



Jeb Bush  
Governor

Robert G. Brooks, M.D.  
Secretary

July 21, 2000

Fredrick Combs, Deputy Director  
Office of State and Tribal Program  
U.S. Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike Mail Stop 3 C10  
Rockville, MD 20852-2738

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OSP

Dear Mr. Combs:

Please find attached Florida's proposed rules which satisfy several U.S. Nuclear Regulatory Commission's rule compatibility requirements. These rules are identified by the following Federal Registry numbers and titles.

	Federal Registry Numbers	Title	NRC	Florida Rules Sections
1	63 FR 1890 63 FR 13773	Deliberate Misconduct by Unlicensed Persons	C	64E-5.201(3) and Enforcement Manual Dated May 2000.
2	62 FR 4120	Criteria for the Release of Individuals Administered Radioactive Materials	Many	See attached 64E-5.622
3	62 FR 63634	Exempt Distribution of a Radioactive Drug containing One Microcurie of Carbon-14 Urea	B	64E-5.203(4)
4	63 FR 39477 63 FR 45393	Minor Corrections, Clarifying Changes, and a Minor Policy Change	A-D	See Attached
5	62 FR 1662	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State	C	64E-5.216(1)
6	61 FR 65119	Resolution of dual Regulations of Airborne Effluents of Radioactive Materials; Clean Air Act	C	See Attached

*RIDSC rule Distribution: SP06*

*OSP-006 Inplate*

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	Federal Registry Numbers	Title	NRC	Florida Rules Sections
7	60 FR 50248	10 CFR Part 71: Compatibility with the International Atomic Energy Agency	Many	See Attached
8	61 FR 24669	Termination of Transfer of Licensed Activities; Record Keeping Requirements	Many	See Attached
9	NONE	Part 20 identified in NRC letter dated 11/24/1997	A A	64E-5.101 64E-5.304(2)
10	60 FR 48623	Medical Administration of Radiation and Radioactive Materials	Many	See Attached
11	NA	Adding Optically Stimulated Luminescent Devices (OSLD) as an personal monitoring device option	NA	See Attached

I hope this provides the information you need. If you have any questions, please contact me. Please provide any comments you may have as soon as possible.

Sincerely,



Michael N. Stephens  
Environmental Administrator

Enclosures: Proposed Rules  
Attachment A – Details

Cc: William A. Passetti, Chief  
Bureau of Radiation Control

Attachment A - Details

	NRC Chronology Identification	FR Notice	RATS ID	Compatibilitiy Due Date	Com	NRC Section	Florida Section	Comments
1	Deliberate Misconduct by Unlicensed Persons	63 FR 1890 63 FR 13773	1998-1	2/12/2001	C	30.10	64E-5.201(3) and Enforcement Manual Dated May 2000.	Text added to enforcement manual to address deliberate misconduct.
2	Criteria for the Release of Individuals Administered Radioactive Materials	62 FR 4120	1997-3	5/29/2000	C, D/H&S, D A A	35.75  20.1003 20.1301 (a)	64E-5.622(1) , (2), (4) 64E-5.101 64E-5.301 64E-5.312	Patient release criteria 35.75 is approved by license amendment only
3	Exempt Distribution of a Radioactive Drug containing One Microcurie of Carbon-14 Urea	62 FR 63634	1997-7	01/02/2001	B	30.21	64E-5.203(4)	
4	Minor Corrections, Clarifying Changes, and a Minor Policy Change	63 FR 39477 63 FR 45393	1998-5	10/26/2001	A A A B  C C C C C D, H&S D D, H&S	20.1003 20.1201 20.1208 32.54  20.2101 20.2106 20.2202 39.33 39.71 20.1101 20.1206 20.1501	64E-5.101 64E-5.304(1)(b)1.,(3) 64E-5.311(4) 64E-5.210(5)  64E-5.334(2) 64E-5.339(1)(a) 64E-5.344 64E-5.1103 64E-5.1113 64E-5.303(2) 64E-5.309(1) 64E-5.314(1)(b)	No Change Florida rules incorporates 32.54 by reference          64E-5.1111 ok (No changes)

Attachment A - Details

	NRC Chronology Identification	FR Notice	RATS ID	Compatibilty Due Date	Com	NRC Section	Florida Section	Comments
					D, H&S D D, H&S D D D, H&S	20.1502 20.1903 20.1906  35.641 35.643 36.23	64E-5.315(1)(2) 64E-5.324(2) 64E-5.327(4)  64E-5.643(1)(b) 64E-5.645 64E-5.1406(1)(g)	Did not change Florida's rule Florida rule has text to notify Department instead of NRC Operations Center.
5	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State	62 FR 1662	1997-2	2/27/2000	C, D (fees)	150.20 (a) (b)	64E-5.216(1)	NRC fees not applicable
6	Resolution of dual Regulations of Airborne Effluents of Radioactive Materials; Clean Air Act	61 FR 65119	1997-1	01/09/2000	C C C C C	20.1003 20.1101 (d) 20.2203 (a)(2)(vi) 20.2203 (b)(1)(vi) 20.2203 (b)(2)	64E-5.101 64E-5.303(5) 64E-5.345(1)(b)6. 64E-5.3459(2)(a) 64E-5.3459(2)(b)	

Attachment A - Details

	NRC Chronology Identification	FR Notice	RATS ID	Compatibility Due Date	Com	NRC Section	Florida Section	Comments
7	10 CFR Part 71:Compatibility with the International Atomic Energy Agency	60 FR 50248	1996-1	04/01/1999	arious	Various	64E-5.1502(2)	The applicable sections in 10 CFR Part 71, duplicates or references 49 CFR. The sections that do not are not applicable to Agreement States. (Ex. Type B Package written QA Program). We have elected to incorporate by reference the 10/01/1997 versions of 49 CFR Parts 171-173, 177, 383, 390-397 instead 10 CFR Part 71.
8	Termination of Transfer of Licensed Activities; Record Keeping Requirements	61 FR 24669	1996-3	6/17/1999	D	20.2108 (b)	64E-5.103	Not Adopted Florida 64E-5.103 serves same purpose. This section indicates which decommissioning records are to be transferred to a new licensee who is accepting the existing license. Florida statutes state that the license is only valid to the person it was originally issued and may not be transferred. Changed to require disposal records if requested by department instead required for license termination.  Note. Subsection 404.031(3), Florida Statute, prohibits the transfer of licenses to others.
					H&S	30.35(g)	None	
					H&S	40.36(f)	None	
					D	70.25(g)	None	
					D	30.36(k) (4)	64E-5.214(4)(b)2.d.	
					D	40.42(k) (4)	"	
					D	70.38(k) (4)	"	
					D	30.51(d)	64E-5.214(4)(b)2.d.	
					D	30.51(f)	"	
D	40.61(d)	"						
D	40.61(f)	"						
D	70.51(b)	"						

Attachment A - Details

	NRC Chronology Identification	FR Notice	RATS ID	Compatibiliy Due Date	Com	NRC Section	Florida Section	Comments
					D H&S H&S H&S	(6) 61.30(a) (3) 30.51(e) 40.61(e) 71.51(b) (7)		
9	Part 20 identified in NRC letter dated 11/24/1997	NA	NA	NA	A A	20.2001 20.1201	64E-5.101 64E-5.309	Modified definition as requested. Adjusted PSE language as requested. Some of these incorporated in item 2 above.
10	Medical Administration of Radiation and Radioactive Materials	60 FR 48623	1995-7	10/20/98	A A	20.1301 35.2	64E-5.101 64E-5.101	
11	NA	NA	NA	NA	NA	NA	Individual Monitoring Device definition 64E-5.101 and several cites regarding personal monitoring devices	Adding Optically Stimulated Luminescent Devices (OSLD) as an personal monitoring device option (Unique to Florida regulations).

phase of the National Pollutant Discharge Elimination System (NPDES) permitting program as required by the Clean Water Act. The NPDES program consists primarily of five elements including Municipal, Industrial, Pretreatment, Stormwater and Federal Facilities. In a phased approach to delegation, the Department has previously been authorized to operate three of the elements, specifically the Municipal, Industrial, and Pretreatment programs. In accordance with the Memorandum of Agreement between EPA and the Department for delegation of the NPDES program, and pursuant to Section 403.0885, F.S., the Department is now seeking authority to administer the Stormwater and Federal Facility components of the NPDES program. The proposed new rule will establish standards for issuing or denying permits that are substantively identical to existing federal regulations. Separate rulemaking for procedural provisions of Chapter 62-624, F.A.C., is being done concurrently under docket number 98-28R. This proposed rule shall become effective twenty (20) days after filing with the Department of State.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: None.

Any person who wishes to provide information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 403.061, 403.087, 403.088, 403.0885, 403.08851, 403.815 FS.

LAW IMPLEMENTED: 403.061, 403.087, 403.0876, 403.088, 403.0885, 403.815 FS.

THIS RULEMAKING IS UNDERTAKEN PURSUANT TO SECTION 403.8055, F.S.

SUBSTANTIALLY AFFECTED PERSONS MAY FILE OBJECTIONS WITH THE ENVIRONMENTAL REGULATION COMMISSION AT THE FOLLOWING ADDRESS: 3900 Commonwealth Boulevard, Mail Station 18, Tallahassee, Florida 32399-3000, Attention: Jacki McGorty. Objections must be received within 14 days of publication of this notice and must specify the portions of the proposed rule to which the person objects and the reason for the objection. Objections that are frivolous will not be considered sufficient to prohibit adoption of the rule as published.

WRITTEN COMMENTS: The Secretary of the Department of Environmental Protection will consider written comments received within 21 days of publication of this notice. Comments should be submitted to: Michael Bateman, Division of Water Resource Management, Bureau of Submerged Lands and Environmental Resources, Mail Station 2505, Florida Department of Environmental Protection, 2600 Blair Stone Road, Tallahassee, Florida 32399-2400.

THE FULL TEXT OF THE PROPOSED RULE IS:

62-624.500 Standards for Issuing or Denying Permits.

(1) The Department shall use the provisions of 40 CFR 122.26 revised as of July 1, 1999, and hereby incorporated by reference, for implementation of the program. Where there are conflicts with general or specific requirements of 40 CFR 122.26, the requirements and procedures set forth in this chapter shall supersede all other procedures and requirements for MS4 facilities.

(2) The Department shall issue a MS4 permit only if the applicant affirmatively provides the Department with reasonable assurance that the stormwater management program will achieve a reduction of the discharge of pollutants from the MS4 to the Maximum Extent Practicable in accordance with 40 CFR 122.26.

(3) The permittee shall at all times properly operate and maintain the facility and systems of treatment and control, and related appurtenances, that are installed and used by the permittee to achieve compliance with the conditions of the permit.

Specific Authority 403.061, 403.087, 403.088, 403.0885, 403.08851, 403.815 FS. Law Implemented 403.061, 403.087, 403.0876, 403.088, 403.0885, 403.815 FS. History-New

NAME OF PERSON ORIGINATING PROPOSED RULE: Mimi Drew, Director, Division of Water Resource Management, Department of Environmental Protection

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Kirby Green, Deputy Secretary, Department of Environmental Protection

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 2, 2000

DEPARTMENT OF HEALTH

Division of Environmental Health and Statewide Programs

RULE TITLES:	RULE NOS.:
Definitions	64E-5.101
Licensing of Radioactive Material	64E-5.201
Radioactive Material Other Than Source Material - Exemptions	64E-5.203
Expiration and Termination of Licenses and Decommission of Sites and Separate Buildings or Outdoor Areas	64E-5.214
Reciprocal Recognition of Licenses for Byproduct, Source, Naturally Occurring and Accelerator Produced Radioactive Material, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass	64E-5.216
Standards for Protection Against Radiation	64E-5.301
Radiation Protection Programs	64E-5.303
Occupational Dose Limits for Adults	64E-5.304
Planned Special Exposures	64E-5.309
Dose to an Embryo or Fetus	64E-5.311
Dose Limits for Individual Members of the Public	64E-5.312

General	64E-5.314
Conditions Requiring Individual Monitoring of	
External and Internal Occupational Dose	64E-5.315
Posting Requirements	64E-5.323
Exemptions to Labeling Requirements	64E-5.326
General Provisions	64E-5.334
Records of Individual Monitoring Results	64E-5.339
Reports of Stolen, Lost, or Missing Licensed	
or Registered Sources of Radiation	64E-5.343
Notification of Incidents	64E-5.344
Reports of Exposures, Radiation Levels,	
Concentrations of Radioactive Material	
Exceeding the Constraints or Limits, and	
Misadministrations	64E-5.345
Personnel Monitoring Control	64E-5.414
Subjects to be Covered During the Instruction	
of Industrial Radiographers	64E-5.420
Release of Patients Containing	
Radiopharmaceuticals or Permanent Implants	64E-5.622
Radiation Surveys for Teletherapy Facilities	64E-5.643
Modification of Teletherapy Unit or Room	
Before Beginning a Treatment Program	64E-5.645
Radiation Survey Instruments	64E-5.1103
Personnel Monitoring	64E-5.1112
Personnel Monitoring	64E-5.1310
Access Control	64E-5.1406
Personnel Monitoring	64E-5.1418
Transportation of Radioactive Material	64E-5.1502

**PURPOSE AND EFFECT:** The purpose of these rules is to maintain the department's compatibility with the U.S. Nuclear Regulatory Commission. The effect is to specify procedures for the release of patients who have been treated with radiopharmaceuticals or have permanent implants containing radioactive material; exempt carbon 14 urea capsules used to detect H. pylori bacteria; specify records of radioactive material disposal; require constraint of air emissions of radioactive material; clarify monitoring and dose requirements to a declared pregnant woman and the embryo or fetus; and allows the use of optically stimulated luminescent devices to monitor radiation exposure.

**SUMMARY:** These proposed rules specify procedures for the release of patients who have been treated with radiopharmaceuticals or have permanent implants containing radioactive material; exempt carbon 14 urea capsules used to detect H. pylori bacteria; specify records of radioactive material disposal; require constraint of air emissions of radioactive material; clarify monitoring and dose requirements to a declared pregnant woman and the embryo or fetus; and allows the use of optically stimulated luminescent devices to monitor radiation exposure.

**SPECIFIC AUTHORITY:** 404.051, 404.061, 404.081, 404.141 FS.

LAW IMPLEMENTED: 404.022, 404.051(1),(4),(10),(11), 404.061(2),(3), 404.081, 404.141 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

TIME AND DATE: 9:00 a.m., August 1, 2000

PLACE: Room 210J, 4042 Bald Cypress Way, Tallahassee, FL 32399-1741

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS William A. Passetti, Chief, Bureau of Radiation Control, (850)245-4266

THE FULL TEXT OF THE PROPOSED RULES IS:

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) through (29) No change.

(30) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

~~(31)~~(30) No change.

(32)(31) "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.

(32) through (56) renumbered (33) through (57) No change.

(58)(57) "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.

(58) through (60) renumbered (59) through (61) No change.

(62)(61) "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.

(62) through (67) renumbered (63) through (68) No change.

(69) "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/cm<sup>2</sup>).

(68) through (84) renumbered (70) through (86) No change.

(87)(85) "Misadministration" means the administration of:

(a) Iodine 123, iodine 125 or iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels):

1. Involving the wrong individual patient or wrong radiopharmaceutical; or
2. When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and the prescribed dosage exceeds 30 microcuries.

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

1. Involving the wrong individual patient, wrong radiopharmaceutical, or wrong route of administration; or
2. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(c) A gamma stereotactic radiosurgery radiation dose:

1. Involving the wrong individual patient or wrong treatment site; or
2. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

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

1. Involving the wrong individual patient, wrong mode of treatment, or wrong treatment;
2. When treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
3. When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
4. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(e) A brachytherapy radiation dose:

1. Involving the wrong individual patient, wrong radioisotope, or wrong treatment site, excluding, for permanent implants, seeds that were implanted in the correct site but which migrated outside the treatment site;
2. Involving a sealed source that is leaking;
3. When, for a temporary implant, one or more seeds are not removed upon completion of the procedure; or
4. When the calculated administered dose differs from the prescribed dose by more than 20 percent from the prescribed dose.

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

1. Involving the wrong individual patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
2. When the dose to the individual patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

(86) through (92) renumbered (88) through (94) No change.

(95)(93) "Occupational dose" means the dose received by an individual in the course of employment ~~while engaged in activities licensed or registered by the department~~ in 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 64E-5.622 ~~as a patient from medical practices,~~ from voluntary participation in medical research programs, or as a member of the public.

(94) through (105) renumbered (96) through (107) No change.

(108)(106) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive materials released by a licensee or registrant, or to any other sources of radiation under the control of the licensee or registrant. Public dose ~~It~~ does not include occupational dose; ~~or doses~~ dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released as specified in 64E-5.622, ~~dose received as a patient from medical practices,~~ or dose from voluntary participation in medical research programs.

(107) through (157) renumbered (109) through (159) No change.

(160)(158) "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.

(159) through (172) renumbered (161) through (174) No change.

Specific Authority 404.042, 404.051, 404.061 FS. Law Implemented 404.022(2) FS. History--New 1-1-94, Formerly 10D-91.113, Amended

## 64E-5.201 Licensing of Radioactive Material.

(1) through (2) No change.

(3) The Procedures for Radioactive Materials Enforcement Actions, May 2000 General Statement of Policy and Procedure for Radioactive Material Enforcement Actions September 1992, which is available from the department and which is herein incorporated by reference, will be used to determine enforcement actions to be taken.

(4) No change.

Specific Authority 404.051(4), 404.061(2), 404.20 FS. Law Implemented 404.022, 404.051(1),(4),(5),(6), 404.061(2), 404.081(1), 404.141, 404.20(1) FS. History—New 7-17-85, Amended 8-25-91, 5-12-93, 5-15-96, Formerly 10D-91.301, Amended \_\_\_\_\_.

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

(1) through (3) No change.

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

(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.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license as specified in these regulations.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license as specified in 10 CFR Part 32, Sec. 32.21.

(d) Nothing in this section relieves a person from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

Specific Authority 404.051, 404.061, 404.141 FS. Law Implemented 404.022, 404.051(1),(4),(10), 404.141 FS. History—New 7-17-85, Amended 4-4-89, 5-15-96, Formerly 10D-91.303, Amended \_\_\_\_\_.

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

(1) through (3) No change.

(4)(a) If a licensee does not submit an application for license renewal under Part II, the licensee shall, on or before the expiration date specified in the license:

1. Terminate the use of radioactive material;
2. Remove radioactive contamination 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 7-17-85; and

5. Submit a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual contamination in some other manner. The licensee shall, as appropriate:

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.

(b)1. If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found.

2. Specific licenses will be terminated by written notice to the licensee when the department determines that:

- a. Radioactive material has been properly disposed; and
- b. A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or
- c. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

d. Department has received the following records, if requested:

I. Disposal records specified in 64E-5.330, 64E-5.331(1)(a)(c),(2),(3), or 64E-5.336(2)(d); and

II. Records specified in 64E-5.214(6).

(c)1. If detectable levels of residual radioactive contamination 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 radioactive material present as contamination 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, the department will inform the licensee of the appropriate further actions required for termination of the license.

(5) through (7) No change.

Specific Authority 404.051(4),(9),(6), 404.061(2), 404.081 FS. Law Implemented 404.051(1),(4),(6),(9), 404.061(2), 404.081(1) FS. History—New 7-17-85, Amended 5-12-93, 5-18-98, Formerly 10D-91.315, Amended

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

(1) Subject to these regulations, any person who holds a specific license from the 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 ~~may~~ 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:

(a) The out-of-state license document does not limit the performance of the function authorized by such document to specified installations or locations;

(b) The out-of-state licensee notifies the Department in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner;

(c) The out-of-state licensee complies with these applicable regulations and with all the terms and conditions of the licensing document, except any such terms and conditions that are which may be inconsistent with these applicable regulations; and

(d) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person:

1. Specifically licensed by the Department, by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive such material, or

2. Exempt from the requirements for a license for such material under 64E-5.203(1)(a).

(2) through (3) No change.

Specific Authority 404.051(4),(11), 404.061(2), 404.081(1), 404.141 FS. Law Implemented 404.051(1),(2),(4),(6),(11), 404.061(2), 404.081(1) FS. History—New 7-17-85, Amended 4-4-89, Formerly 10D-91.321, Amended

64E-5.301 Standards for Protection Against Radiation.

(1) No change.

(2) Except as specifically provided in other parts of these rules, this part applies to persons licensed or registered by the department to receive, possess, use, or transfer sources of radiation. The limits in this part do not apply to doses from background radiation, to exposure of patients to radiation for medical diagnosis or therapy, to exposure from individuals administered radioactive material and released as specified in 64E-5.622, or to voluntary participation in medical research programs.

Specific Authority 404.051(1) FS. Law Implemented 404.022, 404.051(1),(4), 404.181(1)(b) FS. History—New 1-1-94, Amended 5-15-96, Formerly 10D-91.431, Amended

64E-5.303 Radiation Protection Programs.

(1) No change.

(2) The licensee or registrant shall use to the extent practical practicable procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as reasonably achievable.

(3) through (4) No change.

(5) To implement the ALARA requirements of 64E-5.303(2), and notwithstanding the requirements of 64E-5.312 of this part, licensees shall establish constraints on air emissions of radioactive material, excluding radon 222 and

its daughters, to the environment so that individual members of the public who are likely to receive the highest doses are not expected to receive a total effective dose equivalent in excess of 10 millirems (0.10 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the occurrence as specified in 64E-5.345 and promptly take corrective action to ensure against recurrence.

Specific Authority 404.051(4), 404.081(1) FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History--New 1-1-94, Amended 11-20-94, Formerly 10D-91.434, Amended \_\_\_\_\_.

#### 64E-5.304 Occupational Dose Limits for Adults.

(1) The licensee or registrant shall control the occupational dose to individuals adults, except for planned special exposures as specified in 64E-5.309, to the following dose limits:

(a) No change

(b) The annual limits to the lens of the eye, to the skin, and to the extremities which are:

1. A lens eye dose equivalent of 15 rem (0.15 sievert), and
2. No change

(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual could receive receiving during the current year and during the individual's lifetime as specified in 64E-5.309(5)(a) and (b).

(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure. The deep dose equivalent, lens eye dose equivalent and shallow dose equivalent can be assessed from surveys or other radiation measurements to demonstrate compliance with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable.

(4) through (6) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History--New 1-1-94, Formerly 10D-91.435, Amended \_\_\_\_\_.

#### 64E-5.309 Planned Special Exposures.

A licensee or registrant can authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 64E-5.304 if each of the following conditions is satisfied:

(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose ~~higher exposure~~ are unavailable or impractical.

(2) through (7) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History--New 1-1-94, Formerly 10D-91.440, Amended \_\_\_\_\_.

#### 64E-5.311 Dose to an Embryo or Fetus.

(1) through (3) No change.

(4) If by the time the woman declares pregnancy to the licensee or registrant the dose to the embryo or fetus has exceeded 0.5 rem 0.45 rem (5 mSv 4.5 mSv) or is within 0.05 rem (0.5 mSv) of this dose, the licensee or registrant shall be considered in compliance with 64E-5.311(1) if the additional dose to the embryo or fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

(5) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History--New 1-1-94, Formerly 10D-91.442, Amended \_\_\_\_\_.

#### 64E-5.312 Dose Limits for Individual Members of the Public.

(1) Each licensee or registrant shall conduct operations so that:

(a) Except as specified in 64E-5.312(1)(b), the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released as specified in 64E-5.622, from voluntary participation in medical research programs and from the licensee's disposal of radioactive material into sanitary sewerage as specified in 64E-5.330;

(b) In facilities in operation before January 1, 1994, the total effective dose equivalent to individual members of the public from infrequent exposure to radiation from diagnostic and therapeutic radiation machines does not exceed 0.5 rem (5 millisievert) in a year; and

(c) The dose in any unrestricted area from external sources, exclusive of the dose contribution from patients administered radioactive material and released as specified in 64E-5.622, does not exceed 0.002 rem (0.02 millisievert) in any one hour.

(2) through (4) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History--New 1-1-94, Amended 5-15-96, Formerly 10D-91.443, Amended \_\_\_\_\_.

#### 64E-5.314 General.

(1) Each licensee or registrant shall make or cause to be made surveys that:

(a) Are necessary for the licensee or registrant to comply with this part; and

(b) Are necessary under the circumstances to evaluate:

1. The magnitude and extent of rRadiation levels;
2. Concentrations or quantities of radioactive material; and
3. The potential radiological hazards ~~that could be present.~~

(2) through (5) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History—New 1-1-94, Amended 11-20-94, Formerly 10D-91.445, Amended \_\_\_\_\_.

64E-5.315 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum:

(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

(a) Adults likely to receive in 1 year from sources external to the body a dose in excess of 10 percent of the limits in 64E-5.304(1);

(b) ~~Minors and declared pregnant women~~ likely to receive in 1 year from radiation sources external to the body a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv) or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv); 10 percent of any of the applicable limits in 64E-5.310 or 64E-5.311; and

(c) Declared pregnant women likely to receive during the entire pregnancy from radiation sources external to the body a deep dose equivalent in excess of 0.1 rem (1 mSv); and

(d)(e) Individuals entering a high or very high radiation area.

(2) Each licensee shall monitor to determine compliance with 64E-5.307 the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(a) Adults likely to receive in 1 year an intake in excess of 10 percent of the applicable ALI in State of Florida Office of Radiation Control ALIs, DACs, and Effluent Concentrations July 1993, Table 1, Columns 1 and 2; and

(b) ~~Minors and declared pregnant women~~ likely to receive in 1 year a committed effective dose equivalent in excess of 0.1 0.05 rem (1.0 0.5 millisievert); and

(c) Declared pregnant women likely to receive during the entire pregnancy a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History—New 1-1-94, Formerly 10D-91.446, Amended \_\_\_\_\_.

64E-5.323 Posting Requirements.

(1) through (4) No change.

(5) Posting of Areas or Rooms in which Licensed Material is Used or Stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in State of Florida Office of Radiation Control Radioactive Material Requiring Labeling, May 2000 July 1993, which is herein incorporated by reference and which is available from the department, with a conspicuous sign or signs bearing the

radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History—New 1-1-94, Formerly 10D-91.456, Amended \_\_\_\_\_.

64E-5.326 Exemptions to Labeling Requirements.

A licensee is not required to label:

(1) Containers holding licensed material in quantities less than the quantities listed in State of Florida Office of Radiation Control Radioactive Material Requiring Labeling, May 2000 July 1993;

(2) through (6) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History—New 1-1-94, Formerly 10D-91.459, Amended \_\_\_\_\_.

64E-5.334 General Provisions.

(1) No change.

(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this part, such as total effective dose equivalent, ~~total organ dose equivalent~~, shallow dose equivalent, lens eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.051(1),(4), 404.081 FS. History—New 1-1-94, Amended 5-18-98, Formerly 10D-91.469, Amended \_\_\_\_\_.

64E-5.339 Records of Individual Monitoring Results.

(1) Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring is required as specified in 64E-5.315, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before the effective date of the rule need not be changed. These records shall include when applicable:

(a) The deep dose equivalent to the whole body, lens eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

(b) The estimated intake of radionuclides as specified in 64E-5.305;

(c) The committed effective dose equivalent assigned to the intake of radionuclides;

(d) The specific information used to calculate the committed effective dose equivalent as specified in 64E-5.307(3);

(e) The total effective dose equivalent when required by 64E-5.305; and

(f) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(2) through (5) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History--New 1-1-94, Formerly 10D-91.475, Amended \_\_\_\_\_.

64E-5.343 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

(1) Telephone Reports. Each licensee or registrant shall report to the department by telephone the following:

(a) Stolen, lost or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in State of Florida Office of Radiation Control Radioactive Material Requiring Labeling, May 2000 July 1993, immediately after its occurrence becomes known to the licensee if it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

(b) Lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in State of Florida Office of Radiation Control Radioactive Material Requiring Labeling, May 2000 July 1993, that is still missing within 30 days after its occurrence becomes known.

(c) A stolen, lost, or missing radiation machine immediately after its occurrence becomes known.

(2) through (4) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History--New 1-1-94, Formerly 10D-91.480, Amended \_\_\_\_\_.

64E-5.344 Notification of Incidents.

(1) Immediate Notification. Regardless of other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that might have caused or threatens to cause any of the following conditions:

(a) An individual to receive:

1. A total effective dose equivalent of 25 rem (0.25 sievert) or more;

2. A lens ~~An eye~~ dose equivalent of 75 rem (0.75 sievert) or more; or

3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 gray) or more; or

(b) The release of radioactive material inside or outside of a restricted area so that if an individual had been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(2) Twenty-Four Hour Notification. Each licensee or registrant shall report to the department within 24 hours of discovery of the event each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that might have caused or threatens to cause any of the following conditions:

(a) An individual to receive in a period of 24 hours:

1. A total effective dose equivalent exceeding 5 rem (0.05 sievert);

2. A lens ~~An eye~~ dose equivalent exceeding 15 rem (0.15 sievert); or

3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 sievert); or

(b) The release of radioactive material inside or outside of a restricted area so that if an individual had been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations such as hot-cells or process enclosures.

(3) through (8) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History--New 1-1-94, Amended 5-15-96, Formerly 10D-91.481, Amended \_\_\_\_\_.

64E-5.345 Reports of Exposures, Radiation Levels, Concentrations of Radioactive Material Exceeding the Constraints or Limits, and Misadministrations.

(1) Reportable Events. In addition to the notification required by 64E-5.344, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(a) Incidents for which notification is required by 64E-5.344; or

(b) Doses in excess of any of the following:

1. The occupational dose limits for adults in 64E-5.304;

2. The occupational dose limits for a minor in 64E-5.310;

3. The limits for an embryo or fetus of a declared pregnant woman in 64E-5.311;

4. The limits for an individual member of the public in 64E-5.312; or

5. Any applicable limit in the license or registration; or

6. The ALARA constraints for air emissions specified in 64E-5.303(5); or

(c) Levels of radiation or concentrations of radioactive material in:

1. A restricted area in excess of applicable limits in the license or registration; or

2. An unrestricted area in excess of 10 times the applicable limit set forth in this part or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 64E-5.312; or

(d) For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(2) Contents of Reports.

(a) Each report required by 64E-5.345(1) shall describe the extent of exposure of individuals to radiation and radioactive material, including as appropriate:

1. Estimates of each individual's dose;
2. The levels of radiation and concentrations of radioactive material involved;
3. The cause of the elevated exposures, dose rates, or concentrations; and
4. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.

(b) Each report filed as specified in 64E-5.345(1) shall include for each occupationally overexposed individual exposed: the name, social security account number, and date of birth. With respect to the limit for the embryo or fetus in 64E-5.311, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(3) No change.

(4) Reports of Misadministrations.

(a) The licensee or registrant shall notify the department by telephone no later than the next calendar day after the discovery of the misadministration. The licensee or registrant shall also notify the referring physician of the affected individual patient and the individual patient or a responsible relative or guardian, unless the referring physician personally informs the licensee either that he will inform the individual patient or believes, based on medical judgment, that telling the individual patient or the individual's patient's responsible relative or guardian would be harmful to either. These notifications shall be made within 24 hours after the licensee or registrant discovers the misadministration. If the referring physician, individual patient or the individual's patient's responsible relative or guardian cannot be reached within 24 hours, the licensee or registrant shall notify them as soon as practicable. The licensee is not required to notify the individual patient or the individual's patient's responsible relative or guardian without first consulting the referring physician; however, the licensee or registrant shall not delay medical care for the individual patient because of this.

(b) Written Report. Within 15 days after the misadministration report to the department, the licensee or registrant shall report in writing to the department and to the referring physician and furnish a copy of the report to the individual patient or the individual's patient's responsible relative or guardian if either was previously notified by the licensee or registrant as specified in (4)(a), above, or a brief description of both event and consequences as they affect the individual patient or the individual's patient's responsible relative or guardian if a statement is included that the report submitted to the department can be obtained from the licensee or registrant. The written report shall include the licensee's or registrant's name; the prescribing physician's name; the

referring physician's name; a brief description of the event; why the event occurred; the effect on the individual patient; the action taken to prevent recurrence; whether the licensee or registrant informed the individual patient or the individual's patient's responsible relative or guardian and what information was provided to the individual patient or individual's patient's responsible relative or guardian, and if not, a written medical justification. The report shall not include the individual's patient's name or other information that could lead to identification of the individual patient.

(5) Records of Misadministrations. Each licensee or registrant shall retain a record of each misadministration for 20 years. The record shall contain the names of all individuals involved in the event, including the prescribing physician, the allied health personnel, the individual patient, and the individual's patient's referring physician, the individual's patient's identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the individual patient, what improvements are needed to prevent recurrence, and the actions taken, if any, to prevent recurrence.

(6) Rights and Duties of Licensees or Registrants. Aside from the notification requirement, nothing in this section shall affect any rights or duties of licensees, registrants or physicians in relation to each other, the individual patient, or responsible relatives or guardians.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History—New 1-1-94, Formerly 10D-91.482, Amended

#### 64E-5.414 Personnel Monitoring Control.

(1) The licensee or registrant shall not permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter, an alarming ratemeter, and either a film badge, optically stimulated luminescent device (OSLD), or a thermoluminescent dosimeter (TLD). Use of alarm ratemeters is not required for radiography performed in an approved permanent radiographic installation meeting the requirements of 64E-5.410. Pocket dosimeters shall have a range from 0 to 200 milliroentgens ( $2\text{mSv } 5.16 \times 10^{-5}\text{C per kg}$ ) and shall be recharged daily or at the start of each shift. Each film badge, OSLD, or TLD shall be assigned to and worn by only one individual.

(2) through (3) No change.

(4) If an individual's pocket dosimeter is discharged beyond its range, the individual's film badge, OSLD, or TLD shall immediately be sent for processing.

(5) Reports received from the film badge, OSLD, or TLD processor and records of daily pocket dosimeter readings shall be kept for inspection by the Department for 5 years after the death of the individual. If a report is received from the film badge, OSLD, or TLD processor that indicates an individual

has received a radiation exposure in excess of the amounts specified in 64E-5.304(1), the licensee or registrant shall notify the Department pursuant to Part III, Subpart L.

(6) No change.

Specific Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.081 FS. History—New 7-17-85, Amended 1-1-94, Formerly 10D-91.515, Amended \_\_\_\_\_.

64E-5.420 Subjects to be Covered During the Instruction of Industrial Radiographers.

The subjects to be covered during the instruction of industrial radiographers shall include:

(1) No change.

(2) Radiation detection instrumentation to be used, including:

(a) Use of radiation survey instruments, including operation, calibration and limitations;

(b) Survey techniques;

(c) Use of personnel monitoring equipment, including film badges, OSLDs, thermoluminescent dosimeters (TLDs), pocket dosimeters, and alarm ratemeters;

(3) through (6) No change.

Specific Authority 404.051, 404.071 FS. Law Implemented 404.071 FS. History—New 7-17-85, Amended 1-1-94, 5-15-96, Formerly 10D-91.521, Amended \_\_\_\_\_.

64E-5.622 Release of Patients Containing Radiopharmaceuticals or Permanent Implants.

(1) Except as authorized by 64E-5.622(4), F.A.C., a A licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:

(a) The dose rate from the patient is less than 5 millirems (50 µSv) per hour at a distance of 1 meter; or

(b) The activity in the patient is less than 30 millicuries (1.11 GBq).

(2) Except as authorized by 64E-5.622(4), F.A.C., a A licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 5 millirems (50 uSv) per hour at a distance of 1 meter.

(3) No change.

(4) Licensees and license applicants can submit proposed procedures to release individuals from their control who have been administered radiopharmaceuticals or permanent implants containing radioactive material to the department for approval. The procedures must contain:

(a) An analysis and evaluation of pertinent information to demonstrate that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (5 µSv):

(b) A copy of the instructions including written instructions to be given to the released individual on actions recommended to maintain doses to other individuals as low as

is reasonably achievable if the total effective dose equivalent to another individual is likely to exceed 100 millirem (1 µSv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1 µSv) if there were no interruption of breast-feeding, the instructions also shall include:

1. Guidance on the interruption or discontinuance of breast-feeding and

2. Information on the consequences of failing to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual from their control who has been administered radiopharmaceuticals or permanent implants containing radioactive material for 3 years after the date of release.

(5)(4) A licensee shall maintain a record of patient surveys which demonstrates compliance with 64E-5.622(1) for 3 years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient, and the initials of the individual who made the survey.

Specific Authority 404.051, 404.061, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1),(4),(6),(10),(11), 404.061(2),(3), 404.081, 404.141 FS. History—New 8-25-91, Amended 5-15-96, Formerly 10D-91.730, Amended \_\_\_\_\_.

64E-5.643 Radiation Surveys for Teletherapy Facilities.

(1) The licensee shall perform radiation surveys with an operable radiation survey instrument calibrated as provided in 64E-5.615 before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 64E-5.636.

(a) The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field shall not exceed 10 millirems (100 µSv) per hour and 2 millirems (20 µSv) per hour.

(b) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, radiation levels in restricted areas shall be unlikely to cause any personnel exposures occupationally exposed individuals to receive a dose in excess of the limits specified in 64E-5.304; and radiation dose rates of any individual member of the public levels in unrestricted areas shall not exceed the limits specified in 64E-5.312(1)(c).

(2) through (3) No change.

Specific Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1),(4),(5),(6),(8),(9),(10),(11), 404.061(2),(3), 404.071(1), 404.081, 404.141 FS. History—New 8-25-91, Amended 1-1-94, Formerly 10D-91.762, Amended \_\_\_\_\_.

64E-5.645 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.

If the survey required by 64E-5.643 indicates that any an individual member of the public is likely to receive a dose in excess of in an unrestricted area may be exposed to levels of radiation greater than those specified in permitted by 64E-5.312(1)(c), before beginning the treatment program the licensee shall comply with (1) or (2) below:

(1) Equip the unit with stops or add additional radiation shielding to ensure compliance with 64E-5.312(1)(c); perform the survey required by 64E-5.643 again; and include in the report required by 64E-5.646 the results of the initial survey, a description of the modification made to comply with 64E-5.645(1), and the results of the second survey.

(2) No change.

Specific Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1),(4),(5),(6),(8),(9),(10),(11), 404.061(2),(3), 404.071(1), 404.081, 404.141 FS. History—New 8-25-91, Amended 1-1-94, Formerly 10D-91.764, Amended.

64E-5.1103 Radiation Survey Instruments.

(1) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station and temporary jobsite to make physical radiation surveys as required by this part and by Part III. Instrumentation shall be capable of measuring 0.1 milliroentgen (0.001 mSv ~~2.58 x 10<sup>-8</sup> C per kg~~) per hour through at least 50 milliroentgens (0.5 mSv ~~1.29 x 10<sup>-5</sup> C per kg~~) per hour. Survey instruments acquired before January 1, 1989 and capable of measuring 0.1 milliroentgen (2.58 x 10<sup>-8</sup> C per kg) per hour through at least 20 milliroentgens (5.16 x 10<sup>-6</sup> C per kg) per hour also satisfy this requirement until January 1, 1994.

(2) through (3) No change.

Specific Authority 404.051, 404.061, 404.081, 404.22 FS. Law Implemented 404.022, 404.051(1),(4), 404.061(2), 404.081(1), 404.22 FS. History—New 7-17-85, Amended 4-4-89, Formerly 10D-91.1205, Amended.

64E-5.1112 Personnel Monitoring.

No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the use of sources of radiation unless such individual wears either a film badge, optically stimulated luminescent device (OSLD), or a thermoluminescent dosimeter (TLD). Each film badge, OSLD, or TLD shall be assigned to and worn by only one individual.

Specific Authority 404.051, 404.061, 404.081 FS. Law Implemented 404.022, 404.051(1),(4), 404.061(2), 404.081(1),(2) FS. History—New 7-17-85, Amended 5-15-96, Formerly 10D-91.1213, Amended.

64E-5.1310 Personnel Monitoring.

(1) Unless otherwise specified in the license, no licensee shall permit any individual to use or to assist in the use of sealed sources of radiation in portable devices unless such individual wears either a film badge, OSLD, or a TLD.

(2) Unless otherwise specified in the license, no license shall permit any individual to perform installations, maintenance or service, initial radiation surveys, relocations or removal from service of sealed sources in fixed devices unless such individual wears either a film badge, OSLD, or a TLD.

(3) No change.

(4) A whole body film badge, OSLD, or TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of any gamma-emitting isotope with a gamma ray energy greater than 50 kiloelectron volts or the use of any beta-emitting isotope with a maximum beta energy of 300 kiloelectron volts or more.

(5) An extremity film badge, OSLD, or TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of 1,000 microcuries (37 MBq) or more of beta-emitting isotopes with a maximum beta energy of 1,000 kiloelectron volts or more in any month or by any individual who receives a dose of 40 millirem (400 uSv) or more on a whole body film badge, OSLD, or TLD for 2 consecutive months.

(6) Each film, OSLD, and TLD badge shall be assigned to and worn by only one individual. Film badges and extremity OSLDs and TLDs must be replaced monthly. Whole body OSLDs, and TLDs must be replaced quarterly. After replacement, each film badge, OSLD, and TLD must be promptly processed.

Specific Authority 404.051, 404.061, 404.081 FS. Law Implemented 404.022, 404.051(1),(4),(6),(10), 404.061(2), 404.081(1),(2) FS. History—New 5-15-96, Formerly 10D-91.14111, Amended.

64E-5.1406 Access Control.

(1) Panoramic irradiators shall not be operated unless the following are met:

(a) through (f) No change.

(g) Each entrance to the radiation room and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by 64E-5.323, have a sign bearing the radiation symbol and the words:

**CAUTION (OR "DANGER")  
RADIOACTIVE MATERIAL**

Panoramic irradiators also must be posted as required by 64E-5.323, have a sign and the words:

**GRAVE DANGER  
VERY HIGH RADIATION AREA**

The sign can be removed, covered, or otherwise made inoperative when the sources are shielded fully.

(h) through (2) No change.

Specific Authority 404.051(4) FS. Law Implemented 404.051(1),(5),(6), 404.061, 404.081, 404.141 FS. History—New 8-14-96, Formerly 10D-91.1506, Amended.

64E-5.1418 Personnel Monitoring.

(1) Irradiator operators shall wear either a film badge, OSLD or a TLD while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge, OSLD, and TLD processor must be accredited by NVLAP for high energy photons in the normal and accident dose ranges. Each film badge, OSLD, and TLD must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and OSLDs and TLDs must be replaced at least quarterly. After replacement, each film badge OSLD, and TLD must be processed promptly.

(2) No change.

Specific Authority 404.051(4) FS. Law Implemented 404.051(1),(5),(6), 404.061, 404.081, 404.141 FS. History--New 8-14-96, Formerly 10D-91.1518, Amended

64E-5.1502 Transportation of Radioactive Material.

(1) No change.

(2) Each licensee who transports radioactive material outside of the confines of his facility or other place of use, or who offers radioactive material to a carrier for transport shall:

(a) Comply with the applicable requirements, appropriate to the mode of transport, of 49 CFR Parts 171-173, 177, 383, and 390-397, dated 10-1-97, which are herein incorporated by reference and which are available from the department the regulations of the U.S. Department of Transportation;

(b) Establish procedures for safely opening and closing packages in which radioactive material is transported and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(c) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

Specific Authority 404.051, 404.061, 404.141, 404.20 FS. Law Implemented 404.022, 404.051(1),(4),(6),(11), 404.061(2), 404.141, 404.20(1) FS. History--New 7-17-85, Formerly 10D-91.2003, Amended

NAME OF PERSON ORIGINATING PROPOSED RULE: William A. Passetti, Chief, Bureau of Radiation Control

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Sharon Heber, Dr.P.H., Division of Environmental Health

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: May 22, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: June 2, 2000

Section III
Notices of Changes, Corrections and Withdrawals

DEPARTMENT OF EDUCATION

State Board of Education

Table with 2 columns: RULE NOS. and RULE TITLES. Lists rules 6A-6.03020 through 6A-6.03411 with their corresponding titles.

NOTICE OF CONTINUATION

Notice is hereby given that the public hearing on the above rules, as noticed in Vol. 26, No. 21, dated May 26, 2000, Florida Administrative Weekly has been continued from June 26, 2000, to July 25, 2000. The State Board of Education will meet at 9:00 a.m., in Room LL03 of the Capitol in Tallahassee, Florida.

DEPARTMENT OF CITRUS

Table with 2 columns: RULE CHAPTER NO. and RULE CHAPTER TITLE; RULE NO. and RULE TITLE. Lists rule 20-66 and 20-66.004.

NOTICE OF CHANGE

Notice is hereby given that the following change has been made to the proposed rule in accordance with subparagraph 120.54(3)(d), F.S., published in Vol. 26, No. 20, May 19, 2000 issue of the Florida Administrative Weekly: