Luminous Safety Devices for Aircraft.
- (a) A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium 147 contained in luminous safety devices for use in aircraft, provided:
 - 1. Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium 147; and
 - 2. Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in section 32.53 of 10 CFR Part 32.
 - (b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in (5)(a), above, are exempt from the requirements of Parts III and IX except that they shall comply with the provisions of 64E-5.343 and 64E-5.344.
 - (c) This general license does not authorize the manufacture, assembly or repair of luminous safety devices containing tritium or promethium 147.
 - (d) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium 147 contained in instrument dials.
 - (e) 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.
- (6) Calibration and Reference Sources.
- (a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of (6)(d) and (e), below, americium 241 in the form of calibration or reference sources:

1. Any person who holds a specific license issued by the department which authorizes him to receive, possess, use and transfer radioactive material; and
 2. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use and transfer special nuclear material.
- (b) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of (6)(d) and (e), below, to any person who holds a specific license issued by the department which authorizes him to receive, possess, use and transfer radioactive material.
- (c) A general license is hereby issued to own, receive, possess, use and transfer radium 226 in the form of calibration or reference sources in accordance with the provisions of (6)(d) and (e), below, to any person who holds a specific license issued by the department which authorizes him to receive, possess, use and transfer radioactive material.
- (d) The general licenses in (6)(a), (b) and (c), above, apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to section 32.57 of 10 CFR Part 32 or section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the department, an agreement state or Licensing State pursuant to licensing requirements equivalent to those contained in section 32.57 of 10 CFR Part 32 or section 70.39 of 10 CFR Part 70.
- (e) The general licenses provided in (6)(a), (b) and (c), above, are subject to the provisions of 64E-5.103 through 64E-5.104, 64E-5.213, 64E-5.215, Parts III, IX and XV. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:
1. Shall not possess at any given time, at any single location of storage or use, more than 5 microcuries (185 kBq) of americium 241, 5 microcuries (185 kBq) of plutonium, or 5 microcuries (185 kBq) of radium 226 in such sources;
 2. Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:
 - a. The receipt, possession, use and transfer of this source,

model _____, serial no. _____, are subject to a general license and the regulations 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. Do not remove this label. CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM 241) (PLUTONIUM). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

- b. The receipt, possession, use and transfer of this source, model _____, serial no. _____, are subject to a general license and the regulations of a Licensing State. Do not remove this label. CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM 226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

3. Shall not transfer, abandon or dispose of such source except by transfer to a person authorized by a license from the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to receive the source;
 4. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium 241, plutonium or radium 226, which might otherwise escape during storage; and
 5. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.
- (f) These general licenses do not authorize the manufacture of calibration or reference sources containing americium 241, plutonium or radium 226.

(7) Medical Diagnostic Uses.

- (a) A general license shall be issued to any physician to receive, possess, transfer or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of (7)(b), (c) and (d), below, the radioactive material is in the form of capsules, disposable syringes or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued by the department pursuant to 64E-5.210(7), or by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State pursuant to equivalent regulations authorizing distribution to persons under a general license pursuant to this subsection or its equivalent:
1. Chromium 51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time;
 2. Cobalt 57 for the measurement of intestinal absorption of cyanocobalamin;
 3. Cobalt 58 for the measurement of intestinal absorption of cyanocobalamin;
 4. Cobalt 60 for the measurement of intestinal absorption of cyanocobalamin;
 5. Iodine 125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;
 6. Iodine 131 as sodium iodide for measurement of thyroid uptake; and
 7. Iodine 131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.
- (b) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license established by (7)(a), above, until he has submitted the information requested on DH Form 361, entitled "Certificate - Medical Use of Radioactive Material under General License", which is herein incorporated by reference effective July 17, 1985, with the department and received from the department a validated copy of this form with certification number assigned.

- (c) A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by (7)(a), above, shall comply with the following:
1. The physician shall not possess at any given time, pursuant to the general license in (7)(a), above, more than
 - a. Two hundred microcuries (7.4 MBq) of iodine 131,
 - b. Two hundred microcuries (7.4 MBq) of iodine 125,
 - c. Five microcuries (185 kBq) of cobalt 57,
 - d. Five microcuries (185 kBq) of cobalt 58,
 - e. Five microcuries (185 kBq) of cobalt 60,
 - f. Two hundred microcuries (7.4 MBq) of chromium 51;
 2. The physician shall store the pharmaceutical in the original shipping container until administered, or in a container providing equivalent radiation protection;
 3. The physician shall use the pharmaceutical only for the uses authorized by (7)(a), above;
 4. The physician shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the U.S. Nuclear Regulatory Commission, an agreement state or Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.
- (d) The general licensed physician possessing or using radioactive material under the general license of (7)(a), above, shall report in duplicate to the department any changes in the information furnished by him on DH Form 361. The report shall be submitted within 30 days after the effective date of such change.
- (e) Any person using radioactive material pursuant to the general license of (7)(a), above, is exempt from the requirements of Parts III and IX with respect to the radioactive material covered by the general license.
- (f) Manufacturers of radiopharmaceuticals which are under the general license in this subsection are required to affix a certain identifying label to the container, and in the leaflet or brochure which accompanies the radiopharmaceutical, pursuant to 64E-5.210(7).

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- (8) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.
- (a) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of (8)(b), (c), (d), (e) and (f), below, the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:
1. Carbon 14, in units not exceeding 10 microcuries (370 kBq) each.
 2. Cobalt 57, in units not exceeding 10 microcuries (370 kBq) each.
 3. Hydrogen 3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
 4. Iodine 125, in units not exceeding 10 microcuries (370 kBq) each.
 5. Mock Iodine 125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine 129 and 0.005 microcurie (0.185 kBq) of americium 241 each.
 6. Iodine 131, in units not exceeding 10 microcuries (370 kBq) each.
 7. Iron 59, in units not exceeding 20 microcuries (740 kBq) each
 8. Selenium 75, in units not exceeding 10 microcuries (370 kBq) each
- (b) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by (8)(a), above, until he has submitted, in triplicate, the information requested on DH Form 360, entitled "Certificate - In Vitro Testing with Radioactive Material under General License", which is herein incorporated by reference effective July 17, 1985, with the department and received from the department a validated copy of the "Certificate - In Vitro Testing with Radioactive Material under General License" with a certification number assigned.
- (c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by (8)(a), above, shall comply with the following:
1. The general licensee shall not possess at any given time, pursuant to the general license in (8)(a), above, at any single location of storage or use, a combined total amount of iodine 125, iodine 131, selenium 75, iron 59 or cobalt 57 in excess of 200 microcuries (7.4 MBq).

2. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
 3. The general licensee shall use the radioactive material only for the uses authorized by (8)(a), above.
 4. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the U.S. Nuclear Regulatory Commission, an agreement state or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
 5. The general licensee shall dispose of the mock iodine 125 reference or calibration sources described in (8)(a), above, as required by 64E-5.328.
- (d) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to (8)(a), above;
1. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 64E-5.210(8) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state or Licensing State which authorizes the manufacture and distribution of iodine 125, iodine 131, carbon 14, hydrogen 3 (tritium), iron 59, selenium 75, cobalt 57 or mock iodine 125 to persons under a general license described in this subsection or its equivalent, and
 2. Unless one of the following statements, as appropriate or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

- a. This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

- b. This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

Name of manufacturer

- (e) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of (8)(a), above, shall report in writing to the department any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License". The report shall be furnished within 30 days after the effective date of such change.
- (f) Any person using radioactive material pursuant to the general license of (8)(a), above, is exempt from the requirements of Parts III and IX with respect to radioactive material covered by that general license, except that such persons using the mock iodine 125 described in (8)(a)5., above, shall comply with the provisions of 64E-5.328, 64E-5.343 and 64E-5.344.
- (g) The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

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

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

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

History: New July 17, 1985, amended April 4, 1989, Amended January 1, 1994, Formerly 10D-91.306.

**SUBPART C
SPECIFIC LICENSES**

64E-5.207 Filing Application for Specific Licenses.

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

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

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

History: New July 17, 1985, Amended April 4, 1989, Amended May 12, 1993, Amended, May 15, 1996, Formerly 10D-91.307.

64E-5.208 General Requirements for the Issuance of Specific Licenses. A

license application for a new, amended, or renewed license will be approved if the department determines that:

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

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

Law Implemented: 404.022, 404.051(1),(4),(6),(10),(11), 404.061(2), 404.141, F.S.

History: New July 17, 1985, Amended May 12, 1993, Amended, May 15, 1996, Formerly 10D-91.308.

64E-5.209 Special Requirements for Specific Licenses of Broad Scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses. Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing by-product material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

- (1) The different types of broad scope licenses are set forth below:
 - (a) A Type A specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.
 - (b) A Type B specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D of this part, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
 - (c) A Type C specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D of this part, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

- (2) An application for a Type A specific license of broad scope will be approved if:
- (a) The applicant satisfies the general requirements specified in 64E-5.208.
 - (b) The applicant has engaged in more than one type of activity involving the use of radioactive material; and
 - (c) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:
 - 1. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;
 - 2. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and
 - 3. The establishment of appropriate administrative procedures to assure:
 - a. Control of procurement and use of radioactive material;
 - b. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the users, and the operating or handling procedures; and
 - c. Review, approval and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with (2)(c)3.b., above, prior to use of the radioactive material.

- (3) An application for a Type B specific license of broad scope will be approved if:
- (a) The applicant satisfies the general requirements specified in 64E-5.208; and
 - (b) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:
 - 1. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and
 - 2. The establishment of appropriate administrative procedures to assure,
 - a. Control of procurement and use of radioactive material,
 - b. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and
 - c. Review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with (3)(b)2.b., above, prior to use of the radioactive material.
- (4) An application for a Type C specific license of broad scope will be approved if
- (a) The applicant satisfies the general requirements specified in 64E-5.208;
 - (b) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:
 - 1. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and
 - 2. At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and
 - (c) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record

keeping, material control and accounting, and management review necessary to assure safe operations.

- (5) Specific licenses of broad scope are subject to the following conditions:
- (a) Unless specifically authorized, persons licensed pursuant to this section shall not:
 - 1. Conduct tracer studies in the environment involving direct release of radioactive material;
 - 2. Receive, acquire, own, possess, use or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;
 - 3. Conduct activities for which a specific license issued by the department under 64E-5.210 or 64E-5.211 is required; or
 - 4. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.
 - (b) Each Type A specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.
 - (c) Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.
 - (d) Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of (4), above.

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

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

History: New July 17, 1985, Formerly 10D-91.310.

64E-5.210 Special Requirements for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices which Contain Radioactive Material.

- (1) Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations.
- (a) In addition to the requirements set forth in 64E-5.208, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 64E-5.203(1)(a) will be issued if:
1. The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and
 2. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A of this part, that reconcentration of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.
- (b) Each person licensed under this subsection shall file an annual report with the department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to this subsection during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

- (2) Licensing the Distribution of Radioactive Material in Exempt Quantities. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing by-product material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.
- (a) An application for a specific license to distribute NARM to persons exempted from these regulations pursuant to 64E-5.203(2) will be approved if:
1. The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;
 2. The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and
 3. The applicant submits copies of prototype labels and brochures and the department approves such labels and brochures, subject to the provisions of (2)(b)3., below, and requirements herein.
- (b) The license issued under paragraph(2)(a), above, is subject to the following conditions:
1. No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.
 2. Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 64E-5.203(2). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 uSv) per hour.
 3. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

- a. Identifies the radionuclide and the quantity of radioactivity, and
 - b. Bears the words "Radioactive Material".
 4. In addition to the labeling information required by subparagraph (2)(b)3., above, the label affixed to the immediate container, or accompanying brochure, shall:
 - a. State that the contents are exempt from Licensing State requirements,
 - b. Bear the words "Radioactive Material--Not for Human Use-Introduction into Foods, Beverages, Cosmetics, Drugs or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined", and
 - c. Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.
 - (c) Each person licensed under (2), above, shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 64E-5.204(2) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to (2), above, during the reporting period, the report shall so indicate.
- (3) Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material (NARM) into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas or aerosol detectors to be distributed to persons exempt under 64E-5.203(3)(c) will be approved if the application satisfies the requirements of this part and Parts I, III, IX and XV. The maximum quantity of radium 226 in each device shall not exceed 0.1 microcurie (3.7 kBq).
 - (4) Licensing the Manufacture and Distribution of Devices to General Licensees Under 64E-5.206(4).

- (a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons possessing a general license under 64E-5.206(4) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State will be approved if:
 - 1. The applicant satisfies the general requirements of 64E-5.208;
 - 2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
 - a. The device can be safely operated by persons not having training in radiological protection,
 - b. Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive a dose in excess of 10 percent of the limits specified in 64E-5.304 and
 - c. Under accident conditions such as fire and explosion associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:
 - (I) Whole body; head and trunk;
active blood-forming organs;
gonads; or lens of eye 15 rem
..... (150 mSv)
 - (II) Hands and forearms; feet and ankles;
localized areas of skin averaged
over areas no larger than
1 square centimeter 200 rem
..... (2 Sv)
 - (III) Other organs 50 rem
..... (500 mSv); and
 - 3. Each device bears a durable, legible, clearly visible label or labels approved by the department which contain in a clearly identified and separate statement:

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

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

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

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

- (b) In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider the following information:
1. Primary containment or source capsule;
 2. Protection of primary containment;
 3. Method of sealing containment;
 4. Containment construction material;
 5. Form of contained radioactive material;
 6. Maximum temperature withstood during prototype tests;
 7. Maximum pressure withstood during prototype tests;
 8. Maximum quantity of contained radioactive material;
 9. Radiotoxicity of contained radioactive material; and
 10. Operating experience with identical devices or similarly designed and constructed devices.
- (c) In the event the applicant desires that the general licensee under 64E-5.206 or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the limits specified in 64E-5.304.
- (d) Each person licensed under 64E-5.210(4) to distribute devices to persons

under a general license shall:

1. Furnish a copy of the general license contained in 64E-5.206(4) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 64E-5.206(4);
2. Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, agreement state's, or Licensing State's regulation equivalent to 64E-5.206(4), or alternatively, furnish a copy of the general license contained in 64E-5.206(4) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the agreement state, or the Licensing State. If a copy of the general license in 64E-5.206(4) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, agreement state, or Licensing State under requirements substantially the same as those in 64E-5.206(4);
3. Report to the department all transfers of such devices to persons for use under the general license in 64E-5.206(4). Such report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to general licensees 64E-5.206(4) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;
4. Furnish reports to other agencies.
 - a. Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.

- b. Report to the responsible state agency all transfers of devices manufactured and distributed to persons for use under a general license in that State's regulations equivalent to 64E-5.206(4).
 - c. Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact and relationship to the intended user. The report shall be submitted within 30 days after the end of the calendar quarter in which such a device is transferred to the general licensee.
 - d. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.
 - e. If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency; and
 5. Keep records showing the name, address and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 64E-5.206(4), or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person and compliance with the report requirements of this section.
- (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

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

1. This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license 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 material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

Name of Manufacturer

- (e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine 125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Part III.
- (9) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to general licensees under 64E-5.206(9) will be approved if:
 - (a) The applicant satisfies the general requirements of 64E-5.208; and
 - (b) The criteria of sections 32.61, 32.62, and 32.103 of 10 CFR Part 32, are met.
 - (10) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Part VI for the uses listed in 64E-5.626, 64E-5.627, and 64E-5.630 will be approved if:
 - (a) The applicant satisfies the general requirements specified in 64E-5.208;

(b) The applicant submits evidence that:

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1. The applicant is registered or licensed with the U.S. Food and Drug Administration as a drug manufacturer; or
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2. The applicant is registered or licensed as a drug manufacturer as specified in Chapter 499, F.S.; or
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3. The applicant has a nuclear pharmacy permit and only authorized nuclear pharmacists compound or dispense radiopharmaceuticals as specified in Section 465.0193, F.S.

(c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees;

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(d) The applicant satisfies the following labeling requirements:

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1. The label affixed to each transport radiation shield of any material of a radioactive drug transferred for commercial distribution includes the radiation symbol and the words "Caution, Radioactive Material" or "Danger, Radioactive Material"; the name of the radioactive drug or its abbreviation; and the quantity of the radioactive material at a specified date and time. The time can be omitted for radioactive drugs with a half life greater than 100 days.
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2. A label affixed to each syringe, vial, or other container used to hold a radioactive drug transferred for commercial distribution includes the words "Caution, Radioactive Material" or "Danger, Radioactive Material" and an identifier that correlates the syringe, vial, or other container with the information on the transport radiation shield label; and

(e) A licensee shall possess and use instruments to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instruments. The licensee shall measure by direct measurements or by combination of measurements and calculations the amount of radioactivity in doses of alpha-emitting, beta-emitting, or photon-emitting radioactive drugs before transfer for commercial distribution. In addition, the licensee shall:

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1. Perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence appropriate for the use of the instrument and make adjustments when needed; and
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2. Check each instrument for constancy and proper operation at the beginning of each day of use.

- (11) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Part VI for the uses listed in 64E-5.627 will be approved if:
- (a) The applicant satisfies the general requirements specified in 64E-5.208;
 - (b) The applicant submits evidence that:
 - 1. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or
 - 2. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;
 - (c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;
 - (d) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity and date of assay; and
 - (e) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:
 - 1. Adequate information pertaining to radiation safety on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and
 - 2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the department pursuant to Part VI for uses listed in 64E-5.627 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State. The labels, leaflets, or brochures required by this section are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA

- (12) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.
- (a) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part VI for use as a calibration or reference source or for the uses listed in 64E-5.631 or 64E-5.632 will be approved if:
1. The applicant satisfies the general requirements in 64E-5.208;
 2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - a. The radioactive material contained, its chemical and physical form, and amount,
 - b. Details of design and construction of the source or device,
 - c. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,
 - d. For devices containing radioactive material, the radiation profile of a prototype device,
 - e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,
 - f. Procedures and standards for calibrating sources and devices,
 - g. Legend and methods for labeling sources and devices as to their radioactive content, and
 - h. Instructions pertaining to radiation safety for handling and storing the source or device; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, date of assay, and a statement that the name of source or device is licensed by the department for distribution to persons licensed pursuant to Part VI or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State, provided, that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;
- (b) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and
 - (c) In determining the acceptable interval for test of leakage of radioactive material, the department will consider the following information:
 1. Primary containment or source capsule,
 2. Protection of primary containment,
 3. Method of sealing containment,
 4. Containment construction materials,
 5. Form of contained radioactive material,
 6. Maximum temperature withstood during prototype tests,
 7. Maximum pressure withstood during prototype tests,
 8. Maximum quantity of contained radioactive material,
 9. Radiotoxicity of contained radioactive material, and
 10. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.
- (13) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.
- (a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 64E-5.205(4) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

1. The applicant satisfies the general requirements specified in 64E-5.208;
 2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 calendar quarter a radiation dose in excess of 10 percent of the limits specified in Subpart III A of these rules; and
 3. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.
- (b) In the case of an industrial product or device whose unique benefits have not been demonstrated, the department will approve an application for a specific license under this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.
- (c) Each person licensed pursuant to (13)(a), above, shall:
1. Maintain the level of quality control required by the license in the manufacture of the industrial product or device and in the installation of the depleted uranium into the product or device;
 2. Label or mark each unit to:
 - a. Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium and the quantity of depleted uranium in each product or device; and
 - b. State that receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state;
 3. Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

4.
 - a. Furnish a copy of the general license described in 64E-5.205(4) to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license described in 64E-5.205(4), or
 - b. Furnish a copy of the general license certificate of the U.S. Nuclear Regulatory Commission's or an agreement state's, or alternatively, furnish a copy of the general license described in 64E-5.205(4) to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 64E-5.205 4);
 5. Report to the department all transfers of industrial products or devices to persons for use under the general license described in 64E-5.205(4). Such report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the general licensee. If no transfers have been made to general licensees under 64E-5.205(4) during the reporting period, the report shall so indicate;
 6.
 - a. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in section 40.25 of 10 CFR Part 40,
 - b. Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 64E-5.210(3) for use under a general license in that state's rules equivalent to 64E-5.205(4),
 - c. Such report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the general licensee.

- d. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission, and
 - e. If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of that agency; and
7. Keep records showing the name, address and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 64E-5.205(4) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred and compliance with the report requirements of this section.
- (14) A licensee, manufacturer or an initial distributor of a sealed source or device containing a sealed source whose product contains exempt NARM or is intended for use under a general or specific license must submit a request for an evaluation of the sealed source or device containing a sealed source and obtain a registration from the department.
- (a) The request for review of a sealed source or device must be made in triplicate and include information about the design, manufacture, prototype testing, quality control and assurance program, labeling, leak testing and proposed uses. The licensee shall inform customers of current reasonable disposal options for the radioactive material.
 - (b) The request for review of a device must include information about installation, service and maintenance, operating and safety instructions, and its potential hazards. The information shall provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect public health, safety and property.
 - (c) The department shall use criteria and standards sufficient to ensure that the radiation safety properties of the sealed source or device are adequate to protect public health, safety and property. Criteria and standards used by the department in evaluating a sealed source or device include:

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

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

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

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

History: New July 17, 1985, Amended August 25, 1991, Amended May 12, 1993, Amended January 1, 1994, R3 Amended May 15, 1996, Formerly 10D-91.311, Amended August 6, 2001.

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

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

- (a) The amount of funds to be insured by financial surety arrangements shall be based on cost estimates which are furnished by the licensee and which the department shall evaluate to determine that the cost estimates are reasonably comparable to other decontamination or decommissioning estimates in a plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and waste disposal areas. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and that evaluates alternatives for mitigating these impacts. In establishing specific surety arrangements, the licensee's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the department may accept financial sureties that have been consolidated with financial surety arrangements established to meet requirements of other Federal or state agencies or local governing bodies for such decommissioning, decontamination, reclamation and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the department to assure that sufficient funds will be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability shall be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning, decontamination and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time which must be automatically renewed unless the surety agent notifies the beneficiary, the department and the licensee prior to the renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least 60 days for the department to collect.
- (b) The total amount of funds for reclamation or long term surveillance and

control shall be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of a license. Such funds include sums collected for long term surveillance and control. Such funds do not, however, include monies held as surety where no default has occurred and the reclamation or other bonded activity has been performed.

- (5) The applicant shall provide procedures describing the means employed to meet the following requirements during the operational phase of any project.
 - (a) Milling operations shall be conducted so that all effluent releases are below the limits of Part III and are as low as is reasonably achievable.
 - (b) The mill operator shall conduct daily inspections of any tailings or waste retention systems. Such inspections shall be conducted by a licensed engineer. Records of such inspections shall be maintained for review by the department.
 - (c) The mill operator shall immediately notify the department of the following:
 - 1. Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas, and
 - 2. Any unusual condition not contemplated in the design of the retention system which, if not corrected, could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.
- (6) Continued Surveillance Requirements for Source Material Mills Having Reclaimed Residues.

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

Specific Authority: 404.051, 404.061, 404.062, 404.071, 404.081, 404.111, 404.141, F.S.

Law Implemented: 404.022, 404.051(1),(4),(5),(7),(8),(11), 404.061(2), 404.071(1), 404.081(1), 404.111,404.141, F.S.

History: New July 17, 1985, Formerly 10D-91.312.

64E-5.212 Issuance of Specific Licenses.

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

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

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

64E-5.213 Specific Terms and Conditions of License.

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

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

R1 Specific Authority: 404.051, 404.061, F.S.

R1 Law Implemented: 404.051(1)(4), 404.061(2)(3), F.S.

History: New July 17, 1985, Amended April 4, 1989 Amended May 12, 1993, Amended August 29, 1994,

R1 Formerly 10D-91.314, Amended May 18, 1998.

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

- R1 (1) Except as provided in Part II, each specific license shall expire at the end of the
R1 specified day in the month and year stated therein. Each specific license
R1 revoked by the department expires at the end of the day on the date of the
R1 department's final order revoking the license or on the expiration date stated in
R1 the final order.
- R1 (2) (a) Each licensee shall notify the department in writing within 60 days of the
R1 occurrence of any of the following and either begin decommissioning its
R1 site or any separate building or outdoor area that contains residual
R1 radioactivity so that the building or outdoor area is suitable for release as
R1 specified in these rules or send a notice of a decommissioning plan within
R1 12 months as specified in (4)(c) below and begin decommissioning upon
R1 approval of that plan.
- R1 1. The license has expired as specified in (1), above.
- R1 2. The licensee has ceased principal activities permanently at the
R1 entire site or in any separate building or outdoor area.
- R1 3. The licensee has conducted no principal activities under the license
R1 for 24 months.
- R1 4. The licensee has conducted no principal activities for 24 months in
R1 any separate building or outdoor area that contains residual
R1 radioactivity to the extent that the building or outdoor area is
R1 unsuitable for release as specified in these rules.
- R1 (b) The notification and request for termination of the license shall include the
R1 reports and information specified in (4)(a)4. and 5., below.
- R1 (3) No less than 30 days before the expiration date specified in the license, the
R1 licensee shall either:
- R1 (a) Submit an application for license renewal on the same form used for the
R1 initial application under Part II, or
- R1 (b) Notify the department, in writing, if the licensee decides not to apply for
R1 license renewal.
- R1 (4) (a) If a licensee does not submit an application for license renewal under
R1 Part II, the licensee shall, on or before the expiration date specified in the
R1 license:

- 1. Terminate the use of radioactive material;
- R5 2. Remove residual radioactivity to the extent acceptable to the department;
- 3. Properly dispose of the radioactive material;
- 4. Submit a properly completed DH Form 1059, which is herein incorporated by reference effective July 17, 1985; and
- R5 5. Submit a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual radioactivity, unless the licensee demonstrates the absence of residual radioactivity in some other manner. The licensee shall, as appropriate:
 - R5 a. For gamma radiation, report levels of radiation in units of microrentgens per hour at 10 centimeters and at 1 meter from surfaces.
 - b. For alpha and beta radiation, report levels of radioactivity in units of transformations per minute or microcuries per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and
 - c. Specify the instruments used and certify that each instrument is properly calibrated or tested.
- R5 (b) 1. If no residual radioactivity attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable residual radioactivity was found. The department will notify the licensee, in writing, of the termination of the license.
- R5 2. Specific licenses including expired licenses will be terminated by written notice to the licensee when the department determines that:
 - R5 a. Radioactive material has been properly disposed; and
 - R5 b. A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use or satisfies the requirements specified in Rules 64E-5.221, 64E-5.222, 64E-5.223, or 64E-5.224, F.A.C.; or
 - R5 c. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use or satisfies the requirements specified in Rules 64E-5.221, 64E-5.222, 64E-5.223, or 64E-5.224, F.A.C.

- R2 d. Department has received the following records, if
R2 requested:
- R2 (I) Disposal records specified in Rules 64E-5.330,
R2 64E-5.331(1)(a)(c), (2), (3), or 64E-5.336(2)(d),
R2 F.A.C.; and
- R2 (II) Records specified in Rule 64E-5.214(6), F.A.C.

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- (c) 1. If detectable levels of residual radioactivity attributable to activities conducted under the license are found or licensee possesses other radioactive materials, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactivity present or possession of radioactive material, until the department notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of (5), below.
2. In addition to the information submitted under (4)(a)4. and 5., above, the licensee shall submit a plan for decommissioning if decommissioning procedures have not been approved previously by the department and could impact the health and safety of workers or the public as follows:
- a. More than routine cleanup and maintenance is required;
 - b. Workers will be in areas with significantly increased surface contamination or radiation levels;
 - c. Procedures will result in significantly greater airborne concentrations of radioactive materials; or
 - d. Procedures will result in significantly greater releases of radioactive material to the environment.
3. Procedures which could potentially impact health, safety and the environment may not be performed until the decommissioning plan has been approved.
4. The proposed decommissioning plan must include:
- a. A description of the planned decommissioning activities;
 - b. A description of the methods used to assure protection of workers and the environment against radiation hazards during decommissioning;
 - c. The time required to complete the decommissioning plan; and
 - d. A description of the planned final radiation survey.
5. The proposed decommissioning plan will be reviewed by the department and approved or additional information will be requested within 60 days.

6. Upon approval of the decommissioning plan by the department, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in (4)(a)5., above, of this section and shall certify the disposition of accumulated wastes from decommissioning.

7. If the information submitted as specified in (4)(a)5. or (4)(c)6. of this section does not adequately demonstrate that the premises are suitable for release for unrestricted use or does not satisfy the requirements specified in Rules 64E-5.221, 64E-5.222, 64E-5.223, or 64E-5.224, F.A.C., the department will inform the licensee of the appropriate further actions required for termination of the license.

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R1 (5) Each licensee who possesses radioactive material under (4)(c), above, following the expiration date specified in the license shall:

R1 (a) Limit actions involving radioactive material to those related to decontamination, decommissioning, and other activities related to preparation for release for unrestricted use; and

(b) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the department notifies the licensee, in writing, that the license is terminated.

(6) Each licensee shall keep records of the decommissioning of the facility in an identified location until the license is terminated by the department. If records of relevant information are kept for other purposes, reference to these records and their location can be used. Records which must be kept include:

(a) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records can be limited to instances when contamination remains after cleanup procedures or when contaminants may have spread to inaccessible areas such as possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(b) Drawings of structures as originally built, of modifications, and of equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which can be subject to contamination. Drawings and their location can be referenced if not on site. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(c) Except for areas containing only radioactive materials having half-lives of less than 65 days or sealed sources that either have not leaked or no contamination remains after any leak, a list contained in a single document and updated every 2 years, of the following:

1. All areas designated and formerly designated restricted areas as defined in 64E-5.101;
2. All areas outside of restricted areas that require documentation under 64E-5.214(6)(a);
3. All areas outside of restricted areas where current and previous wastes have been buried as documented under 64E-5.340; and
4. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or satisfy the requirements specified in Rules 64E-5.221, 64E-5.222, 64E-5.223, or 64E-5.224, F.A.C.; and

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(d) Records of the cost estimate performed for the performance bond required in 64E-5.217 and records of the funding method used.

(7) Confirmatory or closeout surveys will be performed by the department according to the Closeout Inspection and Survey Procedures, November 1991, which are herein incorporated by reference and which are available from the department.

R1 Specific Authority: 404.051, 404.061, 404.081, 404.141, F.S.

R1 Law Implemented: 404.051(1),(4),(9), 404.061(2), 404.081(1), 404.141, F.S.

R1 History: New July 17, 1985, Amended May 12, 1993, Amended August 14, 1996, Formerly 10D-91.315,

R2, R5 Amended May 18, 1998, Amended October 8, 2000, Amended December 19, 2001.

64E-5.215 Transfer of Material.

- (1) No licensee shall transfer radioactive material except as authorized pursuant to this section.
- (2) Except as otherwise provided in his license and subject to the provisions of (3) and (4), below, a licensee may transfer radioactive material:
 - (a) To the department after receiving approval from the department;
 - (b) To the U.S. Department of Energy;
 - (c) To any person exempt from these regulations to the extent permitted under such exemption;

- (d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the U.S. Nuclear Regulatory Commission, an agreement state, a licensing state, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the department, an agreement state or a Licensing State.
- (3) Before transferring radioactive material to a specific licensee of the department, the U.S. Nuclear Regulatory Commission, an agreement state, a licensing state or to a general licensee who is required to register with the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.
- (4) Any of the following methods for the verification required by (3), above, are applicable:
- (a) The transferor may possess and read a current copy of the transferee's specific or general license.
- (b) The transferor may possess a written certification by the transferee that the transferee is authorized by license to receive the type, form and quantity of radioactive material to be transferred, specifying the license number, issuing agency and expiration date.
- (c) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license to receive the type, form and quantity of radioactive material to be transferred, specifying the license number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.
- (d) The transferor may obtain other information compiled by a reporting service from official records of the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state regarding the identity of licensees and the scope and expiration dates of the licenses.
- (e) When none of the methods of verification described in (4)(a) through (d), above, are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation for the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state that the transferee is licensed to receive the radioactive material.

- (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.

- R2 (1) Subject to these regulations, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing 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, except for areas of exclusive Federal jurisdiction, for a period not in excess of 365 consecutive days provided that:
- R2 (a) The out-of-state license document does not limit the performance of the function authorized by such document to specified installations or locations;
- R2 (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.
- R2 (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
- R2 (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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- (2) Notwithstanding the provisions of (1), above, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a Licensing State authorizing the holder to manufacture, transfer, install or service a device described in 64E-5.206(4)(a) within areas subject to the jurisdiction of the licensing body may be granted a general license by the department to install, transfer, demonstrate or service such a device in this State provided that:
- (a) Such person shall file a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of radioactive material contained in the device;
 - (b) The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State;
 - (c) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
 - (d) The holder of the specific license shall furnish to each general licensee to whom he transfers such device, or on whose premises he installs such device, a copy of the general license contained in 64E-5.206(4) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.
- (3) The department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health, safety or property.

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

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

R2 History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.321, Amended October 8, 2000.

**SUBPART E
BONDING**

64E-5.217 Bonding of Persons Licensed Pursuant to Subpart II C.

- (1) Any applicant or licensee who is not exempt by the provisions of this subpart shall provide a performance bond.
 - (a) The bond shall be payable to the State of Florida and shall be in an amount determined by the department as sufficient to provide for the protection of the environment and the public health and safety in the event of abandonment, insolvency or other inability of the licensee to meet the requirements of the department. The department shall use (3), below, of this part to determine the amount of the bond required for each applicant or licensee. The mathematical product of the risk factors will be the amount of the required bond in dollars. In the event that an applicant or licensee feels that the amount of the bond determined by the use of the applicable risk factors is inappropriate, he may submit evidence to the department in support of a change to the bond amount. The department shall determine whether the evidence supports the requested change in the bond amount.
 - (b) An applicant or licensee may apply to the department for exemption from the requirement of a bond if he can demonstrate that funds will accrue to the State of Florida which are sufficient to provide for the protection of the environment and the public health and safety in the event of abandonment, insolvency or other inability of the licensee to meet the requirements of the department. If the department does not grant the exemption from the requirement of a bond, the licensee may request a hearing in accordance with the provisions of Chapter 120, Florida Statutes.
 - (c) Licensees must provide the required bond within 90 days after being given notice by the department of the requirements of a bond and its amount.
 - (d) The department may re-evaluate, at any time, the adequacy of an existing bond or guaranty and may require an adjustment by either increasing or decreasing the amount of the bonding or guaranty required.
 - (e) A bond may be issued by a fidelity or surety company authorized to do business in the State of Florida or it may be a cash bond. The bond must initially provide for at least 24 months of coverage from the date of issuance and at no time thereafter shall the period of coverage be less than 12 months, for as long as the license remains in effect.

- (f) The department may order the bond to be forfeited if it finds any of the following:
 - 1. The facility or site has been abandoned;
 - 2. The licensee is insolvent; or
 - 3. The licensee is unable to perform to the satisfaction of the department.
 - (g) Upon determining that a bond shall be forfeited, the department shall issue a notice to that effect.
- (2) The following are exempt from the provisions of this subpart:
- (a) Other governmental agencies;
 - (b) Educational institutions accredited by the Southern Association of Colleges and Schools and such other educational institutions as may be specifically exempted by the department if the department determines that such exemption will not endanger the public health, safety and welfare.
 - (c) Licensees of the State Licensing Board for the Healing Arts and those medical facilities possessing or using radioactive materials for medical purposes when supervised by such licensees.
 - (d) Any licensee whose mathematical product of the risk factors in (3), below, is less than 15,000.
- (3) Risk factors for purposes of bonding:

(3) Risk factors for purposes of bonding:

Radioisotope	Risk Factors	Half-Life or Radioisotope	Risk Factors
U-nat, U-235, U-238 and associated decay products	1	Greater than 6 years	30
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, Ac-225, I-129	50	6 months to 6 years	10
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133, I-125, H-3, C-14	5	10 days to 6 months	5
Activity	Risk Factors	Facility and Procedure	Risk Factors
Greater than 100,000 curies	2,000	Greater than 5000 ft. ² -----High Risk -----Low Risk	30 10
10,000 to 100,000 curies	1,000	500 to 5000 ft. ² -----High Risk -----Low Risk	10 5
1,000 to 10,000 curies	500	Less than 500 ft. ² -----High Risk	5
100 to 1,000 curies	200	Licensed issued for storage only	3
10 to 100 curies	30	License issued for manufacturing, benefaction or processing non-encapsulated radioactive materials	3
1 to 10 curies	2	Sealed sources not contained in a device with integral solid shielding	3
Physical Form	Risk Factors	Physical Form	Risk Factors
Single encapsulated or source plated	3	Non- encapsulated form	20

Specific Authority: 404.051, 404.061, 404.111, 404.141, F.S.

Law Implemented: 404.022, 404.051(1),(4), 404.061(2), 404.111, 404.141, F.S.

History: New July 17, 1985, amended April 4, 1989, Amended May 12, 1993, Formerly 10D-91.322.

**SUBPART F
INSPECTION AND ENFORCEMENT**

64E-5.218 Performance of Inspections.

- (1) Radioactive material inspections may be announced or unannounced.
- (2) Inspection procedures for all license categories will include the following:
 - (a) At the time of entrance to a facility, the department will inform the licensee management if available the purpose, extent, and approximate length of time required to complete the inspection;
 - (b) Consultation with workers in accordance with 64E-5.905 may be performed;
 - (c) The department will review any or all records that are required to be maintained by these regulations or by license conditions;
 - (d) Radiation surveys will be performed to determine compliance with the regulations and license. The department's radiation detection and monitoring equipment will be operable and calibrated as required by these regulations;
 - (e) Upon completion of an inspection, the department will inform the licensee of the preliminary findings of the inspection prior to leaving the facility, if possible. Official notification of the inspection findings will be sent in writing to the licensee.
- (3) The department will perform inspections to assure the radioactive materials are used only as specified in these regulations or in the license using instruments calibrated as specified in these regulations.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.324..

64E-5.219 Emergency Planning.

- (1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 64E-5.220, must contain either:
 - (a) An evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed 1 rem (10 mSv) effective dose equivalent or 5 rem (50 mSv) to the thyroid; or
 - (b) An emergency plan for responding to a release of radioactive material.
- (2) One or more of the following factors can be used to support an evaluation submitted under (1)(a) of this section:
 - (a) The radioactive material is physically separated so that only a portion could be involved in an accident.
 - (b) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged.
 - (c) The release fraction in the respirable size range would be lower than the release fraction shown in 64E-5.220 due to the chemical or physical form of the material.
 - (d) The solubility of the radioactive material would reduce the dose received.
 - (e) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 64E-5.220.
 - (f) Operating restrictions or procedures would prevent a release fraction as large as that shown in 64E-5.220.
 - (g) Other factors appropriate for the specific facility.
- (3) Each application to possess source material in the form of uranium hexafluoride in excess of 50 kilograms in a single container or 1,000 kilograms total must contain either:
 - (a) An evaluation showing that the maximum intake of uranium by a member of the public due to a release would not exceed 2 milligrams; or

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- (b) An emergency plan for responding to the radiological hazards of an accidental release of source material and to any associated chemical hazards.
- (4) One or more of the following factors can be used to support an evaluation submitted under (3)(a) of this section:
- (a) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged.
 - (b) Facility design or engineered safety features in the facility would reduce the amount of the release.
 - (c) Other factors pertaining to the specific facility.
- (5) Each application to possess special nuclear material in the form of uranium hexafluoride in excess of 50 kilograms in a single container or 1,000 kilograms total, or in excess of 2 curies (74 GBq) of plutonium in unsealed form or on foils or plated sources, must contain either:
- (a) An evaluation showing that the maximum dose to a member of the public off-site due to a release of radioactive materials would not exceed 1 rem (10 mSv) effective dose equivalent; or
 - (b) An emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and to any associated chemical hazards.
- (6) One or more of the following factors can be used to support an evaluation submitted under (5)(a) of this section:
- (a) The radioactive material is physically separated so that only a portion could be involved in an accident.
 - (b) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged.
 - (c) In the case of fires or explosions, the release fraction would be lower than 0.001 due to the chemical or physical form of the material.
 - (d) The solubility of the material released would reduce the dose received.
 - (e) The facility design or engineered safety features in the facility would cause the release fraction to be lower than 0.001.
 - (f) Operating restrictions or procedures would prevent a release large enough to cause a member of the public off-site to receive a dose exceeding 1 rem (10 mSv) effective dose equivalent.
 - (g) Other factors pertaining to the specific facility.

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- (7) An emergency plan responding to a release of radioactive material submitted under (1)(b), (3)(b) or (5)(b) of this section must include the following information:
- (a) A brief description of the licensee's facility and area near the site.
 - (b) An identification of each type of radioactive materials accident for which protective actions could be needed.
 - (c) A classification system for classifying accidents as alerts or site area emergencies.
 - (d) Identification of the means of detecting each type of accident in a timely manner.
 - (e) A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on site, and a description of the program for maintaining the equipment.
 - (f) A brief description of the methods and equipment to assess releases of radioactive materials.
 - (g) A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the department and the responsibilities of licensee personnel for developing, maintaining, and updating the plan.
- (h) A commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, or some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the department immediately after notification of the appropriate off-site response organizations and not later than 1 hour after the licensee declares an emergency.
- (i) A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and the department.

- (j) A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency, including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.
 - (k) A brief description of the means of restoring the facility to a safe condition after an accident.
 - (l) Provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Participation of off-site response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.
 - (m) A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.
- (8) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the department. The licensee shall provide any comments received within the 60 days to the department with the emergency plan.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.326.

64E-5.220 Radioactive Quantities.

- (1) Listed below are the quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release as required in 64E-5.219:

Material	Release Fraction	Curies
Actinium 228	0.001	4,000
Americium 241	0.001	2
Americium 242	0.001	2
Americium 243	0.001	2
Antimony 124	0.01	4,000
Antimony 126	0.01	6,000
Barium 133	0.01	10,000
Barium 140	0.01	30,000
Bismuth 207	0.01	5,000
Bismuth 210	0.01	600
Cadmium 109	0.01	1,000
Cadmium 113	0.01	80
Calcium 45	0.01	20,000
Californium 252	0.001	9
Carbon 14	0.01 (non CO ₂)	50,000
Cerium 141	0.01	10,000
Cerium 144	0.01	300
Cesium 134	0.01	2,000
Cesium 137	0.01	3,000
Chlorine 36	0.5	100
Chromium 51	0.01	300,000
Cobalt 60	0.001	5,000
Copper 64	0.01	200,000
Curium 242	0.001	60
Curium 243	0.001	3
Curium 244	0.001	4
Curium 245	0.001	2
Europium 152	0.01	500

Material	Release Fraction	Curies
Europium 154	0.01	400
Europium 155	0.01	3,000
Gadolinium 153	0.01	5,000
Germanium 68	0.01	2,000
Gold 198	0.01	30,000
Hafnium 172	0.01	400
Hafnium 181	0.01	7,000
Holmium 166m	0.01	100
Hydrogen 3	0.5	20,000
Iodine 125	0.5	10
Iodine 131	0.5	10
Indium 114m	0.01	1,000
Iridium 192	0.001	40,000
Iron 55	0.01	40,000
Iron 59	0.01	7,000
Krypton 85	1.0	6,000,000
Lead 210	0.01	8
Manganese 56	0.01	60,000
Mercury 203	0.01	10,000
Molybdenum 99	0.01	30,000
Neptunium 237	0.001	2
Nickel 63	0.01	20,000
Niobium 94	0.01	300
Phosphorus 32	0.5	100
Phosphorus 33	0.5	1,000
Polonium 210	0.01	10
Potassium 42	0.01	9,000
Promethium 145	0.01	4,000
Promethium 147	0.01	4,000
Radium 226	0.001	100
Ruthenium 106	0.01	200
Samarium 151	0.01	4,000
Scandium 46	0.01	3,000
Selenium 75	0.01	10,000

Material	Release Fraction	Curies
Silver 110m	0.01	1,000
Sodium 22	0.01	9,000
Sodium 24	0.01	10,000
Strontium 89	0.01	3,000
Strontium 90	0.01	90
Sulfur 35	0.5	900
Technetium 99	0.01	10,000
Technetium 99m	0.01	400,000
Tellurium 127m	0.01	5,000
Tellurium 129m	0.01	5,000
Terbium 160	0.01	4,000
Thulium 170	0.01	4,000
Tin 113	0.01	10,000
Tin 123	0.01	3,000
Tin 126	0.01	1,000
Titanium 44	0.01	100
Vanadium 48	0.01	7,000
Xenon 133	1.0	900,000
Yttrium 91	0.01	2,000
Zinc 65	0.01	5,000
Zirconium 93	0.01	400
Zirconium 95	0.01	5,000
Any other beta-gamma emitter	0.01	10,000
Mixed fission products	0.01	1,000
Mixed corrosion products	0.01	10,000
Contaminated equipment beta-gamma	0.001	10,000
Irradiated material, any form other than solid noncombustible	0.01	1,000
Irradiated material solid noncombustible	0.001	10,000
Mixed radiological waste, beta-gamma	0.01	1,000
Packaged mixed waste, beta-gamma	0.001	10,000
Any other alpha emitter	0.001	2
Contaminated equipment alpha	0.0001	20
Package waste, alpha	0.0001	20

- (2) For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in this section exceeds one.
- (3) Waste packaged in Type B containers as specified in 64E-5.101 does not require an emergency plan.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.327.

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Previous page number is Page II - 78

SUBPART G
RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

R5 **64E-5.221 Radiological criteria for license termination.** The criteria in this
R5 subpart apply to the decommissioning of facilities licensed under this chapter but do not apply
R5 to uranium and thorium recovery facilities as specified in Rule 64E-5.211, F.A.C., or to sites
R5 which previously have submitted and received department approval of a license termination
R5 plan or decommissioning plan as specified in Rule 64E-5.214(2), F.A.C.

R5 (1) After a site has been decommissioned and the license terminated in accordance
R5 with the criteria in this subpart, the department will require additional cleanup
R5 only if based on new information or if it determines that the criteria of this subpart
R5 were not met and residual activity remaining at the site could result in significant
R5 threat to public health and safety.

R5 (2) When calculating total effective dose equivalent to the average member of the
R5 critical group, the licensee shall determine the peak annual total effective dose
R5 equivalent expected within the first 1,000 years after decommissioning.

R5 Specific Authority: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 Law Implemented: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 History: New December 19, 2001.

R5 **64E-5.222 Radiological criteria for unrestricted use.** A site is acceptable for
R5 unrestricted use if the total effective dose equivalent to an average member of the critical
R5 group from the residual radioactivity that is distinguishable from background radiation does not
R5 exceed 25 millirem (0.25 mSv) per year including radioactivity from groundwater sources of
R5 drinking water and the residual radioactivity levels are as low as reasonably achievable.
R5 Determination of the ALARA levels must take into account any detriments such as deaths from
R5 transportation accidents potentially expected to result from decontamination and waste
R5 disposal.

R5 Specific Authority: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 Law Implemented: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 History: New December 19, 2001.

R5 **64E-5.223 Criteria for license termination under restricted conditions.** A site is
R5 acceptable for license termination under restricted conditions if it meets the criteria below.

R5 (1) The residual levels associated with restricted conditions are ALARA or the
R5 licensee can demonstrate that further reductions in residual radioactivity to
R5 comply with the provisions of Rule 64E-5.222, F.A.C., would result in an increase
R5 in public or environmental harm. Determination of the ALARA levels must take
R5 into account any detriments such as traffic accidents potentially expected to
R5 result from decontamination and waste disposal.

R5 (2) The licensee has made provisions for legally enforceable institutional controls
R5 that provide reasonable assurance that the total effective dose equivalent from
R5 residual radioactivity distinguishable from background to the average member of
R5 the critical group will not exceed 25 millirem (0.25 mSv) per year.

- R5 (3) The licensee has provided sufficient financial assurance to enable an
R5 independent third party including a governmental custodian of a site to assume
R5 and carry out responsibilities for any necessary control and maintenance of the
R5 site. Acceptable financial assurance mechanisms are:
- R5 (a) Funds sufficient to pay decommissioning costs placed into an account
R5 segregated from the licensee's assets and outside the licensee's
R5 administrative control before the start of decommissioning operations; or
- R5 (b) A bond as specified in Rule 64E-5.217, F.A.C., or
- R5 (c) An arrangement deemed acceptable by the governmental entity that is
R5 assuming custody and ownership of a site.
- R5 (4) The licensee has submitted a decommissioning or license termination plan as
R5 specified in Rule 64E-5.214(2), F.A.C., to the department indicating the
R5 licensee's intent to decommission in accordance with this part and specifying
R5 that the licensee intends to decommission by restricting use of the site. The
R5 licensee shall document in the license termination or decommissioning plan how
R5 the advice of individuals and institutions in the community who could be affected
R5 by the decommissioning has been sought and incorporated, as appropriate,
R5 following analysis of that advice.
- R5 (a) Licensees proposing to decommission by restricting use of the site shall
R5 seek advice from such affected parties regarding the following matters:
- R5 1. Whether provisions for institutional controls proposed by the
R5 licensee:
- R5 (I) Will provide reasonable assurance that the total effective
R5 dose equivalent from residual radioactivity distinguishable
R5 from background to the average member of the critical group
R5 will not exceed 25 millirem (0.25 mSv) per year;
- R5 (II) Will be enforceable; and
- R5 (III) Will not impose undue burdens on the local community or
R5 other affected parties.
- R5 2. Whether the licensee has provided sufficient financial assurance to
R5 enable an independent third party including a governmental
R5 custodian of a site to assume and carry out responsibilities for any
R5 necessary control and maintenance of the site.

- R5 (b) In seeking advice on the issues identified in (a), above, the licensee shall
R5 provide for:
- R5 1. Participation by representatives of a broad cross section of
R5 community interests who could be affected by the
R5 decommissioning;
 - R5 2. An opportunity for a comprehensive, collective discussion on the
R5 issues by the participants represented; and
 - R5 3. A publicly available summary of the results of all such discussions
R5 including a description of the individual viewpoints of the
R5 participants on the issues and the extent of agreement or
R5 disagreement among the participants on the issues.
- R5 (5) Residual radioactivity at the site has been reduced so that if the institutional
R5 controls were no longer in effect there is reasonable assurance that the total
R5 effective dose equivalent from residual radioactivity distinguishable from
R5 background to the average member of the critical group is as low as reasonably
R5 achievable and would not exceed 100 millirem (1 mSv) per year.

R5 Specific Authority: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 Law Implemented: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 History: New December 19, 2001.

R5 **64E-5.224 Alternate criteria for license termination.** The department will
R5 terminate a license using alternate criteria greater than the dose criterion of Rules 64E-5.222,
R5 64E-5.223(2), and 64E-5.223(4)(a)1.(I), F.A.C., if the licensee:

- R5 (1) Provides assurance that public health and safety would continue to be protected
R5 and that it is unlikely that the total effective dose equivalent from all combined
R5 man-made sources other than medical sources would be more than 100 millirem
R5 per year (1 millisievert per year) by submitting an analysis of possible sources of
R5 exposure;
- R5 (2) Has employed restrictions to the extent practical on site use according to the
R5 provisions of Rule 64E-5.223, F.A.C., in minimizing exposures at the site;
- R5 (3) Reduces doses to ALARA levels considering any detriments such as traffic
R5 accidents potentially expected to result from decontamination and waste
R5 disposal; and
- R5 (4) Has submitted a decommissioning or license termination plan to the department
R5 indicating the licensee's intent to decommission as specified in Rule
R5 64E-5.214(2), F.A.C., and specifying that the licensee proposes to
R5 decommission by use of alternate criteria. The licensee shall document in the
R5 license termination or decommissioning plan how the advice of individuals and
R5 institutions in the community who could be affected by the decommissioning has
R5 been sought and addressed, as appropriate, following analysis of that advice. In
R5 seeking such advice, the licensee shall provide for:

- R5 (a) Participation by representatives of a broad cross section of community
R5 interests who could be affected by the decommissioning;
- R5 (b) An opportunity for a comprehensive, collective discussion on the issues
R5 by the participants represented; and
- R5 (c) A publicly available summary of the results of all such discussions,
R5 including a description of the individual viewpoints of the participants on
R5 the issues and the extent of agreement and disagreement on the issues.
- R5 (5) The use of alternate criteria to terminate a license requires the approval of the
R5 department after consideration of any comments provided by the U. S.
R5 Environmental Protection Agency and any public comments submitted as
R5 specified in Rule 64E-5.225, F.A.C.

R5 Specific Authority: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 Law Implemented: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 History: New December 19, 2001.

R5 **64E-5.225 Public notification and public participation.** Upon the receipt of a
R5 license termination or decommissioning plan or a proposal for release of a site as specified in
R5 Rules 64E-5.223 or 64E-5.224, F.A.C., and the total effective dose equivalent will exceed 50
R5 millirem (0.5 mSv), the department shall:

R5 (1) Notify and solicit comments from:

- R5 (a) Local and other state governments in the vicinity of the site and any Indian
R5 Nation or other indigenous people that could be affected by the
R5 decommissioning; and
- R5 (b) The U. S. Environmental Protection Agency if the licensee proposes to
R5 release a site as specified in Rule 64E-5.224, F.A.C.

R5 (2) Publish a notice in the Florida Administrative Weekly to solicit comments from
R5 affected parties.

R5 Specific Authority: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 Law Implemented: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 History: New December 19, 2001.

R5 **64E-5.226 Minimizing contamination.** After the effective date of this rule,
R5 applicants for licenses other than renewals shall describe in the application how facility design
R5 and procedures for operation will minimize contamination of the facility and the environment to
R5 the extent practical, facilitate eventual decommissioning, and minimize the generation of
R5 radioactive waste to the extent practical.

R5 Specific Authority: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 Law Implemented: 404.051(4)(6)(9), 404.061(2), 404.081, F.S.
R5 History: New December 19, 2001.

Next page number is Page II - 79

**PART III
SCHEDULE A
EXEMPT CONCENTRATIONS**

Element (atomic number)	Isotope	Column I Gas Concentration ($\mu\text{Ci per ml}$)	Column II Liquid and Gas Concentration ($\mu\text{Ci per ml}$)
Antimony (51)	Sb-122 Sb-124 Sb-125		3×10^{-4} 2×10^{-4} 1×10^{-3}
Argon (18)	Ar-37 Ar-41	1×10^{-3} 4×10^{-7}	
Arsenic (33)	As-73 As-74 As-76 As-77		5×10^{-3} 5×10^{-4} 2×10^{-4} 8×10^{-4}
Barium (56)	Ba-131 Ba-140		2×10^{-3} 3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109 Cd-115m- Cd-115		2×10^{-3} 3×10^{-4} 3×10^{-4}
Calcium (20)	Ca-45 Ca-47		9×10^{-5} 5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141 Ce-143 Ce-144		9×10^{-4} 4×10^{-4} 1×10^{-4}
Cesium (55)	Cs-131 Cs-134m Cs-134		2×10^{-2} 6×10^{-2} 9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57 Co-58 Co-60		5×10^{-3} 1×10^{-3} 5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165 Dy-166		4×10^{-3} 4×10^{-4}
Erbium (68)	Er-169 Er-171		9×10^{-4} 1×10^{-3}

Element (atomic number)	Isotope	Column I Gas Concentration ($\mu\text{Ci per ml}$)	Column II Liquid and Gas Concentration ($\mu\text{Ci per ml}$)
Europium (63)	Eu-152 (9.2 h) Eu-155		6×10^{-4} 2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153 Gd-159		2×10^{-3} 8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196 Au-198 Au-199		2×10^{-3} 5×10^{-4} 2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m In-114m		1×10^{-2} 2×10^{-4}
Iodine (53)	I-126 I-131 I-132 I-133 I-134	3×10^{-9} 3×10^{-9} 8×10^{-8} 1×10^{-8} 2×10^{-7}	2×10^{-5} 2×10^{-5} 6×10^{-4} 7×10^{-5} 1×10^{-3}
Iridium (77)	Ir-190 Ir-192 Ir-194		2×10^{-3} 4×10^{-4} 3×10^{-4}
Iron (26)	Fe-55 Fe-59		8×10^{-3} 6×10^{-4}
Krypton (36)	Kr-85m Kr-85	1×10^{-6} 3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52 Mn-54 Mn-56		3×10^{-4} 1×10^{-3} 1×10^{-3}
Mercury (80)	Hg-197m Hg-197 Hg-203		2×10^{-3} 3×10^{-3} 2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147 Nd-149		6×10^{-4} 3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbian) (41)	Nb-95 Nb-97		1×10^{-3} 9×10^{-3}

Element (atomic number)	Isotope	Column I Gas Concentration ($\mu\text{Ci per ml}$)	Column II Liquid and Gas Concentration ($\mu\text{Ci per ml}$)
Osmium (76)	Os-185 Os-191m Os-191 Os-193		7×10^{-4} 3×10^{-2} 2×10^{-3} 6×10^{-4}
Palladium (46)	Pd-103 Pd-109		3×10^{-3} 9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191 Pt-193m Pt-197m Pt-197		1×10^{-3} 1×10^{-2} 1×10^{-2} 1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142 Pr-143		3×10^{-4} 5×10^{-4}
Promethium (61)	Pm-147 Pm-149		2×10^{-4} 4×10^{-3}
Rhenium (75)	Re-183 Re-186 Re-188		6×10^{-4} 9×10^{-3} 6×10^{-4}
Rhodium (45)	Rh-103m Rh-105		1×10^{-1} 1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97 Ru-103 Ru-105 Ru-106		4×10^{-4} 8×10^{-4} 1×10^{-3} 1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46 Sc-47 Sc-48		4×10^{-4} 9×10^{-4} 3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105 Ag-110m Ag-111		1×10^{-3} 3×10^{-4} 4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85 Sr-89 Sr-91 Sr-92		1×10^{-4} 1×10^{-4} 7×10^{-4} 7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}

Element (atomic number)	Isotope	Column I Gas Concentration ($\mu\text{Ci per ml}$)	Column II Liquid and Gas Concentration ($\mu\text{Ci per ml}$)
Technetium (43)	Tc-96m Tc-96		1×10^{-1} 1×10^{-3}
Tellurium (52)	Te-125m Te-127m Te-127 Te-129m Te-131m Te-132		2×10^{-3} 6×10^{-4} 3×10^{-3} 3×10^{-4} 6×10^{-4} 3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200 Tl-201 Tl-202 Tl-204		4×10^{-3} 3×10^{-3} 1×10^{-3} 1×10^{-3}
Thulium (69)	Tm-170 Tm-171		5×10^{-4} 5×10^{-3}
Tin (50)	Sn-113 Sn-125		9×10^{-4} 2×10^{-4}
Tungsten (Wolfram) (74)	W-181 W-187		4×10^{-3} 7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m Xe-133 Xe-135	4×10^{-6} 3×10^{-6} 1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90 Y-91m Y-91 Y-92 Y-93		2×10^{-4} 3×10^{-2} 3×10^{-4} 6×10^{-4} 3×10^{-4}
Zinc (30)	Zn-65 Zn-69m Zn-69		1×10^{-3} 7×10^{-4} 2×10^{-2}
Zirconium (40)	Zr-95 Zr-97		6×10^{-4} 2×10^{-4}
Beta and gamma emitting radioactive material not listed above with a half-life of less than 3 years		1×10^{-10}	1×10^{-6}

Note 1: Many radioisotopes transform into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

Note 2: For purpose of 64E-5.203, where there is involved a combination of isotopes, the limit

for the combination should be derived as follows: Determine for each isotope in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed unity.

Example:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

Note 3: To convert μCi per ml to SI units of megabecquerels per liter multiply the above values by 37

**PART III
SCHEDULE B
EXEMPT QUANTITIES**

Radioactive Material (Symbol)	Microcuries
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 129 (Cs 129)	100
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 57 (Co 57)	100

Radioactive Material (Symbol)	Microcuries
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co.60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 (Eu 152) (9.2 hr)	100
Europium 152 (Eu 152) (13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 67 (Ga 67)	100
Gallium 72 (Ga 72)	10
Germanium 68 (Ge 68)	10
Germanium 71 (Ge 71)	100
Gold 195 (Au 195)	10
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H 3)	1,000
Indium 111 (In 111)	100
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 123 (I 123)	100
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10

Radioactive Material (Symbol)	Microcuries
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 52 (Fe 52)	10
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191m)	100
Osmium 191 (os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100

Radioactive Material (Symbol)	Microcuries
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Potassium 43 (K 43)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 81 (Rb 81)	10
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1

Radioactive Material (Symbol)	Microcuries
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125m (Te 125m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 156)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
Yttrium 90 (Y 90)	10

Radioactive Material (Symbol)	Microcuries
Yttrium 91 (Y 91)	10
Yttrium 92 (Y 92)	100
Yttrium 93 (Y 93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1
Any alpha emitting radioactive material not listed above other than transuranic radioactive material	0.01

(Schedule C Deleted)

PART III
SCHEDULE D
Limits for Broad License (64E-5.209)

Radioactive Material	Column I (curies)	Column II (curies)
Antimony 122	1	0.01
Antimony 124	1	0.01
Antimony 125	1	0.01
Arsenic 73	10	0.1
Arsenic 74	1	0.01
Arsenic 76	1	0.01
Arsenic 77	10	0.1
Barium 131	10	0.1
Barium 140	1	0.01
Beryllium 7	10	0.1
Bismuth 210	0.1	0.001
Bromine 82	10	0.1
Cadmium 109	1	0.01
Cadmium 115m	1	0.01
Cadmium 115	10	0.1
Calcium 45	1	0.01
Calcium 47	10	0.1
Carbon 14	100	1.0
Cerium 141	10	0.1
Cerium 143	10	0.1
Cerium 144	0.1	0.001
Cesium 131	100	1.0
Cesium 134m	100	1.0
Cesium 134	0.1	0.001
Cesium 135	1	0.01
Cesium 136	10	0.1
Cesium 137	0.1	0.001
Chlorine 36	1	0.01
Chlorine 38	100	1.0
Chromium 51	100	1.0
Cobalt 57	10	0.1
Cobalt 58m	100	1.0

Radioactive Material	Column I (curies)	Column II (curies)
Cobalt 58	1	0.01
Cobalt 60	0.1	0.001
Copper 64	10	0.1
Dysprosium 165	100	1.0
Dysprosium 166	10	0.1
Erbium 169	10	0.1
Erbium 171	10	0.1
Europium 152 (9.2h)	10	0.1
Europium 152 (13y)	0.1	0.001
Europium 154	0.1	0.001
Europium 155	1	0.01
Fluorine 18	100	1.0
Gadolinium 153	1	0.01
Gadolinium 159	10	0.1
Gallium 72	10	0.1
Germanium 71	100	1.0
Gold 198	10	0.1
Gold 199	10	0.1
Hafnium 181	1	0.01
Holmium 166	10	0.1
Hydrogen 3	100	1.0
Indium 113m	100	1.0
Indium 114m	1	0.01
Indium 115m	100	1.0
Indium 115	1	0.01
Iodine 125	0.1	0.001
Iodine 126	0.1	0.001
Iodine 129	0.1	0.01
Iodine 131	0.1	0.001
Iodine 132	10	0.1
Iodine 133	1	0.01
Iodine 134	10	0.1
Iodine 135	1	0.01
Iridium 192	1	0.01
Iridium 194	10	0.1
Iron 55	10	0.1

Radioactive Material	Column I (curies)	Column II (curies)
Iron 59	1	0.01
Krypton 85	100	1.0
Krypton 87	10	0.1
Lanthanum 140	1	0.01
Lutetium 177	10	0.1
Manganese 52	1	0.01
Manganese 54	1	0.01
Manganese 56	10	0.1
Mercury 197m	10	0.1
Mercury 197	10	0.1
Mercury 203	1	0.01
Molybdenum 99	10	0.1
Neodymium 147	10	0.1
Neodymium 149	10	0.1
Nickel 59	10	0.1
Nickel 63	1	0.01
Nickel 65	10	0.1
Niobium 93m	1	0.01
Niobium 95	1	0.01
Niobium 97	100	1.0
Osmium 185	1	0.01
Osmium 191m	100	1.0
Osmium 191	10	0.1
Osmium 193	10	0.1
Palladium 103	10	0.1
Palladium 109	10	0.1
Phosphorus 32	1	0.01
Platinum 191	10	0.1
Platinum 193m	100	1.0
Platinum 191	10	0.1
Platinum 193m	100	1.0
Platinum 193	10	0.1
Platinum 197m	100	1.0
Platinum 197	10	0.1
Polonium 210	0.01	0.0001
Potassium 42	1	0.01

Radioactive Material	Column I (curies)	Column II (curies)
Praseodymium 142	10	0.1
Praseodymium 143	10	0.1
Promethium 147	1	0.01
Promethium 149	10	0.1
Radium 226	0.01	0.0001
Rhenium 186	10	0.1
Rhenium 188	10	0.1
Rhodium 103m	1,000	10.0
Rhodium 105	10	0.1
Rubidium 86	1	0.01
Rubidium 87	1	0.01
Ruthenium 97	100	1.0
Ruthenium 103	1	0.01
Ruthenium 105	10	0.1
Ruthenium 106	0.1	0.001
Samarium 151	1	0.01
Samarium 153	10	0.1
Scandium 46	1	0.01
Scandium 47	10	0.1
Scandium 48	1	0.01
Selenium 75	1	0.01
Silicon 31	10	0.1
Silver 105	1	0.01
Silver 110m	0.1	0.001
Silver 111	10	0.1
Sodium 22	0.1	0.001
Sodium 24	1	0.01
Strontium 85m	1,000	10.0
Strontium 85	1	0.01
Strontium 89	1	0.01
Strontium 90	0.01	0.0001
Strontium 91	10	0.1
Strontium 92	10	0.1
Sulphur 35	10	0.1
Tantalum 182	1	0.01
Technetium 96	10	0.1

Radioactive Material	Column I (curies)	Column II (curies)
Technetium 97m	10	0.1
Technetium 97	10	0.1
Technetium 99m	100	1.0
Technetium 99	1	0.01
Tellurium 125m	1	0.01
Tellurium 127m	1	0.01
Tellurium 127	10	0.1
Tellurium 129m	1	0.01
Tellurium 129	100	1.0
Tellurium 131m	10	0.1
Tellurium 132	1	0.01
Terbium 160	1	0.01
Thallium 200	10	0.1
Thallium 201	10	0.1
Thallium 202	10	0.1
Thallium 204	1	0.01
Thulium 170	1	0.01
Thulium 171	1	0.01
Tin 113	1	0.01
Tin 125	1	0.01
Tungsten 181	1	0.01
Tungsten 185	1	0.01
Tungsten 187	10	0.1
Vanadium 48	1	0.01
Xenon 131m	1,000	10.0
Xenon 133	100	1.0
Xenon 135	100	1.0
Ytterbium 175	10	0.1
Yttrium 90	1	0.01
Yttrium 91	1	0.01
Yttrium 92	10	0.1
Yttrium 93	1	0.01
Zinc 65	1	0.01
Zinc 69m	10	0.1
Zinc 69	100	1.0
Zirconium 93	1	0.01

Radioactive Material	Column I (curies)	Column II (curies)
Zirconium 95	1	0.01
Zirconium 97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.01	0.001

Note: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

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