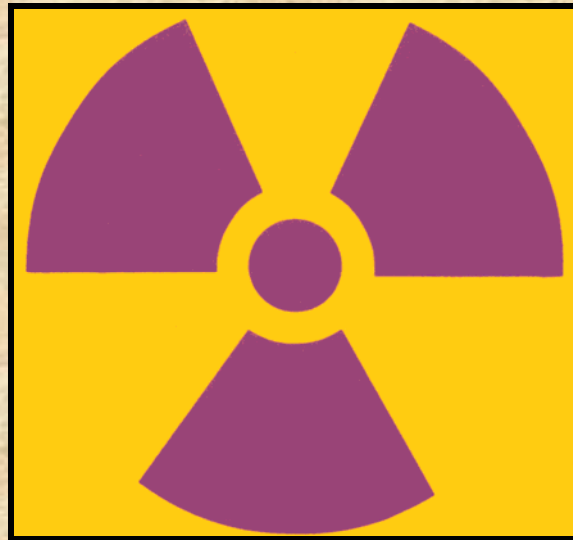


CONTROL OF RADIATION HAZARD REGULATIONS



Chapter 64E-5 Florida Administrative Code

Effective Date July 3, 1997 Includes

Revision 1	May 18, 2000
Revision 2	October 8, 2000
Revision 3	August 6, 2001
Revision 4	September 11, 2001
Revision 5	December 19, 2001
Revision 6	September 28, 2006

Revision 7	August 16, 2007
Revision 8	February 28, 2008
Revision 9	March 12, 2009
Revision 10	February 11, 2010

**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 Community and Environmental Health – Radon and Indoor Air Quality Section for a copy of parts not herein contained.

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

Department of Health
Bureau of Radiation Control
Radiation Machine Section
Suite 300
705 Wells Road,
Orange Park, FL 32073
Telephone: (904) 278-5730 Fax: (904) 278-5737

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

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

PARTS X and XII

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

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

Chronology of Rule Revisions

Revision	Effective Date	Sections Affected
R1	May 18, 1998	64E-5.101, 64E-5.204, 64E-5.213, 64E-5.214, 64E-5.319, 64E-5.332, 64E-5.333, 64E-5.334, 64E-5.347, 64E-5.402, 64E-5.422, 64E-5.502, 64E-5.504, 64E-5.510, 64E-5.617, 64E-5.902, 64E-5.1513, Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997.
R2	October 8, 2000	64E-5.101, 64E-5.201, 64E-5.203, 64E-5.204, 64E-5.214, 64E-5.216, 64E-5.301, 64E-5.303, 64E-5.304, 64E-5.309, 64E-5.311, 64E-5.312, 64E-5.314, 64E-5.315, 64E-5.323, 64E-5.326, 64E-5.334, 64E-5.339, 64E-5.344, 64E-5.345, 64E-5.414, 64E-5.420, 64E-5.422, 64E-5.505, 64E-5.622, 64E-5.625, 64E-5.643, 64E-5.645, 64E-5.1103, 64E-5.1112, 64E-5.1310, 64E-5.1406, 64E-5.1418, 64E-5.1502, 64E-5.1513 Radioactive Material Requiring Labeling, May 2000
R3	August 6, 2001	64E-5.101, 64E-5.201, 64E-5.603, 64E-5.606. 64E-5.626, 64E-5.627, 64E-5.630
R4	September 11, 2001	64E-5.401 - 64E-5.422 repealed and replaced with sections 64E-5.423, 64E-5.424, 64E-5.425, 64E-5.426, 64E-5.427, 64E-5.428, 64E-5.429, 64E-5.430, 64E-5.431, 64E-5.432, 64E-5.433, 64E-5.434, 64E-5.435, 64E-5.436, 64E-5.437, 64E-5.438, 64E-5.439, 64E-5.440, 64E-5.441
R5	December 19, 2001	64E-5.101, 64E-5.214, 64E-5.221, 64E-5.222, 64E-5.223, 64E-5.224, 64E-5.225, 64E-5.226, 64E-5.901, Notice to Employees 3/01
R6	September 28, 2006	64E-5.101, 64E-5.204, 64E-5.206, 64E-5.210, 64E-5.213, 64E-5.304, 64E-5.318, 64E-5.319, 64E-5.427, 64E-5.429, 64E-5.434, 64E-5.440, 64E-5.441, 64E-5.1104, 64E-5.1107, 64E-5.11071, 64E-5.11072, 64E-5.11073, 64E-5.1112, 64E-5.1119, 64E-5.1311, 64E-5.1502, Bureau of Radiation Control Respiratory Protection Factors May 2006, Transfers of Industrial Devices Report 10-2003
R7	August 16, 2007	64E-5.101, 64E-5.204, 64E-5.210, 64E-5.502, 64E-5.504, 64E-5.506, 64E-5.511, 64E-5.1508, Transfers of Industrial Devices Report 04/2007, Radiation Machine Facility Registration DH 03/2007
R8	February 28, 2008	64E-5.101, 64E-5.206, 64E-5.206, 64E-5.210, 64E-5.216, New 64E-5.350, New 64E-5.351, 64E-5.430, 64E-5.440, 64E-5.441, 64E-5.1003, 64E-5.11702, 64E-5.1501, 64E-5.1502
R9	March 12, 2009	New 64E-5.1601, 64E-5.1602, 64E-5.1603, 64E-5.1604

R10	02-11-2010	<p>64E-5.101, 64E-5.207, 64E-5.210, 64E-5.213, 64E-5.216, 64E-5.312, 64E-5.331, 64E-5.344, 64E-5.345, 64E-5.601, New 64E-5.6011, 64E-5.602, 64E-5.603, 64E-5.604, 64E-5.605, 64E-5.606, 64E-5.607, 64E-5.608, 64E-5.609, 64E-5.610, 64E-5.611, 64E-5.612, 64E-5.614, 64E-5.615, 64E-5.616, 64E-5.617, 64E-5.618, 64E-5.621, 64E-5.622, 64E-5.624, 64E-5.625, New 64E-5.6251, 64E-5.626, 64E-5.627, 64E-5.628, 64E-5.629, 64E-5.630, 64E-5.631, 64E-5.633, New 64E-5.6331, New 64E-5.6332, 64E-5.634, 64E-5.635, 64E-5.636, 64E-5.637, 64E-5.638, 64E-5.639, 64E-5.640, 64E-5.641, New 64E-5.6411, New 64E-5.6412, 64E-5.642, New 64E-5.6421, New 64E-5.6422, New 64E-5.6423, 64E-5.643, 64E-5.644, 64E-5.645, 64E-5.647, 64E-5.648, 64E-5.649, 64E-5.650, Repealed 64E-5.651, 64E-5.652, 64E-5.653, 64E-5.654, 64E-5.655, 64E-5.656, 64E-5.657, 64E-5.658, New 64E-5.659, New 64E-5.660, New 64E-5.661, New 64E-5.662, New 64E-5.663, New 64E-5.664, 64E-5.1301, New 64E-5.1320,</p> <p>Application for Radioactive Materials License Non-Human Use, DH Form 1054 12/09, (See 64E-5.207),</p> <p>Application for Radioactive Materials Human Use DH Form 1322 12/09 (See 64E-5.207),</p> <p>New Federal Policy for the Protection of Human Subjects (Federal Policy), as described in 45 CFR Part 46, dated 11/9/2009 (See 64E-5.601)</p>
-----	------------	---

PART I GENERAL PROVISIONS

R10	64E-5.101	Definitions	I-1
	64E-5.102	Exemptions	I-23
	64E-5.103	Records	I-24
	64E-5.104	Tests	I-24
	64E-5.105	Prohibited Use	I-24
	64E-5.106	Units of Exposure and Dose	I-25

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

R8	64E-5.204	Types of Licenses	II-10
----	-----------	-------------------	-------

SUBPART B GENERAL LICENSES

	64E-5.205	General Licenses - Source Material	II-15
R6	64E-5.206	General Licenses - Radioactive Material Other Than Source Material	II-17

SUBPART C SPECIFIC LICENSES

R10	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
R10	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
R10	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 RECIPROCITY

R10	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

R6	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

R10	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

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

R6	64E-5.318.....	Use of Process or Other Engineering Controls.....	III-15
R6	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

	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
R10	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
R10	64E-5.344.....	Notification of Incidents	III-40
R10	64E-5.345.....	Reports of Exposure, Radiation Levels, Concentrations of Radioactive Materials Exceeding the Constraints or Limits, and Medical Events and Dose to an Embryo/Fetus or a Nursing Child.....	III-44a
	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
R8	64E-5.350.....	Reports of Transactions Involving Nationally Tracked Sources	III-47
R8	64E-5.351.....	Nationally Tracked Source Thresholds.	III-50

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
R6	64E-5.427.....	Leak Testing, Repairing, Tagging, Opening, Modifying and Replacing Sealed Sources and Devices.....	IV-6
R4	64E-5.428.....	Quarterly Inventory.....	IV-7
R6	64E-5.429.....	Source Movement Logs, Daily Survey Reports, and Individual Dosimeter Logs.....	IV-8
R8	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
R6	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
R8	64E-5.440.....	Records.....	IV-21
R8	64E-5.441.....	Reporting Requirements.....	IV-23

PART V X-RAYS IN THE HEALING ARTS

	64E-5.501.....	Definitions.....	V-1
R7	64E-5.502.....	General Requirements.....	V-10
	64E-5.503.....	General Requirements for all Diagnostic X-ray Systems.....	V-17
R7	64E-5.504.....	Fluoroscopic X-ray Systems.....	V-23
R2	64E-5.505.....	Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems.....	V-30
R7	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
R7	64E-5.511.....	Registration of Radiation Machines.....	V-68

PART VI USE OF RADIONUCLIDES IN THE HEALING ARTS

R10	64E-5.601.....	License Required.....	VI-1
R10	64E-5.6011.....	Definitions.....	VI-3
R10	64E-5.602.....	License Amendments.....	VI-5
R10	64E-5.603.....	Notification.....	VI-6

SUBPART A GENERAL ADMINISTRATIVE REQUIREMENTS

R10	64E-5.604.....	ALARA Program.....	VI-6
R10	64E-5.605.....	Radiation Safety Officer.....	VI-7
R10	64E-5.606.....	Radiation Safety Committee.....	VI-9
R10	64E-5.607.....	Authority and Responsibilities.....	VI-11
R10	64E-5.608.....	Supervision.....	VI-13
R10	64E-5.609.....	Visiting Authorized User, Visiting Authorized Medical Physicist or Visiting RSO.....	VI-15
R10	64E-5.610.....	Mobile Medical Service Requirements.....	VI-16
R10	64E-5.611.....	Quality Management Program and Notifications, Records and Reports of Medical Events.....	VI-17
R10	64E-5.612.....	Suppliers.....	VI-19

SUBPART B GENERAL TECHNICAL REQUIREMENTS

R10	64E-5.613.....	Quality Control of Diagnostic Instrumentation.....	VI-20
R10	64E-5.614.....	Possession, Use, Calibration, and Check of Dose Calibrators In the Use of Unsealed Radiopharmaceuticals.....	VI-20
R10	64E-5.615	Calibration and Check of Survey Instruments.....	VI-22
R10	64E-5.616	Determination of Dosages of Unsealed Radioactive Materials for Medical Use.....	VI-24
R10	64E-5.617	Authorization for Calibration, Transmission and Reference Sources.....	VI-24
R10	64E-5.618	Requirements for Possession of Sealed Sources and Brachytherapy Sources.....	VI-25
	64E-5.619.....	Syringe Shields and Labels.....	VI-27
	64E-5.620.....	Vial Shields and Labels.....	VI-27
R10	64E-5.621.....	Surveys for Contamination and Ambient Radiation Dose Rate.....	VI-28
R10	64E-5.622.....	Release of Patients or Human Research Subjects Treated with Radiopharmaceuticals, Implants, or Remote Afterloader Units.....	VI-29
	64E-5.623	Storage of Volatiles and Gases.....	VI-30
R10	64E-5.624	Decay in Storage.....	VI-30
R10	64E-5.625	Safety Instruction and Precautions for Liquid Iodine Radiopharmaceutical Therapy, Manual Brachytherapy, Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery.....	VI-31
R10	64E-5.6251	Therapy Related Computer Systems.....	VI-34

SUBPART C UPTAKE, DILUTION, AND EXCRETION

R10	64E-5.626.....	Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies.....	VI-35
-----	----------------	---	-------

SUBPART D IMAGING AND LOCALIZATION

R10	64E-5.627.....	Use of Unsealed Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.....	VI-26
R10	64E-5.628.....	Generators.....	VI-39
R10	64E-5.629.....	Control of Aerosols and Gases.....	VI-41

SUBPART E		RADIOPHARMACEUTICALS FOR THERAPY	
R10	64E-5.630.....	Use of Radiopharmaceuticals for Therapy	VI-42
SUBPART F		SEALED SOURCES FOR DIAGNOSIS	
R10	64E-5.631.....	Use of Sealed Sources for Diagnosis	VI-44
SUBPART G		SOURCES FOR BRACHYTHERAPY	
R10	64E-5.632.....	Use of Sources for Manual Brachytherapy	VI-45
R10	64E-5.633.....	Manual Brachytherapy Sources Inventory and Surveys	VI-46
R10	64E-5.6331.....	Calibration Measurements of Manual Brachytherapy Systems	VI-47
R10	64E-5.6332.....	Decay of Strontium-90 Sources for Ophthalmic Treatments	VI-47
R10	SUBPART H	PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.	
R10	64E-5.634	Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.	VI-48
R10	64E-5.635	Installation, Adjustment, Maintenance and Repair Restrictions.....	VI-49
R10	64E-5.636	Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.	VI-49
R10	64E-5.637	Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units	VI-51
R10	64E-5.638	Radiation Monitoring Devices	VI-52
R10	64E-5.639	Viewing Systems	VI-53
R10	64E-5.640	Dosimetry Equipment Used With Remote Afterloading Units, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units	VI-53
R10	64E-5.641	Full Calibration Measurements On Teletherapy Units	VI-54
R10	64E-5.6411	Full Calibration Measurements On Remote Afterloader Units.....	VI-56
R10	64E-5.6412	Full Calibration Measurements On Gamma Stereotactic Radiosurgery Units.....	VI-57
R10	64E-5.642	Periodic Spot-Checks of Teletherapy Units.....	VI-59
R10	64E-5.6421	Periodic Spot-Checks for Remote Afterloader Units.....	VI-61
R10	64E-5.6422	Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.....	VI-62
R10	64E-5.6423	Additional Technical Requirements for Mobile Remote Afteloder Units	VI-65
R10	64E-5.643	Radiation Surveys for Teletherapy Facilities	VI-66
R10	64E-5.644	Radiation Surveys for Remote Afterloader and Gamma Stereotactic Radiosurgery Facilities.....	VI-67
R10	64E-5.645.....	Therapy-Related Computer Systems	VI-68
	64E-5.646	Reports of Teletherapy Surveys, Checks, Tests, and Measurements.....	VI-68
R10	64E-5.647	Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units	VI-86

SUBPART I TRAINING AND EXPERIENCE REQUIREMENTS

R10	64E-5.648	Radiation Safety Officer.....	VI-69
R10	64E-5.649	Training for Uptake, Dilution, or Excretion Studies.....	VI-72
R10	64E-5.650	Training for Imaging and Localization Studies for Which a Written Directive is Not Required.....	VI-73
R10	64E-5.651	Repealed (See Rules 64E-5.660, 64E-5.661, 64E-5.662 & 64E-5.663).....	VI-75
R10	64E-5.652	Training for Therapeutic Use of Manual Brachytherapy Sources.....	VI-75
R10	64E-5.653	Training for Ophthalmic Use of Strontium 90.....	VI-77
R10	64E-5.654	Training for Use of Sealed Sources for Diagnosis.....	VI-78
R10	64E-5.655	Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.....	VI-79
R10	64E-5.656	Training for an Authorized Medical Physicist.....	VI-81
R10	64E-5.657	Training for Experienced RSO, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.....	VI-83
R10	64E-5.658	Recentness of Training.....	VI-83
R10	64E-5.660	Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required in Rules 64E-5.626, 64E-5.627 or 64E-5.630.....	VI-86
R10	64E-5.661	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries).....	VI-88
R10	64E-5.662	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries).....	VI-90
R10	64E-5.663	Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.....	VI-91
R10	SUBPART J	OTHER MEDICAL USES OR RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL	
R10	64E-5.664	Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.....	VI-94

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
 R8 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

64E-5.1102..... Storage and Transportation Precautions XI-2
 R2 64E-5.1103..... Radiation Survey Instruments..... XI-2
 R6 64E-5.1104..... Leak Testing of Sealed Sources..... XI-3
 64E-5.1105..... Quarterly Inventory XI-4
 64E-5.1106..... Utilization Records..... XI-4
 R6 64E-5.1107..... Design, Performance and Certification Criteria for Sealed Sources
 Used in Downhole Operations XI-4
 R6 64E-5.11071..... Uranium Sinker Bars..... XI-5
 R8 64E-5.11072..... Energy Compensation Sources XI-6
 R6 64E-5.11073..... Tritium Neutron Generator Target Source XI-6
 64E-5.1108..... Labeling XI-6
 64E-5.1109..... Inspection and Maintenance XI-7

SUBPART B		REQUIREMENTS FOR PERSONNEL SAFETY	
	64E-5.1110.....	Training Requirements	XI-7
	64E-5.1111.....	Operating and Emergency Procedures	XI-8
R6	64E-5.1112.....	Personnel Monitoring.....	XI-9
SUBPART C		PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER OPERATIONS	
	64E-5.1113.....	Security	XI-9
	64E-5.1114.....	Handling Tools	XI-9
	64E-5.1115.....	Subsurface Tracer Studies.....	XI-9
SUBPART D		RADIATION SURVEYS AND RECORDS	
	64E-5.1116.....	Radiation Surveys.....	XI-10
	64E-5.1117.....	Documents and Records Required at Field Stations.....	XI-11
	64E-5.1118.....	Documents and Records Required at Temporary Job Sites	XI-11
SUBPART E		NOTIFICATION	
R6	64E-5.1119.....	Notification of Incidents, Abandonment and Lost Sources	XI-12
R6	64E-5.1120.....	Subjects to be Included in Training Courses for Logging Supervisors	XI-14
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	
R10	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	
R6	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 Gases..... XIII-10

64E-5.1318..... Instrumentation XIII-10

64E-5.1319..... Contamination Control Program XIII-11

R10 64E-5.1320..... Bioassay Program XIII-13

PART XIV LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

SUBPART A GENERAL PROVISIONS

64E-5.1401..... IrradiatorsXIV-1

64E-5.1402..... DefinitionsXIV-1

SUBPART B SPECIFIC LICENSE FOR LARGE IRRADIATORS

64E-5.1403..... Specific License for Large IrradiatorsXIV-3

64E-5.1404..... Start of ConstructionXIV-5

SUBPART C DESIGN AND PERFORMANCE REQUIREMENTS FOR LARGE IRRADIATORS

64E-5.1405..... Performance Criteria for Sealed SourcesXIV-5

R2 64E-5.1406..... Access ControlXIV-6

64E-5.1407..... ShieldingXIV-8

64E-5.1408..... Fire ProtectionXIV-8

64E-5.1409..... Radiation MonitorsXIV-9

64E-5.1410..... Control of Source MovementXIV-9

64E-5.1411..... Irradiator PoolsXIV-10

64E-5.1412..... Source Rack ProtectionXIV-11

64E-5.1413..... Power FailuresXIV-11

64E-5.1414..... Design RequirementsXIV-11

64E-5.1415..... Construction ControlXIV-14

SUBPART D OPERATION OF IRRADIATORS

64E-5.1416..... TrainingXIV-15

64E-5.1417..... Operating and Emergency ProceduresXIV-17

R2 64E-5.1418..... Personnel MonitoringXIV-18

64E-5.1419..... Radiation SurveysXIV-19

64E-5.1420..... Detection of Leaking or Contaminated SourcesXIV-20

64E-5.1421..... Inspection and MaintenanceXIV-21

64E-5.1422..... Pool Water PurityXIV-22

64E-5.1423..... Attendance During OperationXIV-22

64E-5.1424..... Entering and Leaving the Radiation RoomXIV-23

64E-5.1425..... Irradiation of Explosive or Highly Flammable MaterialsXIV-23

SUBPART E RECORDS AND REPORTS

64E-5.1426..... Records and Retention PeriodsXIV-24

64E-5.1427..... Reports and NotificationsXIV-26

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

R8	64E-5.1501.....	Purpose and Scope	XV-1a
R8	64E-5.1502.....	Transportation of Radioactive Material	XV-1a
	64E-5.1503.....	Exemptions	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
R7	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 A ₁ and A ₂ Values	XV-11
	Table A-1.....	A ₁ and A ₂ Values for Radionuclides	XV-13
	Table A-2.....	Relationship Between A ₁ and E _{max} for Beta Emitters.....	XV-30
	Table A-3.....	Relationship Between A ₃ for Alpha Emitters and the Atomic Number of the Radionuclide	XV-30
	Table A-4.....	Activity - Mass Relationships for Uranium/Thorium	XV-31

PART XVI ELECTRONIC BRACHYTHERAPY

R9	64E-5.1601.....	Definitions	XVI-1
R9	64E-5.1602.....	Administrative Requirements	XVI-2
R9	64E-5.1603.....	Training and Education	XVI-4
R9	64E-5.1604.....	General Technical Requirements For Electronic Brachytherapy Facilities.....	XVI-7

ATTACHMENTS

ALIs, DACs, and Effluent Concentrations July 1993

R6 Protection Factors for Respirators May 2006

R2 Radioactive Material Requiring Labeling May 2000

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

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

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

R10 Radioactive Materials License Application Non-Human Use Form DH-1054 12/09

R10 Radioactive Materials License Application Human Use Form DH-1322 12/09

R5 Notice to Employees 3/01

R1 Requirements for Transfers of Low-Level Radioactive Waste Intended for
Disposal at Licensed Land Disposal Facilities and Manifest, July 1997

R3 Authorized Nuclear Pharmacist Training Requirements

R4 State of Florida Boundaries (map) – State Constitution Article II, Section 1 (Exact boundaries)

R7 Transfers of Industrial Devices Report 04/2007

R7 Radiation Machine Facility Registration 1107 DH 03/07

R10 Federal Policy for the Protection of Human Subjects (Federal Policy)
as described in 45 CFR Part 46 dated 11/9/2009 (See 64E-5.601)

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.

R10 (184) Annual or Annually means an interval not to exceed 12 months.

- (14) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by Reference Man that would result in a committed effective dose equivalent of 5 rem (0.05 sievert) or a committed dose equivalent of 50 rem (0.5 sievert) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Columns 1 and 2.
- (15) "Area of use" means a portion of a physical structure that has been set aside to receive, use, or store radioactive material.

R10 (175) "Assigned protection factor" or "APF" means the expected workplace level of
 R6 respiratory protection provided by a properly functioning respirator or a class of
 R6 respirators to properly fitted and trained users. Operationally, the inhaled
 R6 concentration can be estimated by dividing the ambient airborne concentration by
 R6 the APF.

R10 (171) "Authorized nuclear pharmacist" means a pharmacist who satisfies the following:

R10 (a) Meets the requirements in subsection 64E-5.659(1) and Rule 64E-5.658,
 R10 F.A.C.; or

R10 (b) Authorized on a radioactive materials license by the department or
 R10 identified as an authorized nuclear pharmacist on one of the following:

R10 1. A specific license issued by the NRC or agreement state that
 R10 authorizes medical use or the practice of nuclear pharmacy;

R10 2. A permit issued by a NRC master material licensee that authorizes
 R10 medical use or the practice of nuclear pharmacy;

R10 3. A permit issued by a NRC or agreement state broad scope medical
 R10 use licensee that authorizes medical use or the practice of nuclear
 R10 pharmacy; or

- R10 4. A permit issued by a NRC master material broad scope licensee
R10 that authorizes medical use or the practice of nuclear pharmacy; or
- R10 (c) Is identified as an authorized nuclear pharmacist by a commercial nuclear
R10 pharmacy that has been authorized to identify authorized nuclear
R10 pharmacists; or
- R10 (d) Is designated as an authorized nuclear pharmacist in accordance with
R10 paragraph 64E-5.210(10)(b)3., F.A.C.
- R10 (176) "Atmosphere-supplying respirator" means a respirator that supplies the respirator
R6 user with breathing air from a source independent of the ambient atmosphere
R6 and includes supplied-air respirators and self-contained breathing apparatus
R6 units.
- R10 (16) "Authorized user" means an individual who is identified on a department, NRC,
R10 agreement state, or licensing state specific license that authorizes the use of
R10 radioactive material.
- R10 (17) "Background radiation" means radiation from cosmic sources; naturally occurring
R5 radioactive materials, including radon, except as a decay product of source or
R5 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.
- R10 (21) "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.

- R10 (188) "C-arm system" means a fluoroscopic C-arm routinely used with the same patient
R7 support device which will have interlocks, detents or positioning marks to allow
R7 reproducible geometry. Measurements of patient entrance exposure for this type
R7 of system will be measured in accordance with subparagraph
R7 64E-5.504(3)(e)2., 3., and 5., F.A.C.
- R10 (22) "Cabinet x-ray system or Cabinet x-ray" means an x-ray system with the x-ray
R7 tube installed in an enclosure independent of existing architectural structures. A
R7 cabinet x-ray system is intended to contain the material being irradiated, and
R7 exclude personnel from its interior during generation of radiation. To be certified
R7 as a cabinet x-ray, the cabinet must be shielded so that every location on the
R7 exterior meets the conditions of 0.5 mRem (0.005 millisievert) in any one hour, at
R7 a distance of 5 cm. An x-ray tube used within a shielded part of a building or x-
R7 ray equipment that may temporarily or occasionally incorporate portable shielding
R7 is not considered a cabinet x-ray system.
- R10 (23) "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.
- R10 (24) "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.
- R10 (25) "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.
- R10 (26) "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.
- R10 (27) "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.
- R10 (28) "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.

- R10 (29) "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 ($H_{E,50} = \sum W_T H_{T,50}$).
- R10 (30) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.
R2
- R10 (172) "Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.
R5
- R10 (31) "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).
- R10 (186) Daily means an interval not to exceed a consecutive 24 hour period or once every calendar day worked.
R6
- R10 (32) "Declared pregnant woman" means a woman who has voluntarily informed her employer in writing of her pregnancy and the estimated date of conception.
R2 The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.
R2
- R10 (33) "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.
- R10 (34) "Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter ($1,000 \text{ mg/cm}^2$).
- R10 (35) "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
- R10 (36) "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.
- R10 (37) "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.
- R10 (38) "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).

- R10 (173) "Distinguishable from background" means that the detectable concentration of a
R5 radionuclide is statistically different from the background concentrations of that
R5 radionuclide in the vicinity of the site or, in the case of structures, in similar
R5 materials using adequate measurement technology, survey, and statistical
techniques.
- R4 (39) "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.
- R10 (40) "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.
- R10 (41) "Dose limits" means the permissible upper bounds of radiation doses established
as specified in these rules. For purposes of these rules, "limits" is an equivalent
term.
- R10 (42) "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.
- R10 (43) "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 ($H_E = \sum W_T H_T$).
- R10 (44) "Embryo" or "fetus" means the developing human organism from conception until
birth.
- R10 (177) "Energy compensation source" or "ECS" means a small sealed source with an
R6 activity not exceeding 100 microcuries (3.7 MBq) used within a logging tool or
R6 other tool components to provide a reference standard to maintain the tool's
R6 calibration when in use.
- R10 (45) "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.
- R10 (46) "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 Rule 64E-5.106, F.A.C., for the SI equivalent.
- R10 (47) "Exposure rate" means the exposure per unit of time, such as roentgen per
minute and milliroentgen per hour.

- R10 (48) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.
- R10 (49) "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.
- R10 (50) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm²).
- R10 (51) "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.
- R10 (52) "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.
- R10 (178) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.
R6
R6
- R10 (179) "Fit test" means the use of a protocol to evaluate qualitatively or quantitatively the fit of a respirator on an individual.
R6
- R10 (53) "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.
- R10 (54) "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.
- R10 (55) "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
- R10 (56) "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.
- R10 (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.
R2

- R10 (58) "Human use" means the internal or external administration of radiation or radioactive material to human beings.
- R10 (59) "Individual" means any human being.
- R10 (60) "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.
- R10 (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.
- R2
- R2
- R2
- R2
- R10 (62) "Industrial radiography" means nondestructive testing using ionizing radiation to make radiographic images or radiographs to detect flaws in objects.
- R10 (63) "Inhalation class" (see "Class").
- R10 (64) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.
- R10 (65) "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.
- R10 (66) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.
- R10 (67) "Large irradiator" means an irradiator where radiation dose rates exceeding 500 rems (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.
- R10 (68) "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
- R10 (69) "License" means a license issued by the Department in accordance with the rules adopted by the Department.

- R10 (70) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the department.
- R10 (71) "Licensee" means any person who is licensed by the Department in accordance with these rules and the Act.
- R10 (72) "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.
- R10 (73) "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.
- R10 (74) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.
- R10 (75) "Logging tool" means a device used subsurface to perform well-logging.
- R10 (76) "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.
- R10 (77) "Low specific activity material (LSA)" means that as defined in 49 C.F.R. 173.403. (Pursuant to Section 120.54(6) Florida Statutes, subsection 64E-5.101(79), F.A.C., is substantively identical to 49 CFR 173.403 published on 10/01/2007.)
- R8
R8
- R10 (78) "Lung class" (see "Class").
- R10 (79) "Major processor" means a user processing, handling or manufacturing radioactive material exceeding A₂ quantities as unsealed sources or material, or exceeding 4 times A₁ quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers or small industrial programs. A₁ and A₂ quantities can be found in Part XV.
- R10 (80) "Management" means the chief executive officer or other individual, or a delegate or the delegates of the chief executive officer or other individual, having the authority to manage, direct, or administer the licensee's activities.
- R10 (81) "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.

- R10 (82) "Member of the public" means any individual except when that individual is receiving an occupational dose.
- R10 (83) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.
- R10 (84) "Minor" means an individual less than 18 years of age.
- R10 (85) "Medical event" means the administration of:
 - R10 (a) Radioactive materials or radiation from radioactive materials requiring a written directive that results in the following:
 - R10 1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin;
 - R10 2. When the total dose delivered differs from the prescribed dose by 20 percent or more;
 - R10 3. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range;
 - R10 4. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;
 - R10 5. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin;
 - R10 6. An administration of a wrong radioactive drug containing radioactive material;
 - R10 7. An administration of a radioactive drug containing radioactive material by the wrong route of administration;
 - R10 8. An administration of a dose or dosage to the wrong individual or human research subject;
 - R10 9. An administration of a dose or dosage delivered by the wrong mode of treatment;
 - R10 10. A leaking sealed source where the patient or human research subject is contaminated;
 - R10 11. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or
 - R10 12. Any medical use that results or will result in unintended permanent functional damage to an individual's organ or a physiological system, as determined by a physician.

- R10 (b) Radioactive materials or radiation from radioactive materials not requiring
R10 a written directive that result in either of the following:
- R10 1. A dose that differs from the prescribed dose or dose that would
R10 have resulted from the prescribed dosage by more than 0.05 Sv (5
R10 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or
R10 tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
- R10 a. When the total dose delivered differs from the prescribed
R10 dose by 20 percent or more;
- R10 b. The total dosage delivered differs from the prescribed
R10 dosage by 20 percent or more or falls outside the prescribed
R10 dosage range;
- R10 c. The fractionated dose delivered differs from the prescribed
R10 dose, for a single fraction, by 50 percent or more; or
- R10 2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5
R10 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose
R10 equivalent to the skin; and
- R10 a. An administration of a wrong radioactive drug containing
R10 radioactive material;
- R10 b. An administration of a radioactive drug containing radioactive
R10 material by the wrong route of administration;
- R10 c. An administration of a dose or dosage to the wrong
R10 individual or human research subject;
- R10 d. An administration of a dose or dosage delivered by the
R10 wrong mode of treatment;
- R10 e. A leaking sealed source where the patient or human
R10 research subject is contaminated;
- R10 f. A dose to the skin or an organ or tissue other than the
R10 treatment site that exceeds by 0.5 Sv (50 rem) to an organ
R10 or tissue and 50 percent or more of the dose expected from
R10 the administration defined in the written directive (excluding,
R10 for permanent implants, seeds that were implanted in the
R10 correct site but migrated outside the treatment site); or
- R10 g. Any medical use that results or will result in unintended
R10 permanent functional damage to an individual's organ or a
R10 physiological system, as determined by a physician.
- R10 (c) Radiation from a therapeutic x-ray machine or particle accelerator that
R10 result in any of the following:
- R10 1. Any medical use that results or will result in unintended permanent
R10 functional damage to an individual's organ or a physiological
R10 system, as determined by a physician;
- R10 2. An administration of a dose to the wrong individual or human
R10 research subject;

- R10 3. An administration of a dose delivered by the wrong mode of
R10 treatment, wrong treatment, or wrong treatment site;
- R10 4. When treatment consists of three or fewer fractions and the
R10 calculated total administered dose differs from the total prescribed
R10 dose by more than 10 percent of the total prescribed dose;
- R10 5. When the calculated weekly administered dose is 30 percent
R10 greater than the weekly prescribed dose; or
- R10 6. When the calculated total administered dose differs from the total
R10 prescribed dose by more than 20 percent of the total prescribed
R10 dose.
- R10 (187) "Mobile C-arm" means a mobile fluoroscopic machine that is designed for and
R7 used without a patient support device such as a radiographic table, cradle or
R7 radiolucent stretcher. This would include machines moved from room to room to
R7 assist in surgical procedures. Measurements of patient entrance exposure for
R7 this type of system will be measured in accordance with subparagraph
R7 64E-5.504(3)(e) 2, 3, and 4, F.A.C.
- R10 (86) "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.
- R10 (87) "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.
- R10 (189) "Nationally tracked source" means a sealed source containing a quantity equal to
R8 or greater than Category 1 or Category 2 levels of any radioactive material listed
R8 in Rule 64E-5.351, F.A.C. In this context a sealed source is defined as
R8 radioactive material that is sealed in a capsule or closely bonded, in a solid form,
R8 and which is not exempt from regulatory control. It does not mean material
R8 encapsulated solely for disposal, or nuclear material contained in any fuel
R8 assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked
R8 sources are those containing radioactive material at a quantity equal to or greater
R8 than the Category 1 threshold. Category 2 nationally tracked sources are those
R8 containing radioactive material at a quantity equal to or greater than the Category
R8 2 threshold but less than the Category 1 threshold. (Pursuant to Section
R8 120.54(6) Florida Statutes, subsection 64E-5.101(194), F.A.C, is substantively
R8 identical to 10 CFR 20.1003 published on 01/01/2007).
- R10 (88) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
- R10 (89) "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.

- R10 (90) "Normal form" means radioactive material which has not been demonstrated to qualify as "special form"; also referred to as "nonspecial form."
- R10 (91) "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.
- R10 (92) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.
- R10 (93) "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
- R10 (94) "Offshore" means within the territorial waters of the State of Florida as specified in Article II, Section 1 of the Constitution of the State of Florida.
- R4
- R10 (95) "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.
- R10 (96) "Package" means that as defined in 49 C.F.R. 173.403. (Pursuant to Section 120.54(6) Florida Statutes, subsection 64E-5.101(100), F.A.C., is substantively identical to 49 CFR 173.403 published on 10/01/2007).
- R8
R8
- R10 (97) "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.
- R10 (98) "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.
- R10 (99) "Permanent radiographic installation" means an enclosed shielded room, cell, or vault, as specified in Rule 64E-5.431, F.A.C., in which industrial radiography is performed.
- R4
R4
- R10 (100) "Permit" means the written authorization issued by the Department for the transportation of radioactive waste as described in Rule 64E-5.1509, F.A.C.

- R10 (101) "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.
- R10 (102) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.
- R10 (103) "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 in which a written directive is not required.
- R10 (104) "Prescribed Dose" means:
- (a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
 - (b) For manual brachytherapy, either the total source strength and exposure time or the total dose as documented in the written directive;
 - (c) For teletherapy, particle accelerator or therapeutic x-ray machine, the total dose and dose per fraction as documented in the written directive; or
 - (d) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.
- R10 (105) "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.
- R10 (170) "Principal activities" means activities authorized by the license that are essential to achieve the purpose for which the department issued or amended the license. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.
- R10 (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 does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released as specified in Rule 64E-5.622, F.A.C., or from voluntary participation in medical research programs.
- R10 (107) "Quality factor" (Q) means the modifying factor listed in the tables in subsections 64E-5.106(3) and (4), F.A.C., used to derive dose equivalent from absorbed dose.

- R10 (108) "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.
- R10 (109) "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).
- R10 (110) "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.
- R10 (111) "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.
- R10 (112) "Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.
- R10 (113) "Radiation Safety Officer or RSO" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules.
- R10 (114) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.
- R10 (115) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.
- R10 (116) "Radiographer" means any individual who has completed successfully the training and testing requirements specified in subsection 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 (117) "Radiographer's assistant or assistant radiographer" means any individual who has completed successfully the training and testing requirements specified in subsection 64E-5.434(1), F.A.C., and who, under the personal supervision of a radiographer, conducts radiographic operations.
- R8 (118) "Radiographic exposure device" means any instrument containing a sealed source, fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed from a shielded position to an unshielded position for the purpose of making a radiographic exposure. It also is known as a camera or a projector. (Pursuant to Section 120.54(6) Florida Statutes, subsection 64E-5.101(122), F.A.C., is substantively identical to 10 CFR 34.3 published on 01/01/2007).

- R10 (119) "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;
 - R10 (c) 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.
 - R10 (d) A therapeutic administration of a radiopharmaceutical other than iodine 131 as sodium iodide, when the administered dosage differs from the prescribed dosage by more than 10 percent from the prescribed dosage;
 - R10 (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
 - R10 (f) A teletherapy, particle accelerator, gamma stereotactic radiosurgery or therapeutic x-ray machine radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.
- R10 (120) "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."
- R10 (121) "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.
- R10 (122) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR, Parts 100-189.
- R10 (123) "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).
- R10 (124) "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.

- R10 (125) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.
- R10 (174) "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.
- R5
R5
R5
R5
R5
R5
- R10 (126) "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.
- R10 (127) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air.
- R10 (128) "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.
- R10 (129) "Sealed source" means radioactive material that is encased in a capsule designed to prevent release or escape of the radioactive material. (Pursuant to Section 120.54(6) Florida Statutes, subsection 64E-5.101(133), F.A.C., is substantively identical to 10 CFR 30.4 published on 01/01/2007).
- R8
R8
R8
- R10 (190) "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both NRC and the agreement states, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.
- R10
R10
R10
R10
- R10 (180) "Self-contained breathing apparatus" or "SCBA" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.
- R6
R6
- R10 (185) Semiannual or Semiannually means an interval not to exceed six months.
- R10 (130) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).
- R6
R6
- R10 (131) "Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.
- R4
R4
- R10 (132) "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.

- R10 (133) "SI" means an abbreviation of the International System of Units.
- R10 (134) "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).
- R10 (135) "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.
- R10 (136) "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.
- R10 (137) "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.
- R10 (138) "Source material milling" means any activity that results in the production of byproduct material as defined by Rule 64E-5.101, F.A.C.
- R10 (139) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.
- R10 (140) "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.

- R10 (141) "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
- R10 (142) "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.
- R10 (191) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.
- R10
- R10
- R10 (143) "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.
- R10 (144) "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.
- R10 (145) "Storage container" means a container in which sealed sources are secured and stored.
- R10 (192) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.
- R10
- R10
- R10 (146) "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.
- R10 (181) "Supplied-air respirator" or "air-line respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.
- R6
- R6

- R10 (147) "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.
- R10 (148) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
- R10 (149) "Temporary job site" means a site, base or facility that is created and maintained to support a single job.
- R10 (150) "Test" means the process of verifying compliance with an applicable rule.
- R10 (182) "Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.
R6
- R10 (151) "Total effective dose equivalent" means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.
- R10 (152) "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.
- R10 (153) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating or refining.
- R10 (154) "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.
- R10 (155) "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.)

- R10 (183) "User seal check" or "fit check" means an action conducted by the respirator user
R6 to determine if the respirator is seated to the face properly. Examples include
R6 negative pressure check, positive pressure check, irritant smoke check, and
R6 isoamyl acetate check.
- R10 (156) "Very high radiation area" means an area, accessible to individuals, in which
R2 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.
- R10 (157) "Visiting authorized user" means an authorized user who is not identified on the
license.
- R10 (158) "Waste handling licensees" means persons licensed to receive and store
radioactive wastes prior to disposal or persons licensed to dispose of radioactive
waste.
- R10 (159) "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.

- R10 (160) "Well-bore" means a drilled hole in which wireline service operations and
subsurface tracer studies are performed
- R10 (161) "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.
- R10 (162) "Whole body" means, for purposes of external exposure, head, trunk including
male gonads, arms above the elbow, or legs above the knee.

- R10 (163) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.
- R10 (164) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.
- R10 (165) "Worker" means an individual engaged in work in a restricted area under the authority of a license or registration issued by the Department.
- R10 (166) "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.
- R10 (167) "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.
- R10 (168) "Written directive" means a written order for a specific patient or human research subject, 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, the radiopharmaceutical, dosage, and route of administration;
 - (b) For any administration of iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels), the dosage;
 - (c) For gamma stereotactic radiosurgery, target coordinates settings per treatment for each anatomically distinct treatment site, 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, number of fractions and overall treatment period;
 - (e) For high dose rate remote afterloading brachytherapy, the radioisotope, treatment site, dose per fraction, number of fractions, and total dose; and
 - (f) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders,
 1. Prior to implantation, the radioisotope, treatment site, dose, 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.

R10 (169) "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.

R10 Editor's Note: Definitions have been alphabetized effective, 02-11-10.

Rulemaking Authority: 404.051, 404.061, F.S.

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

R1- History: New 7-17-85, Amended 4-4-89, 5-12-93, 1-1-94, 5-15-96, Formerly 10D-91.102, Amended 5-18-98, 10-8-00, 8-6-01, 9-

R10 11-01, 12-18-01, 9-28-06, 8-16-07, 2-28-08, Amended 02-11-10.

64E-5.102 Exemptions.

- (1) The Department may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property or the environment.
- (2) Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, transports or acquires sources of radiation:
 - (a) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;
 - (b) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;
 - (c) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and
 - (d) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine:
 1. That the exemption of the prime contractor or subcontractor is authorized by law; and
 2. That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health, safety and environment.

Specific Authority: 404.051, 404.061, F.S.

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

History: New 7-17-85, Amended 5-12-93, 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 7-17-85, 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 7-17-85, Amended 1-1-94, 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:
- Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
 - 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).
 - Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).
 - Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).
- (3) As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown below:

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

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

- (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 Rule 64E-5.106, F.A.C., 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 x 10 ⁻⁸	2	980 x 10 ⁶	980 x 10 ⁸
	1.0 x 10 ⁻⁷	2	980 x 10 ⁶	980 x 10 ⁸
	1.0 x 10 ⁻⁶	2	810 x 10 ⁶	810 x 10 ⁸
	1.0 x 10 ⁻⁵	2	810 x 10 ⁶	810 x 10 ⁸
	1.0 x 10 ⁻⁴	2	840 x 10 ⁶	840 x 10 ⁸
	1.0 x 10 ⁻³	2	980 x 10 ⁶	980x 10 ⁸
	1.0 x 10 ⁻²	2.5	1010 x 10 ⁶	1010 x 10 ⁸
	1.0 x 10 ⁻¹	7.5	170 x 10 ⁶	170 x 10 ⁸
	5.0 x 10 ⁻¹	11	39 x 10 ⁶	39 x 10 ⁸
	1	11	27 x 10 ⁶	27 x 10 ⁸
	2.5	9	29 x 10 ⁶	29 x 10 ⁸
	5	8	23 x 10 ⁶	23 x 10 ⁸
	7	7	24 x 10 ⁶	24 x 10 ⁸
	10	6.5	24 x 10 ⁶	24 x 10 ⁸
	14	7.5	17 x 10 ⁶	17 x 10 ⁸
	20	8	16 x 10 ⁶	16 x 10 ⁸
	40	7	14 x 10 ⁶	14 x 10 ⁸
	60	5.5	16 x 10 ⁶	16 x 10 ⁸
	100	4	20 x 10 ⁶	20 x 10 ⁸
	200	3.5	19 x 10 ⁶	19 x 10 ⁸
	300	3.5	16 x 10 ⁶	16 x 10 ⁸
	400	3.5	14 x 10 ⁶	14 x 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 1-1-94, Formerly 10D-91.113

PART I**GENERAL PROVISIONS**

R10	64E-5.101	Definitions	I-1
	64E-5.102	Exemptions	I-23
	64E-5.103	Records.....	I-24
	64E-5.104	Tests	I-24
	64E-5.105	Prohibited Use.....	I-24
	64E-5.106	Units of Exposure and Dose.....	I-25

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

R8	64E-5.204.....	Types of Licenses.....	II-10
----	----------------	------------------------	-------

SUBPART B GENERAL LICENSES

	64E-5.205.....	General Licenses - Source Material	II-15
R6	64E-5.206.....	General Licenses - Radioactive Material Other Than Source Material	II-17

SUBPART C SPECIFIC LICENSES

R10	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
R10	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
R6	64E-5.213	Specific Terms and Conditions of Licenses.....	II-58
R5	64E-5.214	Expiration and Termination of Licenses and Decommissioning..... of Building Outdoor Areas	II-60
	64E-5.215.....	Transfer of Material	II-63

SUBPART D RECIPROCITY

R10	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.

R1 Specific Authority: 404.051, 404.141, 404.20, F.S.

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).

- (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;
 - 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

- b. Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B, provided that the sum of such fractions shall not exceed unity.
 - c. For americium 241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under this subparagraph.
 9. Spark gap irradiators containing not more than 1 microcurie (37 kBq) of cobalt 60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 l) per hour.
- (b) Self-Luminous Products Containing Radioactive Material.
 1. Tritium, Krypton 85 or Promethium 147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton 85 or promethium 147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton 85 or promethium 147 in self-luminous products manufactured, or processed, produced, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this paragraph does not apply to tritium, krypton 85 or promethium 147 used in products for frivolous purposes or in toys or adornments.
 2. Radium 226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium 226 which were acquired prior to December 1980.
- (c) Gas and Aerosol Detectors Containing Radioactive Material.
 1. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall have been manufactured, imported or transferred in accordance with a specific license issued

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.

R2
R2

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

R2
R2
R2
R2
R2
R2

- (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.

(Page intentionally left Blank
Next page is Page 10)

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 and the department requires registration of certain general licenses described in subsection 64E-5.206(4), F.A.C.. The payment of a fee is also required by all persons possessing general licensed material described in (1)(c), below. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

(a) The annual registration fee set forth in this section for general licenses shall be payable every July 1, for as long as the license remains in effect.

(b) The annual fee for a general license set forth in 64E-5.216 under reciprocal agreement shall be paid before the first entrance into the state and on each anniversary date thereafter, if applicable. Manufacturers, manufacturer's representatives, distributors, and waste treatment, storage or disposal companies servicing Florida radioactive materials license applicants or licensees are not 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). \$30.00 per unit.

2. Measuring, gauging, and control devices as described in 64E-5.206(4). \$30.00 per unit.

3. In Vivo testing as described in 64E-5.206(7). \$150.00 per license.

4. In Vitro testing as described in 64E-5.206(8). \$150.00 per license.

5. Depleted uranium as described in 64E-5.205(4). \$150.00 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.

R2
R2
R2

R2
R2

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.

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

		APPLICATION FEE	ANNUAL FEE
	1. SOURCE MATERIAL.		
R7	a. Licenses for concentration of uranium from phosphate ores for the production of uranium as "yellow cake" or powdered solid;	\$8,288	\$14,330
R7	b. License for concentration of uranium from phosphate ores for the production of "green cake" or equivalent, moist or solid;	\$4,522	\$8,927
R7	c. All other specific source material licenses excluding depleted uranium used as shielding and counterweights.	\$653	\$275
	2. SPECIAL NUCLEAR MATERIAL (SNM).		
R7	a. Licenses for use of SNM in sealed sources contained in devices used in measuring systems;	\$784	\$622
R7	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	\$1,608	\$2,333
R7	c. Licensed for use of SNM to be used as calibration and reference sources	\$246	\$131
	3. BY-PRODUCT, NATURALLY OCCURRING OR ACCELERATOR PRODUCED MATERIAL		
R7	a. Licenses for processing or manufacturing for commercial distribution or industrial uses;	\$3,508	\$3,362
R7	b. Licenses for processing or manufacturing and distribution of radiopharmaceuticals. This category includes radiopharmacies;	\$3,072	\$4,608
R7	c. Licenses industrial radiography performed only in an approved shielded radiography installation;	\$1,870	\$2,593
R7	d. Licenses for industrial radiography performed only at the address indicated in the license, or at temporary job sites of the licensee;	\$1,972	\$3,188

	3. BY-PRODUCT, NATURALLY OCCURRING OR ACCELERATOR PRODUCED MATERIAL			
R7	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;	\$726	\$726
R7	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;	\$1,697	\$1,956
R7	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;	\$4,391	\$4,753
R7	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;	\$11,736	\$5,278
R7	g.	Licenses issued to distribute items containing radioactive materials to persons under a general license;	\$1,972	\$2,580
R7	h.	Fixed gauging devices;	\$726	\$1,159
	i.	Well logging		
R7	(I)	Sealed sources or sub-surface tracer studies	\$1,362	\$1,798
R7	(II)	Sub-surface tracer studies and sealed sources	\$1,723	\$1,913
R7	j.	Nuclear Laundry;	\$3,840	\$6,781
R7	k.	Industrial or Medical Research and Development	\$1,421	\$1,769
R7	I.(I)	Portable gauging devices	\$726	\$1,159
R7	(II)	In Vitro and clinical laboratory	\$870	\$1,102
R7	(III)	Academic	\$1,174	\$1,405
R7	(IV)	Possession of uranium or thorium, or their decay products as a result of mining or processing	\$1,174	\$1,044
R7	(V)	All other specific license except otherwise noted	\$870	\$1,202

	3.	BY-PRODUCT, NATURALLY OCCURRING OR ACCELERATOR PRODUCED MATERIAL		
	m.	Licenses of broad scope		
R7	(I)	Academic	\$3,840	\$8,815
R7	(II)	Medical	\$3,840	\$6,569
R7	(III)	Industrial or Research and Development	\$3,840	\$5,482
R7	n.	Gas chromatography devices	\$521	\$377
R7	o.	Reference or calibration sources equal to or less than one millicurie total;	\$377	\$158
R7	p.	Nuclear service licenses, such as, leak testing, instrument calibration, etc.;	\$622	\$492
	4.	WASTE DISPOSAL OR PROCESSING		
R7	a.	Commercial waste disposal or treatment facilities, including burial or incineration	\$331,010	\$300,666
R7	b.	All other commercial facilities involving compaction, repackaging storage or transfer.	\$32,501	\$29,965
R7	c.	Commercial treatment of radioactive materials for release to unrestricted areas	\$6,913	\$6,882
	5.	MEDICAL USE		
R7	a.(I)	Teletherapy or gamma stereotactic radiosurgery including gamma knife devices;	\$1,838	\$1,791
R7	a.(II)	High dose rate remote afterloading devices;	\$1,697	\$1,654
R7	a.(III)	High dose rate remote afterloading devices and gamma stereotactic radiosurgery including gamma knife devices or teletherapy devices;	\$1,838	\$1,791
R7	b,	Medical institutions, including hospitals, except 5.a.(I), 5.a.(II), 5.a.(III), 5.e. and 5.f.;	\$1,972	\$2,290
R7	c.	Private practice physicians except category 5.a.(I), 5.a.(II), 5.a.(III), 5.d. and 5.f.;	\$1,421	\$1,608
R7	d.	Private practice physicians using only strontium 90 eye applicators, or materials authorized by 64E-5.630, or materials authorized by 64E-5.631	\$726	\$898
R7	e.	Nuclear powered pacemakers	\$521	\$319
R7	f.(I)	Mobile nuclear medicine services	\$1,697	\$1,950
R7	f.(II)	Mobile high dose rate remote afterloading therapy device when the treatment is only performed on the mobile vehicle.	\$2,970	\$3,308

		APPLICATION FEE	ANNUAL FEE
R7	6. CIVIL DEFENSE	\$653	\$985
	7. DEVICE, PRODUCT, OR SEALED SOURCE SAFETY EVALUATION		
R7 R7 R7 R7 R7 R7 R7	a. Safety evaluation of devices or products containing radioactive material, except reactor fuel devices, for commercial distribution or in accordance with the unique specifications of, and for use by, a single applicant; per device remaining in active status. Devices or products in inactive status more than 5 years must submit another application fee and be re-evaluated;	\$4,500	\$2,570
R7 R7 R7 R7 R7 R7 R7	b. Safety evaluation of sealed sources containing radioactive material, for commercial distribution or in accordance with the unique specifications of, and for use by, a single applicant; per source remaining in active status. Sources in inactive status more than 5 years must submit another application fee and be re-evaluated.	\$2,400	\$2,900

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

R7 Law Implemented: 404/032, 404.061, 404.051, 404.081, 404.131, 404.141 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,

R7 Amended September 28, 2006, Amended August 16, 2007

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.
- R6 (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.
- R8 (b)1. The general license in (4)(a), above, applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to 64E-5.210(4) or in accordance with the specifications contained in a specific license issued by the NRC, or an agreement state, which authorizes distribution of devices to persons granted a general license by the U.S. NRC, or an agreement state. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of 21 CFR Part 179. (Pursuant to 120.54(6) Florida Statutes, 64E-5.206(4)(b)1. is substantively identical to 10 CFR 31.5(b)(1) published on 01/01/2007.)
- R8
- R8
- R8
- R8
- R8
- R8
- R6 (b)2. The devices must have been received from one of the specific licenses described in (b)1., above or through a transfer made under subparagraph 6E-5.206(4)(c)8., F.A.C.
- R6
- R6
- R6 (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 **three years** after the next required leak test is performed or until the transfer or disposal of the sealed source. Records of tests of the on-off mechanism and indicator required by (4)(c)2., above, shall be maintained for at least **three years** after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by (4)(c)3., above, shall be maintained for a period of at least **three years** from the date of the recorded event or until the transfer or disposal of the device; (Pursuant to 120.54(6) Florida Statutes, 64E-5.206(4)(c)4. is substantively identical to 10 CFR 31.5(c)(4)i published on 01/01/2007.)

R8

R8

R8

R8

R8

R8

5. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the department, the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the department a report containing a brief description of the event and the remedial action taken; and in the case of removable radioactive materials or failure of or damage to a source likely to result in contamination of the premises or the environment, a plan for ensuring the premise and environment are acceptable for unrestricted use using the criteria described in Rule 64E-5.222, F.A.C.

R6
R6
R6
R6
R6
R6

6. Shall not abandon the device containing radioactive material;

7. Except as provided in (4)(c)8., below, shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph 15 below, transfer to a specific licensee of the department, the NRC, or an agreement state, whose specific license authorizes him to receive the device, and within 30 days after transfer of a device to a specific licensee, shall furnish to the department a report containing identification of the device by manufacturer's or initial transferor's name and model number and serial number, the name, address, license number, where applicable, of the person receiving the device and the date of the transfer;

R8
R8
R8

R6
R6
R6
R6

8. Shall transfer the device by export as provided by paragraph 15 below, or to another general licensee only:

R8
R8

a. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section, a copy of Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C., and any safety documents identified in the label on the device and within 30 days of the transfer, report to the department the manufacturer's or initial transferor's name and model number and serial number of device transferred, the transferor's name and mailing address for the location of use, and the name title, and phone number of the responsible individual identified by the transferee in accordance with paragraph 64E-5.206(4)(c) and subsection (11), F.A.C., to have knowledge of and authority to take actions to ensure compliance with these regulations; or

R8
R8

R6
R6
R6
R6
R6
R6
R6
R6

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

- R6 (III) Name, title, and telephone number of the responsible
R6 person designated a representative of the general
R6 licensee under paragraph 64E-5.206(4)(c) and
R6 subsection (11), F.A.C.;
- R6 (IV) Address or location at which the device(s) are used or
R6 stored. For portable devices, the address of the
R6 primary place of storage;
- R6 (V) Certification by the responsible representative of the
R6 general licensee that the information concerning the
R6 devices(s) have been verified through a physical
R6 inventory and checking the label information; and
- R6 (VI) Certification by the responsible representative of the
R6 general licensee that they are aware of the
R6 requirements of the general license.
- R6 d. Persons generally licensed by other Agreement States,
R6 Licensing States, or the U.S. Nuclear Regulatory
R6 Commission with respect to devices meeting the criteria in
R6 10 CFR 31.5(c)(13)(i) are not subject to registration
R6 requirements if the devices are used in areas subject to the
R6 Department jurisdiction for less than 180 days in any
R6 calendar year. The Department will not request registration
R6 from such licensees.
- R6 13. Shall report to the Department changes in the general licensee
R8 name and the mailing address for each location of use within
R6 30 days of the effective date of the change. For a portable device, a
R6 report of address change is required for a change in the device's
R6 primary place of storage.
- R8 14. Shall not hold devices that are not in use longer than 2 years. If the
R6 devices with shutters are not being used, the shutters must be
R6 locked in the closed position. The testing required by subparagraph
R6 64E-5.206(4)(c)2., F.A.C., need not be performed during the period
R6 of storage only. However, when devices are put back into service or
R6 transferred to another person, and have not been tested within the
R8 required test interval, they must be tested for leakage before use or
R8 transfer and the shutter tested before use. Devices kept in standby
R6 for future use are excluded from the two year time limit if the
R6 general licensee performs physical inventories at intervals not to
R8 exceed three months while they are in standby. (Pursuant to
R8 120.54(6) Florida Statutes, 64E-5.206(4)(c)14. is substantively
R8 identical to 10 CFR 31.5(c)(15) published on 01/01/2007.)
- R8 15. Shall not export the device containing radioactive material except in
R8 accordance with 10 C.F.R. Part 110;

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

Page left intentionally blank

- (d) The general license in paragraph (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).

- (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.

R6 History: New July 17, 1985, amended April 4, 1989, Amended January 1, 1994, Formerly 10D-91.306, Amended September
R8 28, 2006, Amended February 28, 2008.

**SUBPART C
SPECIFIC LICENSES**

64E-5.207 Filing Application for Specific Licenses.

- R10 (1) An original and one copy of an application for specific licenses, license renewals,
R10 and license amendments shall be filed with the department on Application for
R10 Radioactive Materials License Non-Human Use, DH Form 1054 12/09 or
Application for Radioactive Materials Human Use, DH Form 1322 12/09, 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

R10 **Rulemaking** 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.

R10 History: New 7-17-85, Amended 4-4-89, 5-12-93, 5-15-96, Formerly 10D-91.307, **Amended 02-11-10** .

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 Rule 64E-5.208, F.A.C., 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 paragraph 64E-5.203(1)(a), F.A.C., 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 subsection 64E-5.203(2), F.A.C., 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 subparagraph (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 subsection 64E-5.203(2), F.A.C. 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 subsection (2), above, shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under subsection 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 paragraph 64E-5.203(3)(c) F.A.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 subsection 64E-5.206(4) F.A.C.

- (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 subsection 64E-5.206(4), F.A.C., 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 Rule 64E-5.208, F.A.C.;
 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 Rule 64E-5.304, F.A.C., 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 rems
..... (150 mSv)
 - (II) Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter..... 200 rems
..... (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

- R6
R6
R6
R6
R6
R6
4. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the radioisotope and quantity, the words "Caution Radioactive Materials," the radiation symbol described in Rule 64E-5.322, F.A.C., the name of the manufacturer or initial distributor.
- R6
R6
R6
R6
R6
R6
R6
R6
R6
R6
R6
5. Each device containing at least 10 millicuries (370 MBq) of cesium-137, 0.1 millicuries (3.7 MBq) of strontium-90, 1 millicurie (37 MBq) of cobalt-60, or 1 millicurie (37 MBq) of americium-241 or any other element with atomic numbers greater than 92, based on the activity indicated on the label, must bear a permanent label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words "Caution Radioactive Materials," and if practical, the radiation symbol described in Rule 64E-5.322, F.A.C. Example of a permanent label include labels that are embossed, etched, stamped or engraved to the source housing or device as applicable.

(b) In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Department will consider the following information:

1. Primary containment or source capsule;
2. Protection of primary containment;
3. Method of sealing containment;
4. Containment construction material;
5. Form of contained radioactive material;
6. Maximum temperature withstood during prototype tests;
7. Maximum pressure withstood during prototype tests;
8. Maximum quantity of contained radioactive material;
9. Radiotoxicity of contained radioactive material; and
10. Operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under Rule 64E-5.206, F.A.C., 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 Rule 64E-5.304, F.A.C.

R6 (d) If a device containing radioactive material is transferred for use under the
R6 general license described in subsection 64E-5.206(4), F.A.C., each
R6 person that is licensed under subsection 64E-5.210(4), F.A.C., shall
R6 provide the information specified in this section to each person to whom a
R6 device is to be transferred. This information must be provided before the
R6 device may be transferred. In the case of a transfer through an
R6 intermediate person, the information must also be provided to the intended
R6 user prior to the initial transfer to the intermediate person. The required
R6 information includes the following:

- R6 1. A copy of the general license contained in subsection
R6 64E-5.206(4), subparagraphs 64E-5.206(4)(c)2.,3. and 4. or
R6 subparagraph 64E-5.206(4)(c)12., F.A.C., do not apply to the
R6 particular device, those paragraphs may be omitted;
- R8 2. A copy of Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C.;
- R6 3. A list of services that can only be performed by a specific licensee;
- R6 4. Information on acceptable disposal options including costs of
R6 disposal; and
- R6 5. An indication that department policy is to issue high civil penalties
R6 for improper disposal.

R6 (e) If a device containing radioactive material is transferred for use under an
R8 equivalent general license of an Agreement State or the NRC, each
R6 person that is licensed under subsection 64E-5.210(4), F.A.C., shall
R6 provide the information specified in this section to each person to whom a
R6 device is to be transferred. This information must be provided before the
R6 device may be transferred. In the case of a transfer through an
R6 intermediate person, the information must also be provided to the intended
R6 user prior to the initial transfer to the intermediate person. The required
R6 information includes the following:

- R8
R8
R6
R6
R6
R6
R6
1. A copy of the Agreement State or NRC equivalent to Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C. If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it shall be accompanied by a note explaining that the use of the device is regulated by the Agreement State. If certain parts of the regulations do not apply to the particular device, those regulations may be omitted;
- R6
2. A list of services that can only be performed by a specific licensee;
- R6
R6
3. Information on acceptable disposal options including costs of disposal; and
- R6
R6
R6
R6
4. The name or title, address, and phone number of the contact at the Agreement State regulatory agency or U.S. Nuclear Regulatory Commission, as applicable, from which additional information may be obtained.
- R6
R6
- (f) Each device that is transferred must meet the labeling requirements in subparagraphs 64E-5.210(4)(d)3. through 5., F.A.C.
- R6
R6
R6
R7
R6
R7
- (g) If a notification of bankruptcy has been made under subsection 64E-5.213(3), F.A.C., or the license is to be terminated, each person licensed under subsection 64E-5.210(4), F.A.C., shall provide, upon request, to the department, U.S. Nuclear Regulatory Commission and to any appropriate Agreement State, records of final disposition required under paragraph 64E-5.210(4)(j), F.A.C.
- R7
R6
- (h) Each person licensed under subsection 64E-5.210(4), F.A.C., shall comply with the following reporting and record keeping requirements.
- R6
R6
R6
R7
R6
R6
R7
R7
R7
1. Report all transfers of devices to persons for use under the general license described in subsection 64E-5.206(4), F.A.C., and all receipts of devices from persons licensed under subsection 64E-5.206(4), F.A.C., to the department. This report must be submitted at intervals not to exceed 3 months and contain all of the information described in "Transfers of Industrial Devices Report 04/2007" herein incorporated by reference and is available at the address listed in paragraph 64E-5.204(2)(b) or at <http://www.doh.state.fl.us/environment/radiation/>.
- R6
R6
2. This report must be clear and legible and contain the following data:

- R6 a. The identity of each general licensee by name and mailing
R6 address for the location of use; if no mailing address for the
R6 location of use, an alternative address for the general
R6 licensee shall be submitted along with information on the
R6 actual location of use;
- R6 b. The name, title, and phone number of the person identified
R6 by the general licensee as having knowledge of and
R6 authority to take required actions to ensure compliance with
R6 the appropriate regulations and requirements;
- R6 c. The date of transfer;
- R6 d. The type, model number, and serial number of the device
R6 transferred; and
- R6 e. The quantity and type of radioactive materials contained in
R6 the device.
- R6 3. If one or more intermediate persons will temporarily possess the
R6 device at the intended place of use before its possession by the
R6 user, the report must include the same information for both the
R6 intended user and each intermediate person and clearly designate
R6 the intermediate person(s).
- R6 4. For devices received from a subsection 64E-5.206(4), F.A.C.,
R6 general licensee, the report must include the identity of the general
R6 licensee by name and address, the type, model number, and serial
R6 number of the device received, the date of receipt, and, in the case
R6 of devices not initially transferred by the reporting licensee, the
R6 name of the manufacturer or initial transferor.
- R6 5. If the licensee makes changes to the device possessed by a
R6 subsection 64E-5.206(4), F.A.C., general licensee, such that the
R6 label must be changed to update required information, this report
R6 must identify the general licensee, the device, and the changes to
R6 information on the device label.
- R6 6. The report must clearly identify the specific licensee submitting the
R6 report and include the license number of the specific licensee.
- R6 7. If no transfers have been made to or from persons generally
R6 licensed under subsection 64E-5.206(4), F.A.C., during the
R6 reporting period, the report must so indicate.
- R6 (i) Each person licensed under subsection 64E-5.210(4), F.A.C., shall
R6 comply with the following additional reporting and record keeping
R6 requirements for transfers and receipt of devices to Agreement States or
R8 the NRC.

- R6
R8
R6
R8
R8
R6
R7
1. Report all transfers of devices to persons for use under the general license in an Agreement State or the NRC, that are equivalent to subsection 64E-5.206(4), F.A.C., and all receipts of devices from persons licensed under a general license in Agreement State or the NRC jurisdiction to the responsible Agreement State or the NRC agency. This report must contain all of the information described in "Transfers of Industrial Devices Report 04/2007."

R6

 2. The report must be clear and legible and contain the following data:
 - a. The identity of each general licensee by name and mailing address for the location of use; if no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;

R6
R6
R6
R6
R6

 - b. The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

R6
R6
R6
R6

 - c. The date of transfer;

R6
R6

 - d. The type, model number, and serial number of the device transferred; and

R6
R6

 - e. The quantity and type of radioactive materials contained in the device.

R6
R6
R6
R6
R6

 3. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person and clearly designate the intermediate person(s).

R6
R6
R6
R6
R6
R6

 4. For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

R6
R6
R6
R6

 5. If the licensee makes changes to the device possessed by a general licensee, such that the label must be changed to update required information, this report must identify the general licensee, the device, and the changes to information on the device label.

R6
R6

 6. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

R6

 7. If no transfers have been made to or from a particular Agreement

R8 State or the NRC during the reporting period, this information shall
 R8 be reported to the responsible Agreement State or the NRC agency
 R6 upon request of the agency.

R6 8. The report must cover each calendar quarter and must be filed
 R6 within 30 days of the end of the calendar quarter and must clearly
 R6 indicate the period covered by the report.

R7 (j) The persons shall maintain all information concerning transfers and
 R6 receipts of devices that supports the reports required by subsection
 R6 64E-5.210(4), F.A.C. Records and reports described in subsection
 R6 64E-5.210(4), F.A.C., shall be maintained for inspection by the department
 R7 for a period of 3 years following the date of the recorded event.
 R6

- (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 subsection 64E-5.206(5), F.A.C., 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 Rule 64E-5.208, F.A.C., 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 subsection 64E-5.206(6) F.A.C. An application for a specific license to manufacture calibration and reference sources containing americium 241, plutonium or radium 226 to general licensees under subsection 64E-5.206(6), F.A.C., 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 Rule 64E-5.208, F.A.C., are satisfied.
- (7) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In addition to requirements set forth in Rule 64E-5.208, F.A.C., a specific license authorizing the distribution of radioactive material for use by physicians under the general license in subsection 64E-5.206(7), F.A.C., 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

Page left intentionally blank - next page is page 44

- (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 subsection 64E-5.206(8), F.A.C., will be approved if:
- (a) The applicant satisfies the general requirements specified in Rule 64E-5.208 F.A.C..
 - (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 subsection 64E-5.322(1), F.A.C., 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 subsection 64E-5.206(9), F.A.C., will be approved if:

- (a) The applicant satisfies the general requirements of Rule 64E-5.208, F.A.C.; 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 Rules 64E-5.626, 64E-5.627, 64E-5.630 and 64E-5.664, F.A.C. will be approved if:

- (a) The applicant satisfies the general requirements specified in Rule 64E-5.208;

- (b) The applicant submits evidence that:

- R3
R3
1. The applicant is registered or licensed with the U.S. Food and Drug Administration as a drug manufacturer; or
 2. The applicant is registered or licensed as a drug manufacturer as specified in Chapter 499, F.S.; or
 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.
- R3
R3
R3
- (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;
- R3
- (d) The applicant satisfies the following labeling requirements:
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.
 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
- R3
R3
R3
R3
R3
R3
R3
- (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:
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
 2. Check each instrument for constancy and proper operation at the beginning of each day of use.
- R3
R3

R10
R10

- (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 or Rule 64E-5.664, F.A.C., will be approved if:
- (a) The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.;
 - (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 Rule 64E-5.627, F.A.C., 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.

R10
R10

(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, transmission or reference source or for the uses listed in 64E-5.631, 64E-5.634, 64E-5.664 or 64E-5.632, F.A.C., 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 subsection 64E-5.205(4), F.A.C., 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 Rule 64E-5.208 F.A.C.;
 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 paragraph (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 subsection 64E-5.205(4), F.A.C., to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license described in subsection 64E-5.205(4), F.A.C., 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 subsection 64E-5.205(4), F.A.C., 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 subsection 64E-5.205 (4), F.A.C.;
5. Report to the Department all transfers of industrial products or devices to persons for use under the general license described in subsection 64E-5.205(4), F.A.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 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 subsection 64E-5.205(4). F.A.C., 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 subsection 64E-5.210(3), F.A.C., for use under a general license in that state's rules equivalent to subsection 64E-5.205(4), F.A.C.,
 - 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 subsection 64E-5.205(4), F.A.C., 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.

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

R10 Rulemaking Authority: 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

R7 Law Implemented: 404.022, 404.051, 404.061, 404.081, 404.141, F.S.

R3,R6-7 History:7-17-85, Amended 8-25-91, 5-12-93, 1-1-94, 5-15-96, Formerly 10D-91.311, Amended 8-6-01, 9-28-06, 8-16-07
R7,R10 2-28-08, Amended 02-11-10.

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.
- R6 (3) (a) Each **specific or general** licensee shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code (U.S.C.) by or against:
1. The licensee;
 2. An entity, as that term is defined in 11 U.S.C. 101(14), controlling the licensee or listing the license or licensee as property of the estate; or
 3. An affiliate, as that term is defined in 11 U.S.C. 101(2), of the licensee.
- (b) This notification shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition for bankruptcy.
- (4) Each person licensed by the Department pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.
- (5) A separate license is required for the following:
- (a) Each activity as designated by license category in paragraph 64E-5.204(2)(e), F.A.C..

- (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.

R10

- 4. Temporary job sites lasting more than two years.

(c) Each facility operated by an out-of-state licensee under reciprocity as specified in Rule 64E-5.216, F.A.C., and does not meet the definition of a temporary job site.

(d) Each large irradiator as defined in Rule 64E-5.101, F.A.C.

R10
R10

- (6) A separate license is not required for temporary job sites lasting less than two years or for each facility that is authorized under a broad scope license.

R1
R1
R1

- (7) A licensee shall notify the department in writing within 30 days after a radiation safety officer permanently discontinues performance of radiation safety officer duties.

R1

- (8) A licensee shall apply and receive a license amendment or department approval:

R1
R1

(a) Before using radioactive material for a method or type or use not permitted by the license;

R1
R1

(b) Before permitting anyone to use radioactive material as an authorized user as authorized by the license;

R1

(c) Before changing a radiation safety officer

R1
R1

(d) Before ordering or receiving radioactive materials in excess of the amount authorized on the license

R1
R1

(e) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

R1
R1

(f) Before changing statements, representations, and procedures which are incorporated into the license.

R10 Rulemaking Authority: 404.051, 404.061, 404.141F.S.

R1 Law Implemented: 404.051(1)(4), 404.061(2)(3), 404.081(1), 404.141, F.S.

R6 History: New 7-17-85, Amended 4-4-89, 5-12-93, 8-29-94, Formerly 10D-91.314, Amended 5-18-98., 9-28-06,

R10 Amended 02-11-10

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:

- R5
1. Terminate the use of radioactive material;
 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
 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:
 - 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
- 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:
 - 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 satisfies the requirements specified in Rules 64E-5.221, 64E-5.222, 64E-5.223, or 64E-5.224, F.A.C.; or
 - 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.
- R5
- R5
- R5

- 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.

Space intentionally left blank

Next page number is II-61

- R5
R1
R1
- R5
R1
- (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.

R5
R5
R5

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

R5
R5
R5

(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 RECIPROCIITY

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.

- R8 (1) Subject to these regulations, any person who holds a specific license from the NRC, or an Agreement State and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, will be granted a general license by the Department to conduct the activities authorized in such licensing document within the State of Florida, except for areas of exclusive federal jurisdiction, for a period not in excess of 180 consecutive days provided that:
- R2 R8 R10
- (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.
- 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
- (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
 - R2 2. Exempt from the requirements for a license for such material under Rule 64E-5.203(1)(a), F.A.C.

R10 (e) Any licensee using or storing radioactive material at any location not listed
R10 on the license for a period in excess of 180 days in a calendar year, shall
R10 notify the department with the information listed in paragraph
R10 64E-5.216(1)(b), F.A.C., prior to exceeding the 180 days.

R10 (2) In addition to the provisions of subsection (1), above, any person who holds a
R10 specific license issued by the NRC, an agreement state, or a licensing state
authorizing the holder to manufacture, transfer, install or service a device
described in paragraph 64E-5.206(4)(a), F.A.C., 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 subsection 64E-5.206(4), F.A.C., 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.

R10 Rulemaking 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.

R10 History: New 7-17-85, Amended 4-4-89, Formerly 10D-91.321, Amended 10-8-00, 2-28-08, Amended 02-11-10.

**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

- (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.

- (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.

Space Intentionally left Blank

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 subpart
R5 apply to the decommissioning of facilities licensed under this chapter but do not apply to
R5 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 that
R5 the licensee intends to decommission by restricting use of the site. The licensee
R5 shall document in the license termination or decommissioning plan how the
R5 advice of individuals and institutions in the community who could be affected by
R5 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 terminate
R5 a license using alternate criteria greater than the dose criterion of Rules 64E-5.222, 64E-
R5 5.223(2), and 64E-5.223(4)(a)1.(l), 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 decommission
R5 by use of alternate criteria. The licensee shall document in the license
R5 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 by
R5 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.

**PART III
SCHEDULE A
EXEMPT CONCENTRATIONS**

Element (atomic number)	Isotope	Column I Gas Concentration (μCi per ml)	Column II Liquid and Gas Concentration (μCi 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 (μCi per ml)	Column II Liquid and Gas Concentration (μCi 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 ($\mu\text{Ci per ml}$)
Techneium (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.

(Page left intentionally Blank)

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

R6	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

R10	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

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

R6	64E-5.318.. Use of Process or Other Engineering Controls	III-15
R6	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

	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
R10	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
R10	64E-5.344.. Notification of Incidents	III-40
R10	64E-5.345.. Reports of Exposure, Radiation Levels, Concentrations of Radioactive Materials Exceeding the Constraint or Limits, and Medical Events and Dose to an embryo/Fetus or a Nursing Child.....	III-44a
	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
R8	64E-5.350 ... Reports of Transactions Involving Nationally Tracked Sources	III-47
R8	64E-5.351 ... Nationally Tracked Source Thresholds.	III-50

PART III

STANDARDS FOR PROTECTION AGAINST RADIATION

SUBPART A
GENERAL PROVISIONS**64E-5.301 Standards for Protection Against Radiation.**

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

R2
R2

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

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

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

64E-5.302 Implementation.

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

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.433.

SUBPART B-- RADIATION PROTECTION PROGRAMS

64E-5.303 Radiation Protection Programs.

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

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

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

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

SUBPART C -- OCCUPATIONAL DOSE LIMITS

64E-5.304 Occupational Dose Limits for Adults.

- R2 (1) The licensee or registrant shall control the occupational dose to individual adults,
 R2 except for planned special exposures as specified in **Rule** 64E-5.309, **F.A.C.**, to
 the following dose limits:
- (a) An annual limit, which is the more limiting of:
1. The total effective dose equivalent equal to 5 rem (0.05 sievert); or
 2. The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye equal to 50 rem (0.5 sievert).
- R6 (b) The annual limits to the lens of the eye, to the skin **of the whole body**, and
 R6 to the **skin of the** extremities which are:
- R2 1. An **lens** dose equivalent of 15 rem (0.15 sievert), and
 - R6 2. A shallow dose equivalent of 50 rem (0.5 sievert) to the skin **of the**
 R6 **whole body** or to **skin of** any extremity.

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

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

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

R2,R6 History: New January 1, 1994, Formerly 10D-91.435, Amended October 8, 2000, Amended September 28, 2006.

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

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

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

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

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

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

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.437.

64E-5.307 Determination of Internal Exposure.

- (1) To assess dose used to determine compliance with occupational dose equivalent limits when required as specified in 64E-5.315, the licensee shall take suitable and timely measurements of:
 - (a) Concentrations of radioactive materials in air in work areas;
 - (b) Quantities of radionuclides in the body;
 - (c) Quantities of radionuclides excreted from the body; or
 - (d) Combinations of these measurements.
- (2) Unless respiratory protective equipment is used as specified in 64E-5.319 or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.
- (3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee is permitted to:
 - (a) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record;
 - (b) Upon prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
 - (c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993.
- (4) If the licensee chooses to assess intakes of Class Y material using the measurements given in 64E-5.307(1)(b) or (c), the licensee can delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by 64E-5.344 or 64E-5.345. This delay permits the licensee to make additional measurements basic to the assessments.
- (5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:
 - (a) The sum of the ratios of the concentration to the appropriate DAC value, that is D, W, or Y, from State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, for each radionuclide in the mixture; or

- (b) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.
- (6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
- (7) When a mixture of radionuclides in air exists, a licensee is permitted to disregard certain radionuclides in the mixture if:
 - (a) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 64E-5.304 and in complying with the monitoring requirements in 64E-5.315(2);
 - (b) The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and
 - (c) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.
- (8) When determining the committed effective dose equivalent, the following information can be considered:
 - (a) To calculate the committed effective dose equivalent, the licensee can assume that the inhalation of one ALI or an exposure of 2,000 DAC-hours results in a committed effective dose equivalent of 5 rem (0.05 sievert) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
 - (b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rem (0.5 sievert), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 sievert), that is, the stochastic ALI, as listed in parentheses in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I. The licensee can use the stochastic ALI to determine committed effective dose equivalent as a simplifying assumption. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in 64E-5.304(1)(a)2. is met.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.308.

64E-5.308 Determination of Prior Occupational Dose.

- (1) For each individual who is likely to receive in a year an occupational dose requiring monitoring as specified in 64E-5.315, the licensee or registrant shall:
 - (a) Determine the occupational radiation dose received during the current year; and

- (b) Attempt to obtain the records of lifetime cumulative occupational radiation dose.
- (2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
- (a) The internal and external doses from all previous planned special exposures;
 - (b) All doses in excess of the limits received during the lifetime of the individual, including doses received during accidents and emergencies; and
 - (c) All lifetime cumulative occupational radiation doses.
- (3) In complying with the requirements of 64E-5.308(1), a licensee or registrant can:
- (a) Accept a written signed statement from the individual or from the individual's most recent employer for work involving radiation exposure that discloses the nature and the amount of any occupational dose that the individual received during the current year as a record of the occupational dose that the individual received during the current year;
 - (b) Accept an up-to-date DH Form 1623 July 1993, which is herein incorporated by reference and which is available from the department, or an equivalent signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure or the individual's current employer if the individual is not employed by the licensee or registrant as the record of lifetime cumulative radiation dose; and
 - (c) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure or the individual's current employer if the individual is not employed by the licensee or registrant by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.
- (4) The licensee or registrant shall record the exposure history, as required by 64E-5.308(1), on DH Form 1623 July 1993 or other clear and legible record of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing DH Form 1623 July 1993 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on DH Form 1623 July 1993 or equivalent indicating the periods of time for which data are not available.

- (5) Licensees are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed as specified in the rules in this part in effect before the effective date of this rule. Further, occupational exposure histories obtained and recorded on DH Form 1623 or equivalent before the effective date of this rule would not have included effective dose equivalents, but can be used in the absence of specific information on the intake of radionuclides by the individual.
- (6) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:
- (a) That the allowable dose limit for the individual is reduced by 1.25 rem (12.5 millisievert) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure to establish administrative controls as specified in 64E-5.304(6) for the current year; and
 - (b) That the individual is not available for planned special exposures.
- (7) The licensee or registrant shall retain the records on DH Form 1623 July 1993 or equivalent until the department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing DH Form 1623 July 1993 or equivalent for 3 years after the record is made.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.439.

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 **Rule** 64E-5.304, **F.A.C.**, if each of the following conditions is satisfied:

- R2
- (1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the **dose** are unavailable or impractical.
 - (2) The licensee or registrant and employer if the employer is not the licensee or registrant specifically authorizes the planned special exposure in writing before the exposure occurs.
 - (3) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:
 - (a) Informed of the purpose of the planned operation;
 - (b) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

- (c) Instructed in the measures to be taken to keep the dose ALARA considering other risks that might be present.
- (4) The licensee or registrant ascertains prior doses as required by 64E-5.308(2) during the lifetime of each individual involved prior to permitting an individual to participate in a planned special exposure.
- (5) As specified in 64E-5.304(2), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of:
 - (a) The numerical values of any of the dose limits in 64E-5.305(1) in any year; and
 - (b) Five times the annual dose limits in 64E-5.304(1) during the individual's lifetime.
- (6) The licensee or registrant maintains records of the conduct of a planned special exposure as specified in 64E-5.338 and submits a written report to the department as specified in 64E-5.346.
- (7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual in writing of the dose within 30 days after the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual as specified in 64E-5.304(1) but shall be included in evaluations required by 64E-5.309(4) and (5).

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New January 1, 1994, Formerly 10D-91.440, Amended October 8, 2000.

64E-5.310 Occupational Dose Limits for Minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 64E-5.304.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.441.

64E-5.311 Dose to an Embryo or Fetus.

- (1) The licensee or registrant shall ensure that the dose to an embryo or fetus during the entire pregnancy from occupational exposure of a declared pregnant woman does not exceed 0.5 rem (5 mSv). See 64E-5.339 for recordkeeping requirements.
- (2) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 64E-5.311(1). It is recommended that no more than 0.05 rem (0.5 mSv) be received by the embryo or fetus in any one month.

- (3) The dose to an embryo or fetus shall be taken as the sum of:
 - (a) The deep dose equivalent to the declared pregnant woman; and
 - (b) The dose to the embryo or fetus from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.
- (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 (5 mSv) or is within 0.05 rem (0.5 mSv) or this dose, the licensee or registrant shall be considered in compliance with Rule 64E-5.311(1), F.A.C., if the additional dose to the embryo or fetus does not exceed 0.05 rem (0.50 mSv) during the remainder of the pregnancy.
- (5) Each individual who has declared pregnancy shall wear a radiation monitor at waist level at all times at work. This monitor shall be used to estimate the fetal deep-dose equivalent. When the declared pregnant worker wears protective clothing, this monitor shall be worn under the protective clothing. The fetal dose is to be kept as low as reasonably achievable, but shall not exceed 10 percent of the standards specified in 64E-5.304. Each declared pregnant worker whose duties require protective clothing shall also wear a radiation monitor outside the protective clothing to estimate dose to the worker, and the standard occupational limits will apply.

R2
R2
R2

Specific Authority: 404.051, 404.081, F.S.
 Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
 R2 History: New January 1, 1994, Formerly 10D-91.442, Amended October 8, 2000.

SUBPART D
RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

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 Rule 64E-5.312(1)(b), F.A.C., 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 Rule 64E-5.622, F.A.C., from voluntary participation in medical research programs and from the licensee's disposal of radioactive material into sanitary sewerage as specified in Rule 64E-5.330, F.A.C.;
 - (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 Rule 64E-5.622, F.A.C., does not exceed 0.002 rem (0.02 millisievert) in any one hour.

R2

R2
R2
R2
R2
R2

R2
R2
R2

- (2) If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.
- (3) A licensee, registrant, or an applicant for a license or registration can apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 millisievert). This application shall include the following information:
 - (a) Demonstration of the need for and the expected duration of operations in excess of the limit in 64E-5.304(1);
 - (b) The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 millisievert) annual limit; and
 - (c) The procedures to be followed to maintain the dose ALARA.
- (4) In addition to the requirements of this part, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.
- (5) A licensee or applicant for a license may permit visitors to an individual who cannot be released under Rule 64E-5.622, F.A.C., to receive a radiation dose greater than 0.1 rem (1 millisievert) provided the following are satisfied:
 - (a) The radiation dose received does not exceed 0.5 rem (5 millisievert);
 - (b) The authorized user, as defined in Rule 64E-5.6011, F.A.C., has determined before the visit that it is appropriate.

R10
R10
R10
R10
R10
R10

R10 Rulemaking Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
R10 History: New 1-1-94, Amended 5-15-96, Formerly 10D-91.443, Amended 10-8-00, Amended 02-11-10.

64E-5.313 Compliance with Dose Limits for Individual Members of the Public.

- (1) The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in 64E-5.312.
- (2) A licensee or registrant shall show compliance with the annual dose limit in 64E-5.312 by:
 - (a) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual who is likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or
 - (b) Demonstrating that:
 - 1. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in State of Florida Bureau of Radiation Control ALIs, DACs and Effluent Concentrations, July 1993, Table II; and
 - 2. The dose from external sources would not exceed 0.002 rem (0.02 millisievert) in an hour and 0.05 rem (0.5 millisievert) in a year if an individual were continually present in an unrestricted area.

- (3) Upon approval from the department, the licensee can adjust the effluent concentration values in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, for members of the public to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.
- (4) Dental and podiatry registrants are exempt from (1), (2), and (3), above.
- (5) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public until the department terminates each pertinent license or registration requiring the record.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Amended November 20, 1994, Amended May 15, 1996, Formerly 10D-91.444.

SUBPART E SURVEYS AND MONITORING

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:
 - R2 1. The magnitude and extent of radiation levels;
 - 2. Concentrations or quantities of radioactive material; and
 - R2 3. The potential radiological hazards.
- (2) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements such as dose rate and effluent monitoring are calibrated annually for the radiation measured.
- (3) All personnel dosimeters except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 64E-5.304, with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:
 - (a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

- (b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
- (4) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.
- (5) Dental and podiatry registrants are exempt from (1) and (2), above.

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New January 1, 1994, Amended November 20, 1994, Formerly 10D-91.445, Amended October 8, 2000.

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:
 - R2 (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 Rule 64E-5.304(1), F.A.C.;
 - R2 (b) Minors 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);
 - R2 (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
 - R2 (d) Individuals entering a high or very high radiation area.
- R2 (2) Each licensee shall monitor to determine compliance with Rule 64E-5.307, F.A.C., the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
 - R2 (a) Adults likely to receive in 1 year an intake in excess of 10 percent of the applicable ALI in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations July 1993, Table I, Columns 1 and 2; and
 - R2 (b) Minors likely to receive in 1 year a committed effective dose equivalent in excess of 0.10 rem (1.0 millisievert); and
 - R2 (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, F.S.

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

R2 History: New January 1, 1994, Formerly 10D-91.446, Amended October 8, 2000.

SUBPART F**CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS****64E-5.316 Control of Access to High Radiation Areas.**

- (1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:
 - (a) A control device that upon entry into the area causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 millisievert) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates;
 - (b) A control device that energizes a conspicuous visible or audible signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
 - (c) Entryways that are locked except during periods when access to the areas is required with positive control over each individual entry.
- (2) The licensee or registrant can substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry in place of the controls required by 64E-5.316(1) for a high radiation area.
- (3) The licensee or registrant can apply to the department for approval of alternative methods for controlling access to high radiation areas.
- (4) The licensee or registrant shall establish the controls required by 64E-5.316(1) and (3) in a way that does not prevent individuals from leaving a high radiation area.
- (5) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled as specified in the regulations of the U.S. Department of Transportation if:
 - (a) The packages do not remain in the area longer than 3 days; and
 - (b) The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 millisievert) per hour.
- (6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material if there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this part and to operate within the ALARA provisions of the licensee's radiation protection program.

- (7) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 64E-5.316 if the registrant has met all the specific requirements for access and control specified in other applicable parts of these rules, such as Part IV for industrial radiographic operations, Part V for x-rays in the healing arts, and Part VIII for particle accelerators.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.447.

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

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

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.448.

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

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

(1) When it is not practical to apply process or other engineering controls, to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- (a) Control of access;
- (b) Limitation of exposure time;
- (c) Use of respiratory protection equipment; or
- (d) Other controls.

(2) If the licensee performs an ALARA analysis to determine whether or not to use respirators, the licensee can consider safety factors other than radiological factors. The licensee also should consider the impact of respirator use on workers' industrial health and safety.

Specific Authority: 404.051, F.S.

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

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

64E-5.319 Use of Individual Respiratory Protection Equipment.

(1) If the licensee uses respiratory protection equipment to limit intakes as specified in 64E-5.318:

R6
R6

(a) The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety, except as provided in 64E-5.319(1)(b).

R6

(b) If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use demonstrated by testing or on the basis of reliable test information.

R6
R6

(c) The licensee shall implement and maintain a respiratory protection program that includes:

R6

1. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

2. Surveys and bioassays as needed to evaluate actual intakes;

R6
R6
R6

3. Testing of respirators for operability including user seal checks for face sealing devices and functional checks for other devices immediately before to each use;

R6
R6
R6
R6
R6
R6

4. Written procedures regarding supervision and training of respirator users ; monitoring, including air sampling and bioassays; fit testing; respirator selection; breathing air quality; inventory and control; storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment; limitations on periods of respirator use and relief from respirator use; and recordkeeping;

R6
R6
R1

5. Determination by a physician before initial fitting of face sealing respirators, before the first field use of non-face sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician that the individual user is medically fit to use respiratory protection equipment; and

R6
R6
R6
R6
R6
R6

6. Fit testing before the first field use of tight fitting face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year with fit factor ≥ 10 times the APF for negative pressure devices and a fit factor ≥ 500 for any positive pressure, continuous flow, and pressure-demand devices. Fit testing shall be performed with the facepiece operating in the negative pressure mode.

- R6 (d) The licensee shall advise each respirator user that the user can leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.
- R6 (e) The licensee also shall consider limitations appropriate to the type and mode of use. When selecting respiratory devices, the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.
- R6 (f) Standby rescue persons are required whenever one-piece atmosphere-supplying suits or any combination of supplied-air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. Standby persons shall be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers through visual, voice, signal line, telephone, radio, or other suitable means and be available immediately to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons shall be available immediately to assist all users of this type of equipment and to provide effective emergency rescue if needed.
- R6 (g) Atmosphere-supplying respirators shall be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997, which is herein incorporated by reference and, available from the Compressed Gas Association, Inc., and included in the regulations of the Occupational Safety and Health Administration. Grade D quality air criteria include:
- R6 1. Oxygen content (v/v) of 19.5 – 23.5%;
 - R6 2. Condensed hydrocarbon content of 5 milligrams per cubic meter of air or less;
 - R6 3. Carbon monoxide content of 10 ppm or less;
 - R6 4. Carbon dioxide content of 1,000 ppm or less; and
 - R6 5. Lack of noticeable odor.
- R6 (h) The licensee shall ensure that no objects, materials, or substances such as facial hair, or any conditions that interfere with the face-to-facepiece seal or valve function and that are under the control of the respirator wearer are between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

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

Specific Authority: 404.051, 404.081, F.S.

R1 Law Implemented: 404.051(1)(4), 404.081, F.S.

R6 History: New January 1, 1994, Formerly 10D-91.452, Amended May 18, 1998, Amended September 28, 2006.

SUBPART H

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

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

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.453.

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

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

Specific Authority: 404.051, 404.081, F.S.

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

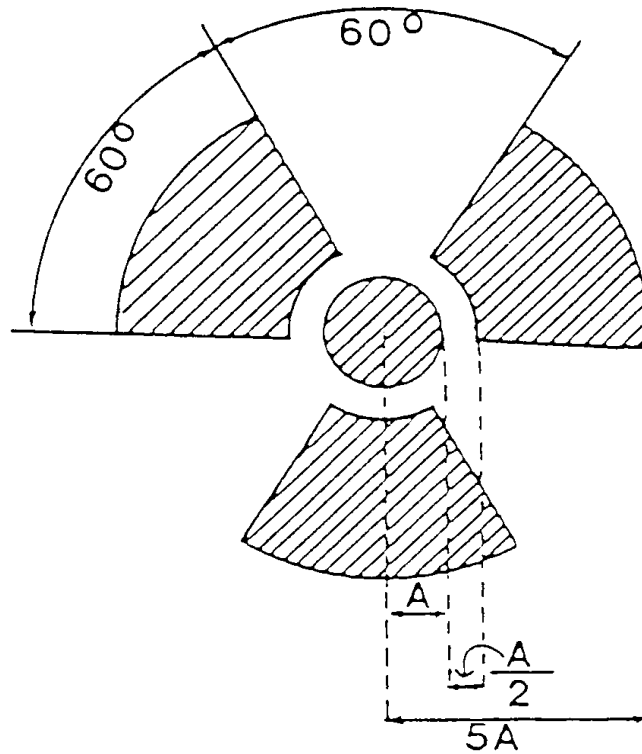
History: New January 1, 1994, Formerly 10D-91.454.

SUBPART I

PRECAUTIONARY PROCEDURES

64E-5.322 Caution Signs.

- (1) Standard Radiation Symbol. Unless otherwise authorized by the department, the symbol prescribed in this section shall use the colors magenta or purple or black on yellow background. The symbol prescribed is the three-bladed design as follows:



- (a) Cross-hatched area is to be magenta or purple or black, and
- (b) The background is to be yellow.
- (2) Exception to Color Requirements for Standard Radiation Symbol. In spite of the requirements of 64E-5.322(1), licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.
- (3) Additional Information on Signs and Labels. In addition to contents of signs and labels prescribed in this part, the licensee or registrant shall provide on or near the required signs and labels additional information to make individuals aware of potential radiation exposures and to minimize the exposures.

Specific Authority: 404.051, 404.081, F.S.
 Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
 History: New January 1, 1994, Formerly 10D-91.455.

64E-5.323 Posting Requirements.

- (1) Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."
- (2) Posting of High Radiation Areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."
- (3) Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."
- (4) Posting of Airborne Radioactivity Areas. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."
- (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 Bureau of Radiation Control Radioactive Material Requiring Labeling, **May 2000**, 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)."

R2

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New January 1, 1994, Formerly 10D-91.456, **Amended October 8, 2000.**

64E-5.324 Exceptions to Posting Requirements.

- (1) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours if each of the following conditions is met:
 - (a) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this part; and
 - (b) The area or room is subject to the licensee's or registrant's control.
- (2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs as specified in 64E-5.323 if the patient could be released from confinement as specified in 64E-5.622.

- (3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.005 rem (0.05 millisievert) per hour.
- (4) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.457.

64E-5.325 Labeling Containers and Radiation Machines.

- (1) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers or working in the vicinity of the containers to take precautions to avoid or minimize exposures.
- (2) Each licensee prior to removal or disposal of empty uncontaminated containers to unrestricted areas shall remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.
- (3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.458.

64E-5.326 Exemptions to Labeling Requirements. A licensee is not required to label:

R2

- (1) Containers holding licensed material in quantities less than the quantities listed in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling, **May 2000**;
- (2) Containers holding licensed material in concentrations less than those specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table III;
- (3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this part;

- (4) Containers when they are in transport and packaged and labeled as specified by the rules of the U.S. Department of Transportation;
- (5) Containers that are accessible only to individuals authorized to handle or use them or to work in the vicinity of the containers if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or
- (6) Installed manufacturing or process equipment, such as piping and tanks.

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New January 1, 1994, Formerly 10D-91.459, **Amended October 8, 2000.**

64E-5.327 Procedures for Receiving and Opening Packages.

- (1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of A_1 or A_2 quantities as defined in Part XV shall make arrangements to receive:
 - (a) The package when the carrier offers it for delivery; or
 - (b) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.
- (2) Each licensee shall:
 - (a) Monitor the external surfaces of a package for radioactive contamination that are labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations in 49 CFR 172.403 and 172.436.440, unless the package contains only radioactive material in the form of gas or in special form as defined in Part XV;
 - (b) Monitor the external surfaces of a package for radiation levels that are labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations in 49 CFR 172.403 and 172.436.440, unless the package contains quantities of radioactive material that are less than or equal to the A_1 or A_2 quantities as defined in Part XV; and
 - (c) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
- (3) The licensee or registrant shall perform the monitoring required by 64E-5.327(2) as soon as practicable after receipt of the package but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

-
- (4) The licensee shall immediately notify the final delivery carrier and the department by telephone and telegram, mailgram, or facsimile when:
 - (a) Removable radioactive surface contamination exceeds the limits of 64E-5.1505(8); or
 - (b) External radiation levels exceed the limits of 64E-5.1505(9).
 - (5) Each licensee shall:
 - (a) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
 - (b) Ensure that the procedures are followed and that consideration is given to special instructions for the type of package being opened.
 - (6) Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of 64E-5.327(2)(a), but are not exempt from the monitoring requirement in 64E-5.327(2)(b) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.460.

SUBPART J WASTE MANAGEMENT

64E-5.328 General Requirements.

- (1) Unless otherwise exempted, a licensee shall transfer waste for disposal, discharge, or decay licensed material only:
 - (a) By transfer to an authorized recipient as specified in 64E-5.332 or in Part II of these regulations or to the U.S. Department of Energy;
 - (b) By decay in storage;
 - (c) By release in effluents within the limits in 64E-5.312; or
 - (d) As authorized in this subpart.
- (2) A person shall be specifically licensed to receive waste containing licensed material from other persons for:
 - (a) Treatment prior to disposal;
 - (b) Treatment by incineration;
 - (c) Decay in storage;

- (d) Disposal at a licensed land disposal facility; or
- (e) Storage until transferred to a storage or disposal facility authorized to receive the waste.

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.461.

64E-5.329 Method of Obtaining Approval of Proposed Disposal Procedures.

- (1) A person can apply to the department for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this part. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and conditions of disposal. The application where appropriate should also include an analysis and evaluation of pertinent information of the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposure.
- (2) The department will not approve any application for a licensee to receive radioactive material from other persons for disposal on land not owned by a state or the federal government.

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.462.

64E-5.330 Discharge by Release into Sanitary Sewerage.

- (1) A licensee can discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:
 - (a) The material is readily soluble or is readily dispersible biological material in water;
 - (b) The quantity of licensed radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table III;
 - (c) If more than one radionuclide is released, the following conditions must also be satisfied;

1. The licensee shall determine the fraction of the limit in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table III represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table III; and
 2. The sum of the fractions for each radionuclide required by 64E-5.330(1)(c)1. does not exceed unity; and
- (d) The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 5 curies (185 gigabecquerels) of hydrogen 3, 1 curie (37 gigabecquerels) of carbon 14, and 1 curie (37 gigabecquerels) of all other radioactive materials combined.
- (2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 64E-5.330(1).

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.463.

64E-5.331 Disposal of Specific Wastes.

- (1) A licensee can dispose of the following licensed material without regard to its radioactivity:
- (a) 0.05 microcurie (1.85 kBq) or less of hydrogen 3 or carbon 14 per gram of medium used for liquid scintillation counting;
 - (b) 0.05 microcurie (1.85 kBq) or less of hydrogen 3 or carbon 14 per gram of animal tissue, averaged over the weight of the entire animal.
 - (c) Any radioactive material which is not a sealed source with a physical half-life of less than 120 days if all of the following are met:
 1. Radioactive material to be disposed is held for decay in storage a minimum of 10 half-lives;
 2. The radioactive material is monitored at the container surface before disposal as ordinary trash and its radioactivity cannot be distinguished from the background radiation level in a low background radiation area with an appropriate radiation survey instrument set on its most sensitive scale and with no interposed shielding;

R10

3. All radiation labels are removed or obliterated, unless specifically authorized in writing or license condition by the department;
 4. Each generator column is separated and monitored individually with all radiation shielding removed to ensure that its contents have decayed to background levels before disposal; and
 5. The licensee shall retain a record of each disposal for 3 years. The record shall include:
 - a. The date of the disposal;
 - b. The date on which the radioactive material was placed in storage;
 - c. The radionuclides disposed;
 - d. The model and serial number of the radiation survey instrument used;
 - e. The background dose rate;
 - f. The radiation dose rate measured at the surface of each container; and
 - g. The name of the individual who performed the disposal.
- (2) A licensee shall not dispose of tissue as specified in 64E-5.331(1) in a manner that would permit its use either as food for humans or as animal feed.
- (3) The licensee shall maintain records as specified in 64E-5.340.

R10 Rulemaking Authority: 404.051, 404.081, F.S.

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

R10 History: New1-1-94, Formerly 10D-91.465, Amended 02-11-10.

64E-5.332 Transfer for Disposal and Manifests.

- R1 (1) The requirements of this section, Requirements for Transfers of Low-Level
R1 Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities
R1 and Manifest, July 1997, hereafter referred to as "Requirements for Low-Level
R1 Radioactive Waste Disposal," which is herein incorporated by reference and
R1 which is available from the department, and Part XV are designed to control
R1 transfers of low-level radioactive waste by any waste generator, waste collector,
R1 or waste processor licensee, as defined in the Requirements for Low-Level
R1 Radioactive Waste Disposal, who ships low-level waste directly or indirectly
R1 through a waste collector or waste processor to a licensed low-level waste land
R1 disposal facility as defined in Requirements for Low-Level Radioactive Waste
R1 Disposal, establish a manifest tracking system, and supplement existing
R1 requirements concerning transfers and recordkeeping for those wastes.
R1 Requirements for Low-Level Radioactive Waste Disposal incorporates NRC
R1 Form 540 (3-95), Uniform Low-Level Radioactive Manifest - Shipping Paper;
R1 NRC Form 541 (11-96), Uniform Low-Level Radioactive Waste Manifest -
R1 Container and Waste Description; and NRC Form 542 (3-95), Uniform Low-Level
R1 Radioactive Waste Manifest - Manifest Index and Regional Compact Tabulation.
- R1 (2) Prior to March 1, 1998, each shipment of radioactive waste designated for
R1 disposal at a licensed low-level radioactive waste disposal facility shall be
R1 accompanied by a shipment manifest as specified in 64E-5.333(12). Beginning
R1 March 1, 1998, any licensee shipping radioactive waste intended for ultimate
R1 disposal at a licensed land disposal facility shall document the information
R1 required on forms specified in Requirements for Low-Level Waste Disposal and
R1 transfer this recorded information to the intended consignee as specified in
R1 Requirements for Low-Level Radioactive Waste Disposal.
- R1 (3) Prior to March 1, 1998, each shipment manifest shall include a certification by the
R1 waste generator as specified in 64E-5.333(12). Beginning March 1, 1998, each
R1 shipment manifest shall include a certification by the waste generator as
R1 specified in Requirements for Low-Level Radioactive Waste Disposal.
- R1 (4) Prior to March 1, 1998, each person involved in the transfer of waste for disposal,
R1 including the waste generator, waste collector, waste processor and disposal
R1 facility operator, shall comply with the requirements specified in
R1 64E-5.333(12). Beginning March 1, 1998, each person participating in the
R1 transfer of waste for disposal, including the waste generator, waste collector,
R1 waste processor and disposal facility operator, shall comply with the
R1 requirements specified in Requirements for Low-Level Radioactive Waste
R1 Disposal.

R1 Specific Authority: 404.051, 404.081, 404.20, F.S.

R1 Law Implemented: 404.051(1)(4), 404.081, 404.20, F.S.

R1 History: New January 1, 1994, Formerly 10D-91.466, Amended May 18, 1998.

This page left intentionally blank
Next page number is 27

64E-5.333 Classification and Characteristics of Low Level Radioactive Waste for Near-Surface Land Disposal, Labeling and Manifest Requirements.

- (1) Physical Half-life Considerations.
 - (a) Consideration by the licensee must be given to the concentration of long-lived radionuclides, and their shorter-lived precursors, whose potential hazard will persist long after such precautions as institutional controls, improved waste form and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure.
 - (b) Consideration by the licensee must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form and disposal methods are effective.
- (2) Classes of Low Level Radioactive Waste.
 - (a) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in (9)(a), below. If Class A waste also meets the stability requirements set forth in (9)(b), below, it is not necessary to segregate the waste for disposal.
 - (b) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in (9), below.
 - (c) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in (9), below.
- (3) Classification of Low Level Radioactive Waste Determined by Long-Lived Radionuclides Present. If the low-level radioactive waste contains only radionuclides listed in Table 1, classification shall be determined as follows:

- (a) If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.
- (b) If the concentration exceeds 0.1 times the value in Table 1, the waste is Class C.
- (c) If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.
- (d) For wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined by the sum of fractions rule described in (7), below.

TABLE 1	
RADIONUCLIDE	CONCENTRATION (Curies per cubic meter)
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.20
Tc-99	3
I-129	0.08
RADIONUCLIDE	(Nanocuries per gram)
Alpha emitting transuranic radionuclides with a half-life greater than 5 years	100
Pu-241	3,100
Cm-242	20,000
Ra-226	100

- (e) To convert nanocuries to becquerels (Bq), multiply by 37. To convert curies to gigabecquerels (GBq), multiply by 37.
- (4) Classification of Low Level Radioactive Waste Determined by Short-Lived Radionuclides Present. If the low level radioactive waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2.
- (a) If the radioactive waste does not contain any radionuclides listed in either Table 1 or 2, the waste is Class A.
 - (b) If the concentration does not exceed the value in Table 2, Column 1, the waste is Class A.
 - (c) If the concentration exceeds the value in Table 2, Column 1, but does not

exceed the value in Column 2, the waste is Class B.

- (d) If the concentration exceeds the value in Table 2, Column 2, but does not exceed the value in Column 3, the waste is Class C.
- (e) If the concentration exceeds the value in Table 2, Column 3, the waste is not generally acceptable for near-surface disposal.
- (f) For wastes containing mixtures of the radionuclides listed in Table 2, the total concentration shall be determined by the sum of fractions rule described in (7), below.

TABLE 2			
	CONCENTRATION (Curies per cubic meter)		
RADIONUCLIDE	Column 1	Column 2	Column 3
Total of all radionuclides with less than 5 year half-life	700	See (4)(g), below	See (4)(g)
H-3	40	See (4)(g), below	See (4)(g)
Co-60	700	See (4)(g), below	See (4)(g)
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7,000
Sr-90	0.04	150	7,000
Cs-137	1	44	4,600

- (g) There are not limits established for the radionuclides specified in Table 2 for Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling and disposal will limit the concentrations for such wastes. Such wastes shall be Class B unless the concentrations of other radionuclides in Table 2 determine the waste to be Class C, independent of these radionuclides.
- (5) Classification of Low Level Radioactive Waste Determined by Both Long- and Short-Lived Radionuclides Present. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table 1, and some of which are listed in Table 2, classification shall be determined as follows:
- (a) If the concentration of a radionuclide listed in Table 1 is less than 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of radionuclides listed in Table 2.
 - (b) If the concentration of a radionuclide listed in Table 1 exceeds 0.1 times the value listed in Table 1, the waste shall be Class C, provided the concentration of radionuclides listed in Table 2 does not exceed the value shown in Table 2, Column 3.
- (6) Classification of Low Level Radioactive Wastes with Radionuclides Other Than Those Listed in Tables 1 and 2. If the radioactive waste does not contain any

radionuclides listed in either Table 1 or 2, it is Class A.

- (7) The Sum of the Fractions Rule for Mixtures of Radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 50 Ci per m³ (1.85 TBq per m³) and Cs-137 in a concentration of 22 Ci per m³ (814 GBq per m³). Since the concentrations both exceed the values in Table 2, Column 1, they must be compared to Column 2 values. For Sr-90 fraction $50/150 = 0.33$; for Cs-137 fraction, $22/44 = 0.5$; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.
- (8) Determination of Concentrations in Low Level Radioactive Wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste, if the units are expressed as nanocuries per gram.
- (9) Low Level Radioactive Waste Characteristics.
- (a) The following are minimum requirements for all three classes of radioactive waste specified in (2), above, and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.
1. Radioactive wastes should be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped.
 2. Radioactive wastes shall not be packaged for disposal in cardboard or fiberboard boxes.
 3. Liquid radioactive waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.
 4. Solid radioactive waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid be corrosive or exceed 1 percent of the volume.

5. Radioactive waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.
6. Radioactive waste shall not contain, or be capable of generating, quantities of toxic gases, vapors or fumes harmful to persons transporting, handling or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with (9)(a)8., below.
7. Pyrophoric materials contained in radioactive wastes shall be treated, prepared and packaged to be nonflammable.
8. Radioactive wastes in gaseous form shall be packaged at a gauge pressure that does not exceed 1.5 atmospheres at 20 degrees Celsius. Total activity shall not exceed 100 curies (3.7 TBq) per container.
9. Radioactive wastes containing hazardous, biological, pathogenic or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.
 - (b) Radioactive waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.
 - (c) Notwithstanding the provisions in (9)(a)3. and 4., above, liquid radioactive wastes, or radioactive wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as reasonably achievable, but in no case shall the liquid be corrosive or exceed 1 percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent of the volume of the waste for waste processed to a stable form.
 - (d) Void spaces within the radioactive waste and between the waste and its package shall be reduced to the extent practicable.
- (10) Package Labeling of Low Level Radioactive Waste. Each package of radioactive waste shall be clearly labeled to identify whether it is Class A, Class B or Class C waste, in accordance with (1) through (8), above.
- (11) Reserved.
- (12) Transfer for Disposal and Manifests of Low Level Radioactive Waste.

- (a) Each shipment of radioactive waste to a licensed land disposal facility shall be accompanied by a shipment manifest that contains the name, address and telephone number of the person generating the waste. The manifest shall also include the name, address and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate as completely as practicable:
1. A physical description of the waste;
 2. The waste volume;
 3. Radionuclide identity and quantity;
 4. The total radioactivity; and
 5. The principal chemical form.

The solidification agent, if used, shall be specified. Wastes containing more than 0.1 percent chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B or Class C in (1) through (8), above, shall be clearly identified as such in the manifest. The total quantity of the radionuclides H-3, C-14, Tc-99 and I-129 shall be shown.

- (b) The manifest required in (12)(a), above, may be shipping papers used to meet U.S. Department of Transportation or U.S. Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included.
- (c) Each manifest shall include a certification by the radioactive waste generator that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the department. An authorized representative of the waste generator shall sign and date the manifest.
- (d) Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the following requirements. Any licensee who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of (12)(d)4. through 8., below. A licensee shall:
1. Prepare all radioactive wastes so that the waste is classified according to (1) through (8), above, and meets the waste characteristics requirements in (9), above;
 2. Label each package of waste to identify whether it is Class A waste, Class B waste or Class C waste, in accordance with (1) through (8), above;

3. Conduct a quality control program to assure compliance with (1) through (9), above; the program must include management evaluation of audits;
 4. Prepare shipping manifests to meet the requirements of (12)(a) and (c), above;
 5. Forward a copy of the manifest to the intended recipient at the time of shipment; or, deliver to a collector at the time the radioactive waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest from the collector;
 6. Include one copy of the manifest with the shipment;
 7. Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these regulations; and
 8. For any low level radioactive waste shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this subsection, conduct an investigation in accordance with (12)(g), below.
- (e) Any waste collector licensee who handles only radioactive wastes that have been prepackaged shall:
1. Acknowledge receipt of the radioactive waste from the generator within 1 week of receipt by returning a signed copy of the manifest;
 2. Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in (12)(a), above. The collector licensee shall certify that nothing has been done to the waste which would invalidate the generator's certification;
 3. Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;
 4. Include the new manifest with the radioactive waste shipment to the disposal site;
 5. Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these regulations, and retain information from generator manifests until disposition

is authorized by the department; and

6. For any low level radioactive waste shipments or any part of a shipment for which acknowledgment of receipt is not received within the times set forth in this subsection, conduct an investigation in accordance with (12)(g), below.
- (f) Any licensed waste processor who treats or repackages low level radioactive wastes shall:
1. Acknowledge receipt of the radioactive waste from the generator within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation;
 2. Prepare a new manifest that meets the requirements of (12)(a) and (c), above. Preparation of the new manifest reflects that the processor is responsible for the waste;
 3. Prepare all low level radioactive wastes so that the waste is classified according to (1) through (8), above, and meets the waste characteristics requirement in (9), above;
 4. Label each package of waste to identify whether it is Class A waste, Class B waste or Class C waste, as specified in (1) through (8) and (10), above;
 5. Conduct a quality control program to assure compliance with (1) through (9), above. The program shall include management evaluation of audits;
 6. Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the radioactive waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest by the collector;
 7. Include the new manifest with the shipment;
 8. Retain copies of original manifests and new manifests with documentation of acknowledgment of receipt as the record or transfer of licensed material required by these regulations; and
 9. For any low level waste shipment or part of a shipment for which acknowledgment if not received within the times set forth in this section, conduct an investigation in accordance with (12)(g), below.

- (g) The land disposal facility operator shall:
1. Acknowledge receipt of the waste within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;
 2. Maintain copies of all completed manifests or equivalent documentation until the department authorizes their disposition; and
 3. Notify the shipper and the department when any shipment or portion of a shipment has not arrived within 60 days after the advance manifest was received.
- (h) Any low level radioactive waste shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:
1. Be investigated by the shipper if the shipper has not received notification of receipt within 20 days after transfer; and
 2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the department. Each licensee who conducts a trace investigation shall file a written report with the department within 2 weeks of completion of the investigation.

- R1 (13) Beginning March 1, 1998, all licensees shall comply with Requirements for Low-
R1 Level Radioactive Waste Disposal. Prior to March 1, 1998, a low-level waste
R1 disposal facility operator or its regulatory authority can require the shipper to use
R1 requirements specified in (12), above.

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

R1 Law Implemented: 404.051(1)(4), 404.061(2), 404.20(1), F.S.

R1 History: New January 1, 1994, Amended May 15, 1996, Formerly 10D-91.468, Amended May 18, 1998.

SUBPART K RECORDS

64E-5.334 General Provisions.

- R1 (1) Each licensee or registrant shall use the SI unit becquerel, gray, sievert and
R1 coulomb per kilogram, or the special units curie, rad, rem and roentgen, including
R1 multiples and subdivisions, and shall clearly indicate the units of all quantities on
records required by this part. The information on shipping manifests, specified in
64E-5.332(2) shall be recorded in SI units or in SI and special units curie, rad,
rem and roentgen.
- R2 (2) The licensee or registrant shall make a clear distinction among the quantities
R2 entered on the records required by this part, such as total effective dose
equivalent, shallow dose equivalent, **lens** dose equivalent, deep dose equivalent,
or committed effective dose equivalent.

Specific Authority: 404.051, 404.081, F.S.

R1 Law Implemented: 404.051(1)(4), 404.081, F.S.

R2 History: New January 1, 1994, Formerly 10D-91.469, Amended May 18, 1998, **Amended October 8, 2000.**

64E-5.335 Records of Radiation Protection Programs.

- (1) Each licensee or registrant shall maintain records of the radiation protection program, including:
- (a) The provisions of the program; and
 - (b) Audits and other reviews of program content and implementation.
- (2) The licensee or registrant shall retain the records required by 64E-5.335(1)(a) until the department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 64E-5.335(1)(b) for 3 years after the record is made.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.470.

64E-5.336 Records of Surveys.

- (1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 64E-5.314 and 64E-5.327(2). The licensee or registrant shall retain these records for 3 years after the record is made.
- (2) The licensee or registrant shall retain each of the following records until the department terminates each pertinent license or registration requiring the record:
 - (a) Records of the results of surveys to determine the dose from external sources of radiation used in the assessment of individual dose equivalents in the absence of or in combination with individual monitoring data;
 - (b) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;
 - (c) Records showing the results of air sampling, surveys, and bioassays specified in 64E-5.319(1)(c)1. and 2.; and
 - (d) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.471.

64E-5.337 Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by these regulations shall be kept in units of becquerel or microcurie and maintained for inspection by the department for 3 years after the records are made.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.472.

This page left intentionally blank

Next page number is 37

64E-5.338 Records of Planned Special Exposures.

- (1) For each planned special exposure, the licensee or registrant shall maintain records that describe:
 - (a) The exceptional circumstances requiring the use of a planned special exposure;
 - (b) The name of the management official who authorized the planned special exposure and a copy of the signed authorization;
 - (c) What actions were necessary;
 - (d) Why the actions were necessary;
 - (e) What precautions were taken to assure that doses were maintained ALARA;
 - (f) What individual and collective doses were expected to result; and
 - (g) The doses actually received in the planned special exposure.
- (2) The licensee or registrant shall retain the records until the department terminates each pertinent license or registration requiring these records.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.474.

64E-5.339 Records of Individual Monitoring Results.

- R2
R2 (1) Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring is required as specified in **Rule** 64E-5.315, **F.A.C.**, 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:
 - R2 (a) The deep dose equivalent to the whole body, **lens** dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;
 - R2
R2 (b) The estimated intake of radionuclides as specified in **Rule** 64E-5.305, **F.A.C.**;
 - (c) The committed effective dose equivalent assigned to the intake of radionuclides;
 - R2 (d) The specific information used to calculate the committed effective dose equivalent as specified in **Rule** 64E-5.307(3), **F.A.C.**;
 - R2
R2 (e) The total effective dose equivalent when required by **Rule** 64E-5.305, **F.A.C.**; and

- (f) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.
- (2) Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in 64E-5.339(1) annually.
- (3) Recordkeeping Format. The licensee or registrant shall maintain the records specified in 64E-5.339(1) on DH Form 1622 July 1993, which is herein incorporated by reference and which is available from the department, according to the instructions for DH Form 1622 July 1993, or in clear and legible records containing all the information required by DH Form 1622 July 1993.
- (4) The licensee or registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy including the estimated date of conception shall also be kept on file but can be maintained separately from the dose records.
- (5) The licensee or registrant shall retain each required form or record until the department terminates each pertinent license or registration requiring the record.

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New January 1, 1994, Formerly 10D-91.475, Amended October 8, 2000.

64E-5.340 Records of Waste Disposal or Transfers.

- (1) Each licensee shall maintain records of the disposal of licensed materials.
- (2) The licensee shall retain the records required by 64E-5.340(1) until the department terminates each pertinent license requiring the record, except as provided in 64E-5.331(1)(c)5. and 64E-5.624(2).

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.477.

64E-5.341 Records of Testing Entry Control Devices for Very High Radiation Areas.

- (1) Each licensee or registrant shall maintain records of tests specified in 64E-5.317(2)(a) on entry control devices for very high radiation areas. The records must include the date, time, and results of each such test of function.
- (2) The licensee or registrant shall retain the records required by 64E-5.341(1) for 3 years after the record is made.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.478.

64E-5.342 Form of Records. Each record required by this part shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record can also be stored in electronic media capable of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications shall include all pertinent information such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.479.

SUBPART L REPORTS

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 Bureau of Radiation Control Radioactive Material Requiring Labeling, **May 2000**, 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 Bureau of Radiation Control Radioactive Material Requiring Labeling **May 2000**, 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) Written Reports. Each licensee or registrant required to make a report as specified in 64E-5.343(1) shall make a written report to the department setting forth the following information within 30 days after making the telephone report:
- (a) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;
 - (b) A description of the circumstances under which the loss or theft occurred;

- (c) A statement of disposition or probable disposition of the licensed or registered source of radiation involved;
 - (d) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
 - (e) Actions that have been or will be taken to recover the source of radiation; and
 - (f) Procedures or measures that have been or will be adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.
- (3) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.
- (4) The licensee or registrant shall prepare any report filed with the department as specified in 64E-5.343 so that names of individuals who have received exposure to radiation are stated in a separate and detachable portion of the report.

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New January 1, 1994, Formerly 10D-91.480, **Amended October 8, 2000.**

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** 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.

R2

- (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** 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) The licensee or registrant shall prepare each report filed with the department as specified in Rule 64E-5.344, F.A.C., so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.
- (4) Licensees or registrants shall make the reports required by subsections 64E-5.344(1) and (2), F.A.C., to the department by telephone, telegram, mailgram, or facsimile to the department.
- (5) The provisions of Rule 64E-5.344, F.A.C., do not apply to doses that result from planned special exposures if such doses are within the limits for planned special exposures and are reported as specified in Rule 64E-5.346, F.A.C.
- (6) Immediate notification. In addition to the other reporting requirements in these regulations, each licensee shall notify the department as soon as possible but not later than 4 hours after the discovery of an event, such as a fire, explosion, or toxic gas release, that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or to avoid releases of licensed material that could exceed regulatory limits.
- (7) Twenty-four hour report. Each licensee shall notify the department within 24 hours after the discovery of any of the following events involving licensed material:
- (a) An unplanned contamination event that:
1. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

2. Involves a quantity of material greater than five times the lowest annual limit on intake of materials as specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993; and
 3. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
- (b) An event in which equipment is disabled or fails to function as designed when:
1. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposure to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
 2. The equipment is required to be available and operable when it is disabled or fails to function; and
 3. No redundant equipment is available and operable to perform the required safety function.
- (c) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body;
- (d) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed materials when:
1. The quantity of material involved is five times the lowest annual limit on intake for material specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993; and
 2. The damage affects the integrity of the licensed material or its container.

R10 (e) Dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose
 R10 equivalent that is a result of an administration of radioactive material or
 R10 radiation from radioactive material to a pregnant individual unless the dose
 R10 to the embryo/fetus was specifically approved, in advance, by the
 R10 authorized user as defined in Rule 64E-5.6011, F.A.C.

R10 (f) Dose to a nursing child that is a result of an administration of radioactive
 R10 material to a breast-feeding individual that meets one of the following:

R10 1. Greater than 50 mSv (5 rem) total effective dose equivalent; or

R10 2. Has resulted in unintended permanent functional damage to an
 R10 organ or a physiological system of the child, as determined by a
 R10 physician.

- (8) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:
- (a) Licensees shall make reports required by subsections 64E-5.344(6) and (7), F.A.C., by telephone to the department. If the information is available at the time of notification, the information provided in these reports must include:
1. The caller's name and call back telephone number;
 2. A description of the event, including date and time;
 3. The exact location of the event;
 4. The isotopes, quantities, and chemical and physical forms of the licensed material involved; and
 5. Any personnel radiation exposure data available.
- (b) Written report. Each licensee who makes a report required by subsections 64E-5.344(6) and (7), F.A.C., shall submit a written follow-up report within 30 days of the initial report. Written reports prepared as required by other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information. The reports must include the following:
1. A description of the event, including the probable cause and the manufacturer and model number of any equipment that failed or malfunctioned;
 2. The exact location of the event;
 3. The isotopes, quantities, and chemical and physical form of the licensed material involved;
 4. Date and time of the event;
 5. Corrective actions taken or planned and the results of any evaluations or assessments; and
 6. The extent of exposure of individuals to radiation or to radioactive materials without identification of the individuals by name.

R10 **Rulemaking** Authority: 404.051, 404.081, F.S.

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

R10 History: New 1-1-94, Amended , 5-15-98, Formerly 10D-91.481, Amended 10-8-00, **Amended 02-11-10.**

64E-5.345 Reports of Exposures, Radiation Levels, Concentrations of**R10 Radioactive Material Exceeding the Constraints or Limits, Medical Events and Dose to
R10 an Embryo/Fetus or a Nursing Child.**

- R2 (1) Reportable Events. In addition to the notification required by Rule 64E-5.344,
R2 F.A.C., each licensee or registrant shall submit a written report within 30 days
after learning of any of the following occurrences:
- R2 (a) Incidents for which notification is required by Rule 64E-5.344, F.A.C.; or
- R2 (b) Doses in excess of any of the following:
- R2 1. The occupational dose limits for adults in Rule 64E-5.304, F.A.C.;
- R2 2. The occupational dose limits for a minor in Rule 64E-5.310, F.A.C.;
- R2 3. The limits for an embryo or fetus of a declared pregnant woman in
R2 Rule 64E-5.311, F.A.C.;
- R2 4. The limits for an individual member of the public in Rule 64E-5.312,
R2 F.A.C.;
- R2 5. Any applicable limit in the license or registration;
- R2 6. The ALARA constraints for air emissions specified in subsection
R2 64E-5.303(5), F.A.C.; or
- R2 (c) Levels of radiation or concentrations of radioactive material in:
- R2 1. A restricted area in excess of applicable limits in the license or
registration; or
- R2 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
R2 Rule 64E-5.312, F.A.C.; 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.

- R2 (a) Each report required by subsection 64E-5.345(1), F.A.C., 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.
- R2 (b) Each report filed as specified in subsection 64E-5.345(1), F.A.C., shall include for each occupationally overexposed individual: the name, social security account number, and date of birth. With respect to the limit for the embryo or fetus in Rule 64E-5.311, F.A.C., 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) All licensees or registrants who make reports as specified in subsection 64E-5.345(1), F.A.C., shall submit the report in writing to the department.
- R10 (4) Reports of Medical Events.
- R10 (a) The licensee or registrant shall notify the department by telephone no later than the next calendar day after the discovery of the medical event. The licensee or registrant shall also notify the referring physician of the affected individual and the individual or a responsible relative or guardian, unless the referring physician personally informs the licensee either that he will inform the individual or believes, based on medical judgment, that telling the individual or the individual'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 medical event. If the referring physician, individual or the individual'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 or the individual's responsible relative or guardian without first consulting the referring physician; however, the licensee or registrant shall not delay medical care for the individual because of this. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

- R10 (b) Written Report. Within 15 days after the **medical event** report to the
 R2 department, the licensee or registrant shall report in writing to the
 R2 department and to the referring physician and furnish a copy of the report
 R2 to the **individual** or the **individual's** responsible relative or guardian if either
 R2 was previously notified by the licensee or registrant as specified in (4)(a),
 R2 above, or a brief description of both event and consequences as they
 R2 affect the **individual** or the **individual's** responsible relative or guardian if a
 R2 statement is included that the report submitted to the department can be
 R2 obtained from the licensee or registrant. The written report shall include
 R2 the licensee's or registrant's name; the prescribing physician's name; the
 R2 referring physician's name; a brief description of the event; why the event
 R2 occurred; the effect on the **individual**; the action taken to prevent
 R2 recurrence; whether the licensee or registrant informed the **individual** or
 R2 the **individual's** responsible relative or guardian and what information was
 R2 provided to the **individual** or **individual's** responsible relative or guardian,
 R2 and if not, a written medical justification. The report shall not include the
 R2 **individual's** name or other information that could lead to identification of
 R2 the **individual**.
- R10 (5) Records of **medical event**. Each licensee or registrant shall retain a record of
 R10 each **medical event** for 20 years. The record shall contain the names of all
 R2 individuals involved in the event, including the prescribing physician, the allied
 R2 health personnel, the **individual**, and the **individual's** referring physician, the
 R2 **individual's** identification number if one has been assigned, a brief description of
 R2 the event, why it occurred, the effect on the **individual**, what improvements are
 R2 needed to prevent recurrence, and the actions taken, if any, to prevent
 R2 recurrence.
- R2 (6) Rights and Duties of Licensees or Registrants. Aside from the notification
 R2 requirement, nothing in this section shall affect any rights or duties of licensees,
 R2 registrants or physicians in relation to each other, the **individual**, or responsible
 R2 relatives or guardians.

R10 (7) Reports of a dose to an embryo/fetus or a nursing child.

R10 (a) The licensee shall provide notification of the event to the referring
R10 physician and also notify the pregnant individual or mother, both hereafter
R10 referred to as the mother, no later than 24 hours after discovery of an
R10 event that would require reporting under paragraph 64E-5.344(7)(e) or (f),
R10 F.A.C., unless the referring physician personally informs the licensee
R10 either that he or she will inform the mother or that, based on medical
R10 judgment, telling the mother would be harmful. The licensee is not
R10 required to notify the mother without first consulting with the referring
R10 physician. If the referring physician or mother cannot be reached within
R10 24 hours, the licensee shall make the appropriate notifications as soon as
R10 possible thereafter. The licensee may not delay any appropriate medical
R10 care for the embryo/fetus or for the nursing child, including any necessary
R10 remedial care as a result of the event, because of any delay in notification.
R10 To meet the requirements of this subsection, the notification may be made
R10 to the mother or child's responsible relative or guardian instead of the
R10 mother. If a verbal notification is made, the licensee shall inform the
R10 mother, or the mother or child's responsible relative or guardian, that a
R10 written description of the event can be obtained from the licensee upon
R10 request. The licensee shall provide such a written description if
R10 requested.

R10 (b) Written Report.

R10 1. Within 15 days after the discovery of an event that would require
R10 reporting under paragraph 64E-5.344(7)(e) or (f), F.A.C., the
R10 licensee or registrant shall report in writing as described below, to
R10 the department and to the referring physician

R10 2. Within 15 days after the discovery of an event that would require
R10 reporting under paragraph 64E-5.344(7)(e) or (f), F.A.C., the
R10 licensee or registrant shall also furnish a copy of the report or a
R10 brief description of both the event and the consequences of the
R10 event as they affect the embryo/fetus or nursing child, to the
R10 mother, or the mother or child's responsible relative or guardian if
R10 either was previously notified by the licensee or registrant as
R10 specified in paragraph (7)(a), above. If a brief description of both
R10 the event and consequences of the event is provided in lieu of the
R10 report, such description shall include a statement that the report
R10 submitted to the department can be obtained from the licensee or
R10 registrant.

R10 3. The written report shall include the licensee's or registrant's name,
R10 the prescribing physician's name, the referring physician's name, a
R10 brief description of the event, why the event occurred, the effect on
R10 the embryo/fetus or nursing child, the action taken to prevent
R10 recurrence, whether the licensee or registrant informed the
R10 pregnant individual or mother or the mother's or child's responsible
R10 relative or guardian and what information was provided to the
R10 individual or individual's responsible relative or guardian, and if not,
R10 a written medical justification. The report shall not include the
R10 individual's or child's name or other information that could lead to
R10 identification of the individual or child.

R10 (8) Records of reports of dose to an embryo/fetus or a nursing child. Each licensee
R10 or registrant shall retain a record of each report of dose to an embryo/fetus or a
R10 nursing child for 20 years. The record shall contain the names of all individuals
R10 involved in the event, including the prescribing physician, the allied health
R10 personnel, mother or the nursing child's name, and the mother or nursing child's
R10 referring physician, the social security number of the mother, the nursing child's
R10 social security number or identification number if either has been assigned, a
R10 brief description of the event, why it occurred, the effect on the individual, what
R10 improvements are needed to prevent recurrence, and the actions taken, if any, to
R10 prevent recurrence.

R10 Rulemaking Authority: 404.051, 404.081, F.S.

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

R10 History: New 1-1-94, Formerly 10D-91.482, Amended 10-8-00, Amended 02-11-10.

Page Left Blank Intentionally to Align Page Numbering

64E-5.346 Reports of Planned Special Exposures. The licensee or registrant shall submit a written report to the department within 30 days following any planned special exposure as specified in 64E-5.309, informing the department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 64E-5.338.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.483.

64E-5.347 Notifications and Reports to Individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Part IX of these regulations.

R1 (2) When a licensee or registrant is required by 64E-5.345, 64E-5.346 or 64E-5.347
 R1 to report to the department any occupational exposure of an individual or an
 R1 identified member of the public to radiation or radioactive material, the licensee
 R1 or registrant shall also provide a copy of the report submitted to the department
 R1 to the individual. Such notice shall be transmitted no later than the transmittal to
 the department, and shall comply with the provisions of Part IX.

Specific Authority: 404.051, 404.081, F.S.

R1 Law Implemented: 404.051(1)(4), 404.081, F.S.

R1 History: New January 1, 1994, Formerly 10D-91.484, Amended May 18, 1998.

64E-5.348 Reports of Leaking or Contaminated Sealed Sources. The licensee shall immediately notify the department if the test for leakage or contamination required by these regulations indicates a sealed source is leaking or contaminated. A written report of a leaking or contaminated source shall be submitted to the department within 5 days. The report shall include the equipment involved, the test results and the corrective action taken.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.485.

64E-5.349 Vacating Premises. Each specific licensee or registrant shall notify the department in writing of the intent to vacate no less than 30 days before vacating or relinquishing possession or control of premises which might have been contaminated with radioactive material as a result of his activities. The licensee shall decommission the premises for subsequent use as an unrestricted area.

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.486.

R8 **64E-5.350 Reports of Transactions Involving Nationally Tracked Sources.** Each
R8 licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally
R8 tracked source shall complete and submit to the NRC a National Source Tracking Transaction
R8 Report as specified in paragraphs (1) through (5) of this section for each type of transaction.
R8 (Pursuant to 120.54(6) Florida Statutes, 64E-5.350, except 64E-5.350(8) as noted below, is
R8 substantively identical to 10 CFR 20.2207 effective 02/06/2007.)

R8 (1) Each licensee who manufactures a nationally tracked source shall complete and
R8 submit a National Source Tracking Transaction Report. The report must include
R8 the following information:

R8 (a) The name, address, and license number of the reporting licensee;

R8 (b) The name of the individual preparing the report;

R8 (c) The manufacturer, model, and serial number of the source;

R8 (d) The radioactive material in the source;

R8 (e) The initial source strength in becquerels (curies) at the time of
R8 manufacture; and

R8 (f) The manufacture date of the source.

R8 (2) Each licensee that transfers a nationally tracked source to another person shall
R8 complete and submit a National Source Tracking Transaction Report. The report
R8 must include the following information:

R8 (a) The name, address, and license number of the reporting licensee;

R8 (b) The name of the individual preparing the report;

R8 (c) The name and license number of the recipient facility and the shipping
R8 address;

R8 (d) The manufacturer, model, and serial number of the source or, if not
R8 available, other information to uniquely identify the source;

R8 (e) The radioactive material in the source;

R8 (f) The initial or current source strength in becquerels (curies);

R8 (g) The date for which the source strength is reported;

R8 (h) The shipping date;

R8 (i) The estimated arrival date; and

R8 (j) For nationally tracked sources transferred as waste under a Uniform Low-
R8 Level Radioactive Waste Manifest, the waste manifest number and the
R8 container identification of the container with the nationally tracked source.

- R8 (3) Each licensee that receives a nationally tracked source shall complete and
R8 submit a National Source Tracking Transaction Report. The report must include
R8 the following information:
- R8 (a) The name, address, and license number of the reporting licensee;
 - R8 (b) The name of the individual preparing the report;
 - R8 (c) The name, address, and license number of the person that provided the
R8 source;
 - R8 (d) The manufacturer, model, and serial number of the source or, if not
R8 available, other information to uniquely identify the source;
 - R8 (e) The radioactive material in the source;
 - R8 (f) The initial or current source strength in becquerels (curies);
 - R8 (g) The date for which the source strength is reported;
 - R8 (h) The date of receipt; and
 - R8 (i) For material received under a Uniform Low-Level Radioactive Waste
R8 Manifest, the waste manifest number and the container identification with
R8 the nationally tracked source.
- R8 (4) Each licensee that disassembles a nationally tracked source shall complete and
R8 submit a National Source Tracking Transaction Report. The report must include
R8 the following information:
- R8 (a) The name, address, and license number of the reporting licensee;
 - R8 (b) The name of the individual preparing the report;
 - R8 (c) The manufacturer, model, and serial number of the source or, if not
R8 available, other information to uniquely identify the source;
 - R8 (d) The radioactive material in the source;
 - R8 (e) The initial or current source strength in becquerels (curies);
 - R8 (f) The date for which the source strength is reported;
 - R8 (g) The disassemble date of the source.

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

R8 (8) Each licensee that possesses Category 1 nationally tracked sources shall report
R8 its initial inventory of Category 1 nationally tracked sources to the National
R8 Source Tracking System by January 31, 2009 or as specified in 10 C.F.R.
R8 20.2207(h), whichever is the latest. Each licensee that possesses Category 2
R8 nationally tracked sources shall report its initial inventory of Category 2 nationally
R8 tracked sources to the National Source Tracking System by January 31, 2009 or
R8 as specified in 10 C.F.R. 20.2207(h), whichever is the latest. The information
R8 may be submitted by using any of the methods identified by paragraph (6)(a)
R8 through (6)(e) of this section. The initial inventory report must include the
R8 following information: (Pursuant to 120.54(6) Florida Statutes, 64E-5.350(8) is
R8 substantively identical to 10 CFR 20.2207(h) effective 10/19/2007.)

R8 (a) The name, address, and license number of the reporting licensee;

R8 (b) The name of the individual preparing the report;

R8 (c) The manufacturer, model, and serial number of each nationally tracked
R8 source or, if not available, other information to uniquely identify the source;

R8 (d) The radioactive material in the sealed source;

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

R8 (f) The date for which the source strength is reported.

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

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

R8 History: New February 28, 2008.

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

R8

Table 1

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

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

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

R8 History: New February 28, 2008.

Page intentionally left blank

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
R6	64E-5.427	Leak Testing, Repairing, Tagging, Opening, [REDACTED] Modifying and Replacing Sealed Sources and Devices	IV-6
R4	64E-5.428	Quarterly Inventory.....	IV-7
R6	64E-5.429	Source Movement Logs, Daily Survey Reports, and Individual Dosimeter Logs.....	IV-8
R8	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
R6	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
R8	64E-5.440	Records.....	IV-21
R8	64E-5.441	Reporting Requirements	IV-23

R4 Sections 64E-5.401 - 64E-5.422 repealed September 11, 2001 and replaced with
 R4 sections 64E-5.423 - 64E-5.441.

PART IV

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

- R4 **64E-5.423 Definitions.** As used in this part, the following definitions apply:
- R4 (1) "Associated equipment" means equipment, such as guide tubes, control tubes,
 R4 control cables, removable source stops, J-tubes, and collimators, used in
 R4 conjunction with a radiographic exposure device that drives, guides, or comes in
 R4 contact with the sealed source.
- R4 (2) "Certifying entity" means:
- R4 (a) For radiographic operations using radioactive materials, an independent
 R4 certifying organization that meets the requirements of Appendix A of 10
 R4 CFR Part 34, which is herein incorporated by reference and which is
 R4 available from the department, or an agreement state that meets the
 R4 requirements of Appendix A, Parts II and III of 10 CFR Part 34.
- R4 (b) For radiographic operations using radiation machines, any agreement
 R4 state or organization approved by the Conference of Radiation Control
 R4 Directors, Inc.
- R4 (3) "Collimator" means a radiation shield that is placed on the end of the guide tube
 R4 or directly onto a radiographic exposure device to restrict the size of the radiation
 R4 beam when the sealed source is cranked into position to make a radiographic
 R4 exposure.
- R4 (4) "Control cable" means the cable that is connected to the source assembly and
 R4 used to drive the source from and return it to the shielded position. It also is
 R4 known as a drive cable.
- R4 (5) "Control drive mechanism" means a device that enables the source assembly to
 R4 be moved to and from the shielded position. It also is known as a crank
 R4 assembly.
- R4 (6) "Control tube" means a protective sheath for guiding the control cable. The
 R4 control tube connects the control drive mechanism to the radiographic exposure
 R4 device.
- R4 (7) "Exposure head" means a device that locates the sealed source in the selected
 R4 position. It also is known as a source stop.
- R4 (8) "Guide tube" means a flexible or rigid tube for guiding the source assembly and
 R4 the attached control cable from the radiographic exposure device to the exposure
 R4 head and includes the connections to attach to the radiographic exposure device
 R4 and to the exposure head. It also is known as a projection sheath or source tube.
 R4

- R4 (9) "Industrial cabinet x-ray system" means a cabinet x-ray system used to perform
R4 industrial radiography excluding baggage x-ray systems.
- R4 (10) "Lay-barge radiography" means industrial radiography performed on any water
R4 vessel used for laying pipe.
- R4 (11) "Platform radiography" means industrial radiography performed on an offshore
R4 platform or other structure over a body of water.
- R4 (12) "Radiographer certification" means a written document received from a certifying
R4 entity stating that an individual has met radiation safety training, testing, and
R4 experience criteria satisfactorily.
- R4 (13) "Radiographic operations" means all activities including surveys that involve the
R4 use or transport of radiation machines, radiographic exposure devices, source
R4 changers, or industrial cabinet x-ray systems to conduct industrial radiography.
- R4 (14) "Radiographic personnel" means radiographers and radiographer's assistants.
- R4 (15) "Reference survey" means a survey made with a radiation survey instrument
R4 within 6 inches (15 cm) of the surface of a radiographic exposure device or
R4 source changer at a location established by the licensee. The reference survey
R4 is used to verify that the sealed source is located properly in the shielded position
R4 and to establish a radiation level for reference before, during, and after
R4 radiographic operations.
- R4 (16) "S-tube" means a tube through which the radioactive source travels inside a
R4 radiographic exposure device.
- R4 (17) "Source assembly" means a set of assembled parts consisting of a sealed source
R4 and a connector that attaches the source to the control cable. The source
R4 assembly sometimes includes a stop ball used to secure the source in the
R4 shielded position. It also is known as a pigtail.
- R4 (18) "Special training session" means training not conducted during production
R4 radiography.
- R4 (19) "Transport container" means a package that is designed to provide radiation
R4 safety and security when sealed sources are transported and that meets all
R4 applicable requirements of the U.S. Department of Transportation (USDOT).
- R4 (20) "Underwater radiography" means industrial radiography performed when the
R4 radiation machine, radiographic exposure device, or related equipment are
R4 beneath the surface of the water.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.031, 404.051(1), (4), (6), F.S.

R4 History: New September 11, 2001.

R4
R4
R4

SUBPART D
(Formerly Subpart A)
EQUIPMENT CONTROL

R4
R4

64E-5.424 Requirements for Industrial Radiography Equipment Using Sealed Sources.

R4
R4

(1) Equipment used in radiographic operations shall meet the criteria specified below.

R4
R4
R4
R4
R4
R4
R4
R4
R4

(a) Each radiographic exposure device, source assembly or sealed source, and all associated equipment shall meet the requirements specified in American National Standards Institute (ANSI) N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," published as National Bureau of Standards Handbook 136, January 1981, which is herein incorporated by reference and which is available from the department. Engineering analyses that demonstrate that the radiography equipment components are equivalent are an acceptable alternative to actual testing of the component.

R4
R4
R4
R4
R4

(b) Equipment used in radiographic operations is not required to comply with section 8.9.2(c) of the Endurance Test in ANSI N432-1980 if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment realistically can exert on the lever or crankshaft of the drive mechanism.

R4
R4
R4

(2) In addition to the requirements specified in 64E-5.424(1), F.A.C., radiographic exposure devices, source changers, source assemblies, and sealed sources must meet the requirements specified below.

R4
R4

(a) Each radiographic exposure device shall have a durable, legible, clearly visible label attached that specifies:

R4
R4

1. The chemical symbol and mass number of the radionuclide in the radiographic exposure device;

R4
R4

2. The activity of the sealed source and the date on which this activity was last measured;

R4
R4

3. The manufacturer's name and the model and serial number of the sealed source; and

R4

4. The name, address, and telephone number of the licensee.

R4
R4
R4
R4
R4
R4

(b) Each radiographic exposure device, source changer, storage container, and transport container shall have a durable, legible, clearly visible marking or label attached that includes the standard radiation symbol as specified in 64E-5.322, F.A.C., in conventional colors of magenta, purple, or black on a yellow background, has a minimum diameter of 25 millimeters, and has the following wording:

CAUTION (or DANGER)

RADIOACTIVE MATERIAL – DO NOT HANDLE

NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)

- R4
R4
R4
- R4 (c) Modification of radiographic exposure devices, source changers, source assemblies, and associated equipment is prohibited unless the design of any replacement component, including source holder, source assembly, controls, or guide tubes will not compromise design safety features.
- R4
R4
R4
R4
- R4 (3) Radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the radiographic exposure device for radiographic operations or to source changers must meet the requirements specified below.
- R4 (a) The coupling between the source assembly and the control cable shall be designed so that the source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be designed so that it cannot be disconnected unintentionally under normal and reasonably foreseeable abnormal conditions.
- R4 (b) The radiographic exposure device shall secure the source assembly automatically when it is cranked back into the fully shielded position within the device. This securing system shall be able to be released only by a deliberate operation on the exposure device.
- R4 (c) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers that are installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter.
- R4 (d) 1. Each sealed source or source assembly shall have attached to it or engraved on it a durable, legible, visible label with the words: "DANGER – RADIOACTIVE."
- R4 2. The label cannot interfere with the safe operation of the radiographic exposure device, source changer, or associated equipment.
- R4 (e) The guide tube shall be able to withstand a crushing test that approximates closely the crushing forces that are likely to be encountered during use and be able to withstand a kinking resistance test that approximates closely the kinking forces that are likely to be encountered during use.
- R4 (f) Guide tubes shall be used when moving the source out of the device.
- R4 (g) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.

- R4 (h) The guide tube exposure head connection shall be able to withstand the
R4 tensile test for control units specified in ANSI N432-1980.
- R4 (i) Source changers shall have a system to ensure that the source will not be
R4 withdrawn from the changer accidentally when connecting or
R4 disconnecting the drive cable to or from a source assembly.
- R4 (4) The maximum exposure rate limits for storage containers and source changers
R4 are 200 millirem (2 mSv) per hour at any exterior surface and 10 millirem (0.1
R4 mSv) per hour at 1 meter from any exterior surface with the sealed source in the
R4 shielded position.
- R4 (5) Each radiographic exposure device, source changer, and storage container shall
R4 have a lock or outer locked container designed to prevent unauthorized or
R4 accidental removal of the sealed source from its shielded position.

R4 Specific Authority: 404.051, F.S.

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

R4 History: New September 11, 2001.

R4 **64E-5.425 Locking of Sources of Radiation, Storage Precautions, and
Surveillance.**

- R4 (1) Each radiation machine, radiographic exposure device, source changer, and
R4 storage container shall be kept locked with the key removed from any keyed lock
R4 except when under the direct supervision of radiographic personnel or as
R4 specified in section (6), below.
- R4 (2) Each radiation machine, radiographic exposure device, source changer, and
R4 storage container shall be locked and the key removed from any keyed lock
R4 before being moved or transported and before being stored at a given location,
R4 except at permanent radiographic installations as specified in 64E-5.431, F.A.C.
R4 Keys to radiation machines, radiographic exposure devices, source changers,
R4 storage containers, transport containers, and transport vehicles shall be
R4 maintained in the possession of the radiographer or radiographer's assistant
R4 responsible for the equipment in a manner that prevents access to sources of
R4 radiation by unauthorized personnel.
- R4 (3) Locked radiographic exposure devices, source changers, storage containers, and
R4 radiation machines shall be secured physically except when under the direct
R4 surveillance of radiographic personnel or as specified in section (6), below, to
R4 prevent tampering or removal by unauthorized personnel. The licensee shall
R4 store licensed material in a manner that minimizes danger from explosion or fire.
- R4 (4) Each sealed source shall be secured in its shielded position by locking the
R4 radiographic exposure device or source changer each time the sealed source is
R4 returned to the shielded position.
- R4 (5) Transport containers containing licensed material shall be locked and secured in
R4 the transporting vehicle to prevent accidental loss, tampering, or unauthorized
R4 removal of the licensed material from the vehicle.

R4 (6) During each radiographic operation, the radiographer or radiographer's assistant
 R4 shall maintain continuous direct visual surveillance of the operation to protect
 R4 against unauthorized entry into a high radiation area, except at permanent
 R4 radiographic installations where all entryways are locked and the requirements of
 R4 64E-5.431, F.A.C., are met.

R4 (7) During each radiographic operation using an industrial cabinet x-ray system,
 R4 direct surveillance of the operation shall be maintained to protect against
 R4 unauthorized entry into a high radiation area.

R4 Specific Authority: 404.051, F.S.

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

R4 History: New September 11, 2001.

R4 **64E-5.426 Radiation Survey Instruments.**

R4 (1) The licensee or registrant shall maintain enough calibrated and operable
 R4 radiation survey instruments to make physical radiation surveys as required by
 R4 the rules contained in this part and Chapter 64E-5, Part III, F.A.C. Such
 R4 instrumentation shall be able to measure a range from 2 millirem (0.02 mSv) per
 R4 hour through 1 rem (0.01 Sv) per hour.

R4 (2) Radiation survey instruments used to establish dose rates shall be calibrated:

R4 (a) At intervals not to exceed 6 months and after each instrument servicing
 R4 other than battery replacement;

R4 (b) At energies and geometries appropriate for use;

R4 (c) To demonstrate accuracy within 20% of the true radiation level at each
 R4 point checked;

R4 (d) For linear scale instruments, at two points located approximately 1/3 and
 R4 2/3 of full-scale on each scale; for logarithmic scale instruments, at
 R4 midrange of each decade and at two points at least one decade apart; and
 R4 for digital instruments, at three points between 2 millirem (0.02 mSv) per
 R4 hour and 1 rem (0.01 Sv) per hour; and

R4 (e) By a person licensed by the department, another agreement state,
 R4 licensing state or the NRC.

R4 Specific Authority: 404.051, F.S.

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

R4 History: New September 11, 2001.

R4 **64E-5.427 Leak Testing, Repairing, Tagging, Opening, Modifying, and Replacing**
 R4 **Sealed Sources and Devices.**

R4 (1) The replacement, leak testing, leak test sample analysis, repair, tagging,
 R4 opening, or any other modification of any sealed source shall be performed only
 R4 by persons authorized specifically to do so by the department, another
 R4 agreement state, licensing state, or the NRC.

- R4 (2) Each sealed source shall be tested for radioactive contamination leakage at
R4 intervals not to exceed 6 months. In the absence of a certificate from a transferor
R4 indicating that a test has been made within the 6 months before the transfer, the
R4 sealed source shall not be used until tested. Sealed sources that are listed in a
R4 department license for storage only do not require leak testing during storage but
R4 shall be tested before use or transfer to another person if the interval of storage
R4 exceeds 6 months.
- R4 (3) Each exposure device using depleted uranium (DU) shielding and an S-tube
R4 configuration shall be tested for DU contamination at intervals not to exceed 12
R4 months. DU shielded devices do not have to be tested for DU contamination
R4 while in storage and not in use. However, the DU devices shall be tested for DU
R4 contamination before use or transfer if the interval of storage exceeds 12 months.
R4 Licensees must comply with the DU leak testing requirements of this section
R4 within 6 months after the effective date of this rule.
- R4 (4) Leak testing as specified in 64E-5.427(2) and (3), F.A.C., shall be capable of
R4 detecting the presence of 0.005 microcurie (185 Bq) of removable contamination
R4 on the test sample. The wipe sample shall be taken from the nearest accessible
R6 point to the sealed source **where** contamination could accumulate.
- R4 (5) If any test conducted pursuant to this section reveals the presence of 0.005
R4 microcurie (185 Bq) or more of removable radioactive material, the licensee
R4 immediately shall withdraw the equipment from use and cause it to be
R6 decontaminated and repaired or disposed of in accordance with **Rule 64E-**
R6 **5.1303, F.A.C., and** the applicable sections of rules contained in Parts III and XV
R4 of Chapter 64E-5, F.A.C. If DU leak testing reveals the presence of 0.005
R4 microcurie (185 Bq) or more of removable DU contamination, the exposure
R4 device shall be removed from use until an evaluation of the wear on the S-tube
R4 has been made. If the evaluation reveals that the S-tube is worn through, the
R4 device shall not be used. The licensee shall file a report with the department
R4 describing the equipment involved, the test results, and the corrective action
R4 taken within 5 days after obtaining results of the test.

R4 Specific Authority: 404.051, F.S.

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

R6 History: New September 11, 2001, **Amended September 28, 2006.**

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

R4 Specific Authority: 404.051, F.S.

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

R4 History: New September 11, 2001.

- R4
R4
- 64E-5.429 Source Movement Logs, Daily Survey Reports, and Individual Dosimeter Logs.**
- R4
R4
R4
- (1) Each time a radiation source is removed from storage, the licensee or registrant shall complete and maintain source movement logs for each radiation source with the following information, as applicable:
- R4
R6
- (a) The locations where used, the names of the jobs or clients, and the dates of use **including the dates removed and returned to storage** ;
- R4
R4
- (b) The manufacturer's name, model, and serial number of the radiographic exposure device, source changer, or radiation machine used;
- R4
R4
R4
- (c) The sealed source manufacturer's name, model, and serial number, activity in curies (becquerels) on the date of receipt and each date of use, and the due date of the next leak test;
- R4
R4
- (d) The results of the reference survey of the radiographic exposure device or source changer performed upon removal and return to storage; and
- R6
R4
- (e) The **identity and** signature or initials of the radiographer to whom the radiation source has been assigned.
- R4
R4
R4
R4
- (2) Before performing industrial radiography, leak tests, source exchanges, or quarterly inspection and maintenance of radiographic equipment, the licensee or registrant shall prepare and maintain a daily survey report for each radiation source with the information described below as it becomes available:
- R4
R4
- (a) The location where used, the name of the job or client, and the date of use;
- R4
R4
- (b) The manufacturer's name, model, and serial number of the radiographic exposure device, source changer, or radiation machine used;
- R4
R4
- (c) The sealed source manufacturer's name, model, and serial number and activity in curies (becquerels) for the date of use;
- R4
R4
- (d) The names and titles of the radiographic personnel working with the radiation source;
- R4
R4
- (e) The serial number of the personnel monitoring badge, pocket dosimeter, and alarm ratemeter used by each of the radiography crew members;
- R4
R4
- (f) The manufacturer's name, model, serial number, and date of calibration or calibration due date for each survey meter used;
- R4
R4
R4
- (g) The results of the reference survey performed when the radiographic exposure device or source changer is removed from or returned to storage;

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

R4 Specific Authority: 404.051, F.S.

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

R6 History: New September 11, 2001, [Amended September 28, 2006.](#)

R4 **64E-5.430 Inspection and Maintenance.**

- R4 (1) Each licensee or registrant shall perform visual and operability checks on survey
R4 instruments, radiation machines, radiographic exposure devices, associated
R4 equipment, transport containers, storage containers, and source changers before
R4 use on each day the equipment is to be used to ensure the equipment is in good
R4 working condition, the sources are shielded adequately, and required labeling is
R4 present. All appropriate parts shall be maintained in accordance with the
R4 manufacturer's specifications. Each radiation survey instrument shall be visually
R4 inspected, have its batteries checked, and have its operability checked with a
R4 radiation source at the beginning of each day of use and at the beginning of each
R4 work shift. If equipment problems are found, the equipment shall be removed
R4 from service until repaired.

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

R4 Specific Authority: 404.051, F.S.

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

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

R4 **64E-5.431 Permanent Radiographic Installations.**

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

R4 Specific Authority: 404.051, F.S.

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

R4 History: New September 11, 2001.

R4
R4

SUBPART E
(Formerly Subpart B)
RADIATION SAFETY REQUIREMENTS

R4 **64E-5.432 Radiation Protection Program.** The radiation protection program
R4 specified in 64E-5.303, F.A.C., for registrants performing radiography and license
R4 applications, renewals, and requests for amendments for licensees performing radiography
R4 shall include the components specified below and the location of all records required.

- R4 (1) A description of the overall organizational structure pertaining to the licensee's or
R4 registrant's radiation protection program, including specific delegation of authority
R4 and responsibility, the name of the RSO, and the minimum qualifications of the
R4 RSO and the RSO's designees.
- R4 (2) A radiation safety training program for radiographic personnel that meets the
R4 requirements of 64E-5.434, F.A.C., and includes the components described
R4 below.
- R4 (a) Initial, periodic, and on-the-job training.
- R4 (b) Written and practical examinations to determine knowledge, understanding
R4 of, and ability to comply with department and applicable USDOT rules,
R4 licensee or registrant requirements, operating and emergency procedures,
R4 and use of radiographic and related equipment.
- R4 (3) Procedures to verify the certification of radiographers and to ensure that the
R4 certification remains valid.
- R4 (4) A written policy to maintain radiation doses as low as reasonably achievable as
R4 specified in 64E-5.303, F.A.C. The policy shall include:
- R4 (a) A commitment by management to keep radiation doses as low as
R4 reasonably achievable and a description of the participation of
R4 management, the RSO, and radiographic personnel in the implementation
R4 of the policy;
- R4 (b) Investigation within 30 days by the RSO of any exposure level that
R4 exceeds established monthly and quarterly levels and implementation of
R4 corrective actions to halt unnecessary exposures and prevent recurrence;
R4 and
- R4 (c) An audit of the program to evaluate its effectiveness in minimizing
R4 exposures in conjunction with the annual review of the radiation protection
R4 program specified in 64E-5.303(3), F.A.C. A summary of the results of
R4 each audit, including a description of corrective actions taken, shall be
R4 prepared by the RSO and approved by the licensee or registrant.
- R4 (5) An auditing program for internal inspections of the job performance of all
R4 radiographic personnel at intervals not to exceed 6 months as described in 64E-
R4 5.434, F.A.C.

- R4 (6) Written operating and emergency procedures as described in 64E-5.436, F.A.C.
R4
- R4 (7) Leak testing procedures, including a description of:
- R4 (a) The method of taking wipes and preparing samples for analysis using only
R4 radiographers or radiographer's assistants working under the personal
R4 supervision of a radiographer or persons specifically licensed by the
R4 department, another agreement state, licensing state, or the NRC to
R4 perform such services; and
- R4 (b) The method of performing leak test sample analyses, including
R4 instrumentation to be used and experience of the individuals who will
R4 perform the analyses or a commitment to use vendors specifically licensed
R4 to perform such analyses by the department, another agreement state,
R4 licensing state, or the NRC.
- R4 (8) Procedures for the semiannual calibration of survey instruments and the annual
R4 calibration of alarm ratemeters, including a description of the calibration
R4 instrumentation and the experience of the person who will perform the
R4 calibrations or a commitment to use persons specifically licensed to perform such
R4 calibrations by the department, another agreement state, licensing state, or the
R4 NRC. All survey instrument calibrations shall be performed in accordance with
R4 64E-5.426(2), F.A.C.
- R4 (9) Procedures for quarterly inspection and maintenance of survey instruments,
R4 radiation machines, radiographic exposure devices, associated equipment,
R4 source changers, storage containers, and transport containers to assure proper
R4 function of components important to safety, performed in accordance with 64E-
R4 5.430, F.A.C.
- R4 (10) Procedures for annual calibration of pocket or electronic dosimeters, including a
R4 description of the calibration instrumentation and the experience of the person
R4 who will perform the calibrations or a commitment to use persons specifically
R4 licensed to perform such calibrations by the department, another agreement
R4 state, licensing state, or the NRC.
- R4 (11) Procedures for lay-barge, offshore platform and underwater radiography if
R4 conducting such activities.

R4 Specific Authority: 404.051, 404.061, F.S.

R4 Law Implemented: Implemented 404.022; 404.051(1), (4), (6), (9), (10), 404.061(2); 404.081(1); 404.141, F.S.

R4 History: New September 11, 2001.

R4 **64E-5.433 Radiation Safety Officer.**

- R4 (1) The licensee or registrant shall appoint an RSO and delegate the authority
R4 needed to fulfill the duties of the position. Except as specified in 64E-5.433(2),
R4 F.A.C., below, the minimum qualifications, training, and experience for the RSO
R4 shall be:
- R4 (a) One year of documented industrial radiography experience as a
R4 radiographer; and
- R4 (b) Sixteen hours of formal instruction in the establishment and maintenance
R4 of a radiation protection program, including training to perform internal
R4 audits and mitigation of radiological incidents. Individuals identified as an
R4 RSO on an industrial radiography license or registration before the
R4 effective date of this rule are not required to comply with the training
R4 requirements of this paragraph.
- R4 (2) Equivalent alternative radiation and safety training and experience in radiographic
R4 operations and formal training in the establishment and maintenance of a
R4 radiation protection program can substitute for the requirements specified in 64E-
R4 5.433(1)(a) and (b), F.A.C., above.
- R4 (3) In addition to other duties specified in this part, the RSO shall:
- R4 (a) Ensure compliance with all components of the licensee's or registrant's
R4 radiation protection program as specified in 64E-5.432, F.A.C., the terms
R4 and conditions of the license, and this rule;
- R4 (b) Investigate incidents and direct corrective actions, including halting
R4 operations when necessary;
- R4 (c) Serve as the licensee's or registrant's contact with the department; and
- R4 (d) Ensure that radiation safety activities are performed using approved
R4 procedures and requirements in Chapter 64E-5, F.A.C., in the daily
R4 operation of the licensee's program.

R4 Specific Authority: 404.051, 404.061, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.061(2), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.434 Training, Testing, Certification, and Audits.**

- R4 (1) The licensee or registrant shall not permit any individual to act as a
R4 radiographer's assistant until such individual:
- R4 (a) Receives a copy of the licensee's or registrant's operating and emergency
R4 procedures;
- R4 (b) Completes 8 hours of training, including instruction in the licensee's or
R4 registrant's operating and emergency procedures and supervised
R4 instruction in use of the licensee's or registrant's radiographic equipment,
R4 related handling tools, radiation survey instruments, and personnel
R4 monitoring devices during a special training session; and
- R4 (c) Successfully completes a closed-book, written examination on the
R4 licensee's or registrant's operating and emergency procedures and a
R4 practical examination that is not conducted during production radiography
R4 to demonstrate competence in the use of the licensee's or registrant's
R4 radiographic equipment, related handling tools, radiation survey
R4 instruments, and personnel monitoring devices.
- R4 (2) Licensees and registrants can allow individuals who have completed the training
R4 and testing specified in 64E-5.434(2)(a) – (d), F.A.C., below, to perform industrial
R4 radiography for 12 months after the effective date of these rules. The licensee or
R4 registrant shall not permit any individual to act as a radiographer until such
R4 individual:
- R4 (a) Receives copies of rules contained in Chapter 64E-5, Parts I – IV, IX and
R4 XV, F.A.C., applicable USDOT regulations, the appropriate license or
R4 certificate of registration, and the licensee's or registrant's operating and
R4 emergency procedures;
- R4 (b) 1. For radioactive material radiographic operations, completes 320
R4 hours of on-the-job training in industrial radiography, excluding
R4 hours as specified in 64E-5.434(2)(b)2., F.A.C., below, as a
R4 radiographer's assistant using radioactive material; or
- R4 2. For machine produced radiographic operations, completes 200
R4 hours of on-the-job training using radiation machines;
- R4 (c) Receives 40 hours of formal instruction in the subjects outlined in
R4 64E-5.434(6), F.A.C., and supervised instruction during a special training
R4 session in the inspection and use of the licensee's or registrant's
R4 radiographic equipment, related handling tools, radiation survey
R4 instruments, and personnel monitoring devices;
- R4 (d) Successfully completes a closed-book, written examination on the subjects
R6 outlined in **subsection 64E-5.434(6)**, F.A.C., and a practical examination to
R4 demonstrate competence in the use of the licensee's or registrant's
R4 radiographic and safety equipment; and
- R4 (e) Is certified by a certifying entity.

- R4 (3) Radiographers who work for an out-of-state radioactive materials license under
R4 reciprocal recognition are authorized to conduct radiographic operations within
R4 the state if they have a valid certification from a certifying entity for the activities
R4 being conducted before entering the state.
- R4 (4) Any individual who has completed all requirements specified in 64E-5.434(2),
R4 F.A.C., above, and begins work for a different Florida licensee or registrant shall
R4 complete 4 hours of additional training and testing before conducting radiographic
R4 operations. The training shall consist of instructions in the licensee's or
R4 registrant's operating and emergency procedures and supervised instruction
R4 during a special training session in the use of the licensee's or registrant's
R4 radiographic and safety equipment. The testing shall consist of successful
R4 completion of the written and practical examinations described in 64E-
R4 5.434(1)(c), F.A.C. The RSO shall document how the prior radiation training and
R4 experience was verified.
- R4 (5) Personnel using industrial cabinet x-ray systems for industrial radiography shall
R4 complete 16 hours of training and testing as described below:
- R4 (a) Ten hours of training and testing as described in 64E-5.434(6), F.A.C.; and
R4
- R4 (b) Two hours of instruction in the registrant's operating and emergency
R4 procedures pertaining to industrial radiography using industrial cabinet x-
R4 ray systems, 2 hours of supervised instruction during a special training
R4 session in the use of the registrant's industrial cabinet x-ray system,
R4 related handling tools, radiation survey instruments, and personnel
R4 monitoring devices, and 2 hours of testing, which shall consist of a written
R4 examination covering operating and emergency procedures and
R4 equipment use and a practical examination to demonstrate competence in
R4 the use of the registrant's industrial cabinet x-ray system and related
R4 equipment.
- R4 (6) The subjects to be covered during the instruction of radiographers shall include:
- R4 (a) Fundamentals of radiation safety, including characteristics of radiation,
R4 units of radiation dose, quantities of radioactivity, hazards of radiation
R4 exposure, radiation protection standards, radiation levels from sources of
R4 radiation, and methods of minimizing radiation dose.
R4
- R4 (b) Radiation detection instruments, including:
- R4 1. Use, operation, calibration, and limitations of radiation survey
R4 instruments;
- R4 2. Survey techniques; and
- R4 3. Use of personnel monitoring equipment.

- R4 (c) Equipment to be used, including, as applicable:
- R4 1. Operation and control of radiation machines, radiographic exposure
R4 equipment, remote handling equipment, source changers, storage
R4 containers, and transport containers, including pictures or models of
R4 source assemblies;
- R4 2. Storage, control, and disposal of licensed material; and
- R4 3. Inspection and maintenance of equipment.
- R4 (d) The applicable requirements of these rules and NRC and USDOT
R4 regulations.
- R4 (e) The licensee's or registrant's operating and emergency procedures.
- R4 (f) Case histories of industrial radiography accidents.
- R6 (7) Each licensee or registrant shall provide 8 hours of **refresher** annual radiation
R4 safety training to all radiographic personnel, which can be conducted in multiple
R4 sessions.
- R4 (8) The RSO or the RSO's designee shall audit the job performance of each
R4 radiographer and radiographer's assistant to ensure that the department's
R4 regulations, license requirements, and the licensee's or registrant's operating and
R4 emergency procedures are followed. The audits shall include observation of the
R4 performance of each radiographer or radiographer's assistant during an actual
R4 radiographic operation at intervals not to exceed 6 months. Radiographers or
R4 radiographer's assistants who have not participated in a radiographic operation
R4 for more than 6 months since the last audit shall demonstrate knowledge of the
R4 licensee's or registrant's operating and emergency procedures and safe use of
R4 radiographic and related equipment by a practical examination before
R4 participating in a radiographic operation. Audits of the RSO are not required.
- R4 (9) Individuals conducting internal radiation safety training or audits shall meet the
R4 minimum qualifications specified in 64E-5.433(1), F.A.C., for the RSO.

R4 Specific Authority: 404.051404.061, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.061(2), F.S.

R6 History: New September 11, 2001, **Amended September 28, 2006.**

R4 **64E-5.435 Conducting Industrial Radiographic Operations.**

- R4 (1) With the exception of industrial cabinet x-ray systems, the radiographer shall be
 R4 accompanied by at least one other radiographer or radiographer's assistant
 R4 whenever radiography is performed at a location other than a permanent
 R4 radiographic installation. The additional qualified individual shall observe the
 R4 radiographic operations and be capable of providing immediate assistance to
 R4 prevent unauthorized entry. Radiography is prohibited if only one qualified
 R4 individual is present. Radiography performed in an industrial cabinet x-ray
 R4 system by a single individual meeting the training and testing requirements
 R4 specified in 64E-5.434(5), F.A.C., is permitted.
- R4 (2) The radiographer's assistant shall be under the personal supervision of a
 R4 radiographer when using a radiation machine, radiographic exposure device,
 R4 source changer, or related source handling tools or conducting radiation surveys
 R4 to determine that the sealed source has returned to the shielded position or that
 R4 the radiation machine is off after an exposure.
- R4 (3) All radiographic operations conducted at a licensee's or registrant's permanent
 R4 facility shall be conducted in a permanent radiographic installation or an industrial
 R4 cabinet x-ray system or using equipment, facilities, and procedures that are
 R4 adequate to protect public health, safety, and property and included in the
 R4 radiation protection program specified in 64E-5.432, F.A.C.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), (11), 404.081(1), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.436 Operating and Emergency Procedures.** The licensee's or registrant's
 R4 procedures shall include instructions in the following:

- R4 (1) Handling and use of sources of radiation to be used so that exposures are
 R4 maintained as low as reasonably achievable and no individual is likely to be
 R4 exposed to radiation doses in excess of the limits established in rules contained
 R4 in Part III of Chapter 64E-5, F.A.C.;
- R4 (2) Methods and occasions to conduct radiation surveys;
- R4 (3) Methods to control access to radiographic areas;
- R4 (4) Methods and occasions to lock and secure sources of radiation;
- R4 (5) Personnel monitoring and the use of personnel monitoring equipment, including
 R4 steps to be taken immediately by radiography personnel when a pocket
 R4 dosimeter is found off-scale, an alarm ratemeter alarms unexpectedly, or a
 R4 personnel monitoring badge is damaged or lost;
- R4 (6) Transportation of licensed material to field locations and preparation of packages
 R4 for shipment by common or contract carriers, including packaging, marking,
 R4 labeling, shipping papers, emergency response information, blocking and
 R4 bracing, security, surveys, and vehicle placarding in accordance with applicable
 R4 requirements of the USDOT;

- R4 (7) Leak testing, quarterly inventories, and equipment inspection, maintenance and
R4 operability checks, and disposal of licensed material;
- R4 (8) Source exchanges for licensees who perform source exchanges;
- R4 (9) Calibration of survey instruments, dosimeters, and alarm ratemeters for licensees
R4 who perform calibrations;
- R4 (10) Emergency response, including response to loss, damage, or theft of sources of
R4 radiation, unauthorized entries into restricted areas, notifications, exposure
R4 minimization, and source recovery;
- R4 (11) Identifying and reporting equipment defects and noncompliance issues; and
- R4 (12) Maintenance of records.

R4 Specific Authority: 404.051, 404.20, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), (6), 404.081, 404.20(1), F.S..

R4 History: New September 11, 2001.

R4 **64E-5.437 Personnel Monitoring.**

- R4 (1) The licensee or registrant shall not permit any individual to act as a radiographer
R4 or a radiographer's assistant unless the individual wears on the trunk of his or her
R4 body at all times during radiographic operations:
- R4 (a) A NVLAP-approved personnel monitoring badge such as a film badge,
R4 thermoluminescent dosimeter (TLD) or optically stimulated luminescent
R4 device (OSLD);
- R4 (b) A direct reading pocket dosimeter, which can be either an ion chamber or
R4 electronic personal dosimeter; and
- R4 (c) An alarming ratemeter. Alarm ratemeters are not required for radiography
R4 performed in an approved permanent radiographic installation meeting the
R4 requirements of 64E-5.431, F.A.C.
- R4 (2) Each personnel monitoring badge shall be assigned to and worn by only one
R4 individual and shall be exchanged monthly. After exchange each badge shall be
R4 processed as soon as possible. If a report is received from the badge processor
R4 that indicates an individual has received a radiation exposure in excess of 5 rem
R4 (0.05 Sv), the licensee or registrant shall notify the department within 24 hours as
R4 specified in 64E-5.344(2), F.A.C. If a personnel monitoring badge is lost or
R4 damaged, the worker shall cease work immediately until a replacement badge is
R4 provided and the exposure is calculated by the RSO or the RSO's designee for
R4 the time period from issuance to loss or damage of the badge. The results of the
R4 calculated exposure and the time period for which the personnel monitoring
R4 badge was lost or damaged shall be provided to the processor to adjust the
R4 individual's occupational exposure record.

- R4 (3) Pocket dosimeters shall have a range from 0 to 200 millirem (2 mSv) and shall be
R4 recharged at the start of each shift and when 75% of the full scale of the
R4 dosimeter is exceeded. Initial, final, and total pocket dosimeter readings shall be
R4 recorded at the start and end of each shift.
- R4 (4) If an individual's pocket dosimeter is found to be off-scale or if an individual's
R4 electronic personal dosimeter reads more than 200 millirem (2 mSv) and the
R4 possibility of radiation exposure cannot be ruled out as the cause, the individual's
R4 personnel monitoring badge shall be sent for processing within 24 hours. In
R4 addition, the individual shall not resume radiographic operations until a
R4 determination of the individual's radiation exposure has been made by the RSO
R4 or the RSO's designee. The results of this determination shall be reported in
R4 writing to the department within 30 days of the determination.
- R4 (5) Each alarming ratemeter shall:
- R4 (a) Have a function test without being exposed to radiation to ensure that the
R4 audible alarm is functioning properly before use at the start of each work
R4 shift;
- R4 (b) Give an alarm at a preset dose rate of no more than 500 millirem (0.5
R4 mSv) per hour; and
- R4 (c) Require special means to change the preset alarm function.
- R4 (6) Pocket dosimeters and alarm ratemeters shall be calibrated annually for correct
R4 response to radiation by a person licensed by the department, another
R4 agreement state, licensing state, or the NRC. Acceptable dosimeters shall read
R4 within 20% of the true radiation exposure. Ion chamber dosimeters also shall be
R4 checked for response to drift by setting the dosimeter at zero and storing it in a
R4 low background area for at least 24 hours and for electrical leakage, which shall
R4 be no more than 1% of full scale for each 24 hours. Acceptable ratemeters shall
R4 alarm within 20% of the true radiation dose rate.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), (2), F.S.

R4 History: New September 11, 2001.

R4
R4

SUBPART F
(Formerly Subpart C)
PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

R4

64E-5.438 Radiation Surveys.R4
R4
R4
R4
R4
R4

- (1) No radiographic operations shall be conducted unless at least one calibrated and operable radiation survey instrument meeting the requirements of 64E-5.426, F.A.C., is available for each radiographic exposure device and radiation machine in use at each site where radiographic exposures are made. All radiation surveys shall be performed with a calibrated and operable radiation survey instrument meeting the requirements of 64E-5.426, F.A.C.

R4
R4

- (2) The surveys described below shall be performed by the licensee or registrant where applicable.

R4
R4
R4

- (a) A reference survey of each radiographic exposure device or source changer immediately following removal from a storage area, including removal from storage following transportation.

R4
R4
R4
R4

- (b) An area survey during the first radiographic exposure to verify that the posting requirements specified in 64E-5.439(1), F.A.C., have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 64E-5.312(1)(c), F.A.C.

R4
R4
R4
R4
R4

- (c) A survey of the radiographic exposure device and the length of the guide tube after each exposure when approaching the device or guide tube, concluding with a reference survey of the radiographic exposure device at the location established by the licensee after each radiographic exposure. The surveys shall be performed before exchanging film, repositioning the exposure head, or dismantling equipment.

R4
R4

- (d) A reference survey of the radiographic exposure device and source changer before and after source exchanges.

R4
R4

- (e) A reference survey of the radiographic exposure device, source changer, or storage container after returning the sealed source to a storage area.

R4
R4

- (f) A survey after each radiographic exposure using radiation machines to verify that the machine is off.

R4 Specific Authority: 404.051, F.S.

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

R4 History: New September 11, 2001.

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

R4 (1) Radiation areas and high radiation areas created by radiographic operations shall
 R4 be posted conspicuously as specified in 64E-5.323(1) and (2), F.A.C. Areas or
 R4 rooms in which licensed material is used or stored shall be posted as specified in
 R4 64E-5.323(5), F.A.C. The exceptions to posting specified in 64E-5.324(1),
 R4 F.A.C., do not apply to industrial radiography.

R4 (2) Source movement logs specified in 64E-5.429, F.A.C., that document the current
 R4 location of each source of radiation and source movements for the previous 30
 R4 days shall be posted conspicuously adjacent to the area where the source of
 R4 radiation is stored.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), 404.20, F.S.

R4 History: New September 11, 2001.

R4 **64E-5.440 Records.**

R4 (1) Each licensee or registrant shall maintain the following records for 3 years after
 R4 the event at the location specified in 64E-5.432, F.A.C., for inspection by the
 R4 department:

R4 (a) Survey instrument, dosimeter, and alarm ratemeter calibrations specified
 R4 in 64E-5.426 and 64E-5.437(5) – (6), F.A.C.;

R4 (b) Leak test results specified in 64E-5.427, F.A.C., which shall contain the
 R4 manufacturer's name, model, and serial number of each sealed source or
 R4 device tested, including the device the source was stored in, the identity of
 R4 each radionuclide, the estimated activity of each sealed source, the
 R4 measured activity of each test sample expressed in microcuries
 R4 (becquerels), the date of the test, and the signature or initials of the RSO
 R4 or the RSO's designee;

R4 (c) Quarterly inventories specified in 64E-5.428, F.A.C., which shall include
 R4 the name of the person conducting the inventory, the radionuclide, number
 R4 of curies (becquerels) or mass in each device, location of each sealed
 R4 source, device, and machine, the manufacturer, model, and serial number
 R4 of each sealed source, device, and machine, the date of the inventory, and
 R4 the signature or initials of the RSO or the RSO's designee;

R4 (d) Source movement logs and daily survey reports specified in 64E-5.429,
 R4 F.A.C.

R4 (e) Quarterly equipment inspection and maintenance specified in 64E-
 R4 5.430(2), F.A.C., including the date of the inspection, the name of
 R4 inspector, the equipment involved, any problems found, and what repair or
 R4 maintenance was done;

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

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

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), 404.20, F.S.

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

R4 **64E-5.441 Reporting Requirements.**

- R4 (1) In addition to the reporting requirements specified in rules contained in Chapter
R6 64E-5, Parts III and IX, F.A.C., and other sections of this part, each licensee shall
R4 provide a written report to the department within 30 days of the occurrence of any
R4 of the incidents involving radiographic equipment described below. Such reports
R4 shall be mailed to the Bureau of Radiation Control, Radioactive Materials Section,
R4 Bin C21, 4052 Bald Cypress Way, Tallahassee, Florida 32399-1741 for incidents
R4 involving radioactive materials or to the Bureau of Radiation Control, Radiation
R4 Machine Section, 705 Wells Road, Suite 300, Orange Park, Florida 32073 for
R4 incidents involving radiation machines.
- R4 (a) Unintentional disconnection of the source assembly from the control cable.
R4
- R4 (b) Inability to retract and secure the source assembly to the fully shielded
R4 position.
- R4 (c) Failure of any component critical to safe operation of the device to perform
R4 its intended function properly.
- R4 (2) The licensee shall include the information described below in each report
R4 submitted as specified in this section.
- R4 (a) A description of the equipment problem.
- R4 (b) Cause of each incident if known.
- R4 (c) Manufacturer name and model number of the equipment involved in the
R4 incident.

- R4 (d) Place, time, and date of the incident.
- R4 (e) Actions taken to establish normal operations.
- R4 (f) Corrective actions taken or planned to prevent recurrence.
- R4 (g) Qualifications of the personnel involved in the incident.
- R4 (3) Reports of overexposures submitted as specified in rules contained in Part III of
 R4 Chapter 64E-5, F.A.C., that involve failure of safety components of radiography
 R4 equipment also must include the information specified in 64E-5.441(2), F.A.C.
- R8 (4) Any licensee conducting radiographic operations or storing radioactive material at
 R8 any location not listed on the license for a period in excess of 180 days in a
 R8 calendar year, shall notify the Department prior to exceeding the 180 days.
 R8 (Pursuant to 120.54(6) Florida Statutes, 64E-5.441(4) is substantively identical to
 R8 10 CFR 34.101(c) published on 01/01/2007.)

R4 Specific Authority: 404.051, F.S.

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

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

PART V X-RAYS IN THE HEALING ARTS

	64E-5.501 ... Definitions	V-1
R7	64E-5.502 ... General Requirements	V-10
	64E-5.503 ... General Requirements for all Diagnostic X-ray Systems.....	V-17
R7	64E-5.504 ... Fluoroscopic X-ray Systems.....	V-23
R2	64E-5.505 ... Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems.....	V-30
R7	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
R7	64E-5.511 ... Registration of Radiation Machines.....	V-68

PART V

X-RAY IN THE HEALING ARTS

64E-5.501 Definitions. As used in this part, the following definitions apply:

- (1) "Accessible surface" means the external surface of any enclosure or housing
- (2) "Added filtration" means any filtration which is in addition to the inherent filtration.
- (3) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same degree of radiation attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.
- (4) "Assembler" means any person engaged in the business of assembling, replacing or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.
- (5) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.
- (6) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation. See also "Phototimer".
- (7) "Barrier". See "Protective barrier".
- (8) "Beam axis" means a line from the source through the centers of the x-ray field.
- (9) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field, except for beam-blocking or beam-shaping devices used in radiation therapy.
- (10) "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.
- (11) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
- (12) "Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.
- (13) "Certified system" means any x-ray system which has one or more certified components.

- (14) "Changeable filters" means any filter which can be readily removed from the useful beam through any electronic, mechanical or physical process.
- (15) "Contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five centimeters of the surface being treated.
- (16) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, push buttons and other hardware necessary for manually setting the technique factors and operating modes.
- (17) "Cooling curve" means the graphical relationship between the heat units stored and cooling time.
- (18) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
- (19) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.
- (20) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body as an aid to diagnosis through visualization of anatomical parts.
- (21) "Direct scattered radiation" means that radiation which has been deviated in direction only by materials irradiated by the useful beam. See also "Scattered radiation".
- (22) "Entrance exposure rate" means the roentgens (C per kg) per unit time at the point where the center of the useful beam enters the patient.
- (23) "Equipment". See "X-ray equipment".
- (24) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
- (25) "Filter" means material placed in the useful beam to preferentially absorb selected radiation.
- (26) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot film device, equipment housings, electrical interlocks, if any, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.
- (27) "General purpose radiographic x-ray system" means any diagnostic radiographic x-ray system, except computed tomography systems, which, by design, is not limited to radiographic examination of a specific anatomical region.
- (28) "Gonad shield" means a primary protective barrier for the testes or ovaries.

- (29) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
- (30) "Healing arts self-referral" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purposes of diagnosis or medical treatment.
- (31) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, seconds, and a quality factor dependent on the voltage wave form (QF=1 for single phase, 1.35 for three phase) or kVp x mA x seconds x QF.
- (32) "Image intensifier" means a device, when installed in its housing, that instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.
- (33) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further electronic or chemical transformations.
- (34) "Image receptor support" means that part of a mammographic system designed to support the image receptor in a horizontal plane during the mammographic examination.
- (35) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the x-ray tube housing assembly.
- (36) "Irradiation" means the exposure of matter to ionizing radiation.
- (37) "Kilovolts peak(kVp)". See "Peak tube potential".
- (38) "kV" means kilovolts.
- (39) "kWs" means kilowatt second. It is equivalent to kV x mA x seconds x 10⁻³.
- (40) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- (41) "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly, except for the useful beam and radiation produced when the exposure switch or timer is not activated.
- (42) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

-
- (a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being ten milliamperere seconds(10 mAs) or the minimum obtainable from the unit, whichever is larger.
- (b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.
- (c) For all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.
- (43) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
- (44) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation: $\text{Percent line-voltage regulation} = 100(V_n - V_1)/V_1$ where V_n = no-load line potential and V_1 = load line potential.
- (45) "mAs" means milliamperere second.
- (46) "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.
- (47) "Mobile x-ray equipment". See "X-ray equipment".
- (48) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
- (49) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.
- (50) "Photofluorographic" means an x-ray system designed to superimpose a patient's anatomical x-ray image from a fluoroscopic input phosphor onto a film strip through a system of lenses.
- (51) "Phototimer" means a device for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is energized. See also "Automatic exposure control".
- (52) "Portable x-ray equipment". See "X-ray equipment".

- (53) "Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.
- (54) "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been delivered.
- (55) "Primary protective barrier". See "Protective barrier".
- (56) "Protective apron" means an apron made of radiation absorbing material used to reduce radiation exposure.
- (57) "Protective barrier" means a barrier containing radiation absorbing material used to reduce radiation exposure. The types of protective barriers are as follows:
- (a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure by a required degree, for protection purposes.
 - (b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation by a required degree, for protection purposes.
- (58) "Protective glove" means a glove made of radiation absorbing material and used to reduce radiation exposure.
- (59) "Qualified person" means an individual who has the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.
- (60) "Radiation detector" means a device which, in the presence of radiation, provides a signal or other indication suitable for use in measuring single or multiple quantities of incident radiation.
- (61) "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system, intended for localizing the volume to be exposed during radiation therapy, and confirming the position and size of the therapeutic irradiation field.
- (62) "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.
- (63) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.
- (64) "Radiological physicist" means an individual who meets one of the following criteria:
- (a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x and gamma ray physics; or

- (b) Has a bachelor's degree in a physical science or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
 - (c) Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics or engineering; has had one year of full-time training in therapeutic radiological physics; and has had one year of full-time work experience in a radiotherapy facility where the individual's duties involved calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
 - (d) Has performed radiation physics work for a period of at least ten years full time, prior to the effective date of these rules, in the field of therapeutic radiological physics in radiotherapy facilities where the individual's duties involved calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.
- (65) "Rating" means the operating limits of a component as specified by the component manufacturer.
- (66) "Recording" means producing a permanent form of an image resulting from x-ray photons, such as film or video tape.
- (67) "Registrant", as used in this part and in Parts IV, VI and VIII, means any person who possesses and administratively controls an x-ray system or other radiation producing machine and is required by the provisions in Part I to register with this department.
- (68) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.
- (69) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. See "Direct scattered radiation".
- (70) "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system
- (71) "Secondary protective barrier". See "Protective barrier".
- (72) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
- (73) "Source" means the focal spot of the x-ray tube.

- (74) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.
- (75) "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.
- (76) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
- (77) "Spot-film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
- (78) "SSD" means the distance between the source and the skin of the patient.
- (79) "Stationary x-ray equipment". See "X-ray equipment".
- (80) "Stray radiation" means the sum of leakage and scattered radiation.
- (81) "Technique factors" means the conditions of operation. They are specified as follows:
- (a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
 - (b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
 - (c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
- (82) "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
- (83) "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
- (84) "Tube" means an x-ray tube, unless otherwise specified. See "X-ray tube".
- (85) "Tube housing assembly" means the tube housing with tube installed. It includes high voltage or filament transformers and other appropriate elements when such are contained within the tube housing.
- (86) "Tube rating chart" means the set of curves provided by the manufacturer which specify the rated limits of operation of the tube in terms of the technique factors.

- (87) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.
- (88) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.
- (89) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
- (90) "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.
- (91) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an x-ray exposure.
- (92) "X-ray equipment" means an x-ray system, subsystem or component thereof.
- (a) "Mobile" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
 - (b) "Portable" means x-ray equipment designed to be hand-carried.
 - (c) "Stationary" means x-ray equipment which is installed in a fixed location.
 - (d) "Special Purpose" means x-ray equipment or a system designed for radiographic examinations of a specific anatomical area of the human body utilizing image receptors of more than one size; for example, the head or the spinal column.
- (93) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
- (94) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube, high-voltage switches, electrical protective devices and other appropriate elements.
- (95) "X-ray system" means an assemblage of components for the controlled production of x-rays. It minimally includes an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

- (96) "X-ray subsystem" means any combination of two or more components of an x-ray system.
- (97) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.
- (98) "Medical physicist" means a person who practices the branch of physics that is associated with the practice of medicine.
- (99) "Clinical image" means a radiograph.
- (100) "Pulsed mode" means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Specific Authority: 404.051, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4), F.S.

History: New July 17, 1985, amended April 4, 1989.,

Amended November 20, 1994, Amended January 5, 1995, Amended , May 15, 1996, Formerly 10D-91.602

(Space intentionally left blank)

64E-5.502 General Requirements.

(1) Administrative Controls.

- (a) Registrant. The registrant shall be responsible for directing the operation of the x-ray systems which are subject to registration as described in 64E-5.511. The registrant or the registrant's agent shall assure that the following requirements are met in the operation of the x-ray system.
1. Any x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes unless the department determines that such operation will not endanger the public health, safety and welfare.
 2. Individuals who will be operating any x-ray system shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. Nonphysician operators of medical x-ray systems shall be certified in accordance with 64E-3, FAC.
 3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel, which specifies techniques and procedures to be used for all examinations performed by that system.
 4. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
 - a. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
 - b. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
 - c. Other patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the useful beam.
 - d. When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving one-fourth of the maximum permissible dose as defined in Part III, additional protective devices may be required by the department.

5. Gonad shields of not less than 0.25 millimeter lead equivalent shall be used for patients who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
6. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits the following:
 - a. Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and a proper prescription has been provided.
 - b. Exposure of an individual for the purpose of healing arts self-referral program except when authorized by 64E-5.502(1)(a)10.
 - c. Advertisement of free x-ray examinations unless the advertisement states that a determination of need will be made prior to the x-ray examination.
7. When a patient or film must be provided with auxiliary support during a radiation exposure:
 - a. Mechanical holding devices shall be used when the technique permits;
 - b. Written safety procedures shall be available to indicate the requirements for selecting a holder, list the individual projections where holding devices cannot be used and describe the procedure the holder shall follow;
 - c. The human holder shall be protected as required by (1)(a)4., above; and,
 - d. No individual shall be used routinely to hold film or patients.
8. Exposure Procedures Designed to Minimize Patient and Personal Exposure
 - a. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objectives of the examination.
 - b. The radiation exposure to the patient shall be the minimum required to produce images of good diagnostic quality.

- c. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.
- d. X-ray systems subject to 64E-5.505 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

R7
R7
R7

R7
R7

R7
R7
R7

R7
R7
R7
R7
R7
R7
R7
R7
R7
R7

- e. A person shall not perform fluoroscopic imaging or otherwise expose a human to x-rays from a fluoroscopic system unless the person is a:
 - (I) Licensed practitioner as that term is defined in section 468.301, Florida Statutes; or
 - (II) Certified radiologist assistant practicing in accordance with the requirements of Chapter 468, Part IV, Florida Statutes; or
 - (III) Certified general radiographer practicing in accordance with the requirements of Chapter 468, Part IV, Florida Statutes; and
 - (A) The general radiographer has been trained and authorized in writing by the licensed practitioner in charge to perform the specified imaging; and
 - (B) The specified imaging does not rely upon the general radiographer to provide any diagnostic interpretation, or to determine suspicious areas for additional imaging, or to otherwise modify the scope of authorization for the imaging; and
 - (C) The specified imaging is designed to prevent or reduce exposure to patients by facilitating proper location and positioning for the authorized radiographic imaging.

- 9. Personnel Monitoring. All individuals who are associated with the operation of an x-ray system are subject to the occupational exposure limits and the requirements for the determination of the doses stated in 64E-5.304 and 64E-5.308, FAC. In addition, when protective clothing or devices are worn on portions of the body and a personnel monitoring device is required, at least one such device shall be utilized as follows:
 - a. When a protective apron is worn, the monitoring device shall be worn at the collar outside of the apron
 - b. The dose to the whole body shall be recorded in the records required by 64E-5.339, FAC. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

R1
R1

- 10. Healing arts self-referral. Only healing arts self-referral programs for mammography screening will be authorized by the department.

- (b) Information and Maintenance Records and Associated Information. The registrant shall maintain at least the following information for each x-ray system:
 - 1. Tube rating charts and cooling curves.
 - 2. Record of surveys, calibrations, maintenance, modifications from the original schematics and drawings performed on the x-ray machine along with the names of persons who performed the service.
 - 3. A copy of all correspondence with the department regarding each x-ray system.
 - 4. An x-ray log containing the patient's name, the type of examination and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.
 - (c) Maintenance of x-ray Equipment. X-ray systems and accessory devices shall be maintained in good working condition, both mechanically and electrically, so that the clinical objectives may be fulfilled without risk of unproductive exposure due to equipment failure or malfunction.
- (2) Shielding.
- (a) Each x-ray facility shall have primary and secondary protective barriers as needed to assure that an individual will not receive a radiation dose in excess of the limits specified in Part III of these regulations.
 - (b) Structural shielding in walls and other vertical barriers required for personnel protection shall extend without breach from the floor to a height of at least seven feet (2.1 m).
 - (c) Doors, door frames, windows and window frames shall have the same lead equivalent shielding as that required in the wall or other barrier in which they are installed.
 - (d) In computation of protective barrier requirements, the maximum anticipated workload, use factors, occupancy factors and the potential for radiation exposure from other sources shall be taken into consideration.

- (e) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-ray energies of 200 keV and above for diagnostic or therapeutic purposes shall be submitted to the department for review and approval.
1. The plans shall show, as a minimum, the following:
 - a. The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.
 - b. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor and ceiling of the room concerned.
 - c. The dimensions of the room concerned.
 - d. The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest area where it is likely that individuals may be present.
 - e. The make and model of the x-ray equipment and the maximum technique factors.
 - f. The type of examinations or treatments which will be performed with the equipment.
 2. Information on the anticipated maximum workload of the x-ray system.
 3. If the services of a qualified person have been utilized to determine the shielding requirements, a copy of the report, including all basic assumptions used, shall be submitted with the plans.
- (3) X-ray Film Processing Facilities and Practices.
- (a) Processing Facilities. Each installation using a radiographic x-ray system shall provide suitable equipment for handling and processing radiographic film in accordance with the following provisions:
 1. The area in which undeveloped films are handled for processing shall be devoid of light with the exception of light in the wave lengths having no significant effect on the radiographic film.
 2. Film pass boxes, if provided, shall be so constructed as to exclude light when film is placed in or removed from the boxes, and shall incorporate adequate shielding to prevent exposure of undeveloped film to stray radiation.

3. Darkrooms used by more than one individual shall be provided a positive method to prevent accidental entry while undeveloped films are being handled or processed.
4. Where film is developed manually,
 - a. At least one tri-sectional tank made of mechanically rigid, corrosion resistant material shall be utilized; and
 - b. The temperature of each solution shall be maintained within the range of 60 °F to 80 °F (16 °C to 27 °C). Film shall be developed in accordance with the time-temperature relationships specified by the film manufacturer, or, in the absence of such recommendations by the film manufacturer, with the following time temperature chart:

TIME-TEMPERATURE CHART		
Thermometer Reading		Minimum Developing Time (minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2 ½
25.0	77	2 ½
24.4	76	3
23.9	75	3
23.3	74	3 ½
22.8	73	3 ½
22.2	72	4
21.7	71	4
21.1	70	4 ½
20.6	69	4 ½
20.0	68	5
19.4	67	5 ½
18.9	66	5 ½
18.3	65	6
17.8	64	6 ½
17.2	63	7
16.7	62	8
16.1	61	8 ½
15.6	60	9 ½

- c. Devices shall be utilized which will:
 - (I) Indicate the actual temperature of the developer; and
 - (II) Signal the passage of a preset time as short as two minutes.

- (b) Precautionary Practices.
1. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.
 2. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.
 3. Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base fog and speed.
 4. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.
 5. Safe light and darkroom fog shall be such that, when a radiographic film is exposed to radiation to achieve a density of 1.0 and is exposed for one minute on any darkroom working surface, the film shall not have a density change greater than 0.1.
- (c) Automatic Processors and Other Closed Processing Systems. Preventive maintenance shall be performed on the unit, except for extended periods of nonuse, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer, a maintenance schedule shall be established which will preserve good diagnostic film quality.
- (d) Radiographic Film Quality.
1. Developed radiographs of patients or phantoms shall have an optical density of 0.5 to 2.0 in the area of clinical interest to allow for diagnostic interpretation of the image, unless justified due to special circumstances. Radiographs which provide the necessary diagnostic information shall not be repeated for the sole purpose of meeting the stated density range.
 2. Radiographic film used for diagnostic purposes shall be free from light fog and artifacts.

Specific Authority: 404.051, 404.081, 404.141, 404.22, F.S.

R7 Law Implemented: 404.051, 404.081, 404.141, 404.22, F.S.

History: New July 17, 1985, amended April 4, 1989, Amended January 1, 1994, Amended November 20, 1994,

R7 Amended January 1, 1995, Formerly 10D-91.603, Amended May 18, 1998, Amended August 16, 2007.

64E-5.503 General Requirements for All Diagnostic X-ray Systems. In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

- (1) **Warning label.** The main control panel and all auxiliary control panels of the x-ray system shall bear the equivalent warning statement, legible and accessible to view, "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
- (2) **Battery Charge Indicator.** Visual means shall be provided on the control panel of battery-powered x-ray generators to indicate whether the battery is in a state of charge adequate for proper operation.
- (3) **Leakage Radiation from the Diagnostic Source Assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC per kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (4) **Radiation from Components Other than the Diagnostic Source Assembly.** The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgens (0.516 μC per kg) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (5) **Beam Quality.**
 - (a) **Half-value Layer.** The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown below. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed below, linear interpolation or extrapolation may be made.

Design Operating Range (kVp)	Measured Potential (kVp)	Half-value Layer (mm of Al)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
150	4.1	

- The above HVL criteria will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown below:

Filtration Required vs. Operation Voltage	
Operating Voltage (kVp)	Total Filtration (inherent plus added)
Below 50	0.5 mm Al equivalent
50 to 70	1.5 mm Al equivalent
Above 70	2.5 mm Al equivalent

- Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.
- For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure
- The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the focal spot of the tube and the patient.
- In addition to the requirements of (5)(a)1., above, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 mm aluminum equivalent filtration permanently installed in the useful beam.

- (b) Filtration Controls. For x-ray systems which have variable kVp and changeable filters, and which are used for low filtration techniques, a positive means shall be provided that will prevent an exposure unless the minimum required amount of filtration is in the useful beam for the selected kVp.
- (6) Aluminum equivalent of material between patient and image receptor. The aluminum equivalent of each of the items listed below, which are used between the patient and image receptor, shall not exceed the indicated limits. This requirement is applicable to the front panel of cassette holders and film changers provided by the manufacturer for purposes of patient support or to prevent foreign object intrusions. It does not apply to such items as a screen and its associated mechanical support panel or grids.

Item	Maximum Aluminum Equivalent
Front panel of cassette holder (total of all)	1.0 mm
Front panel of film changer (total of all)	1.0 mm
Stationary tabletop	1.0 mm
Movable tabletop (including stationary subtop)	1.5 mm
Cradle Above 70	2.0 mm

- (7) Multiple Tube Heads. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the selected tube housing assembly.
- (8) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the x-ray system.
- (9) Technique Indicators.
- (a) Each x-ray system shall be equipped with devices, such as labeled control settings or meters, correctly indicating the physical factors and modes of operation used for exposures. x-ray systems utilizing arbitrary number or letter designators for kVp, time and milliamperage shall be accompanied by a chart giving the value of physical factors for each arbitrary designator.
- (b) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

- (c) On equipment having fixed technique factors, the requirement in (9)(a), above, may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of fluoroscopy or spot films made by the fluoroscopist.
- (d) Reproducible technique factor indicators may be relabeled to meet the accuracy requirements of this part. Such relabeling shall be conspicuous and clearly legible and shall be utilized by the registrant in setting technique factors.
- (10) Accuracy of Technique Factors. Meters, labeled control settings, exposure time selectors and other physical factor indicators shall be accurate within the following tolerances:
- (a) Milliamperage (mA) for Radiographic: $\pm 10\%$
- (b) Milliamperage (mA) for Fluoroscopic: ± 0.2 mA
- (c) Kilovolt peak (kVp): $\pm 5\%$
- (d) Timer at settings
1. Greater than ten seconds: \pm one second
 2. Ten seconds or less: $\pm 10\%$
- (11) Timer Reproducibility. When four timer tests are performed at the same timer settings, the average time period (T_{mean}) shall be greater than or equal to 12 times the maximum time period (T_{max}) less the minimum time period (T_{min}). Expressed mathematically, $T_{\text{mean}} \geq 12 (T_{\text{max}} - T_{\text{min}})$.
- (12) Exposure Reproducibility. The x-ray exposure produced by radiographic systems shall be reproducible to within the following criteria: When all technique factors are held constant and four or more exposures at the same technique factors are made, the value of the average exposure (E_{mean}) shall be greater than or equal to 12 times the quantity of maximum exposure (E_{max}) minus the minimum exposure (E_{min}). Expressed mathematically, $E_{\text{mean}} \geq 12 (E_{\text{max}} - E_{\text{min}})$.
- (13) Exposure Linearity. The x-ray output produced by radiographic systems utilizing means other than automatic exposure controls shall be linear to within the following criteria:
- (a) When a choice of two or more current settings (mA) or current-time product settings (mAs) may be selected and where $X_{1\text{mean}}$ and $X_{2\text{mean}}$ are the average mR per mAs values obtained from four exposures on each of two mA or mAs settings at a fixed tube potential (kVp) setting, within the range of 40 to 100 percent of the maximum tube rating, the average of four exposures (mR) for a given milliamperere-second (mAs) product in mR per mAs shall not differ by more than:

-
1. Five hundredths times the sum of any two consecutive mA or mAs averaged settings; expressed mathematically,
$$|X_{1\text{mean}} - X_{2\text{mean}}| \leq 0.05 (X_{1\text{mean}} + X_{2\text{mean}});$$
 and
 2. One tenth times the sum of any other two mA or mAs averaged settings; expressed mathematically,
$$|X_{1\text{mean}} - X_{2\text{mean}}| \leq 0.10 (X_{1\text{mean}} + X_{2\text{mean}});$$
- (b) Equipment, which after calibration cannot be made to meet the requirements of (13)(a) above, may be relabeled to indicate the effective mA or mAs, providing that use of such relabeled stations will meet the requirements of (13)(a), above.
- (c) Equipment, which after calibration cannot be made to meet the requirements of (13)(a) or (b) above, shall not be used unless written approval is obtained from the department. Approval shall not be granted when the linearity determination exceeds the federal standard for certified systems.
- (14) Automatic Exposure Controls. When automatic exposure control is provided
- (a) Indication shall be made on the control panel when this mode of operation is selected.
 - (b) When the x-ray tube potential is greater than or equal to 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be less than or equal to a time interval equivalent to two pulses.
 - (c) The minimum exposure time for all equipment other than that specified in (14)(b), above, shall be less than or equal to 1/60 second or a time interval required to deliver five mAs, whichever is greater.
 - (d) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure.
 - (e) A visible signal shall indicate when an exposure has been terminated at the limits described in (14)(d), above, and manual resetting shall be required before further automatically timed exposures can be made.

- (f) Exposure Linearity. When a choice of two or more tube current settings (mA) may be selected, the average of four consecutive exposures ($E_{1\text{mean}}$) made at any one tube current setting minus the average of four consecutive exposures ($E_{2\text{mean}}$) made at any other tube current setting shall be less than or equal to 0.05 times the sum of the two averages. Expressed mathematically, $|E_{1\text{mean}} - E_{2\text{mean}}| \leq 0.05 (E_{1\text{mean}} + E_{2\text{mean}})$. Measuring compliance for the above shall be based on the following criteria:
1. An attenuation block as described in 64E-5.501(5) shall be in the useful beam.
 2. Exposure (mR) shall be measured on the exit side of the attenuation block.
 3. The tube potential (kVp) shall be maintained at a fixed setting within the range of 40 to 100 percent of the maximum tube rating.
- (15) Beam Limiting Devices.
- (a) Beam limiting devices capable of restricting the useful beam to the area of clinical interest shall be used during exposures.
 - (b) Beam limiting devices shall provide a degree of attenuation not less than that required for the tube housing.
- (16) Remote Exposure Switches. Where an x-ray control is equipped with two or more remote exposure switches, each remote switch shall serve a single x-ray tube, and exposures with any tube shall be possible only by the remote switch with which that particular tube is associated.
- (17) Electrical Power Supply. The electrical power supply and service lines to x-ray systems shall be of sufficient capacity to permit operation without significant variation in voltage or machine output.

Specific Authority: 404.051, 404.151, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, Formerly 10D-91.604

(Space intentionally left blank)

64E-5.504 Fluoroscopic X-ray Systems. All fluoroscopic x-ray systems shall meet the following requirements:

- (1) Limitation of the Useful Beam.
 - (a) The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire cross section of the useful beam.
 - (b) A means shall be provided between the x-ray source and the patient for stepless adjustment of the size of the x-ray field.
 - (c) With the collimating shutters adjusted to the closed position, the minimum field size at the maximum SID shall not be greater than five by five centimeters when measured at the point where the beam enters the patient.
 - (d) Limitation to the Imaging Surface.
 1. The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the useable area of the largest image receptor at any SID.
 2. The longitudinal and transverse dimensions of the x-ray field produced by image-intensified fluoroscopic equipment shall not extend beyond the corresponding dimensions of the image receptor by more than three percent of the SID in either dimension in the plane of the image receptor and the sum of the excess shall be no greater than four percent of the SID. If the collimation is automatically accomplished, the x-ray field dimension criteria above shall apply to all film sizes and portions thereof that the spot film device accommodates and to the dimensions of the input phosphor, as appropriate. If collimation is not automatic, the x-ray field dimension criteria shall apply to the **useful area of the** input phosphor.
 3. Compliance shall be determined with the beam axis perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which passes through the center of the visible area of the image receptor.
 4. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent of the SID.
 5. Adjustable automatic and manual collimators shall operate smoothly throughout the entire range of use.

R1
R7
R1
R1
R1
R7
R1

6. For fluoroscopic systems with spot film capability, means shall be provided for adjustment of the x-ray field size in the plane of the film to a size smaller than the selected portion of the film.
- (e) The requirements of (1)(b) and (c), above, are not applicable to mobile fluoroscopic systems.
- (2) Activation of the Fluoroscopic Tube. A control of the dead-man type shall be incorporated into each fluoroscopic system such that x-ray production will be terminated at any time pressure is released from the switch except during the recording of serial fluoroscopic images with equipment in which means have been provided to permit completion of any single exposure of the series in progress.
- R1 (3) Allowable Entrance Exposure Rate Limits for Fluoroscopic Equipment.
- R1 (a) Fluoroscopic equipment manufactured after June, 1995, operable at any combination of tube potential and current that results in an exposure rate greater than five roentgens (1.29×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure control. Provision for manual selection of technique factors can be provided.
- (b) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of ten roentgens (2.58×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient except:
1. During the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode.
 2. When an optional high-level control is activated. When the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 20 roentgens (5.16×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient. Special means to activate high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator.
- (c) Special means to activate high level controls such as additional pressure applied continuously by the operator shall be required to avoid accidental use.
- (d) A continuous signal audible to the fluoroscopist shall indicate when the high level control is being employed.
- (e) Measuring Compliance of Entrance Exposure Rate Limits. Compliance with this subsection shall be determined as follows:

-
1. Movable grids and compression devices shall be removed from the useful beam during the measurement.
 - R7 2. If the source **can be operated** below the **patient support device**, the exposure rate shall be measured at least one centimeter above the **patient support device** and corrected for distance to show the actual entrance exposure rate.
 - R7 3. If the source **can be operated** above the **patient support device**, the exposure rate shall be measured at 30 centimeters above the **patient support device** with the end of the beam-limiting device or spacer assembly positioned as closely as possible to the point of measurement.
 - R7 4. In a **mobile** C-arm type of fluoroscope, **not associated with a specific patient support device**, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.
 - R7 5. **If the source can be operated laterally to the patient support device**, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.
 6. X-ray systems that incorporate automatic exposure controls such as automatic brightness control shall have sufficient lead or lead equivalent placed in the useful beam to produce the maximum output of the x-ray system.
 7. X-ray systems that do not incorporate automatic exposure control shall use the maximum combination of current and potential to produce the highest output. Attenuating materials shall be placed in the useful beam to protect the imaging system.
- R1 (f) Periodic Measurement of Entrance Exposure Rates. The entrance exposure rate shall be measured before use on humans after the completion of any initial or subsequent installation and after any maintenance of the system that might affect the exposure rate.
- R1 (g) For cinefluoroscopy, the maximum exposure at the face of the input phosphor with the grid removed and with an attenuation block in the beam shall not exceed 40 microroentgens (0.01 μC per kg) per frame. The maximum exposure shall be measured before use on humans after the completion of any initial or subsequent installation and after any maintenance of the system which might affect the maximum exposure.

- R1 (4) Barrier Transmitted Radiation Limits.
- R1 (a) The exposure rate due to transmission through the primary protective
R1 barrier and frame assembly with the attenuation block in the useful beam
R1 combined with radiation from the image intensifier if provided shall not
R1 exceed 2 milliroentgens (0.516 μC per kg) per hour at 10 centimeters from
R1 any accessible surface of the fluoroscopic image assembly beyond the
R1 plane of the image receptor for each roentgen per minute of entrance
R1 exposure rate.
- R1 (b) Measuring Compliance with Barrier Transmission Limits
- R1 1. The exposure rate due to transmission through the primary
R1 protective barrier combined with radiation from the image intensifier
R1 shall be determined by measurements averaged over an area no
R1 greater than 100 square centimeters with no linear dimension
R1 greater than 20 centimeters.
- R1 2. If the source is below the tabletop, the measurement shall be made
R1 with the input surface of the fluoroscopic imaging assembly position
R1 30 centimeters above the tabletop.
- R1 3. If the source is above the tabletop and the SID is variable, the
R1 measurement shall be made with the end of the beam limiting
R1 device or spacer assembly as close to the table top as it can be
R1 placed but not closer than 30 centimeters.
- R1 4. Movable grids and compression devices shall be removed from the
R1 useful beam during the measurements.
- R1 5. The attenuation block shall be positioned in the useful beam 10
R1 centimeters toward the input surface of the imaging assembly from
the point at which the entrance exposure rate was measured.
- R1 6. The maximum beam size shall be used during measurements.
- R1 (5) Indication of Potential and Current. During fluoroscopy and cinefluorography,
x-ray tube potential and current shall be continuously indicated.
- R1 (6) Source-to-Skin Distance. Positive means shall be provided to assure the source-
to-skin distance shall not be less than:
- R1 (a) Thirty-eight centimeters on stationary fluoroscopes installed after
January 1, 1977,
- R1 (b) Thirty-five and one-half centimeters on stationary fluoroscopes installed
prior to January 1, 1977,
- R1 (c) Thirty centimeters on all mobile fluoroscopes,

-
- (d) Twenty centimeters for image intensified fluoroscopes used for specific surgical applications. Written safety procedures must be provided and precautionary measures followed during the use of this device.
- R1 (7) Fluoroscopic Timer. A cumulative timing device activated by the fluoroscopic exposure switch shall be provided, the maximum cumulative time of which shall not exceed five minutes without resetting. The timer shall indicate the passage of the predetermined period of exposure by an audible signal or termination of the exposure. If such a signal is utilized, it shall continue while x-rays are produced until the timing device is reset.
- R1 (8) Mobile Fluoroscopes. In addition to the other requirements of this section, mobile fluoroscopes shall provide intensified imaging.
- R1 (9) Control of Scatter Radiation.
- (a) Fluoroscopic table designs shall be such that scattered radiation which originates beneath the tabletop is attenuated by not less than 0.25 mm lead equivalent, and that no unprotected part of any staff or ancillary person's body shall be exposed to unattenuated scattered radiation.
- (b) Fluoroscopic equipment configuration shall be such that no portion of any staff or ancillary person's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless:
1. Such person is at least 120 centimeters from the center of the useful beam, or
 2. The radiation has passed through not less than 0.25 millimeter lead equivalent material.
- (c) Exceptions to (10)(b), above, may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the department shall not permit such exception.
- R1 (10) Photofluorographic Medical x-ray Systems.
- (a) In addition to other applicable sections of these regulations, photofluorographic x-ray systems shall conform with the following requirements:
1. Usage shall be limited to diagnostic radiography of the lungs and other soft tissues of the thoracic region.
 2. Personnel monitoring shall be provided for all individuals who operate photofluorographic apparatus.
 3. The average exposure, including backscatter, for chests measuring 25 centimeters in thickness shall not exceed 100 millirems (1.0 mSv) at the point where the x-ray beam enters the patient.

(b) Photofluorographic x-ray systems shall not be installed unless specifically approved by the department.

R1 (11) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of (1), (3), (4), (5) and (8), above, provided that:

(a) Such systems are designed and used in such a manner that no person other than the patient is in an unprotected area during periods of time when the system is producing x-rays; and

(b) Systems that do not meet the requirements of (8), above, are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. In such cases, the timer shall be reset between examinations

(c) The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 20 roentgens (5.16 mC per kg) per minute, except during the recording of fluoroscopic images.

R7 (12) For remotely operated fluoroscopic systems:

R7 (a). The control panel shall be arranged or configured to allow the operator to
R7 have both auditory and visual communication with the patient during
R7 exposures.

R7 (b). The operator's protective barrier shall have a window or mirror system
R7 arranged so that the operator can keep the patient under constant visual
R7 surveillance during exposures.

R7 (c). Windows shall have lead equivalent shielding equal to that required in the
R7 operator's protective barrier.

Specific Authority: 404.051, 404.22, F.S.

R7 Law Implemented: 404.05, 404.22, F.S.

R1 History: New July 17, 1985, amended April 4, 1989., March 17, 1992,

R7 Amended January 5, 1995, Formerly 10D-91.605, Amended May 18, 1998, Amended August 16, 2007.

Space left intentionally blank

Page left intentionally blank

Next page number is 30.

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

- (1) Beam Limitation. The useful beam shall be limited to the area of clinical interest.
 - (a) General Purpose Stationary and Mobile X-ray Systems.
 1. A means for stepless adjustment of the size of the x-ray field shall be provided.
 2. Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
 3. Mobile x-ray systems shall be equipped with an attached rule to accurately measure the SID at any distance up to 72 in (183 cm).
 - (b) Stationary general purpose diagnostic x-ray systems shall be equipped with the following additional features:
 1. Positive means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; to align the center of the x-ray field with the center of the image receptor to within two percent of the SID; and to indicate the SID to within two percent.
 2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.
 3. Indication of field size dimensions and SID's shall be specified in inches or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam limiting device to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.
 - (c) X-ray Systems Used for One Image Receptor Size. Radiographic equipment used for only one image receptor size shall have a fixed SID and shall be provided with positive means to limit the x-ray field at the plane of the image receptor to the area of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.

(d) Special Purpose x-ray Systems.

1. **For x-ray systems with more than one image receptor size,**
 - a. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
 - b. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
2. The requirements in this paragraph are met by a system that meets the requirements for a general purpose x-ray system as specified in (1)(a), above, or, when positive alignment means are also provided, may be met with either:
 - a. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed; each such device shall have clear markings to indicate the image receptor size and SID for which it is designed; or
 - b. A beam-limiting device having multiple fixed apertures sufficient to meet the requirements for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(2) Radiation Exposure Control Devices.

- (a) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor.
 1. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to 0.
 2. It shall not be possible to make an exposure when the timer is set to a zero or off position, if either position is provided.

- (b) X-ray Exposure Control Switch Type and Location.
1. A control of the dead-man type shall be incorporated into each x-ray system such that an exposure will be terminated at any time pressure is released from the switch, except during serial radiography, when means have been provided to permit completion of any single exposure of the series in progress.
 2. Each x-ray control shall be located in such a way as to meet the following requirements:
 - a. The operator's station at the control panel shall be behind a protective barrier so positioned that leakage radiation and once scattered radiation will be intercepted.
 - b. For panoramic dental units with intensifying screens and a beam stop, the operator shall stand at least four feet (1.25 m) from the patient and the tube head or behind a protective barrier during exposures.
 - c. The operator's protective barrier shall be equipped with a window or mirror system so arranged that the operator may keep the patient under constant visual surveillance during exposures. The window shall have lead equivalent shielding equal to that required in the operator's protective barrier.
 - d. Each exposure switch, except those used in conjunction with fluoroscopic spot film devices and movable protective barriers, shall be securely fixed so that the operator cannot conveniently make exposures from an unshielded position.
 - e. Provision shall be made for aural communication with the patient from the control panel.
 - f. Mobile and portable x-ray systems which are:
 - (I) Used continually in a single location for a period greater than one week shall be considered a stationary radiographic system and shall meet the requirements for such an installation.
 - (II) Used at multiple locations shall be provided either with an adequate protective barrier or protective apron for the operator and with a method of control which will permit the operator to be at least 12 feet (3.75 m) from the tube head and the nearest edge of the useful beam during exposures.
 3. The x-ray control shall provide a visual indication observable from the operator's protected position whenever x-rays are produced.

4. A sound audible to the operator shall indicate that the exposure has terminated or is in progress.
- (3) Source-to-Skin Distance Limitations. All mobile or portable radiographic systems shall be provided with a positive means to limit the source-to-skin distance to not less than 30 centimeters.
- (4) Standby Radiation from Capacitor Energy Storage Equipment. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens (0.516 mC per kg) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.
- (5) Intracavitary x-ray Systems. Use of intracavitary x-ray systems on humans is prohibited unless specific approval has been granted by the department. Application for such use must include evidence attesting to the exclusive advantages to be gained in the use of intracavitary radiographic techniques as opposed to conventional radiographic procedures.

Specific Authority: 404.051, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, amended March 17, 1993, Amended January 5, 1995, Formerly 10D-91.606

(Space intentionally left blank)

64E-5.506 Intraoral Dental Radiographic Systems.

- (1) Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:
 - (a) 18 centimeters if operable at or above 50 kVp, or
 - (b) Ten centimeters if not operable above 50 kVp.
- (2) Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:
 - (a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters; and
 - (b) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six centimeters.
 - (c) An open-ended position indicating device shall be used on machines procured after September 19, 1972. The attenuation shall be equivalent to that required for the diagnostic source assembly as described in 64E-5.503(3).
- (3) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:
 - (a) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero; and
 - (b) It shall not be possible to make an exposure when the timer is set to a zero or off position, if either position is provided.
- (4) X-ray Exposure Control Switch.
 - (a) A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time. This switch shall be of the dead-man type.
 - (b) Each x-ray control shall be located in such a way as to meet the following criteria:
 1. The operator shall observe the patient during an exposure.
 2. The operator shall stand as far as practicable and at least six feet (1.8 m) from the patient and tube head and outside the useful beam or behind a protective barrier during exposures.

- (c) The x-ray control shall provide visual indication observable at or from the operator's position whenever x-rays are produced.
- (d) A sound audible to the operator shall indicate that the exposure has terminated or is in progress.
- (5) Operating Controls.
- (a) The dentist, operator or assistant shall not hold the film in place for the patient during the exposure. Patient and film holding devices shall be used when the techniques permit.
- (b) No person other than the patient shall be exposed to the useful beam.
- (c) Neither the tube housing nor the position indicating device shall be held during an exposure.
- (d) The x-ray system shall be arranged and operated in such a manner that the useful beam at the patient's skin does not exceed the dimensions specified in (2)(a), above.
- (e) Dental fluoroscopy without image intensification is prohibited.
- (f) Each user of intraoral units that are specifically designed to be handheld shall:
1. Have and use individual monitoring devices to document safe use practices; and
 2. Successfully complete training provided by the manufacturer using electronic media such as CD/DVD or a website. Training on the safe use of the unit shall be documented and include at a minimum:
 - a. Proper positioning of the unit to ensure an adequate protected position;
 - b. Limitations on the use of position indicating devices that require longer distances to the patients face;
 - c. Diagrams (ie: drawings, illustrations, schematics, etc.) of protected position and location in relationship to the unit;
 - d. Diagrams (ie, drawings, illustrations, schematics, etc.) of the effect of improper distance or removal of shielding device; and
 - e. Diagrams (ie. drawings, illustrations, schematics, etc.) of common examples of improper positioning of the unit and or location of the operator.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051, 404.22, F.S.

History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.607, Amended August 16, 2007

64E-5.507 Therapeutic X-Ray Systems of Less Than 1 MeV.

- (1) Equipment Requirements.
- (a) Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the following classification of that x-ray system:
1. Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) per hour at five centimeters from the surface of the tube housing assembly.
 2. Zero to 150 kVp Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) per hour at one meter from the source.
 3. 151 to 999 kVp Systems. The leakage radiation shall not exceed 0.1 percent of the useful beam one meter from the source, for any of its operating conditions.
- (b) Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.
- (c) Removable and Adjustable Beam Limiting Devices.
1. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.
 2. Adjustable beam limiting devices shall transmit not more than five percent of the useful beam at the maximum kilovoltage and with the maximum treatment filter in the useful beam.
- (d) Filter System. The filter system shall be so designed that:
1. The filters cannot be accidentally displaced at any possible tube orientation;
 2. The radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.7 mC per kg) per hour under any operating conditions;
 3. Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray; and

4. A filter indication system shall be used on all therapy machines using changeable filters. It shall be designed to permit easy recognition of any added filter in place. The presence or absence of any filter shall be discernible at the control panel.
- (e) Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.
- (f) Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.
- (g) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.
- (h) Beam Monitor System. Systems of greater than 150 kVp manufactured after January 1, 1985, shall be provided with a beam monitor system which:
 1. Shall have the detector of the monitor system interlocked to prevent incorrect positioning;
 2. Shall not allow irradiation until a pre-selected value of exposure has been made at the treatment control panel;
 3. Shall independently terminate irradiation when the preselected exposure has been reached;
 4. Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;
 5. Shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;
 6. Shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and
 7. Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.
- (i) Timer.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
 2. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
 3. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation.
 4. The timer shall permit accurate presetting and determination of exposure times as short as one second.
 5. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.
- (j) Control Panel Functions. The control panel, in addition to the displays required in other provisions of this section, shall have:
1. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
 2. An indication of whether x-rays are being produced;
 3. Means for indicating x-ray tube potential and current;
 4. Means for terminating an exposure at any time; and
 5. A locking device which will prevent unauthorized use of the x-ray system.
- (k) Multiple Tubes. When a control panel may energize more than one x-ray tube
1. It shall be possible to activate only one x-ray tube at any time;
 2. There shall be an indication at the control panel identifying which x-ray tube is energized; and
 3. There shall be an indication at the tube housing assembly when that tube is energized.
- (l) Source-to-Skin Distance (SSD). There shall be means of determining the SSD to within one centimeter.
- (m) Low Filtration x-ray Tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

- (2) Facility Design Requirements for x-ray Systems Operable Above 50 kVp.
- (a) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
 - (b) Viewing Systems. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
 - (c) Additional Requirements for x-ray Systems Operable Above 150 kVp:
 - 1. All protective barriers shall be fixed except for entrance doors or beam interceptors.
 - 2. The control panel shall be located outside the treatment room.
 - 3. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening:
 - a. The exposure at a distance of one meter from the source shall be reduced to less than ten milliroentgens (2.58 $\mu\text{C}/\text{kg}$) per hour; and
 - b. It shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
 - 4. Treatment rooms to which access is possible through more than one entrance shall be provided with flashing warning lights located in a readily observable position near the outside of all access doors to indicate when the useful beam is on.
- (3) Surveys, Calibrations, Spot Checks and Operating Procedures.
- (a) Surveys.
 - 1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified person. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
 - 2. The registrant shall transmit a copy of the survey report to the department within 30 days of the receipt of the report.

3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified person, is in violation of applicable regulations.
- (b) Calibrations.
1. The calibration of an x-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.
 2. The calibration of the radiation output of an x-ray system shall be performed by or under the direction of a radiological physicist who is physically present at the facility during such calibration.
 3. Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated within the preceding two years.
 4. The calibration shall be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty not to exceed five percent.
 5. The calibration of the x-ray system shall include, but not be limited to, the following determinations:
 - a. Verification that the x-ray system is operating in compliance with the design specifications;
 - b. The exposure rates as a function of field size, technique factors, filter and treatment distance used;
 - c. The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and
 - d. An evaluation of the uniformity of the largest radiation field used.
 6. Records of calibration shall be maintained by the registrant for five years after completion of the calibration.
 7. A copy of the most recent x-ray system calibration shall be available at the facility for inspection by the department.
- (c) Spot-checks. Spot-checks shall be performed on x-ray systems operable at greater than 150 kVp. Such spot-checks shall meet the following requirements:

1. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist.
 2. If a radiological physicist does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.
 3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot-check shall be performed during the calibration specified in (3)(b), above. The acceptable tolerance for each parameter measured in the spot-check when compared to the value for that parameter determined in the calibration specified in (3)(a), above, shall be stated.
 4. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
 5. Whenever a spot-check indicates a significant change in the operating characteristics of a system, the system shall be recalibrated as required in (3)(b), above.
 6. Records of spot-check measurements and any necessary corrective actions shall be maintained by the registrant for two years.
 7. Where a spot-check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of (3)(b), above, or which has been compared within the previous year with a system meeting those requirements.
- (d) Operating Procedures.
1. X-ray systems shall not be left unattended unless the system is secured against unauthorized use.
 2. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
 3. The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeter lead equivalency at 100 kVp.

4. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of 64E-5.304. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp.
5. Machines capable of having an output of more than 1,000 roentgens (258 mC per kg) per minute at any accessible place shall not be left unattended without the power being shut off at the disconnect switch in addition to the control panel switch.

Specific Authority: 404.051, 404.081, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6), 404.081(1) 404.22(1)(3), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.608

(Space intentionally left blank)

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

- (1) Definitions. In addition to the definitions provided in 64E-5.501, the following definitions shall be applicable to this section:
- (a) "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.
 - (b) "Beam scattering filter" means a filter used in order to scatter a beam of electrons.
 - (c) "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.
 - (d) "Dose monitoring system" means a system of devices for the detection, measurement and display of quantities of radiation.
 - (e) "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.
 - (f) "Existing equipment" means therapy systems subject to this section which were manufactured on or before January 1, 1985.
 - (g) "Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.
 - (h) "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.
 - (i) "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.
 - (j) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
 - (k) "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beam passes in all conditions.
 - (l) "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy and rotational therapy.

- (m) "New equipment" means systems subject to this section which were manufactured after January 1, 1985.
 - (n) "Normal treatment distance" means:
 - 1. For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.
 - 2. For x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.
 - (o) "Radiation head" means the structure from which the useful beam emerges.
 - (p) "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.
 - (q) "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam or the patient during irradiation.
 - (r) "Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation
 - (s) "Virtual source" means a point from which radiation appears to originate.
- (2) Requirements for Equipment.
- (a) Leakage Radiation to the Patient Area.
 - 1. New equipment shall meet the following requirement: For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons may be obtained from the manufacturer and shall be averaged over an area up to, but not exceeding, 200 square centimeters.

2. Existing equipment shall meet the following requirement: For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of two meters radius centered on a perpendicular to the central axis of the beam one meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified.
 3. For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified and for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the department.
- (b) Leakage of Radiation Outside the Patient Area for New Equipment.
1. The absorbed dose in rads (grays) due to leakage radiation, except in the area specified in (2)(a), above, when measured at any point one meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in (2)(a), above.
 2. The registrant shall determine or obtain from the manufacturer the actual leakage radiation existing at the positions specified and for specified operating conditions. Radiation measurements, excluding neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters. Neutron measurements shall be averaged over an area up to, but not exceeding, 200 square centimeters.
- (c) Beam Limiting Devices. Adjustable or interchangeable beam-limiting devices shall be provided, and such devices shall transmit no more than five percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.
- (d) Filters.

1. Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
 2. If the absorbed dose rate data indicated at the control panel relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.
 3. For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters:
 - a. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - c. A display shall be provided at the treatment control panel showing the filter in use; and
 - d. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
- (e) Beam Quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:
1. The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten centimeters greater than the practical range of the electrons shall not exceed the values stated below. Linear interpolation shall be used for values not stated.

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction or maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

2. Compliance with (2)(e)1., above, shall be determined using:

- a. A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
 - b. The largest field size available which does not exceed 15 by 15 centimeters; and
 - c. A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.
- (f) Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.
1. New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
 2. Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
 3. The detector and the system into which that detector is incorporated shall meet the following requirements:
 - a. Each detector shall be removable only with tools and shall be designed to prevent incorrect positioning.
 - b. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.
 - c. Each dose monitoring system shall be capable of independently monitoring, interrupting and terminating irradiation.
 - d. For new equipment, the design of the dose monitoring systems shall assure that:
 - (I) The malfunctioning of one system shall not affect the correct functioning of the second system; and
 - (II) The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

- e. Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall
 - (I) Maintain a reading until intentionally reset to zero;
 - (II) Have only one scale and no scale multiplying factors;
 - (III) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and
 - (IV) In the event of power failure, the dose monitoring information required to be displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.
- (g) **Beam Symmetry.** In new equipment inherently capable of producing useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds five percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds ten percent, the irradiation is terminated.
- (h) **Selection and Display of Dose Monitor Units.**
 - 1. Irradiation shall not be possible until a selection of a number of dose monitor units or exposure time has been made at the treatment control panel.
 - 2. The pre-selected number of dose monitor units or exposure time shall be displayed at the treatment control panel until reset manually for the next irradiation.
 - 3. After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated
 - 4. For new equipment, after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.
- (i) **Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy.**

1. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.
 2. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
 3. For new equipment, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than ten percent or 30 dose monitoring units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
 4. For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.
- (j) Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.
- (k) Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.
- (l) Timer.
1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
 2. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
 3. For new equipment, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

4. The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.
- (m) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:
1. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
 2. An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.
 3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 4. An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.
 5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.
 6. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
- (n) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
 2. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 3. The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
- (o) Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
1. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

2. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.
 3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 4. The mode of operation shall be displayed at the treatment control panel.
 5. For new equipment, an interlock system shall be provided to terminate irradiation if:
 - a. Movement of the gantry occurs during stationary beam therapy; or
 - b. Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.
 6. Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
 - a. For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of arc differs by more than 20 percent from the selected value.
 - b. For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle relationship.
 7. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by (2)(i), above.
- (p) Absorbed Dose Rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. In addition:
1. The dose monitor unit rate shall be displayed at the treatment control panel.
 2. The radiation detectors specified in (2)(f), above, may form part of this system.

- (q) Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:
 - 1. The x-ray target or the virtual source of x rays; and
 - 2. The electron window or the virtual source of electrons if the system has electron beam capabilities.
 - (r) System Checking Facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.
- (3) Facility and Shielding Requirements. In addition to Part III, the following design requirements shall apply:
- (a) Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.
 - (b) Control Panel. The control panel shall be located outside the treatment room.
 - (c) Viewing System. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.
 - (d) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
 - (e) Room Entrance. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors or other entrances to indicate when the useful beam is on.
 - (f) Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any barrier penetration or door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
- (4) Surveys, Calibrations, Spot Checks and Operating Procedures.
- (a) Surveys.

1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified person. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
 2. The registrant shall obtain a written report of the survey from the qualified person, and a copy of the report shall be transmitted by the registrant to the department within 30 days of receipt of the report.
 3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified person, is in violation of applicable regulations.
- (b) Calibration.
1. The calibration of systems subject to 64E-5.508 shall be performed in accordance with an established calibration protocol acceptable to the department, such as the calibration protocol published by the American Association of Physicists in Medicine, before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution or other characteristics of the therapy beam.
 2. The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.
 3. Calibration radiation measurements required by (4)(b), above, shall be performed using a dosimetry system:
 - a. Having a calibration factor for cobalt 60 gamma rays traceable to a national standard;
 - b. Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;
 - c. Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and
 - d. Which has had constancy checks performed on the system as specified by a radiological physicist.
 4. Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent.

5. The calibration of the therapy beam shall include the following determinations:
 - a. Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth.
 - b. The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.
 - c. The uniformity of the radiation field and any dependency upon the direction of the useful beam.
 - d. Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.
 - e. Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.
 6. Records of calibration measurements and dosimetry system calibrations required in (4)(b), above, shall be maintained for five years after completion of the full calibration.
 7. A copy of the latest calibration performed shall be available in the facility for inspection by the department.
- (c) Spot-checks. Spot-checks shall be performed on systems subject to this section during calibrations and thereafter at intervals not to exceed one month. Such spot-checks shall meet the following requirements:
1. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. Acceptable tolerance for each parameter measured in the spot-check shall not exceed manufacturer's recommendations.
 2. If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.

3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot-check when compared to the value for that parameter determined in the calibration.
 4. At intervals established in the spot-check procedures, spot-checks shall be made of absorbed dose measurements at a minimum of two depths in a phantom.
 5. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.
 6. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
 7. Whenever a spot-check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in (4)(b), above.
 8. Records of spot-check measurements and any necessary corrective actions shall be maintained by the registrant for a period of two years.
 9. Where a spot-check involves an absolute radiation measurement, such measurement shall be obtained using a system satisfying the requirements of (4)(b)3, above, or which has been compared with a system meeting those requirements within the previous year.
- (d) Additional Operating Procedures.
1. No individual other than the patient shall be in the treatment room during treatment of a patient.
 2. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used
 3. The system shall not be used in the administration of radiation therapy unless the requirements of (4)(a), (4)(b) and (4)(c), above, have been met.

Specific Authority: 404.031, 404.051, 404.071, 404.081, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4)(5)(6), 404.071(1), 404.081(1), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.609

(Space intentionally left blank)

64E-5.509 Veterinary Medicine X-ray Operations.

- (1) Applicable Regulations. Veterinary medical x-ray operations shall conform with requirements of the following sections of these regulations:
 - (a) 64E-5.502, General Requirements, except 64E-5.502(1)(a)5., 64E-5.502(1)(a)6., 64E-5.502(1)(a)7. and 64E-5.502(1)(a)8.
 - (b) 64E-5.503, General Requirements for all Diagnostic X-Ray Systems.
 - (c) 64E-5.504, Fluoroscopic x-ray Systems.
- (2) Additional Requirements.
 - (a) Positive means of beam alignment shall be provided in the form of accurate linear rulings, beam defining or beam centering lights, optical viewing devices or the equivalent. Such alignment means or devices shall be adjusted to indicate the beam center or beam area to within two percent of the SID.
 - (b) Means shall be provided to limit the useful beam to the area of diagnostic interest or to the area of the image receptor used in each particular case. Beam limitation may be accomplished by any of the means described in 64E-5.505(1).
 - (c) Each x-ray system shall be equipped with a device which will terminate the exposure after a preset time or exposure.
 - (d) Each exposure switch shall be of the dead-man type.
 - (e) Each exposure switch shall be located in such a way as to meet the following criteria:
 1. The operator shall stand as far as practicable and at least six feet (1.8 m) from the animal and tube head and outside the useful beam or behind a protective barrier during exposures.
 2. In lieu of distance or a protective barrier the operator shall wear a protective apron and monitoring device as provided in (3)(c), below.
- (3) Operating Procedures.
 - (a) The operator shall stand in a protected position as indicated in (2)(e), above, during radiographic exposures with no other individuals in the x-ray room unless assistance of the nature described in (3)(c), below, is required.

- (b) To the greatest practicable extent, animals must be immobilized by anesthetics, straps, sandbags, foam wedges, and other supporting or restraining devices.
- (c) If an animal must be held by an individual, that individual shall be protected by appropriate shielding devices such as a protective apron and gloves, and the holder shall be so positioned that no part of his body will be struck by the useful beam. The exposure of that individual shall be monitored when engaged in such purposes.

Specific Authority: 404.051, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.610

(Space intentionally left blank)

64E-5.510 Mammographic Systems.

- (1) Mammographic medical x-ray systems shall meet the requirements of 64E-5.502 and 64E-5.503. Registrants who provide mammography services shall:
 - (a) Have a written quality assurance program specific to mammography imaging that includes an equipment quality control program for performance monitoring and an evaluation of all components of the equipment from the x-ray generator to the image processor.
 - (b) Establish standards for clinical image evaluations that include breast positioning, compression and overall image quality.
 - (c) Assign qualified and trained personnel to each part of the quality assurance program.
 - (d) Conduct a general review of the effectiveness of the quality assurance program annually and maintain a written report of the review.
 - (e) Have available the services of a medical physicist to furnish diagnostic x-ray physics support who is able to establish and conduct the equipment quality control program and who meets the requirements specified in (12), below. The specific duties of the medical physicist must include:
 1. Monitoring equipment performance or verifying the qualifications and training of others to monitor equipment performance.
 2. Evaluating the monitoring results to identify problems.
 3. Verifying that corrections are effective and meet regulatory requirements.
- (2) Mammographic x-ray examinations shall be performed on systems specifically designed for and used only for mammography. Mammographic medical x-ray systems shall meet the following requirements:
 - (a) Image receptor. The image receptor systems and their individual components must be designed for mammography.
 - (b) Target/filter. The x-ray system must be able to provide kVp/target/filter combinations that are compatible with the image receptor systems.
 - (c) Focal spot size measurement. Focal spot dimensions shall be measured both parallel and perpendicular to the anode-cathode axis with a slit camera or star pattern. Measured focal spot size shall result in minimal acceptable phantom image as specified in (8)(c) or comply with the manufacturer's specified nominal focal spot size within the following tolerances:

Nominal Focal Spot Size (mm)	Maximum Measured Dimensions *	
	Width (mm)	Length (mm)
0.01	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

* Width is the dimension perpendicular to the anode-cathode axis, length is the dimension parallel to the anode-cathode axis.

- (d) Compression. Devices parallel to the imaging plane must be available to immobilize and compress the breast. These devices must be able to compress the breast with a force of at least 25 pounds and be able to maintain this compression for at least 15 seconds. For systems with automatic compression, the maximum force applied without manual assistance shall not be allowed to exceed 40 pounds. The chest wall edge of the compression paddle must be aligned with the chest wall edge of the image receptor to within one percent of the SID when the compression paddle is placed six centimeters above the patient support device.
- (e) Anti-scatter grids. A mammographic x-ray system using screen-film image receptors shall be able to use anti-scatter grids that are integral to the x-ray system and available for all image receptor sizes of the system.
- (f) Automatic exposure control. The department recommends that all x-ray equipment installed after September 1, 1993 have automatic exposure control that meets the requirements of 64E-5.503(14). The automatic exposure control shall be able to maintain constant film density within the diagnostic range of 1.05 to 1.60 optical density for 2, 4, and six centimeters of acrylic or of BR-12 phantoms. Density selection and kVp can be manually adjusted and recorded on technique charts if necessary to maintain film density.
- (3) Beam quality. The useful beam shall have a half-value layer between the values of measured kVp/100 and measured kVp/100 ± 0.1 millimeter aluminum equivalent when used with screen-film image receptors and the contribution to filtration made by the compression device is included. For xeroradiography, the half-value layer of the useful beam with the compression device in place shall be at least 1.0 and not more than 1.6 mm aluminum equivalent, tested at the kVp recommended by the manufacturer. Mammographic units using only rhodium filters and anodes are exempt from these beam quality requirements.

- (4) The x-ray system shall meet safety standards and be free from unnecessary hazards to patients, personnel and others. Identified hazards must be corrected promptly. Technique charts, procedures for all equipment use, proper safety precautions for both mechanical and electrical operation, adequate shielding, and emergency procedures must be available to the equipment operator. Staff or a medical physicist as specified in (12), below, shall conduct and document periodic inspections of the equipment and of the adequacy of procedures as part of the annual quality assurance review.
- (5) Collimation. The mammographic system shall be able to limit the useful beam so that the x-ray field at the plane of the image receptor at any SID does not extend beyond the left, right, and nipple edges of the image receptor and does not extend beyond the image receptor adjacent to the chest wall by more than two percent of the SID. The sum of the collimated light field edges shall not differ from the sum of the respective edges of the x-ray field along either the length or the width of the visually defined field by more than two percent of the SID.
- (6) Average glandular tissue dose. The average glandular tissue dose for one craniocaudal view of a 4.5 centimeter compressed breast with 50 percent adipose/50 percent glandular tissue shall not exceed the following values:
- (a) One hundred millirads (one milligray) for film/screen without grid.
 - (b) Three hundred millirads (three milligray) for film/screen with grid.
 - (c) Four hundred millirads (four milligray) for Xeroradiographic systems.
- (7) The film processor shall be optimized for the specific mammography film used by the facility. Its performance shall be checked for consistency of speed, contrast, and base plus fog prior to processing patient films and after being idle more than six hours.
- (a) These performance checks shall be plotted and compared to established limits. If these limits are exceeded, documented corrective actions including an image quality check as specified in (8), below, are required.
 - (b) Corrective action shall be taken when:
 - 1. Optical density deviates by more than 0.15 from established operating levels for readings of mid-density and density difference on the sensitometric control charts
 - 2. Base plus fog exceeds the established operating level by more than 0.03 optical density.
 - (c) These records for processor optimization, performance, image quality checks and documented corrective actions shall be maintained for inspection by the department for at least one year.

- (8) Mammographic x-ray systems shall be monitored and evaluated using the following standards:
- (a) The image quality shall be checked using a standard phantom approved by the U.S. Food and Drug Administration which meets the criteria below at least monthly and whenever service which could affect image quality is performed on the x-ray system or the film processor. The image quality shall be scored on the ability to image fibers, specks, and low density masses. If quality control limits are exceeded, image quality checks also must be performed after any corrective actions have been taken. This standard phantom must be designed to evaluate image quality in the 1.05 to 1.60 optical density range, shall not change more than 0.2 optical density from its previous reading, and must be composed of material that is equivalent to a nominal 4.5 centimeter compressed breast of average density of approximately 50 percent adipose and 50 percent glandular tissue. It shall contain the following objects:
 - 1. Nylon fibers with thicknesses of 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 millimeters.
 - 2. Aluminum oxide specks with diameters of 0.54, 0.40, 0.32, 0.24, and 0.16 millimeters.
 - 3. Phenolic plastic spherical masses with thicknesses of 2.00, 1.00, 0.75, 0.50, and 0.25 millimeters.
 - (b) Phantom checks which indicate a decrease in image quality shall require immediate investigation of possible corrective actions.
 - (c) The minimum acceptable image quality of a standard phantom described in (8)(a), above, shall demonstrate the ability to image at least 1.56, 1.12, 0.89, and 0.75 millimeter fibers; 0.54, 0.40, and 0.32 millimeter specks; and 2.00, 1.00, and 0.75 millimeter spherical masses. Mammographic examinations shall not be performed on systems which do not meet the minimum image quality standard.
 - (d) The registrant must document in the annual review required in (1), above, that the following equipment quality control items were performed under the direction and approval of the medical physicist when the equipment or components were initially installed or replaced and were performed thereafter at least as often as the frequency specified in (8)(e), below. When the results of performed tests do not meet established limits, corrective action must be taken and documented. The equipment quality control items which must be monitored are:
 - 1. Processor performance through sensitometric-densitometric means, before processing patient films and as specified in (7), above.
 - 2. Darkroom cleaning, daily.

3. Screen cleaning, weekly.
 4. Image quality, monthly and as specified in (8)(a),(b) and (c), above.
 5. Equipment observation check, monthly.
 6. Analysis of fixer retention in film, quarterly
 7. Compression device performance, semiannually
 8. Screen film contact and screen artifact detection, semiannually.
 9. Uniformity of screen speed, annually.
 10. Beam limiting device alignment, annually.
 11. Accuracy of kVp, annually.
 12. Output reproducibility and linearity, annually.
 13. Automatic exposure control reproducibility, kVp response and phantom thickness response, annually.
 14. Half-value layer, annually.
 15. Average glandular tissue dose, annually.
 16. Focal spot size, annually.
 17. Analysis of clinical images repeated or rejected, quarterly.
Corrective action shall be taken and documented if the retake rate of the facility exceeds five percent.
 18. Viewbox uniformity and integrity of devices used to block extraneous light, semiannually. A means shall be provided to block extraneous light from the viewer's eye when the illuminated surface of the viewbox is larger than the film size or area of clinical interest.
 19. Darkroom integrity, semiannually. Darkroom fog shall not exceed 0.05 optical density when sensitized film is exposed to darkroom conditions with the safelight on for two minutes.
- (e) Mammography system performance must be evaluated regularly. The registrant must document the evaluation of the equipment quality control tests in the annual review specified in (1), above. Those components and parameters of the equipment quality control program tested for performance daily, weekly, monthly or quarterly shall be evaluated quarterly. The annual evaluation by the medical physicist must include a summary of the quarterly evaluations and the following:

1. Unit assembly.
 2. Collimation assessment.
 3. Focal spot size measurement.
 4. Accuracy and reproducibility of the kVp.
 5. Beam quality assessment.
 6. Automatic exposure control system performance.
 7. Uniformity of screen speed.
 8. Breast entrance exposure and average glandular tissue dose.
 9. Image quality.
 10. Artifacts.
- (f) The registrant shall document the qualifications and training of the personnel responsible for each part of the mammography quality assurance program, including the clinical image review, the establishment, monitoring, and evaluation of the equipment quality control program, and the annual review of the quality assurance program effectiveness.
- (9) All image receptors shall be clearly marked to indicate on the film which receptor was used on any given examination to facilitate the detection and removal of artifacts.
- (10) Xerox mammography systems shall be exempt from the requirements of (2)(e), (2)(f), (7), (8)(d)1., 2., 3., 6., 8., 9., 13., 18., 19., (8)(e)6., and 7 above.
- (11) Xerox mammography systems which exceed an average glandular dose for one craniocaudal view of a 4.5 centimeter compressed breast with a 50/50 percent ratio of glandular/fat tissue of 400 mrad (4 mGy) shall have the exposure techniques, processing, and image quality of the system investigated by a medical physicist, as specified in (12), below.
- (12) The following requirements apply to personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities.
- (a) Interpreting physicians shall meet the following requirements
1. Licensed to practice medicine in the State of Florida, as specified in Chapters 458 and 459, Florida Statutes.
 2. a. Certified by a certifying body approved by the U.S. Food and Drug Administration; or

-
- b. (I) Have two months of documented full-time training in the interpretation of mammograms, including instruction in radiation physics, radiation effects, and radiation protection; and
 - (II) Have 40 hours of documented continuing medical education in mammography. Time spent in residency specifically devoted to mammography is acceptable if documented in writing by the physician.
 - 3. a. Have read and interpreted mammograms from the examinations of at least 240 patients in the last six months; or
 - b. Have read and interpreted mammograms as specified above under the direct supervision of a fully qualified interpreting physician.
 - 4. a. Read and interpret mammograms from the examinations of an average of at least 40 patients per month over 24 months; and
 - b. Teach or complete an average of at least five continuing medical education credits in mammography per year.
 - (b) Radiologic technologists shall meet the following requirements
 - 1. Certified as a general radiographer in the state of Florida as specified in Chapter 64E-3, Florida Administrative Code.
 - 2. Obtain training specific to mammography, either through a training curriculum or special mammography course.
 - 3. Accumulate an average of five continuing education hours in mammography per year.
 - (c) 1. Prior to April 28, 1999, a medical physicist qualified to conduct surveys of mammography facilities and provide oversight of the facility quality assurance program shall meet the criteria specified in
 - a. and b. and c., below:
 - a. Licensed in Florida as a medical physicist as specified in Chapter 483, F.S.; and

R1
R1
R1
R1

R1
R1

- b. (I) Holds a Master of Science, Master of Arts, or a higher degree in an appropriate field from an accredited institution. Appropriate fields include physics, applied physics, radiological physics, biophysics, health physics, engineering, and public health when the Bachelor's degree is in a physical science; and
- (II) Has had training in biological sciences; and
- (III) Has had at least 1 year of training in medical physics in the area of diagnostic radiological physics; and
- (IV) Has had at least 2 years of experience conducting mammography equipment performance evaluations..

R1

- c. Has received or taught at least an average of 5 hours of documented continuing education related to mammography per year.

R1

- 2. After April 28, 1999, the medical physicist must meet the criteria specified in 1.a. and 1.b.(I), above, and the qualification and experience specified in 21 CFR 900.12(a)(3)(i), (iii), and (iv), which is herein incorporated by reference and which is available from the department.

R1

R1

R1

R1

R1

- (13) Documentation, records and surveys. Each facility shall maintain records, policies, procedures and documentation to demonstrate compliance with these requirements, including corrective actions taken.

- (a) Clinical images. Each facility shall establish and maintain a clinical image quality control program, including:

- 1. Monitoring of mammograms repeated because of poor image quality; and
- 2. Maintaining records, analysis of results, and a description of any remedial action taken as a result of this monitoring.

(b) Clinical image interpretation. To ensure that quality clinical images are produced routinely at the facility, each facility shall submit clinical images to the department for review as required by the department. Each facility also will establish a system to review outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports.

R1

(c) Surveys. A medical physicist who meets the qualifications specified in (12), above, and who establishes, monitors, evaluates, and directs the equipment quality control program must perform an on-site survey of the facility to assure that it meets quality control and equipment standards. These surveys shall be performed at least annually and shall be available for inspection by the department. Each survey report shall be retained by the facility until the next annual survey is completed satisfactorily.

(d) Medical records.

1. Each facility shall maintain mammograms and associated records in a permanent medical record of the patient as follows:

- a. For at least five years, or, if no additional mammograms of the patient are performed at the facility, for at least ten years; or
- b. Until the records are transferred as requested by the patient to a medical institution, to a physician of the patient, or to the patient.

R1

2. Each facility shall prepare a written report of the results of each mammography examination. This report shall be completed as soon as reasonably possible and shall:

- a. Be signed by the interpreting physician; and
- b. Be provided to the patient's physician or to the patient if the patient's physician is not available or if the patient does not have a physician. If this report is sent to the patient, it shall include a summary written in language easily understood by a lay person. A copy of the report shall be maintained in the patient's medical record.

(14) In addition to the above requirements, effective October 1, 1994, no facility can conduct mammography procedures unless the facility also obtains a certificate issued by the U.S. Food and Drug Administration as described in Public Law 102-539, the Mammography Quality Standards Act of 1992.

R1 Specific Authority: 404.051, 404.22, F.S.

R1 Law Implemented: 404.051(1)(4), 404.141, 404.22(1)(3)(6), F.S.

History: New March 17, 1992, Amended January 1, 1994

R1 Amended November 20, 1994, Formerly 10D-91.611, Amended May 18, 1998

64E-5.511 Registration of Radiation Machines.

(1) Exemptions.

- (a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from registration and notification requirements if the dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 millirem (five μ Sv) per hour at five centimeters from any accessible surface of the equipment. The production, testing or factory servicing of such equipment shall not be exempt.
- (b) Radiation machines that are non-operational and under the control of a registered vendor prior to final installation are exempt from the registration and fee requirements of this section.

R7
R7
R7

(2) Application and Fees for Registration of Radiation Machines.

- (a) Each person who acquires a radiation machine or an additional radiation machine shall:
 - 1. Apply for registration of the radiation machine with the department within 30 days after acquisition and before use. Application for registration shall be on DH 1107 3/07, which is herein incorporated by reference and available from the department at <http://www.doh.state.fl.us/environment/radiation/>.
 - 2. Designate an individual who will be responsible for radiation protection.
 - 3. Prohibit any person who is not registered with the department as a provider of services as specified in (3), below, from furnishing radiation machine servicing or services to his radiation machine
- (b) An annual fee for the registration and inspection of radiation machines shall be paid according to the following schedule:

R7
R7
R7
R7

Medical or Chiropractic or Osteopathic or Naturopathic	One Tube\$ 145 Each Additional Tube\$ 85
Veterinary	One Tube\$ 50 Each Additional Tube\$ 34
Educational or Industrial	One Tube\$ 47 Each Additional Tube\$ 23
Dental or Podiatry	One Tube\$ 31 Each Additional Tube\$ 11
Medical Accelerator	One Unit\$ 258 Each Additional Unit\$ 148

Non Medical	One Unit	\$ 81
	Each Additional Unit	\$ 48

1. Renewal fees are due before October 28 annually.
 2. Registration fees are due within 30 days after acquiring a radiation machine. If the machine is acquired within 120 days before the October 28 annual renewal date, the registration fee will be due on October 28 and shall be the annual renewal fee.
- (3) Application for Registration of Servicing and Services.
- (a) Each person who installs or offers to install radiation machines or furnishes or offers to furnish radiation machine servicing or services in Florida shall apply to the department to register such services before furnishing or offering to furnish such services.
 - (b) Application for registration shall be completed on DH Form 1113, which is herein incorporated by reference and which is available from the department.
 - (c) Services include the installation or servicing of radiation machines and associated radiation machine components.
- (4) Report of Changes. The registrant shall report in writing within 30 days any changes to the information in the Certificate of Registration. The report shall include name, address of installation change, receipt, sale, transfer, or disposal of any radiation machine or major component.
- (5) Assembler or Transferor Obligation.
- (a) Any person who sells, leases, transfers, relocates, lends, assembles, installs or disposes of radiation machines or major components of such machines shall notify the department within 15 days after such action. Notification shall be made on DH Form 1114, which is herein incorporated by reference and available from the department, or, if the system contains certified components, on FORM FDA 2579, which is herein incorporated by reference and which is available from the department.
 - (b) No person shall sell, offer to sell, lease, transfer, lend or install radiation machines unless such machines meet the requirements of these regulations.

- (6) Out-of-State Radiation Machines.
- (a) Any person proposing to bring a radiation machine into Florida shall notify the department in writing at least ten days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration and scope of use; and the exact location where the radiation machine will be used. If the 10-day period is an undue hardship, the department can grant permission to proceed sooner.
 - (b) Any person proposing to bring a radiation machine into Florida shall register the machine with the department and pay the registration fee.
 - (c) Any out-of-state person using a radiation machine in Florida shall notify the department when the use of the machine has been completed.
- (7) Enforcement. The General Statement of Policy and Procedure for Radiation Machine Enforcement Actions, August 1996, which is available from the department and which is herein incorporated by reference, will be used to determine enforcement actions to be taken.

R7 Specific Authority 404.051, F.S.
R7 Law Implemented 404.071, 404.091, 404.101, 404.141, 404.161, 404.162, 404.163, 404.22, F.S.
R7 History--New December 12, 1996, Formerly 10D-91.612, Amended August 16, 2007

PART VI USE OF RADIONUCLIDES IN THE HEALING ARTS

R10	64E-5.601	License Required	VI-1
R10	64E-5.6011	Definitions	VI-3
R10	64E-5.602	License Amendments	VI-5
R10	64E-5.603	Notification	VI-6

SUBPART A GENERAL ADMINISTRATIVE REQUIREMENTS

R10	64E-5.604	ALARA Program	VI-6
R10	64E-5.605	Radiation Safety Officer	VI-7
R10	64E-5.606	Radiation Safety Committee	VI-9
R10	64E-5.607	Authority and Responsibilities	VI-11
R10	64E-5.608	Supervision	VI-13
R10	64E-5.609	Visiting Authorized User, Visiting Authorized Medical Physicist or Visiting RSO	VI-15
R10	64E-5.610	Mobile Medical Service Requirements	VI-16
R10	64E-5.611	Quality Management Program and Notifications, Records and Reports of Medical Events	VI-17
R10	64E-5.612	Suppliers	VI-19

SUBPART B GENERAL TECHNICAL REQUIREMENTS

R10	64E-5.613	Quality Control of Diagnostic Instrumentation	VI-20
R10	64E-5.614	Possession, Use, Calibration, and Check of Dose Calibrators In the Use of Unsealed Radiopharmaceuticals	VI-20
R10	64E-5.615	Calibration and Check of Survey Instruments	VI-22
R10	64E-5.616	Determination of Dosages of Unsealed Radioactive Materials for Medical Use	VI-24
R10	64E-5.617	Authorization for Calibration, Transmission and Reference Sources	VI-24
R10	64E-5.618	Requirements for Possession of Sealed Sources and Brachytherapy Sources	VI-25
	64E-5.619	Syringe Shields and Labels	VI-27
	64E-5.620	Vial Shields and Labels	VI-27
R10	64E-5.621	Surveys for Contamination and Ambient Radiation Dose Rate	VI-28
R10	64E-5.622	Release of Patients or Human Research Subjects Treated with Radiopharmaceuticals, Implants, or Remote Afterloader Units	VI-29
	64E-5.623	Storage of Volatiles and Gases	VI-30
R10	64E-5.624	Decay in Storage	VI-30
R10	64E-5.625	Safety Instruction and Precautions for Liquid Iodine Radiopharmaceutical Therapy, Manual Brachytherapy, Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery	VI-31
R10	64E-5.6251	Therapy Related Computer Systems	VI-34

SUBPART C UPTAKE, DILUTION, AND EXCRETION

R10	64E-5.626	Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies	VI-35
-----	-----------	--	-------

SUBPART D IMAGING AND LOCALIZATION

R10	64E-5.627.....	Use of Unsealed Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.....	VI-26
R10	64E-5.628.....	Generators	VI-39
R10	64E-5.629.....	Control of Aerosols and Gases	VI-41

SUBPART E RADIOPHARMACEUTICALS FOR THERAPY

R10	64E-5.630.....	Use of Radiopharmaceuticals for Therapy	VI-42
-----	----------------	---	-------

SUBPART F SEALED SOURCES FOR DIAGNOSIS

R10	64E-5.631.....	Use of Sealed Sources for Diagnosis.....	VI-44
-----	----------------	--	-------

SUBPART G SOURCES FOR BRACHYTHERAPY

R10	64E-5.632.....	Use of Sources for Manual Brachytherapy.....	VI-45
R10	64E-5.633.....	Manual Brachytherapy Sources Inventory and Surveys.....	VI-46
R10	64E-5.6331.....	Calibration Measurements of Manual Brachytherapy Systems	VI-47
R10	64E-5.6332.....	Decay of Strontium-90 Sources for Ophthalmic Treatments	VI-47

R10

SUBPART H PHOTON EMITTING**REMOTE AFTERLOADER UNITS, THERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

R10	64E-5.634	Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.....	VI-48
R10	64E-5.635	Installation, Adjustment, Maintenance and Repair Restrictions.....	VI-49
R10	64E-5.636	Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units	
R10	64E-5.637	Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units	VI-51
R10	64E-5.638	Radiation Monitoring Devices.....	VI-52
R10	64E-5.639	Viewing Systems	VI-53
R10	64E-5.640	Dosimetry Equipment Used With Remote Afterloading Units, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units	VI-53
R10	64E-5.641	Full Calibration Measurements On Teletherapy Units.....	VI-54
R10	64E-5.6411	Full Calibration Measurements On Remote Afterloader Units.....	VI-56
R10	64E-5.6412	Full Calibration Measurements On Gamma Stereotactic Radiosurgery Units.....	VI-57
R10	64E-5.642	Periodic Spot-Checks of Teletherapy Units.....	VI-59
R10	64E-5.6421	Periodic Spot-Checks for Remote Afterloader Units	VI-61
R10	64E-5.6422	Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.....	VI-62
R10	64E-5.6423	Additional Technical Requirements for Mobile Remote Afterloader Units	VI-65
R10	64E-5.643	Radiation Surveys for Teletherapy Facilities	VI-66
R10	64E-5.644	Radiation Surveys for Remote Afterloader and Gamma Stereotactic Radiosurgery Facilities	VI-67
R10	64E-5.645.....	Therapy-Related Computer Systems	VI-68
	64E-5.646	Reports of Teletherapy Surveys, Checks, Tests, and Measurements.....	VI-68
R10	64E-5.647	Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units	VI-86

SUBPART I TRAINING AND EXPERIENCE REQUIREMENTS

R10	64E-5.648	Radiation Safety Officer	VI-69
R10	64E-5.649	Training for Uptake, Dilution, or Excretion Studies	VI-72
R10	64E-5.650	Training for Imaging and Localization Studies for Which a Written Directive is Not Required	VI-73
R10	64E-5.651	Repealed (See Rules 64E-5.660, 64E-5.661, 64E-5.662 & 64E-5.663).....	VI-75
R10	64E-5.652	Training for Therapeutic Use of Manual Brachytherapy Sources	VI-75
R10	64E-5.653	Training for Ophthalmic Use of Strontium 90	VI-77
R10	64E-5.654	Training for Use of Sealed Sources for Diagnosis.....	VI-78
R10	64E-5.655	Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units	VI-79
R10	64E-5.656	Training for an Authorized Medical Physicist.....	VI-81
R10	64E-5.657	Training for Experienced RSO, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.....	VI-83
R10	64E-5.658	Recentness of Training	VI-83
R10	64E-5.660	Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required in Rules 64E-5.626, 64E-5.627 or 64E-5.630	VI-86
R10	64E-5.661	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries)	VI-88
R10	64E-5.662	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries)	VI-90
R10	64E-5.663	Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.....	VI-91

R10	SUBPART J MEDICAL USES OR RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL
-----	--

R10	64E-5.664	Other Medical Uses of Radioactive Material or Radiation From Radioactive Material	VI-94
-----	-----------	--	-------

PART VI

USE OF RADIONUCLIDES IN THE HEALING ARTS

64E-5.601 License Required.

- R10 (1) Radioactive materials shall not be manufactured, produced, acquired, received, possessed, prepared, used, or transferred for medical use except as provided in a specific license.
- (2) Any licensee who is licensed for one or more of the medical uses in Rule 64E-5.626, 64E-5.627, 64E-5.630, or 64E-5.632, F.A.C., also is authorized to use radioactive material under a general license in subsection 64E-5.206(8), F.A.C., for specified in vitro uses without filing the certificate required by paragraph 64E-5.206(8)(b), F.A.C., but is subject to the other provisions of subsection 64E-5.206(8), F.A.C.
- R10 (3) (a) Unless prohibited by license condition, a physician in training may receive, R10 possess, acquire, prepare, use, or transfer radioactive materials as R10 provided in these regulations under the supervision of an authorized user R10 as provided in subsections 64E-5.608(1) and 64E-5.608(3), F.A.C.
- R10 (b) Current and active certified radiologic technologists as authorized in Part R10 IV Chapter 468, F.S., may receive, possess, acquire, prepare, use, or R10 transfer radioactive materials as provided in these regulations under the R10 supervision of an authorized user as provided in paragraph R10 64E-5.607(3)(e) and subsection 64E-5.608(3), F.A.C.
- R10 (c) Unless prohibited by license condition, a medical physicist in training may R10 receive, acquire, prepare, use, possess, or transfer radioactive materials R10 as provided in these regulations under the supervision of an authorized R10 medical physicist as provided in subsections 64E-5.608(2) and R10 64E-5.608(3), F.A.C.
- R10 (4) Unless authorized by the department, no individual shall manufacture, produce, R10 acquire, receive, possess, prepare, use, or transfer radioactive materials for medical use unless:
- R10 (a) That individual is listed on the licensee's specific license as an authorized R10 user, authorized medical physicist, or an authorized nuclear pharmacist;
- (b) Authorized by Rule 64E-5.609, F.A.C.;
- (c) Authorized by subsection 64E-5.601(2), F.A.C., with approval of the radiation safety committee at medical institutions or by management for licensees that are not medical institutions; or
- R10 (d) That individual is in training, authorized by subsection 64E-5.601(3), F.A.C., and subpart I of Part VI.

- R10 (5) Provisions for the protection of human research subjects are:
- R10 (a) A licensee may conduct research involving human research subjects only
R10 if it uses the radioactive materials specified on its license for the uses
R10 authorized on its license.
- R10 (b) If the research is conducted, funded, supported, or regulated by another
R10 federal agency that has implemented the “Federal Policy for the
R10 Protection of Human Subjects (Federal Policy)”, as described in 45 CFR
R10 Part 46, dated 11/9/2009, which is herein incorporated by reference, and
R10 may be accessed at <http://www.doh.state.fl.us/environment/radiation/>, or
R10 requested in writing from the Department of Health, Bureau of Radiation
R10 Control, Bin C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741,
R10 the licensee shall, before conducting research:
- R10 1. Obtain review and approval of the research from an “Institutional
R10 Review Board (IRB),” as defined and described in the Federal
R10 Policy; and
- R10 2. Obtain “informed consent,” as defined and described in the Federal
R10 Policy, from the human research subject.
- R10 (c) If the research will not be conducted, funded, supported, or regulated by
R10 another federal agency that has implemented the Federal Policy, the
R10 licensee shall, before conducting research, apply for and receive a specific
R10 amendment to its radioactive materials medical use license. The
R10 amendment request must include a written commitment that the licensee
R10 will, before conducting research:
- R10 1. Obtain review and approval of the research from an IRB as defined and
R10 described in the Federal Policy; and
- R10 2. Obtain “informed consent”, as defined and described in the Federal
R10 Policy, from the human research subject.
- R10 (d) Nothing in this section relieves licensees from complying with the other
R10 requirements in this part.
- R10 (6) Authorized nuclear pharmacists must be actively licensed as a nuclear
R10 pharmacist by the Department of Health, Division of Medical Quality Assurance
R10 as specified in Rule 64B16-28.903, F.A.C., and authorized medical physicists
R10 must have an active medical physicist license, in the area they are practicing,
R10 issued by the Department of Health, Division of Medical Quality Assurance.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.707, Amended 8-6-01, Amended 02-11-10.

R10 **64E-5.6011 Definitions. (Entire section New)**

R10 (1) "Authorized medical physicist" means an individual who meets the requirements:

R10 (a) Specified in subsection 64E-5.656(1) and Rule 64E-5.658, F.A.C.; or

R10 (b) Is identified as an authorized medical physicist or teletherapy physicist on:

R10 1. A specific medical use license issued by the NRC or an agreement
R10 state;

R10 2. A medical use permit issued by a NRC master material licensee;

R10 3. A permit issued by a NRC or agreement state broad scope medical
R10 use licensee; or

R10 4. A permit issued by a NRC master material license broad scope
R10 medical use permittee.

R10 (2) "Authorized user" means:

R10 (a) A physician who meets the requirements in Rule 64E-5.658 and
R10 subsection 64E-5.549(1), 64E-5.550(1), 64E-5.660(1), 64E-5.661(1),
R10 64E-5.662(1), 64E-5.652(1), 64E-5.654(1) or 64E-5.655(1), F.A.C.; or

R10 (b) An individual identified for medical use of radioactive materials on:

R10 1. A NRC or agreement state license that authorizes the medical use
R10 of radioactive material;

R10 2. A permit issued by a NRC master material licensee that is
R10 authorized to permit the medical use of radioactive material;

R10 3. A permit issued by a NRC or agreement state specific licensee of
R10 broad scope that is authorized to permit the medical use of
R10 radioactive material; or

R10 4. A permit issued by a NRC master material license broad scope
R10 permittee that is authorized to permit the medical use of
R10 radioactive material.

R10 (3) "Brachytherapy" means a method of radiation therapy in which sources are used
R10 to deliver a radiation dose by surface, intracavitary, intraluminal or interstitial
R10 application.

R10 (4) "Brachytherapy source" means a radioactive source or a manufacturer-
R10 assembled source train or a combination of these sources that is designed to
R10 deliver a therapeutic dose within a distance of a few centimeters.

- R10 (5) "Diagnostic clinical procedures manual" means a collection of written procedures
R10 that describes each method by which the licensee shall perform diagnostic
R10 clinical procedures, and provides other instructions and precautions related
R10 thereto. Each diagnostic clinical procedure shall be approved by the authorized
R10 user and shall include the radiopharmaceutical, dosage, and route of
R10 administration.
- R10 (6) "High dose-rate remote afterloader," as used in this part, means a brachytherapy
R10 device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per
R10 hour at the point or surface where the dose is prescribed.
- R10 (7) "Low dose-rate remote afterloader," as used in this part, means a brachytherapy
R10 device that remotely delivers a dose rate of less than or equal to 2 gray
R10 (200 rads) per hour at the point or surface where the dose is prescribed.
- R10 (8) "Manual brachytherapy," as used in this part, means a type of brachytherapy in
R10 which the brachytherapy sources (e.g., seeds, ribbons) are manually delivered.
- R10 (9) "Medical use" means the intentional internal or external administration of
R10 radioactive material, or the radiation therefrom, to patients or humans research
R10 subjects under the supervision of an authorized user.
- R10 (10) "Medium dose-rate remote afterloader," as used in this part, means a
R10 brachytherapy device that remotely delivers a dose rate of greater than 2 gray
R10 (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the
R10 point or surface where the dose is prescribed.
- R10 (11) "Mobile medical service" means the ability to transport and use radioactive
R10 materials for medical use at the client's address.
- R10 (12) "Output" means the exposure rate, dose rate, or a quantity related in a known
R10 manner to these rates from a brachytherapy source or a teletherapy, remote
R10 afterloader, or gamma stereotactic radiosurgery unit for a specified set of
R10 exposure conditions.
- R10 (13) "Preceptor" means an individual who provides, directs, or verifies training and
R10 experience required for an individual to become an authorized user under
R10 Chapter 64E-5, Part VI, F.A.C., an authorized medical physicist, an authorized
R10 nuclear pharmacist or a RSO under Chapter 64E-5 Part VI, F.A.C.
- R10 (14) "Pulsed dose-rate remote afterloader," as used in this part, means a special type
R10 of remote afterloading brachytherapy device that uses a single source capable of
R10 delivering dose rates in the "high dose-rate" range, provided that the source is:
- R10 (a) Approximately one-tenth of the activity of typical high dose-rate remote
R10 afterloader sources; and
- R10 (b) Used to simulate the radiobiology of a low dose-rate treatment by inserting
R10 the source for a given fraction of each hour.

- R10 (15) "Radiation Safety Officer" or "RSO" means an individual who:
- R10 (a) Meets the requirements in subsection 64E-5.648(1) or paragraph
R10 64E-5.648(3)(a) and Rule 64E-5.658, F.A.C.; or
- R10 (b) Is identified as a RSO on a specific medical use license issued by the
R10 NRC or an agreement state or a medical use permit issued by a NRC
master material licensee.
- R10 (16) "Teletherapy physicist" means an individual identified as the qualified teletherapy
R10 physicist on a department license.
- R10 (17) "Therapeutic dosage" means a dosage of unsealed radioactive materials that is
R10 intended to deliver a radiation dose to a patient or human research subject for
R10 palliative or curative treatment.
- R10 (18) "Therapeutic dose" means a radiation dose delivered from a source containing
R10 radioactive materials to a patient or human research subject for palliative or
R10 curative treatment.
- R10 (19) "Treatment site" means the anatomical description of the tissue intended to
R10 receive a radiation dose, as described in a written directive.
- R10 (20) "Unit dosage" means a dosage prepared for medical use for administration as a
R10 single dosage to a patient or human research subject without any further
R10 manipulation of the dosage after it is initially prepared.

R10 Rulemaking Authority: 404.051, 404.061.

R10 Law Implemented: 404.031, 404.061(2), 404.20, 404.22, 404.30 FS.

R10 History: New 02-11-10.

64E-5.602 License Amendments. A licensee shall apply for and receive a license amendment or departmental approval:

- (1) Before using radioactive material for a method or type of medical use not permitted by the license;
- R10 (2) Before permitting anyone, except a visiting authorized user, visiting authorized
R10 medical physicist, or visiting authorized nuclear pharmacist described in Rule
R10 64E-5.609, F.A.C., to work as an authorized user, authorized nuclear pharmacist,
R10 or authorized medical physicist.
- R10 (3) Before changing a RSO or authorized medical physicist;
- R10 (4) Before ordering or receiving radioactive material in excess of the amount, in a
R10 different form, or receiving a different radionuclide than is authorized on the
license;
- (5) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

- (6) Before changing statements, representations, and procedures which are incorporated into the license.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.708, Amended 02-11-10.

- R10 **64E-5.603 Notification. (Entire section Changed)** A licensee shall notify the
 R10 department in writing within 30 days when the licensee changes its mailing address or when an
 R10 authorized user, RSO, authorized nuclear pharmacist, or authorized medical physicist
 R10 permanently discontinues performance of their duties under the licensee.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.709, Amended August 6, 2001, Amended 02-11-10.

SUBPART A

GENERAL ADMINISTRATIVE REQUIREMENTS

64E-5.604 ALARA Program.

- (1) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable as provided in Rule 64E-5.303, F.A.C.
- (2) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the radiation safety committee.
- R10 (3) For licensees that are not required to have a radiation safety committee, medical
 R10 institutions, management and all authorized users shall participate in the program
 R10 as required by the RSO.
- R10 (4) The ALARA program shall include an annual review by the radiation safety
 R10 committee for medical licensees required to have a radiation safety committee, or
 R10 by management and the RSO for licensees that are not required to have a
 R10 radiation safety committee. The review shall include summaries of the types,
 amounts and purposes of radioactive material used; occupational dose reports;
 and continuing education and training of all personnel who work with or in the
 vicinity of radioactive material. The purpose of the review is to ensure that
 individuals make every reasonable effort to maintain occupational doses, doses
 to the general public, and releases of radioactive material as low as reasonably
 achievable, taking into account the state of technology and the cost of
 improvements in relation to benefits.

- (5) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:
- (a) A commitment by management to keep occupational doses as low as reasonably achievable;
 - (b) A requirement that the radiation safety officer annually report to management in writing on the radiation safety program; and
 - (c) Categories of personnel exposure levels that, when exceeded, will initiate investigation by the radiation safety officer of the cause of the exposure and actions taken to reduce the probability of recurrence.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.710, Amended 02-11-10.

64E-5.605 Radiation Safety Officer.

- R10 (1) A licensee shall appoint a RSO who agrees in writing to be responsible for
R10 implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are performed with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive materials program.
- (2) The radiation safety officer shall promptly investigate and implement corrective actions as necessary regarding:
- (a) Overexposures;
 - (b) Accidents;
 - (c) Spills;
 - (d) Losses;
 - (e) Thefts;
 - (f) Unauthorized receipts, uses, transfers, and disposals; and
 - (g) Other deviations from approved radiation safety practice. A written report of these investigations and the corrective actions taken shall be given to management.
- (3) The radiation safety officer shall implement written policies and procedures to:
- (a) Authorize the purchase of radioactive material;
 - (b) Receive and open packages of radioactive material;
 - (c) Store radioactive material;

- (d) Keep an inventory record of radioactive material;
 - (e) Use radioactive material safely;
 - (f) Take emergency action if control of radioactive material is lost;
 - (g) Perform periodic radiation surveys;
 - (h) Perform checks of survey instruments and other safety equipment;
 - (i) Dispose of radioactive material;
 - (j) Train personnel who work in or frequent areas where radioactive material is used or stored; and
 - (k) Keep a copy of all records and reports required by department regulations, a copy of these regulations, a copy of each licensing request and license including amendments, and the written policies and procedures required by the regulations.
- (4) The radiation safety officer shall approve radiation safety program changes for medical use not at a medical institution with the consent of management prior to sending to the department for licensing action.
- (5) The radiation safety officer shall assist the radiation safety committee for medical use at a medical institution.
- R10 (6) The RSO shall review, sign and date, at least every 3 months the occupational radiation exposure records of all personnel working with radioactive material.
- R10 (7) The licensee shall retain a copy of both authority, duties, and responsibilities of the RSO and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program for the duration of the license. The records must include the signature of the RSO and licensee management.
- R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
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, F.S.
R10 History: New 8-25-91, Formerly 10D-91.711, Amended 02-11-10.

- R10 **64E-5.606 Radiation Safety Committee.**
- R10 (1) Each license listed below shall establish a radiation safety committee to oversee
R10 the use of radioactive materials;
- R10 (a) Medical institutions as defined in Rule 64E-5.101, F.A.C.; or
- R10 (b) Other licenses authorized for any of the following medical uses:
- R10 1. Subsection 64E-5.627(2), F.A.C., and any subsection of
R10 Rule 64E-5.632 or 64E-5.634, F.A.C.;
- R10 2. Subsection 64E-5.627(3), F.A.C., and any subsection of
R10 Rule 64E-5.632 or 64E-5.634, F.A.C.;
- R10 3. Subsection 64E-5.627(4), F.A.C., and any subsection of
R10 Rule 64E-5.632 or 64E-5.634, F.A.C.;
- R10 4. Any subsection of Rule 64E-5.630, F.A.C., and any
R10 subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;
- R10 5. Subsections 64E-5.634(1) and 64E-5.634(2), F.A.C.;
- R10 6. Subsections 64E-5.634(1) and 64E-5.634(3), F.A.C.; or
- R10 7. Subsections 64E-5.634(2) and 64E-5.634(3), F.A.C.
- R10 (2) Membership of the radiation safety committee shall include an authorized user of
R10 each type of use permitted by the license, the RSO, a representative of the
R10 nursing service, and a representative of management who is neither an
R10 authorized user nor a RSO. Other members who are experienced in the assay of
R10 radioactive material and protection against radiation, such as an authorized
R10 medical physicist or a nuclear medicine technologist employed by or working
R10 under contract with the institution may be included as appropriate.
- R10 (3) The committee shall meet at least every 6 months. To establish a quorum and to
R10 conduct business, one-half of the committee's membership shall be present,
R10 including the RSO, or designee and the management representative, or
R10 designee.
- R10 (4) The minutes of each radiation safety committee meeting shall include:
- R10 (a) The date of the meeting;
- R10 (b) Members present;
- R10 (c) Members absent;
- R10 (d) Summary of deliberations and discussions;
- R10 (e) Recommended actions and the numerical results of all ballots; and
- R10 (f) Documentation of any reviews required in Rules 64E-5.604 and
R10 64E-5.606, F.A.C.

- R10 (5) The committee shall provide each member with a copy of the meeting minutes and shall retain a copy for 5 years or until the department authorizes its disposition.
- R10 (6) The committee shall be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable.
- R10 (7) The committee shall review and approve any individual to be an authorized user, an authorized nuclear pharmacist, the RSO, or an authorized medical physicist based on safety and the training and experience standards of this part before sending a license application or request for amendment or renewal.
- R10 (8) The committee shall review and approve each proposed method of use of radioactive material based on safety.
- R10 (9) The committee shall review and approve procedures and radiation safety program changes based on safety and with the advice of the RSO and the management representative prior to sending to the department for licensing action.
- R10 (10) The committee shall review occupational radiation exposure records of all personnel working with radioactive material and all incidents involving radioactive material at least every 6 months, with the assistance of the RSO, to determine cause and review subsequent actions taken.
- R10 (11) The committee shall review the radioactive materials program at least every 12 months with the assistance of the RSO as described in subsection 64E-5.604(4), F.A.C.
- R10 (12) The committee shall establish levels for occupational dose that will result in investigations and considerations of action by the RSO when exceeded.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.712, Amended 8-6-01, Amended 02-11-10.

64E-5.607 Authority and Responsibilities.

- (1) A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:
- (a) Identify radiation safety problems;
 - (b) Initiate, recommend, or provide solutions; and
 - (c) Require and verify implementation of corrective actions.
- (2) A licensee shall establish in writing and keep current the authority, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.
- (3) Authorized users shall have the following special responsibilities:

- R10 (a) For written directives;
- R10 1. A written directive must be dated and signed by an authorized user
R10 before the administration of I-131 as sodium iodide greater than
R10 1.11 megabecquerels (MBq) (30 microcuries ([micro]Ci)), any
R10 therapeutic dosage of unsealed radioactive material or any
R10 therapeutic dose of radiation from material; or
- R10 2. Due to the emergent nature of the patient's condition, a delay in
R10 order to provide a written directive would jeopardize the patient's
R10 health, an oral directive is acceptable provided:
- R10 a. The information contained in the oral directive must be
R10 documented as soon as possible in writing in the patient's
R10 record; and
- R10 b. A written directive must be prepared within 48 hours of the
R10 oral directive.
- R10 3. The written directive must contain the patient or human research
R10 subject's name and the following information:
- R10 a. For any administration of quantities greater than 1.11 MBq
R10 (30 [micro]Ci) of sodium iodide I-131: the dosage;
- R10 b. For an administration of a therapeutic dosage of unsealed
R10 radioactive material other than sodium iodide I-131: the
R10 radioactive drug, dosage, and route of administration;
- R10 c. For gamma stereotactic radiosurgery: the total dose,
R10 treatment site, and values for the target coordinate settings
R10 per treatment for each anatomically distinct treatment site;
- R10 d. For teletherapy: the total dose, dose per fraction, number of
R10 fractions, and treatment site;

- R10 e. For high dose-rate remote afterloading brachytherapy: the
R10 radionuclide, treatment site, dose per fraction, number of
R10 fractions, and total dose; and
- R10 f. For all other brachytherapy;
- R10 (I) Before implantation: treatment site, the radionuclide,
R10 and dose; and
- R10 (II) After implantation but before completion of the
R10 procedure: the radionuclide, treatment site, number of
R10 sources, and total source strength and exposure time
R10 (or the total dose).
- R10 4. A written revision to an existing written directive may be made if the
R10 revision is dated and signed by an authorized user before the
R10 administration of the dosage of unsealed radioactive material, the
R10 brachytherapy dose, high dose remote afterloader dose, the
R10 gamma stereotactic radiosurgery dose, the teletherapy dose, or the
R10 next fractional dose; or
- R10 5. Due to the emergent nature of the patient's condition, a delay in
R10 order to provide a written directive would jeopardize the patient's
R10 health, an oral directive is acceptable provided:
- R10 a. The information contained in the oral directive must be
R10 documented as soon as possible in the patient's record; and
- R10 b. A written directive must be prepared within 48 hours of the
R10 oral directive.
- (b) Review personally the patient's case to assure that the therapeutic radiation procedure is appropriate;
- R10 (c) Review personally the patient's case or develop and implement adequate
R10 written procedures to assure that the diagnostic radiation procedure is
R10 appropriate.
- R10 (d) Prior to administration, the authorized user must document deviations
R10 from the diagnostic clinical procedures manual for each patient.
- (e) Use radioactive material or direct technologists and physicians in training in using radioactive material;
- (f) Interpret results of diagnostic procedures; and
- (g) Review regularly the progress of the patient receiving therapy and modify the originally prescribed dose if needed.
- R10 (4) The licensee shall retain a copy of the written directives specified in paragraph
R10 64E-5.607(3)(a), F.A.C., for three years.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.713, Amended 02-11-10.

64E-5.608 Supervision. (Entire section Changed)

- R10 (1) Supervision of a physician in training to become an authorized user:
- R10 (a) A licensee who permits the receipt, acquisition, possession, use,
R10 preparation, or transfer of radioactive material by a physician in training
R10 under the supervision of an authorized user as allowed by paragraph
R10 64E-5.601(3)(a), F.A.C., shall:
- R10 1. Instruct the supervised individual in the principles of radiation safety
R10 appropriate to that individual's use of radioactive material and in the
R10 licensee's written quality management program;
 - R10 2. Review the supervised individual's use of radioactive material,
R10 provide reinstruction as needed and review records kept to reflect
R10 this use;
 - R10 3. Require the preparation of radioactive materials use only under the
R10 supervision of an authorized user or authorized nuclear pharmacist;
 - R10 4. Require the authorized user to be immediately available to
R10 communicate with the supervised individual; and
 - R10 5. Require that only those individuals specifically designated by the
R10 authorized user be permitted to administer radionuclides or
R10 radiation to patients.
- R10 (b) A licensee shall require the supervised individual receiving, possessing,
R10 acquiring, preparing, using or transferring radioactive material specified in
R10 paragraph 64E-5.601(3)(a), F.A.C., to:
- R10 1. Follow the instructions of the supervising authorized user;
 - R10 2. Follow the written radiation and quality management program
R10 procedures established by the licensee; and
 - R10 3. Comply with these regulations and the license conditions regarding
R10 the use of radioactive material.
- R10 (c) The licensee's management or radiation safety committee shall provide
R10 written approval prior to any training of a physician to receive, acquire,
R10 prepare, possess or use radioactive material under the supervision of an
R10 authorized user. After the training has been completed, the licensee shall
R10 provide documentation to the supervised individual that the individual
R10 received the training and experience required by this section. The
R10 licensee shall maintain records that identify physicians currently in training
R10 and the physicians who have completed training for 7 years after the last
R10 date training was received; and

- R10 (2) Supervision of an individual in training to become an authorized medical
R10 physicist:
- R10 (a) A licensee who permits the receipt, preparation, acquisition, possession,
R10 use, or transfer of radioactive material to an individual in training under the
R10 supervision of an authorized medical physicist as allowed by paragraph
R10 64E-5.601(3)(c), F.A.C., shall:
- R10 1. Instruct the supervised individual in the principles of radiation safety
R10 appropriate to that individual's use of radioactive material and in the
R10 licensee's written quality management program;
 - R10 2. Review the supervised individual's use of radioactive material,
R10 provide reinstruction as needed and review records kept to reflect
R10 this use; and
 - R10 3. Require the authorized medical physicist to be immediately
R10 available to communicate with the supervised individual.
- R10 (b) A licensee shall require the supervised individual receiving, acquiring or
R10 preparing, possessing, using or transferring radioactive material specified
R10 in paragraph 64E-5.601(3)(c), F.A.C., to:
- R10 1. Follow the instructions of the supervising authorized medical
R10 physicist;
 - R10 2. Follow the written radiation and quality management program
R10 procedures established by the licensee; and
 - R10 3. Comply with these regulations and the license conditions regarding
R10 the use of radioactive material.
- R10 (c) The licensee's management or radiation safety committee shall provide
R10 written approval prior to any individual to receive, possess or use
R10 radioactive material under the supervision of an authorized medical
R10 physicist. After the training has been completed, the licensee shall
R10 provide documentation to the supervised individual that the individual
R10 received the training and experience required by this section. The
R10 licensee shall maintain records that identify individuals currently in training
R10 and the individuals who have completed training for 7 years after the last
R10 date training was received.
- R10 (3) A licensee that permits any supervised activities regarding the use of radioactive
R10 materials or radiation from radioactive materials is responsible for the acts and
R10 omissions of the supervised individual.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.714, Amended 02-11-10.

R10 **64E-5.609 Visiting Authorized User, Visiting Authorized Medical Physicist, or**
 R10 **Visiting RSO.**

- (1) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:
- (a) The licensee has a copy of a license issued by the department, the NRC, or an agreement state that identifies the visiting authorized user by name as an authorized user for medical use; and
- (b) The visiting authorized user performs only those procedures for which he is specifically authorized by the license described in paragraph 64E-5.609(1)(b), F.A.C., above.
- (2) For up to 60 days each year, a licensee may permit an authorized medical physicist or an individual qualified under Rules 64E-5.656 and 64E-5.658, F.A.C., to function as a visiting authorized medical physicist as authorized by the license.
- (3) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a RSO, under Rules 64E-5.648 and 64E-5.658, F.A.C., to function as a visiting RSO and to perform the functions of a RSO, as provided in Rule 64E-5.605 and subsection 64E-5.607(1), F.A.C.
- (4) A license amendment is not needed to permit a visiting authorized user, visiting authorized medical physicist, or visiting RSO to use licensed material or perform functions in accordance with this section.
- (5) The visiting authorized user, visiting authorized medical physicist, or visiting RSO shall have the prior written permission of the licensee's management and, if the use or function occurs on behalf of a medical institution, the institution's radiation safety committee.
- (6) Licensee records shall include a copy of the record described in Rule 64E-5.657, F.A.C., or some other form of documentation that verifies the individual has met the perspective training and experience requirements listed in Subpart I. A licensee shall retain copies of the records specified in Rule 64E-5.609, F.A.C., for 3 years after the last visit.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.715, Amended 02-11-10.

R10 **64E-5.610 Mobile Medical Service Requirements.** The department shall license
R10 mobile **medical** services or clients of such services. The mobile **medical** service shall be
R10 licensed if the service receives, uses or possesses radioactive material. The client of the
R10 mobile **medical** service shall be licensed if the client receives or possesses radioactive material
R10 to be used by a mobile **medical** service.

- R10 (1) The mobile medical licensee shall obtain a letter signed by the management of
R10 each client for which services are rendered that permits the use of radioactive
R10 materials at the client's address and clearly delineates the authority and
R10 responsibility of the licensee and the client. A licensee providing mobile medical
R10 services shall retain this letter for 3 years after the provision of service.
- R10 (2) Mobile **medical** service licensees shall secure or keep under constant
surveillance and immediate control all radioactive material when in transit or at a
location of use.
- R10 (3) The mobile medical licensee shall check instruments used to measure the
R10 activity of unsealed or sealed radioactive materials for proper function before
R10 medical use at each client's address or on each day of use, whichever is more
R10 frequent. At a minimum, the check for proper function required by this paragraph
R10 must include a constancy check and shall perform all daily quality control tests on
R10 all equipment used to obtain images or information from radionuclide studies
before medical use at each location of use.
- R10 (4) Before leaving a client location, mobile **medical** service licensees shall perform a
R10 survey of all areas where radioactive materials are used with a radiation survey
R10 instrument in order to ensure that they have complied with the requirements in
R10 Rule 64E-5.621, F.A.C., that radiation dose rates are at background levels, and
R10 that removable contamination is below 2000 disintegrations per minute per 100
R10 square centimeters sampled. A licensee shall check each survey instrument for
R10 proper operation with a dedicated check source before each use at each
R10 location. The licensee is not required to keep records of these dedicated source
R10 survey instrument checks.
- R10 (5) Mobile **medical** service licensees shall retain a record of each survey required for
R10 3 years. The record must include the date of the survey, a **diagram** of each area
that was surveyed, the measured dose rate at several points in each area of use
in millirems (microsieverts) per hour, the model and serial number of the
instrument used to make the survey, and the initials of the individual who
performed the survey.
- R10 (6) A physician shall be on site at each client's address at the time **radioactive**
R10 **materials** are administered. An authorized user shall be immediately available to
R10 communicate with the supervised individuals or individuals under their direction.

- R10 (7) Radioactive material will be received at the permanent location of the mobile
R10 medical service or delivered directly to an authorized individual in the vehicle at a
R10 place of use. A mobile medical service may not have radioactive materials
R10 delivered from the manufacturer or the distributor to the client unless the client
R10 has a radioactive materials license allowing possession of the radioactive
R10 material. Radioactive material delivered to the client must be received and
R10 handled in conformance with the client's license.
- R10 (8) Restrooms contained in mobile vehicles shall not routinely be used by patients
R10 who have been administered radioactive material.
- R10 (9) Radioactive gases or aerosols shall not be used by mobile medical service
R10 licenses.
- R10 (10) Prior to administration, the mobile medical service licensee shall assure that
R10 individuals or human research subjects meet the patient release criteria specified
R10 in Rule 64E-5.622, F.A.C.
- R10 (11) A licensee authorized to use mobile remote afterloaders for medical use shall
R10 follow the requirements specified in Rule 64E-5.6423, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
 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, F.S.
 R10 History: New8-25-91, Formerly 10D-91.716, Amended 02-11-10.

64E-5.611 Quality Management Program and Notifications, Records and

R10 Reports of Medical Events.

- (1) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide a high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following objectives:
 - (a) Except where a delay to provide a written directive would jeopardize the patient's health as specified in paragraphs (b) and (c) of this section, a written directive is prepared prior to administration for the following:
 1. Any teletherapy radiation dose;
 2. Any gamma stereotactic radiosurgery radiation dose;
 3. Any brachytherapy radiation dose;
 - R10 4. Any administration of iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels);
 - R10 5. Any therapeutic administration of a radiopharmaceutical other than iodine 131 as sodium iodide; or
 - R10 6. Any high dose rate remote afterloader radiation dose.

- R10 (b) An oral directive is acceptable when a delay to provide a written directive would jeopardize the patient's health because of the emergent nature of the patient's condition. The information contained in the oral directive must be documented immediately in the patient's record and a written directive prepared within 48 hours of the oral directive.
- (c) An oral revision to an existing written directive is acceptable when a delay to provide a written revision to an existing written directive would jeopardize the patient's health. The oral revision must be documented immediately in the patient's record and a revised written directive must be signed by the authorized user within 48 hours of the oral revision.
- R10 (d) A written directive which changes an existing written directive can be made for any diagnostic or therapeutic procedure if the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, high dose rate remote afterloader dose, the teletherapy dose, or the next fractional dose.
- R10 (e) The patient's or human research subject's identity is verified by more than one method as the individual named in the written directive prior to administration;
- R10 (f) The final plans of treatment and related dose calculations, manually or computer generated, for brachytherapy, teletherapy, high dose rate remote afterloader, and gamma stereotactic radiosurgery agree with the respective written directives:
- R10 (g) Verify that any computer-generated calculations are correctly transferred into the consoles of therapeutic medical units authorized by Rule 64E-5.634, F.A.C.;
- R10 (h) Each administration agrees with the written directive; and
- R10 (i) Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.
- (2) The licensee shall develop procedures for and conduct a review of the quality management program including an evaluation of the following:
 - (a) A representative sample of patient administrations within the review period;
 - (b) All recordable events within the review period; and
 - R10 (c) All medical events within the review period to verify compliance with all aspects of the quality management program.
- (3) The review of the quality management program specified in (2) above shall be conducted at intervals not to exceed 12 months. A record of each review shall be maintained for inspection by the department in an auditable form for 3 years and shall include evaluations and findings of the review.

- (4) The licensee shall evaluate each of these reviews to determine the effectiveness of the quality management program and make modifications to meet the objectives in subsection 64E-5.611(1), F.A.C.
- (5) Within 30 days of discovery of each recordable event, the licensee shall:
- Assemble the relevant facts including the cause;
 - Identify any corrective action required to prevent recurrence;
 - Retain a record in an auditable form for 3 years of the relevant facts and any corrective action taken.
- (6) The licensee shall retain in an auditable form for 3 years each written directive and a record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required by subsection 64E-5.611(1), F.A.C.
- R10 (7) Each applicant for a new license shall submit to the department a quality management program as part of the application for a license and implement the program upon issuance of the license by the department.
- R10 (8) Each licensee shall maintain copies of the quality management program for the duration of the license.
- R10 (9) Each licensee shall submit and maintain records and reports of medical events as required by subsections 64E-5.345(4) and (5), F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.717, Amended 02-11-10.

64E-5.612 Suppliers. A licensee shall use for medical use only:

- Radioactive material manufactured, labeled, packaged, and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission;
- Generators and reagent kits that have been manufactured, labeled, packaged, and distributed as specified in an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration unless the kits are not subject to the Federal Food, Drug, and Cosmetics Act and the Public Health Services Act.
- Teletherapy sources manufactured and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the NRC; or
- Sealed sources or devices containing radioactive materials that are either:
 - Manufactured, labeled, packaged, and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the NRC; or
 - Noncommercially transferred from a medical use licensee authorized by Chapter 64E-5, Part VI, F.A.C., or equivalent medical use license issued by another agreement state or the NRC.

R10 **Rulemaking** Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
 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, F.S.
 R10 History: New 8-25-91, Formerly 10D-91.718, **Amended 02-11-10**.

SUBPART B GENERAL TECHNICAL REQUIREMENTS

64E-5.613 Quality Control of Diagnostic Instrumentation. Each licensee shall establish written quality control procedures for all equipment used to obtain images or information from radionuclide studies. The procedures shall be recommended by equipment manufacturers or be approved by the department. The licensee shall perform quality control as specified in written procedures and retain a copy of the quality control results for 3 years.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
 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, F.S.
 History: New 8-25-91, Amended 5-13-93, Formerly 10D-91.719.

R10 **64E-5.614 Possession, Use, Calibration, and Check of Dose Calibrators in the** R10 **Use of Unsealed Radiopharmaceuticals.**

- (1) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient **or human research subject**.
- R10 (2) A licensee shall check each dose calibrator before use each day of use, **or during an assigned shift for facilities operating continuously**, for constancy with a dedicated check source. The check shall be performed on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium 226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days. A record shall be made of each check, which shall include:
- (a) The model and serial number of the dose calibrator;
 - (b) The identity and decay corrected activity of the radionuclide contained in the check source;
 - (c) The date of the check;
 - (d) The activity measured;
 - (e) The percent error;
 - (f) The instrument settings; and
 - (g) The initials of the individual who performed the check.
- R10 (3) The licensee shall test each dose calibrator for accuracy at the time of installation and at least every 12 months. The test shall be completed by assaying at least two sealed sources containing different radionuclides, the activity of which has been determined by the National Institute of Standards and Technology **(NIST)** or by the manufacturer who has compared their source to a source calibrated by the **NIST**. The sources shall have a minimum activity of 10 microcuries (370 kBq) for radium 226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide. At least one of the sources shall have a principal photon energy between 100 kilo-electron volts and 500 kiloelectron volts. A record shall be made of each test, which shall include:

- (a) The model and serial number of the dose calibrator;
 - (b) The model and serial number of each source used and the identity of the radionuclide contained in the source and its activity;
 - (c) The date of the test;
 - (d) The results of the test;
 - (e) The instrument settings; and
 - R10 (f) The name of the individual performing this test.
- (4) The licensee shall test each dose calibrator for linearity at the time of installation and at least every 3 months over the range of use between 10 microcuries (370 kBq) and the highest dosage that will be administered. A record shall be made of each test, which shall include:
- (a) The model and serial number of the dose calibrator;
 - (b) The calculated activities;
 - (c) The measured activities;
 - (d) The date of the test; and
 - R10 (e) The name of the individual performing this test.
- (5) The licensee shall test each dose calibrator for geometry dependence at the time of installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator. A record shall be made of each test, which shall include:
- (a) The model and serial number of the dose calibrator;
 - (b) The configuration of the source measured;
 - (c) The activity measured and the instrument setting for each volume measured;
 - (d) The date of the test; and
 - R10 (e) The name of the individual performing this test.
- (6) A licensee shall correct mathematically dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

- (7) A licensee shall also perform checks and tests required by Rule 64E-5.614, F.A.C., following adjustment or repair of the dose calibrator.
- (8) A licensee shall retain a record of each check and test required by Rule 64E-5.614, F.A.C., for 3 years.

R10 (9) A licensee may calibrate instrumentation used in Rule 64E-5.614, F.A.C., using
 R10 nationally recognized standards or the manufacturer's instructions. The
 R10 standards or instructions used by the licensee must be available for inspection by
 R10 the department.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.720, Amended 02-11-10.

R10 **64E-5.615 Use, Calibration and Check of Survey Instruments.** A licensee shall
 R10 ensure that the survey instruments used to comply with this part have been calibrated before
 R10 first use, at least every 12 months, and after repair.

- R10 (1) A record shall be made of each calibration, which shall include:
- (a) A description of the source used;
 - (b) The certified dose rates from the source;
 - (c) The rates indicated by the instrument being calibrated;
 - (d) The correction factors deduced from the calibration data;
 - R10 (e) The name of the individual who performed the calibration;
 - (f) The date of calibration.
 - R10 (g) The model number and serial number of the instrument being calibrated;
 R10 and
 - R10 (h) The results of the calibration.
- (2) The licensee shall:
- (a) Calibrate all required scale readings up to 1,000 millirems (10 mSv) per hour with a radiation source;
 - (b) Calibrate each linear scale instrument at two points located approximately 1/3 and 2/3 of full-scale, calibrate each logarithmic scale instrument at midrange of each decade and at two points of at least one decade, and calibrate each digital instrument at appropriate points; and
 - R10 (c) Conspicuously note on the instrument the date of calibration.

- (3) The licensee shall:
 - (a) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and
 - (b) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent and a correction chart or graph is attached conspicuously to the instrument.
- (4) A licensee shall check each survey instrument for proper operation with a dedicated check source before each use. The licensee is not required to keep records of these checks.
- (5) The licensee shall retain a record of each calibration required in subsection 64E-5.615(1), F.A.C., for 3 years.
- (6) The licensee may use persons licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations required by subsection 64E-5.615(1), F.A.C., shall be maintained by the licensee.
- (7) A licensee authorized to use radioactive material for uptake, dilution, and excretion studies or sealed sources for diagnostic purposes shall possess a portable radiation survey instrument with a range from 0.1 millirem (1.0 μ Sv) per hour to at least 1,000 millirem (10 mSv) per hour.
- (8) A licensee authorized to use radioactive material for imaging and localization studies, radiopharmaceutical therapy or implant therapy shall possess portable radiation survey instruments with a range from 0.1 millirem (1.0 μ Sv) per hour to at least 1,000 millirem (10 mSv) per hour.
- (9) A licensee authorized to use radioactive material in Rule 64E-5.634, F.A.C., shall possess a radiation survey instrument as described in subsection (7) or (8), above.
- (10) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.
- (11) A licensee may calibrate instrumentation used in Rule 64E-5.615, F.A.C., using nationally recognized standards or the manufacturer's instructions. The standards or instructions used by the licensee must be available for inspection by the department

R10 Rulemaking Authority: 404.051, 404.061 404.081, 404.141, F.S.
 Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.
 R10 History: New 8-2591, Amended 5-15-96, Formerly 10D-91.721, Amended 02-11-10.

R10 **64E-5.616 Determination of Dosages of Unsealed Radioactive Material for**
R10 **Medical Use.**

- R10 (1) The licensee shall determine by assay or direct measurement within 30 minutes
R10 before each radiopharmaceutical dosage and record the activity of each dosage
R10 before medical use. A record of the assay shall be made which shall include:
- (a) The generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number; expiration date; and the radionuclide;
 - R10 (b) The patient's or human research subject's name or identification number if one has been assigned;
 - (c) The prescribed dosage and activity of the dosage at the time of assay or a notation that the total activity assayed is less than 10 microcuries (370 kBq);
 - (d) The date and time of the assay and administration; and
 - R10 (e) The name of the individual who performed the assay.
- R10 (2) Unless directed by the authorized user, a licensee may not use a dosage if the
R10 dosage does not fall within the prescribed dosage range or if the dosage differs
R10 from the prescribed dosage by more than 20 percent.
- R10 (3) A licensee shall retain a record of the assays listed in Rule 64E-5.616, F.A.C., for
R10 3 years.

R10 **Rulemaking** Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
R10 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, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.722, Amended 02-11-10.

R10 **64E-5.617 Authorization for Calibration, Transmission and Reference Sources.**
R10 Any person authorized by Rule 64E-5.601, F.A.C., for medical use of radioactive material may
R10 receive, possess, and use the following radioactive material for check, calibration, transmission
and reference use:

- R10 (1) Sealed sources that:
- R10 (a) Do not exceed 1.11 GBq (30 mCi) each, manufactured and distributed by
R10 a person licensed by the department, the NRC, an agreement state; or
 - R10 (b) Do not exceed 1.11 GBq (30 mCi) each, which are redistributed by a
R10 licensee that is authorized to redistribute sealed sources that are
R10 manufactured and distributed by a person licensed by the department, the
R10 NRC, or an agreement state, provided the redistributed sealed sources
R10 are in the original packaging and shielding, and are accompanied by the
R10 manufacturer's approved instructions;
- R10 (2) Any radioactive material with a half-life of 120 days or less in individual amounts
not to exceed 15 millicuries (555 MBq) each;

- R10 (3) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and
- R10 (4) Unless approved by the department, the maximum possession limit of radioactive materials described in subsections 64E-5.617(1), (2) and (3), F.A.C., above, shall not exceed a combined activity of 1 curie (37 GBq), This includes radioactive materials as waste in storage.
- R10 (5) Unless approved by the department, the maximum possession limit for Technetium 99m in individual amounts shall not exceed 300 millicuries (11.1 GBq) each and a combined activity of 900 millicuries (33.3 GBq).

R10 Rulemaking Authority: 404.051, 404.061, 404.141, F.S.

R1 Law Implemented: 404.051(1)(4)(6)(10), 404.061(2), 404.141, F.S.

R10 History: New 8-25-91, Formerly 10D-91.723, Amended 5-18-98, Amended 02-11-10.

64E-5.618 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

- (1) A licensee who possesses any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the department and shall maintain the instructions for the duration of source use in a legible form and convenient to users.
- (2) A licensee in possession of a sealed source shall assure that:
 - (a) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and
 - (b) The source is tested for leakage at least every 6 months or at intervals approved by the department, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.
 - (c) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample, or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) each 24 hours;
 - (d) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and
 - (e) Teletherapy and other device source samples are taken when the source is in the off position.
 - (f) Leak tests are analyzed by individuals who are licensed by the department, U.S. Nuclear Regulatory Commission, an agreement state or licensing state to perform leak test services.

- R10 (3) A licensee shall retain leak test records for 3 years. The records shall contain the model number and serial number if assigned of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), the date of the test, and the name of the individual who performed the test analysis..
- (4) If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:
- (a) Immediately withdraw the sealed source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with these regulations; and
- R10 (b) File a written report with the department within 5 days of receiving the leak test results describing the equipment involved, the test results, the action taken, the model number and serial number or the leaking source if assigned, the radioisotope and its estimated activity, and the date of the test.
- R10
- R10
- R10
- (5) A leak test is not required on the following sources:
- (a) Sources containing only radioactive material with a half-life of less than 30 days;
- (b) Sources containing only radioactive material as a gas;
- (c) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; and
- (d) Seeds of iridium 192 encased in nylon ribbon.
- (6) Leak tests are not required on calibration and reference sources stored and not being used. The licensee shall, however, clearly indicate on the inventory records that these sources are for storage only and the date placed in storage. The licensee shall test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.
- (7) Leak tests are not required on brachytherapy and teletherapy sources that are listed on a department license for storage only. The licensee shall test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

- R10 (8) A licensee who possesses sealed sources or brachytherapy sources, except
 R10 gamma stereotactic radiosurgery sources, shall conduct a physical inventory of
 R10 all such sources at intervals not to exceed six months. The licensee shall retain
 each inventory record for 3 years. The inventory records shall contain the model
 number of each source and serial number if one has been assigned, the identity
 of each source radionuclide and its estimated activity, the location of each
 R10 source, the date of the inventory, and the name of the individual who performed
 R10 the inventory.
- (9) A licensee who possesses a sealed source or brachytherapy source shall survey
 all areas where such sources are stored with a radiation survey instrument at
 least every 3 months. This does not apply to teletherapy sources in teletherapy
 units or sealed sources in diagnostic devices.
- (10) A licensee shall retain a record of each survey required in subsection
 64E-5.618(9), F.A.C., for 3 years. The record shall include the date of the
 survey, a sketch of each area that was surveyed, the measured dose rate at
 several points in each area expressed in millirems (microsieverts) per hour, the
 model number and serial number of the survey instrument used to make the
 R10 survey, and the name of the individual who performed the survey.
- R10 (11) Sealed sources designated as radioactive waste and held for decay in storage as
 R10 in Rule 64E-5.624, F.A.C., are not required to be leak tested or inventoried as
 R10 required by this section.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.724, Amended 02-11-10.

64E-5.619 Syringe Shields and Labels.

- (1) A licensee shall keep syringes that contain radioactive material to be
 administered in a radiation shield. Each individual who prepares or administers
 radiopharmaceuticals shall use a syringe radiation shield unless the use of the
 shield is contraindicated for that patient.
- (2) Unless used immediately, a licensee shall label conspicuously each syringe or
 syringe radiation shield that contains a syringe with a radiopharmaceutical with
 the patient's name or the radiopharmaceutical name or its abbreviation and the
 type of diagnostic study or therapy procedure to be performed.

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

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

History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.725.

64E-5.620 Vial Shields and Labels. A licensee shall require each individual
 preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial
 radiation shield and conspicuously label each vial with the radiopharmaceutical name or its
 abbreviation.

Specific Authority: 404.022, 404.051, 404.061, 404.081, 404.141, F.S.

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

History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.727.

64E-5.621 Surveys for Contamination and Ambient Radiation Dose Rate.

- R10
- (1) A licensee shall survey with a radiation survey instrument at the end of each day of use, or during an assigned shift for facilities operating continuously, all areas where radiopharmaceuticals are routinely prepared for use or administered.
 - (2) A licensee shall survey all areas where radiopharmaceuticals or radioactive wastes are stored with a radiation survey instrument at least once each week.
 - (3) A licensee shall conduct the surveys required by subsections 64E-5.621(1) and (2), F.A.C., with an instrument capable of measuring dose rates as low as 0.1 millirem (1 μ Sv) per hour.
 - (4) A licensee shall establish dose rate action levels for the surveys required by subsections 64E-5.621(1) and (2), F.A.C., and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.
 - (5) A licensee shall perform a wipe survey for removable contamination weekly of all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.
 - (6) A licensee shall analyze the wipe surveys required by subsection 64E-5.621(5), F.A.C., with an instrument capable of detecting contamination of 2,000 disintegrations per minute (33.3 Bq) or shall monitor each wipe sample in a low background area with a radiation survey instrument using a probe with a maximum window thickness of 2.0 mg/cm² and a minimum probe diameter of 1.5 inches.
 - (7) A licensee shall establish removable contamination action levels for the wipe surveys required by subsection 64E-5.621(5), F.A.C., and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.
 - (8) A licensee shall retain a record of each survey required by subsection subsections 64E-5.621(1), (2), and (5), F.A.C., for 3 years. The record shall include:
 - R10 (a) The date of the survey;
 - (b) A diagram of each area surveyed;
 - (c) Action levels established for each area;
 - (d) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, or counts per minute if performed with a radiation survey instrument as described in subsection 64E-5.621(6), F.A.C.;
 - (e) The serial number and the model number of the instrument used to make the survey or analyze the samples; and
 - R10 (f) The name of the person who performed the survey.

R10 (9) The licensee does not need to perform the radiation surveys in subsection
 R10 64E-5.621(1) or (2), F.A.C., in areas where patients or human research subjects
 R10 are currently confined when such patients or subjects cannot be released under
 R10 Rule 54E-5.622, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 04.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.729, Amended 02-11-10.

R10 **64E-5.622 Release of Patients or Human Research Subjects Treated with**
 R10 **Radiopharmaceuticals, Implants or Remote Afterloader Units.**

- R2 (1) Except as authorized by subsection 64E-5.622(4), F.A.C., 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 μ Sv) per hour at a distance of 1 meter; or
- (b) The activity in the patient is less than 30 millicuries (1.11 GBq).
- R2 (2) Except as authorized by subsection 64E-5.622(4), F.A.C., 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 μ Sv) per hour at a distance of 1 meter.
- (3) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation survey instrument to confirm that all sources have been removed. The licensee shall not release a patient treated by temporary implant from confinement for medical care until all sources have been removed.
- R2 (4) Licensees and license applicants whose proposed procedures to release
 R2 individuals who have been administered radiopharmaceuticals or permanent
 R2 implants containing radioactive material from the control of licensees differ from
 R2 those specified in subsections (1) and (2), above, must submit their proposed
 R2 procedures to the department for approval. The procedures must:
- (a) 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 μ Sv);
- (b) Contain a copy of the instructions including written instructions to be given to the released individual, or the individual's parent or guardian, 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 μ Sv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1 μ Sv) 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.

R2 (c) Specify that the licensee shall maintain a record of the basis for
 R2 authorizing the release of an individual from their control who has been
 R2 administered radiopharmaceuticals or permanent implants containing
 R2 radioactive material for 3 years after the date of release.

R2 (5) A licensee shall maintain a record of patient surveys which demonstrates
 R10 compliance with subsections 64E-5.622(3) and (6), F.A.C., 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
 R10 within 1 meter from the patient, and the initials of the individual who performed
 the survey.

R10 (6) Before releasing a patient or human research subject from licensee control, a
 R10 licensee shall survey the patient or the human research subject and the remote
 R10 afterloader unit with a portable radiation detection survey instrument to confirm
 R10 that the source(s) has been removed from the patient or human research subject
 R10 and returned to the safe shielded position.

R10 Rulemaking Authority: 404.051, 404.061, 404.081, 404.141, F.S.

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

R10 History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.730, Amended 10-8-00, Amended 02-11-10.

64E-5.623 Storage of Volatiles and Gases. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container or an equivalent shield and container. A licensee shall store and use a multidose container in a properly functioning fume hood.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

History: New 8-25-91, Formerly 10D-91.731.

64E-5.624 Decay In Storage.

- R10 (1) A licensee shall hold radioactive material with a physical half life of less than
 R10 120 days for decay in storage before disposal as ordinary trash. A licensee is
 R10 exempt from the requirements of paragraph 64E-5.331(1)(c), F.A.C., of these
 regulations if:
- (a) The radioactive material is held for decay a minimum of 10 half-lives;
 - (b) The radioactive material is monitored at the container surface before disposal as ordinary trash and its radioactivity cannot be distinguished from the background radiation level in a low background radiation area with a radiation survey instrument set on its most sensitive scale and with no interposed shielding;
 - (c) All radiation labels are removed or obliterated; and
 - (d) Each generator column is separated and monitored individually with all radiation shielding removed to ensure that its contents have decayed to background radiation levels before disposal.

- (2) The licensee shall retain a record of each disposal for 3 years. The record shall include:
- (a) The date of the disposal;
 - (b) The date on which the radioactive material was placed in storage;
 - (c) The radionuclides disposed;
 - (d) The model and serial number of the radiation survey instrument used;
 - (e) The background dose rate;
 - (f) The radiation dose rate measured at the surface of each waste container; and
 - (g) The name of the individual who performed the disposal.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.732, Amended 02-11-10.

64E-5.625 Safety Instructions and Precautions for Liquid Iodine,

R10 Radiopharmaceutical Therapy, Manual Brachytherapy, Remote Afterloader Units, R10 Teletherapy Units, and Gamma Stereotactic Radiosurgery.

- (1) A licensee shall provide oral and written radiation safety instructions to all personnel caring for patients or human research subjects, who cannot be released under Rule 64E-5.622, F.A.C., undergoing radiopharmaceutical therapy or manual brachytherapy. This training shall be provided initially prior to caring for patients and refresher training shall be provided at least every 12 months. The instruction shall describe the licensee's procedures for notification of the RSO and an authorized user in case of the patient's death or medical emergency.
- (2) The instruction for radiopharmaceutical therapy shall be commensurate with the duties of the personnel and describe the procedures for:
- (a) Patient or human research subject control;
 - (b) Visitor control, including:
 - 1. Routine visitation to hospitalized individuals in accordance with paragraph 64E-5.312(1)(a), F.A.C.; and
 - 2. Visitation authorized in accordance with subsection 63E-5.312(5), F.A.C.
 - (c) Contamination control; and
 - (d) Waste control.

- R10 (3) The instruction for manual brachytherapy shall be commensurate with the duties
R10 of the personnel and describe:
- (a) Size and appearance of the brachytherapy sources;
- R10 (b) Safe handling and shielding instructions;
- R10 (c) Procedures for patient or human research subject control; and
- R10 (d) Procedures for visitor control, including;
- R10 1. Routine visitation to hospitalized individuals in accordance with
R10 paragraph 64E-5.312(1)(a), F.A.C.; and
- R10 2. Visitation authorized in accordance with paragraph 64E-5.312(5),
R10 F.A.C.
- R10 (4) A licensee shall provide instruction for remote afterloader units, teletherapy units,
R10 and gamma stereotactic radiosurgery units as described in Rule 64E-5.636,
R10 F.A.C.
- R10 (5) A licensee shall keep a record of individuals receiving instruction required by
subsections (1), (2), (3), and (4) above, which includes a list of topics covered,
the date of instruction, and the name of the individual who gave the instruction.
Such record shall be maintained for inspection by the department for 3 years.
- R10 (6) A licensee shall take the following safety precautions for each patient or human
R10 research subject receiving manual brachytherapy or radiopharmaceutical therapy
R10 who cannot be released under Rule 64E-5.622, F.A.C.
- R10 (a) Post the patient's or human research subject's door with a "Caution:
Radioactive Material" sign and note on the door or on the patient's chart
where and how long visitors may stay in the patient's room.
- R10 (b) Measure promptly, after administration of the dosage, the dose rates in
contiguous restricted and unrestricted areas with a radiation measurement
survey instrument to demonstrate compliance with the requirements of
Rule 64E-5.312, F.A.C. Retain for 3 years a record of each survey that
includes the time and date of the survey, a plan of the area or list of points
surveyed, the measured dose rate at several points expressed in millirems
per hour, the instrument used to make the survey, and the initials of the
individual who made the survey.
- R10 (c) Provide the patient with radiation safety guidance before authorizing
release of the patient that will help to keep radiation dose to household
members and the public as low as reasonably achievable.
- R10 (d) Notify the RSO and an authorized user immediately if the patient dies or
has a medical emergency.

R10 (7) Individuals receiving radiopharmaceutical therapy shall be provided a private
 R10 room with a private sanitary facility or a room with another individual who is
 R10 receiving unsealed radioactive materials who cannot be released under Rule
 R10 64E-5.622, F.A.C. Individuals receiving manual brachytherapy shall be provided
 R10 a private room or a room with another individual who is receiving manual
 R10 brachytherapy and cannot be released under Rule 64E-5.622, F.A.C. The
 R10 licensee shall not place an individual receiving manual brachytherapy in the same
 R10 room with a patient who is not receiving manual brachytherapy.

R2 (8) A licensee shall take these additional safety precautions for radiopharmaceutical
 R10 therapy patients or human research subjects who cannot be released by Rule
 R10 64E-5.622, F.A.C.:

- R10 (a) Monitor material and items removed from the patient's or human research
 R10 subject's room to determine that any contamination cannot be
 distinguished from the natural background radiation level with a radiation
 detection survey instrument set on its most sensitive scale and with no
 interposed shielding, or handle these materials and items as radioactive
 waste.
- (b) Survey the patient's room and private sanitary facility for removable
 contamination before assigning another patient to the room. The room
 shall not be reassigned until removable contamination is less than
 200 disintegrations per minute (3.33 Bq) per 100 square centimeters or
 the wipe samples are equal to background when surveyed with an
 instrument using a probe with a maximum window thickness of 2.0 mg/cm²
 and a minimum probe diameter of 1.5 inches.

R10 (9) For manual brachytherapy patients or human research subjects who cannot be
 R10 released by Rule 64E-5.622, F.A.C., the licensee shall have the applicable
 R10 emergency response equipment available near each treatment room to respond
 R10 to the following:

R10 (a) A source that is dislodged from the patient or human research subject;
 R10 and

R10 (b) A sealed source lodged within the patient following removal of the source
 R10 applicators.

R10 (10) The licensee shall establish a bioassay program to measure the thyroid burden
 R10 of each individual who helps prepare, prepares or administers a dosage of
 R10 unsealed iodine 131 or iodine 125 in accordance with Rule 64E-5.1320, F.A.C.

R10 Rulemaking Authority 404.051, 404.061, 404.081, 404.141, F.S.

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

R10 History: New 5-15-96, Formerly 10D-91.721, Amended 02-11-10.

R10 **64E-5.6251 Therapy Related Computer Systems. (Entire section New)** The licensee shall
R10 perform acceptance testing on the treatment planning system of therapy-related computer
R10 systems in accordance with published protocols accepted by nationally recognized bodies. At a
R10 minimum, the acceptance testing must include, as applicable, verification of:

R10 (1) The source-specific input parameters required by the dose calculation algorithm;

R10 (2) The accuracy of dose, dwell time, and treatment time calculations at
R10 representative points;

R10 (3) The accuracy of isodose plots and graphic displays; and

R10 (4) The accuracy of the software used to determine sealed source positions from
R10 radiographic images.

R10 The licensee shall maintain records of this acceptance testing and protocols used in
R10 performing these tests for inspection by the department.

R10 Rulemaking Authority 404.051, 404.061, 404.081, 404.141 FS.

R10 Law Implemented: 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), (3), 404.081, 404.141 FS.

R10 History: New 02-11-10.

SUBPART C
UPTAKE, DILUTION, AND EXCRETION

64E-5.626 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion

R10 **Studies.** (Entire section Changed) A licensee is allowed to use any unsealed radioactive
R3 material in a radiopharmaceutical for a diagnostic use involving measurements of uptake,
R10 dilution, or excretion for medical use under the following conditions:

- R10 (1) When a written directive is not required by subsection 64E-5.607(3), F.A.C., the
R10 licensee must satisfy the following:
- R10 (a) Radioactive material is obtained from a manufacturer or pharmacy
R10 licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent
R10 NRC or agreement state regulations; or
- R10 (b) Radioactive material is obtained from and prepared by a NRC or
R10 agreement state licensee for use in research in accordance with a
R10 Radioactive Drug Research Committee-approved protocol, or a Notice of
R10 Claimed Investigational Exemption for a New Drug (IND) protocol
R10 accepted by U.S. Food and Drug Administration (FDA); or
- R10 (c) Radioactive material is prepared by the licensee for use in research in
R10 accordance with a Radioactive Drug Research Committee-approved
R10 application, or an IND protocol accepted by FDA; or
- R10 (d) Radioactive material is prepared by:
- R10 1. An authorized nuclear pharmacist;
- R10 2. Except for sodium iodide I-131 in quantities greater than
R10 30 microcuries (1.11 MBq), a physician who is an authorized user
R10 and meets the training requirements specified in Rule 64E-5.650 or
R10 64E-5.660, and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C.; or
- R10 3. An individual under the supervision of an authorized user as
R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e),
R10 or subsection 64E-5.608(1), F.A.C., or;
- R10 (e) The authorized user must satisfy the training and experience specified in
R10 Rule 64E-5.649 or 64E-5.657, F.A.C.
- R10 (2) When a written directive is required by subsection 64E-5.607(3), F.A.C., the
R10 licensee must satisfy the following:
- R10 (a) Radioactive material is obtained from a manufacturer or pharmacy
R10 licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent
R10 NRC or agreement state regulations; or
- R10 (b) Radioactive material is obtained from and prepared by an NRC or
R10 agreement state licensee for use in research in accordance with a
R10 Radioactive Drug Research Committee-approved protocol or an IND
R10 protocol accepted by FDA; or

- R10 (c) Radioactive material is prepared by the licensee for use in research in
- R10 accordance with a Radioactive Drug Research Committee-approved
- R10 application, or an IND protocol accepted by FDA; or

- R10 (d) Radioactive material is prepared by:
 - R10 1. An authorized nuclear pharmacist;
 - R10 2. For sodium iodide I-131 in quantities greater than 30 microcuries
 - R10 (1.11 MBq), a physician who is an authorized user and meets the
 - R10 training requirements specified in Rule 64E-5.650 or 64E-5.660,
 - R10 F.A.C.; or
 - R10 3. An individual under the supervision of an authorized user as
 - R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or
 - R10 subsection 64E-5.608(1), F.A.C.

- R10 (e) The authorized user must satisfy the applicable training and experience
- R10 specified in Rule 64E-5.657, 64E-5.660, 64E-5.661, 64E-5.662 or
- R10 64E-5.663, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
 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, F.S.
 R10 History: New 8-25-91, Formerly 10D-91.733, Amended 8-6-01, Amended 02-11-10.

**SUBPART D
 IMAGING AND LOCALIZATION**

R10 **64E-5.627 Use of Unsealed Radiopharmaceuticals, Generators, and Reagent**
 R10 **Kits for Imaging and Localization Studies.** A licensee is allowed to use any radioactive
 R10 material in a diagnostic radiopharmaceutical, or any generator, or reagent kit, for preparation
 R10 and diagnostic use of a radiopharmaceutical containing radioactive material for medical use
 R10 under the following conditions: **(Entire section Changed)**

- R10 (1) When a written directive is not required by subsection 64E-5.607(3), F.A.C., the
- R10 licensee must satisfy the following:
 - R3 (a) Obtained from a manufacturer or pharmacy licensed as specified in
 - R3 subsection 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear
 - R3 Regulatory Commission or Agreement State regulations; or
 - R10 (b) Radioactive material is obtained from and prepared by a NRC or
 - R10 agreement state licensee for use in research in accordance with a
 - R10 Radioactive Drug Research Committee-approved protocol or an IND
 - R10 protocol accepted by FDA; or
 - R10 (c) Radioactive material is prepared by the licensee for use in research in
 - R10 accordance with a Radioactive Drug Research Committee-approved
 - R10 application or an IND protocol accepted by FDA; or
 - R10 (d) Radioactive material is prepared by:

- R10 1. An authorized nuclear pharmacist;
- R10 2. Except for sodium iodide I-131 in quantities greater than
R10 30 microcuries (1.11 MBq), a physician who is an authorized user
R10 and meets the training requirements specified in Rules 64E-5.650,
R10 64E-5.660 and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C.; or
- R10 3. An individual under the supervision of an authorized user as
R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or
R10 subsection 64E-5.608(1), F.A.C.; or
- R10 (e) The authorized user must satisfy the training and experience specified in
R10 Rule 64E-5.650 or 64E-5.657, F.A.C.
- R10 (2) When a written directive is required by subsection 64E-5.607(3), F.A.C., the
R10 licensee must satisfy the following:
- R10 (a) Radioactive material is obtained from a manufacturer or pharmacy
R10 licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent
R10 NRC or agreement state regulations; or
- R10 (b) Radioactive material is obtained from and prepared by an NRC or
R10 agreement state licensee for use in research in accordance with a
R10 Radioactive Drug Research Committee-approved protocol or an IND
R10 protocol accepted by FDA; or
- R10 (c) Radioactive material is prepared by the licensee for use in research in
R10 accordance with a Radioactive Drug Research Committee-approved
R10 application or an IND protocol accepted by FDA; or
- R10 (d) Radioactive material is prepared by:
- R10 1. An authorized nuclear pharmacist;
- R10 2. For sodium iodide I-131 in quantities greater than 30 microcuries
R10 (1.11 MBq) a physician who is an authorized user and meets the
R10 training requirements specified in Rule 64E-5.650 or 64E-5.660,
R10 F.A.C.; or
- R10 3. An individual under the supervision of an authorized user as
R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e),
R10 or subsection 64E-5.608(1), F.A.C.
- R10 (e) The authorized user must satisfy the applicable training and experience
R10 specified in Rules 64E-5.657, 64E-5.660, 64E-5.661, 64E-5.662 or
R10 64E-5.663, F.A.C.
- R10 (3) Only for oral administration of sodium iodide I-131 in quantities less than or equal
R10 to 33 millicuries (1.22 gigabecquerels) and when a written directive is required by
R10 subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

- R10 (a) Radioactive material is obtained from a manufacturer or pharmacy
R10 licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent
R10 NRC or agreement state regulations; or
- R10 (b) Radioactive material is obtained from and prepared by a NRC or
R10 agreement state licensee for use in research in accordance with a
R10 Radioactive Drug Research Committee-approved protocol or an IND
R10 protocol accepted by FDA; or
- R10 (c) Radioactive material is prepared by the licensee for use in research in
R10 accordance with a Radioactive Drug Research Committee-approved
R10 application or an IND protocol accepted by FDA; or
- R10 (d) Radioactive material is prepared by:
- R10 1. An authorized nuclear pharmacist;
 - R10 2. For sodium iodide I-131 in quantities greater than 30 microcuries
R10 (1.11 MBq), a physician who is an authorized user and meets the
R10 training requirements specified in Rule 64E-5.650 or 64E-5.660,
R10 F.A.C.; or
 - R10 3. An individual under the supervision of an authorized user as
R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or
R10 subsection 64E-5.608(1), F.A.C.
- R10 (e) The authorized user must satisfy the applicable training and experience
R10 specified in Rules 64E-5.657, 64E-5.660 or 64E-5.661, F.A.C.
- R10 (4) A licensee shall use radioactive aerosols or gases only if application on
R10 DH Form 1322 12/09 is made to and approved by the department and the
R10 requirements of Rule 64E-5.629, F.A.C., are met.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.735, Amended 8-6-01, Amended 02-11-10.

- R10 **64E-5.628 Generators. (Entire section Changed)**
- R10 (1) **Permissible Molybdenum/Technetium Concentration.**
- R10 (a) A licensee shall not administer a radiopharmaceutical containing more
R10 than 0.15 microcurie of molybdenum 99 per millicurie of technetium 99m
R10 (5.55 kilo-becquerel of molybdenum 99 per 37 megabecquerel of
R10 technetium 99m).
- R10 (b) A licensee preparing technetium 99m radiopharmaceuticals from
R10 molybdenum 99/technetium 99m generators shall measure the
R10 molybdenum 99 concentration in each eluate or extract.
- R10 (c) A licensee who is required to measure molybdenum concentrations shall
R10 retain a record of each measurement for 3 years. The record shall include
R10 for each elution or extraction of technetium 99m:
- R10 1. The measured activity of the technetium expressed in millicuries
R10 (megabecquerels);
- R10 2. The measured activity of molybdenum expressed in microcuries
R10 (kilobecquerels);
- R10 3. The ratio of the measures expressed as microcuries of
R10 molybdenum per millicurie of technetium (kilobecquerels of
R10 molybdenum per megabecquerel of technetium);
- R10 4. The date of the test; and
- R10 5. The initials of the individual who performed the test.
- R10 (d) A licensee shall report immediately to the department each occurrence of
R10 molybdenum 99 concentration exceeding the limits specified in subsection
R10 64E-5.628(1), F.A.C.
- R10 (2) **Permissible Strontium/Rubidium Concentration.**
- R10 (a) A licensee shall not administer a radiopharmaceutical containing more
R10 than 0.02 microcurie of strontium 82 per millicurie of rubidium 82
R10 (0.74 kilobecquerel of strontium 82 per 37 megabecquerel of rubidium 82)
R10 or more than 0.2 microcurie of strontium 85 per millicurie of rubidium 82
R10 (7.4 kilobecquerel of strontium 85 per 37 megabecquerel of rubidium 82).
- R10 (b) A licensee preparing rubidium 82 radiopharmaceuticals from
R10 strontium 82/rubidium 82 generators shall measure and calculate the
R10 strontium 82 and strontium 85 concentration on each day of use prior to
R10 the use of rubidium chloride for injection.
- R10 (c) A licensee who is required to measure strontium 82 and strontium 85
R10 concentrations shall retain a record of each measurement for 3 years.
R10 The record shall include for each day of use assay:

- R10
R10
1. The measured activity of the rubidium 82 expressed in millicuries (megabecquerels);
- R10
R10
2. The measured activity of strontium 82 expressed in microcuries (kilobecquerels);
- R10
R10
3. The calculated activity of strontium 85 expressed in microcuries (kilobecquerels);
- R10
R10
R10
R10
R10
R10
4. The ratio of the measures expressed as microcuries of strontium 82 per millicurie of rubidium 82 (kilobecquerels of strontium 82 per megabecquerel of rubidium 82) and the ratio of the measures expressed as microcuries of strontium 85 per millicurie of rubidium 82 (kilobecquerels of strontium 85 per megabecquerel of rubidium 82);
- R10
5. The date of the test; and
- R10
6. The initials of the individual who performed the test.
- R10
R10
R10
- (d) A licensee shall report immediately to the department each occurrence of strontium 82 or strontium 85 concentrations exceeding the limits specified in subsection 64E-5.628(2), F.A.C.
- R10 (3) Other Permissible Parent/Daughter Concentration.
- R10 (a) If a licensee seeks to utilize a Parent/Daughter concentration other than those listed in subsection (1) or (2) above, the licensee must submit a license amendment to the department for review and approval of the maximum parent isotope or other contaminate concentrations breakthrough per daughter isotope concentration allowed for administration to patients or human research subjects, and the instrumentation and procedures used in determining parent isotope or other contaminate breakthrough concentrations;
- R10 (b) Each licensee must perform the determination listed in paragraph (3)(a), above, on each day of use prior to the administration to patients or human research subjects;
- R10 (c) Retain a record of each measurement for 3 years. The record shall include for each day of use assay:
- R10
R10
1. The measured activity of the daughter isotope expressed in millicuries (megabecquerels);
- R10
R10
2. The measured activity of parent isotope(s) and other contaminants expressed in microcuries (kilobecquerels);
- R10
R10
3. The calculated activity of parent isotope(s) and other contaminants expressed in microcuries (kilobecquerels) as applicable;

- R10 4. The ratio of the measures expressed as microcuries of parent
R10 isotope(s) and other contaminates per millicurie of daughter isotope
R10 (kilobecquerels of parent isotope(s) per megabecquerel of daughter
isotope);
- R10 5. The date of the test; and
- R10 6. The initials of the individual who performed the test.
- R10 (d) A licensee shall report immediately to the department each occurrence of
R10 parent isotope(s) or other contaminates concentrations exceeding the
R10 limits specified in paragraph 64E-5.628(3)(a), F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
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, F.S.
R10 History: New 8-25-91, Formerly 10D-91.736., Amended 02-11-10

64E-5.629 Control of Aerosols and Gases.

- (1) A licensee shall only administer radioactive aerosols or gases when airborne concentrations are within the limits prescribed by State of Florida Bureau of Radiation Control ALLs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3, and Table II.
- (2) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- (3) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.
- (4) Before receiving, using, or storing radioactive gas, the licensee shall calculate the time needed after a release to reduce the concentration in the area of use to the occupational limit listed in State of Florida Bureau of Radiation Control ALLs, DACs, and Effluent Concentrations, July 1993. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.
- (5) A licensee shall post the time calculated in subsection 64E-5.629(4), F.A.C., at the area of use and require that individuals evacuate the room until the posted time has elapsed if a gas spill occurs.
- (6) A licensee shall check the operation of collection systems prior to use each month of use and measure the ventilation rates in areas of use every 6 months. Records of these checks and measurements shall be maintained for 3 years.
- (7) A copy of the calculations required in subsection 64E-5.629(4), F.A.C., shall be recorded and retained for the duration of the license.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
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, F.S.
R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.737, Amended 02-11-10.

SUBPART E
RADIOPHARMACEUTICALS FOR THERAPY

64E-5.630 Use of Radiopharmaceuticals for Therapy. A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical that requires a written directive as described in subsection 64E-5.607(3), F.A.C., and for a therapeutic medical use provided the following is met **(Entire section Changed)**

(1) For any unsealed radiopharmaceutical including parenteral use listed in subsection 64E-5.630(4), F.A.C., and sodium iodide I-131 use listed in subsections 64E-5.630(2) and (3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 54E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.660 or 64E-5.657, F.A.C.

(2) Only for oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

- R10 (c) Radioactive material is prepared by the licensee for use in research in
R10 accordance with a Radioactive Drug Research Committee-approved
R10 application or an IND protocol accepted by FDA; or
- R10 (d) Radioactive material is prepared by:
- R10 1. An authorized nuclear pharmacist;
- R10 2. A physician who is an authorized user and meets the training
R10 requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or
- R10 3. An individual under the supervision of an authorized user as
R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or
R10 subsection 64E-5.608(1), F.A.C.
- R10 (e) The authorized user must satisfy the training and experience specified in
R10 Rule 64E-5.661 or 64E-5.657, F.A.C.
- R10 (3) Only for oral administration of sodium iodide I-131 in quantities greater than
R10 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:
- R10 (a) Radioactive material is obtained from a manufacturer or pharmacy
R10 licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent
R10 NRC or agreement state regulations; or
- R10 (b) Radioactive material is obtained from and prepared by an NRC or
R10 agreement state licensee for use in research in accordance with a
R10 Radioactive Drug Research Committee-approved protocol or an IND
R10 protocol accepted by FDA; or
- R10 (c) Radioactive material is prepared by the licensee for use in research in
R10 accordance with a Radioactive Drug Research Committee-approved
R10 application or an IND protocol accepted by FDA; or.
- R10 (d) Radioactive material is prepared by:
- R10 1. An authorized nuclear pharmacist;
- R10 2. A physician who is an authorized user and meets the training
R10 requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or
- R10 3. An individual under the supervision of an authorized user as
R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or
R10 subsection 64E-5.608(1), F.A.C.
- R10 (e) The authorized user must satisfy the training and experience specified in
R10 Rule 64E-5.662 or 64E-5.657, F.A.C.
- R10 (4) Only parenteral use of radioactive materials the licensee must satisfy the
R10 following:
- R10 (a) Radioactive material is obtained from a manufacturer or pharmacy
R10 licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent
R10 NRC or agreement state regulations; or

- R10 (b) Radioactive material is obtained from and prepared by an NRC or
R10 agreement state licensee for use in research in accordance with a
R10 Radioactive Drug Research Committee-approved protocol or an IND
R10 protocol accepted by FDA; or
- R10 (c) Radioactive material is prepared by the licensee for use in research in
R10 accordance with a Radioactive Drug Research Committee-approved
R10 application or an IND protocol accepted by FDA; or
- R10 (d) Radioactive material is prepared by:
 - R10 1. An authorized nuclear pharmacist;
 - R10 2. A physician who is an authorized user and meets the training
R10 requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or
 - R10 3. An individual under the supervision of an authorized user as
R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or
R10 subsection 64E-5.608(1), F.A.C.
- R10 (e) The authorized user must satisfy the training and experience specified in
R10 Rule 64E-5.663 or 64E-5.657, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
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, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.739, Amended 8-6-01, Amended 02-11-10.

SUBPART F SEALED SOURCES FOR DIAGNOSIS

R10 **64E-5.631 Use of Sealed Sources for Diagnosis.** The licensee is allowed to use
R10 the sealed sources listed below, provided they are approved by and used as specified in, the
R10 Sealed Source and Device Registry, for diagnostic medical uses, or in research in accordance
R10 with an active IDE application accepted by the FDA and the requirements of Rule 64E-5.612,
R10 F.A.C., are met.

- (1) Iodine 125 as a sealed source in a device for bone mineral analysis;
- (2) Iodine 125 as a sealed source in a portable device for imaging;
- R10 (3) Gadolinium 153 as a sealed source in a device for bone mineral analysis;
- R10 (4) Americium 241 as a sealed source in a device for bone mineral analysis; or
- R10 (5) For isotopes or uses not listed in subsections 64E-5.631(1) through (4), F.A.C.,
R10 above, the licensee must amend their radioactive materials license.

R10 In order to use isotopes in accordance this Rule, an authorized user must satisfy the training
R10 and experience requirements specified in Rule 64E-5.654 or 64E-5.657, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
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, F.S.
R10 History: New 8-25-91, Formerly 10D-91.743, Amended 02-11-10.

SUBPART G
SOURCES FOR BRACHYTHERAPY

R10 **64E-5.632 Use of Sources for Manual Brachytherapy.** The licensee is allowed to
 R10 use the brachytherapy sources listed below, provided they are approved by and used as
 R10 specified in, the Sealed Source and Device Registry, for diagnostic medical uses, or in
 R10 research in accordance with an active IDE application accepted by the FDA and the
 R10 requirements of Rule 64E-5.612, F.A.C., are met.

- (1) Cobalt 60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (2) Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions;
- (3) Palladium 103 as a sealed source in seeds for interstitial treatment of cancer;
- (4) Iodine 125 as a sealed source in seeds for interstitial treatment of cancer;
- (5) Cesium 137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (6) Iridium 192 as seeds encased in nylon ribbon for interstitial treatment of cancer;
- (7) Gold 198 as a sealed source in seeds for interstitial treatment of cancer;
- R10 (8) Radon 222 as seeds for interstitial treatment of cancer;
- R10 (9) Radium 226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- R10 (10) Cesium 131 as a sealed source in seeds for interstitial treatment of cancer; or
- R10 (11) For isotopes or uses not listed in subsections 64E-5.632(1) through (10), F.A.C.,
 R10 above, the licensee must amend their radioactive materials license.

R10 In order to use isotopes in accordance with Rule 64E-5.632, F.A.C., an authorized user must
 R10 satisfy the training and experience requirements specified in Rule 64E-5.652 or 64E-5.657,
 R10 F.A.C. An authorized user of only Strontium 90 as a sealed source in an applicator for
 R10 treatment of superficial eye conditions listed in subsection 64E-5.632(2), F.A.C., above must
 R10 satisfy the training and experience specified in Rule 64E-5.652, 64E-5.653 or 64E-5.657,
 R10 F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.745, Amended 02-11-10.

- R10 **64E-5.633 Manual Brachytherapy Sources Inventory and Surveys.**
- R10 (1) The licensee shall maintain accountability at all times for all manual
R10 brachytherapy sources in storage or use. As soon as possible each time
brachytherapy sources are returned to an area of storage from an area of use,
the licensee shall immediately count or otherwise verify the number returned to
ensure that all sources taken from the storage area have been returned.
- R10 (2) A licensee shall make a record of the use of manual brachytherapy sources
which includes:
- R10 (a) For temporary implants;
- R10 1. The number and activity of sources removed from storage, the
R10 room number of use and patient's name, the time and date the
R10 sources were removed from storage, the number and activity of
R10 sources in storage after the removal, and the name of the individual
R10 who removed the sources from storage; and
- R10 2. The number and activity of sources returned to storage, the room
R10 number of use and patient's name, the time and date the sources
R10 were returned to storage, the number and activity of sources in
R10 storage after the return, and the name of the individual who
R10 returned the sources to storage.
- R10 (b) For permanent implants;
- R10 1. The number and activity of sources removed from storage, the
R10 room number of use and patient's name, the time and date the
R10 sources were removed from storage, the number and activity of
R10 sources in storage after the removal, and the name of the individual
R10 who removed the sources from storage;
- R10 2. The number and activity of sources returned to storage, the room
R10 number of use and patient's name, the time and date the sources
R10 were returned to storage, the number and activity of sources in
R10 storage after the return, and the name of the individual who
R10 returned the sources to storage; and
- R10 3. The number and activity of sources permanently implanted in the
R10 patient or human research subject.
- R10 (3) Immediately after implanting sources in a patient or human research subject and
R10 immediately after removal of sources from a patient or human research subject ,
R10 the licensee shall make a radiation survey of the patient or human research
R10 subject and the area of use to confirm that no sources have been misplaced.
R10 The licensee shall make a record of each survey. This record shall contain the
R10 date and results of the survey, the survey instrument used and the name of the
R10 individual who performed the survey.
- R10 (4) A licensee shall maintain the records required in 64E-5.633(2) and (3) for 3
years.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.748, Amended 02-11-10.

R10 64E-5.6331 Calibration Measurements of Manual Brachytherapy Sources.**(Entire section New)**

- R10 (1) Before the first medical use of a brachytherapy source, the licensee shall, using
R10 published protocols currently accepted by nationally recognized bodies,
R10 determine the following:
- R10 (a) Source output or activity using a dosimetry system that meets the
R10 requirements of subsection 64E-5.640(1), F.A.C.; and
- R10 (b) Source positioning accuracy within applicators.
- R10 (2) Instead of a licensee making its own measurements as required in subsection
R10 64E-5.6331(1), F.A.C., the licensee may use measurements provided by the
R10 source manufacturer or by a calibration laboratory accredited by the American
R10 Association of Physicists in Medicine (AAPM) that are made in accordance with
R10 subsection 64E-5.6331(1), F.A.C.
- R10 (3) A licensee shall mathematically correct the outputs or activities determined in
R10 subsection 64E-5.6331(1), F.A.C., for physical decay at intervals consistent with
R10 1 percent physical decay.
- R10 (4) For each brachytherapy source the licensee shall retain the following records for
R10 three years after the last use of the source:
- R10 (a) The date of calibration;
- R10 (b) The manufacturer's name, model number, and serial number for the
R10 source and the instruments used to calibrate the source;
- R10 (c) The source output or activity;
- R10 (d) The source positioning accuracy within the applicators; and
- R10 (e) The name of the individual, the source manufacturer, or the calibration
R10 laboratory that performed the calibration.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.

R10 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, F.S.

R10 History: New 02-11-10.

R10 64E-5.6332 Decay of Strontium-90 Sources for Ophthalmic Treatments.**(Entire section New)**

- R10 (1) Only an authorized medical physicist or authorized user qualified to perform
R10 procedures described in subsection 64E-5.632(2), F.A.C., shall calculate the
R10 activity of each strontium-90 source that is used to determine the treatment times
R10 for ophthalmic treatments. The decay must be based on the activity determined
R10 under Rule 64E-5.6331, F.A.C.
- R10 (2) For each Strontium 90 source the licensee shall retain the following records for
R10 the life of the source:

R10 (a) The date and activity of the source as determined under Rule 64E-5.6331,
R10 F.A.C.; and

R10 (b) For each decay calculation, the date and the source activity as
R10 determined under Rule 64E-5.6332, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.

R10 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, F.S.

R10 History: New 02-11-10.

SUBPART H

R10 **PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND**
R10 **GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

R10 **64E-5.634 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy**
R10 **Unit, or Gamma Stereotactic Radiosurgery Unit. (Entire section Changed)**

R10 (1) A licensee shall use sealed sources in photon emitting gamma stereotactic
R10 radiosurgery units for therapeutic medical uses:

R10 (a) As approved in the Sealed Source and Device Registry; or

R10 (b) In research in accordance with an active IDE application accepted by the
R10 FDA provided the requirements of Rule 64E-5.612, F.A.C. are met.

R10 (2) A licensee shall use sealed sources in photon emitting remote afterloader units
R10 for therapeutic medical uses:

R10 (a) As approved in the Sealed Source and Device Registry; or

R10 (b) In research in accordance with an active IDE application accepted by the
R10 FDA provided the requirements of Rule 64E-5.612, F.A.C., are met.

R10 (3) A licensee shall use sealed sources in photon emitting teletherapy units for
R10 therapeutic medical uses:

R10 (a) As approved in the Sealed Source and Device Registry; or

R10 (b) In research in accordance with an active IDE application accepted by the
R10 FDA provided the requirements of Rule 64E-5.612, F.A.C., are met.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

R10 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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.751, Amended 02-11-10.

R10 **64E-5.635 Installation, Adjustment, Maintenance and Repair Restrictions.**
(Entire section Changed)

- R10 (1) Only a person specifically licensed by the NRC or an agreement state shall
 R10 install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or
 R10 gamma stereotactic radiosurgery unit that involves work on the source(s)
 R10 shielding, the source(s) driving unit, or other electronic or mechanical component
 R10 that could expose the source(s), reduce the shielding around the source(s), or
 R10 compromise the radiation safety of the unit or the source(s).
- R10 (2) Except for low dose-rate remote afterloader units, only a person specifically
 R10 licensed by the NRC or an agreement state shall install, replace, relocate, or
 R10 remove a sealed source or source contained in other remote afterloader units,
 R10 teletherapy units, or gamma stereotactic radiosurgery units.
- R10 (3) For a low dose-rate remote afterloader unit, only a person specifically licensed by
 R10 the NRC or an agreement state or an authorized medical physicist shall install,
 R10 replace, relocate, or remove a sealed source(s) contained in the unit.
- R10 (4) A licensee shall retain a record of the installation, maintenance, adjustment, and
 R10 repair of remote afterloader units, teletherapy units, and gamma stereotactic
 R10 radiosurgery units for 3 years. For each installation, maintenance, adjustment
 R10 and repair, the record must include the date, description of the service, and
 R10 name(s) of the individual(s) who performed the work.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.752, Amended 02-11-10.

R10 **64E-5.636 Safety Procedures and Instructions for Remote Afterloader Units,**
 R10 **Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**
(Entire section Changed)

- R10 (1) Listed below are the safety and instruction requirements for a licensee;
- R10 (a) Secure the unit, the console, the console keys, and the treatment room
 R10 when not in use or unattended;
- R10 (b) Permit only individuals approved by the authorized user, RSO, or
 R10 authorized medical physicist to be present in the treatment room during
 R10 treatment with the source(s);
- R10 (c) Prevent dual operation of more than one radiation producing device in a
 R10 treatment room if applicable; and
- R10 (d) Develop, implement, and maintain written procedures for responding to an
 R10 abnormal situation when the operator is unable to place the source(s) in
 R10 the shielded position, or remove the patient or human research subject
 R10 from the radiation field with controls from outside the treatment room.
 R10 These procedures must include the following:

- R10 1. Instructions for responding to equipment failures and the names of
R10 the individuals responsible for implementing corrective actions;
- R10 2. The process for restricting access to and posting of the treatment
R10 area to minimize the risk of inadvertent exposure; and
- R10 3. The names and telephone numbers of the authorized users, the
R10 authorized medical physicist, and the RSO to be contacted if the
R10 unit or console operates abnormally.
- R10 (2) A copy of the procedures required by paragraph 64E-5.636(1)(d), F.A.C., of this
R10 section must be physically located at the unit console.
- R10 (3) A licensee shall post instructions at the unit console to inform the operator of the
R10 following:
- R10 (a) The location of the procedures required by paragraph (4)(a) of this
R10 section; and
- R10 (b) The names and telephone numbers of the authorized users, the
R10 authorized medical physicist, and the RSO to be contacted if the unit or
R10 console operates abnormally.
- R10 (4) A licensee shall provide instruction, initially and at least annually, to all individuals
R10 who operate the unit, as appropriate to the individual's assigned duties, in the
R10 following:
- R10 (a) The procedures identified in paragraph 64E-5.636(1)(d), F.A.C., of this
R10 section; and
- R10 (b) The operating procedures for the unit.
- R10 (5) A licensee shall ensure that operators, authorized medical physicists, and
R10 authorized users participate in drills of the emergency procedures, initially and at
R10 least annually.
- R10 (6) A licensee shall retain a record of individuals receiving instruction required by
R10 paragraph 64E-5.636(4), F.A.C., of this section. These records shall be
R10 maintained for 3 years and must include the list of topics covered, the date of the
R10 instruction, the name(s) of the attendee(s) and the name(s) of the individual(s)
R10 who provided the instruction.
- R10 (7) A licensee shall retain a copy of the procedures required by paragraphs
R10 64E-5.636(1)(d) and 64E-5.636(4)(b), F.A.C., until the licensee no longer
R10 possesses the remote afterloader, teletherapy unit or gamma stereotactic
R10 radiosurgery unit.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.753, Amended 02-11-10.

R10 **64E-5.637 Safety Precautions for Remote Afterloader Units, Teletherapy Units,**
R10 **and Gamma Stereotactic Radiosurgery Units . (Entire section Changed)**

- R10 (1) A licensee shall control access to the treatment room by a door at each entrance.
- R10 (2) A licensee shall equip each entrance to the treatment room with an electrical interlock system that shall:
- R10 (a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
- R10 (b) Cause the source(s) to be shielded when an entrance door is opened; and
- R10 (c) Prevent the source(s) from being exposed following an interlock
R10 interruption until all treatment room entrance doors are closed and the
R10 source(s) on-off control is reset at the console.
- R10 (3) A licensee shall require any individual entering the treatment room to assure,
R10 through the use of appropriate radiation monitors, that radiation levels have
R10 returned to ambient levels.
- R10 (4) Except for low-dose remote afterloader units, a licensee shall construct or equip
R10 each treatment room with viewing and intercom systems to permit continuous
R10 observation of the patient or the human research subject from the treatment
R10 console during irradiation.
- R10 (5) For licensed activities where sources are placed within the patient's or human
R10 research subject's body, a licensee shall only conduct treatments which allow for
R10 expeditious removal of a decoupled or jammed source.
- R10 (6) In addition to the requirements specified in paragraphs 64E-5.637(1) through (5),
R10 F.A.C., of this section, a licensee shall:
- R10 (a) For medium dose-rate and pulsed dose-rate remote afterloader units,
R10 require:
- R10 1. An authorized medical physicist and either, an authorized user or a
R10 physician, under the supervision of an authorized user, who have
R10 been trained in the operation and emergency response for the unit,
R10 to be physically present during the initiation of all patient treatments
R10 involving the unit; and
- R10 2. An authorized medical physicist and either, an authorized user or
R10 an individual under, the supervision of an authorized user, who
R10 have been trained to remove the source applicator(s) in the event
R10 of an emergency involving the unit, to be immediately available
R10 during continuation of all patient treatments involving the unit.

- R10 (b) For high dose-rate remote afterloader units, require:
- R10 1. An authorized user and an authorized medical physicist to be
R10 physically present during the initiation of all patient treatments
R10 involving the unit; and
- R10 2. An authorized medical physicist and either, an authorized user or a
R10 physician, under the supervision of an authorized user, who have
R10 been trained in the operation and emergency response for the unit,
R10 to be physically present during continuation of all patient treatments
R10 involving the unit.
- R10 (c) For gamma stereotactic radiosurgery units, require an authorized user and
R10 an authorized medical physicist to be physically present throughout all
R10 patient treatments involving the unit.
- R10 (d) Notify the RSO, or his/her designee, and an authorized user as soon as
R10 possible if the patient or human research subject has a medical
R10 emergency or dies.
- R10 (7) A licensee shall have applicable emergency response equipment available near
R10 each treatment room in order to respond to a source remaining in the unshielded
R10 position or lodged within the patient following completion of the treatment.
- R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
R10 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, F.S.
R10 History: New 8-25-91, Formerly 10D-91.755, Amended 02-11-10.

64E-5.638 Radiation Monitoring Devices.

- R10 (1) A licensee shall have a permanent radiation monitor in each teletherapy, medium
R10 or high dose rate remote afterloader, or gamma stereotactic radiosurgery room
R10 capable of continuously monitoring radiation levels.
- R10 (2) Each radiation monitor shall be capable of providing visible notice of a
R10 teletherapy unit, medium or high dose rate remote afterloader unit, or gamma
R10 stereotactic radiosurgery unit malfunction that results in an exposed or partially
R10 exposed source. The visible indicator of high radiation levels shall be observable
R10 by an individual entering the teletherapy, medium or high dose rate remote
R10 afterloader, or gamma stereotactic radiosurgery room.
- R10 (3) Each radiation monitor shall be equipped with a backup power supply separate
R10 from the power supply to the teletherapy unit, medium or high dose rate remote
R10 afterloader unit, or gamma stereotactic radiosurgery unit. This backup power
supply may be a battery system.
- R10 (4) Each radiation monitor shall be checked daily with a dedicated check source for
R10 proper operation before the teletherapy unit, medium or high dose rate remote
R10 afterloader unit, or gamma stereotactic radiosurgery unit is used.

(5) A licensee shall maintain a record of the check required by subsection 64E-5.638(4), F.A.C., for 3 years. The record shall include the date of the check, notation what the monitor indicates when its detector is and is not exposed to the source, and the initials of the individual who performed the check.

R10
R10

(6) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room to use a radiation survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The radiation survey instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in subsection 64E-5.638(5), F.A.C.

(7) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.757, Amended 02-11-10.

R10 **64E-5.639 Viewing Systems.** A licensee shall construct or equip each teletherapy,
R10 medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery
R10 room to permit continuous observation of the patient, or human research subject from the teletherapy
R10 unit console during irradiation.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.758, Amended 02-11-10.

R10 **64E-5.640 Dosimetry Equipment Used With Remote Afterloading Units,**
R10 **Teletherapy Units, or Gamma Stereotactic Radiosurgery Units.**

R10 (1) Except for low dose-rate remote afterloader source output or where the activity is
R10 determined by the manufacturer, a licensee shall have a dosimetry system
R10 available for use calibrated by paragraph (a) or (b) below.

R10 (a) The system must have been calibrated using a system or source traceable
R10 to the NIST and published protocols accepted by nationally recognized
R10 bodies; or by a calibration laboratory accredited by the AAPM. The
R10 calibration must have been performed within the previous 2 years and
R10 after any servicing that may have affected system calibration.

R10 (b) The system shall have been calibrated within the previous 4 years and
R10 shall have been intercompared 18 to 30 months after the calibration at an
R10 intercomparison meeting with another dosimetry system that has been
R10 calibrated within the previous 2 years by the NIST or by a calibration
R10 laboratory accredited by the AAPM. The intercomparison meeting shall be
R10 sanctioned by a calibration laboratory or radiologic physics center
R10 accredited by the AAPM. The calibration factor of the licensee's system
R10 shall not have changed by more than 2 percent. The licensee shall not
R10 use the intercomparison result to change the calibration factor. When
R10 intercomparing dosimetry systems to be used for calibrating sealed
R10 sources for therapeutic units, the licensee shall use a comparable unit with
R10 beam attenuators or collimators, as applicable, and sources of the same
R10 radionuclide as the source used at the licensee's facility.

- (2) The licensee shall have available for use a dosimetry system for spot-check measurements. The spot-check system shall be the same system used to meet the requirement in 64E-5.640(1), or shall be a system that has been compared with a system that has been calibrated as provided in subsection 64E-5.640(1), F.A.C. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration.
- (3) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:

- R10
- (a) The date, the **manufacturer's name**, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subsections 64E-5.640(1) and (2), F.A.C.;
 - (b) The correction factors that were determined;
 - (c) The names of the individuals who performed the calibration, intercomparison, or comparison; and

R10 **Rulemaking** Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.759, **Amended 02-11-10**.

R10 **64E-5.641 Full Calibration Measurements on Teletherapy Units.**

- (1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:
 - (a) Before the first medical use of the unit;
 - (b) Before medical use whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (c) Before medical use following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - (d) Before medical use following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - (e) At least every 12 months.
- (2) Full calibration measurements shall include the determination of:
 - (a) The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
 - (b) The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - (c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

- (d) Timer constancy and linearity over the range of use;
 - (e) On-off error; and
 - (f) The accuracy of all distance measuring and localization devices in medical use.
- (3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C., to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 64E-5.641(2)(a), F.A.C., may be made using a dosimetry system that indicates relative dose rates.
- (4) A licensee shall make full calibration measurements required by subsection 64E-5.641(1), F.A.C., using the manufacturer's published protocols, published protocols as accepted by nationally recognized bodies or equivalent procedures that have been submitted to the department. An example of a nationally recognized body is the American Association of Physicists in Medicine.
- (5) A licensee shall correct mathematically the outputs determined in paragraph 64E-5.641(2)(a), F.A.C., for physical decay monthly for cobalt 60 and at least every 6 months for cesium 137.
- (6) Full calibration measurements required by subsection 64E-5.641(1), F.A.C., and physical decay corrections required by 64E-5.641(5) shall be performed by the authorized medical physicist.
- (7) A licensee shall maintain a record of each calibration of each teletherapy unit for three years. The record shall include:
- (a) The date of the calibration;
 - (b) The manufacturer's name, model number, and serial number for both the teletherapy unit and the source;
 - (c) The model numbers and serial numbers of the instruments used to calibrate the teletherapy unit;
 - (d) The results and an assessment of the full calibration to include the following:
 - 1. The tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy;
 - 2. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
 - 3. The measured timer accuracy for a typical treatment time;
 - 4. The calculated on-off error;
 - 5. The estimated accuracy of each distance measuring or localization device; and
 - 6. The signature of the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
 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, F.S.
 R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.760, Amended 02-11-10.

R10 **64E-5.6411 Full Calibration Measurements on Remote Afterloader Units.**
(Entire section New)

R10 (1) A licensee authorized to use a remote afterloader unit for medical use shall
 R10 perform full calibration measurements on each remote afterloader unit:

R10 (a) Before the first medical use of the unit;

R10 (b) 1. Before medical use following replacement of the source or following
 R10 reinstallation of the unit in a new location outside the facility; and
 R10

R10 2. Before medical use following any repair of the unit that includes
 R10 removal of the source or major repair of the components associated
 R10 with the source exposure assembly; and

R10 (c) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate,
 R10 and pulsed dose-rate remote afterloader units with sources whose half-life
 R10 exceeds 75 days; and

R10 (d) At intervals not exceeding 1 year for low dose-rate remote afterloader
 R10 units.

R10 (2) Full calibration measurements of remote afterloader unit shall include the
 R10 determination of:

R10 (a) The output within 5 percent;

R10 (b) Source positioning accuracy to within 1 millimeter;

R10 (c) Source retraction with backup battery upon power failure;

R10 (d) Timer constancy and linearity over the range of use;

R10 (e) Length of the source transfer tubes;

R10 (f) Length of the applicators; and

R10 (g) Function of the source transfer tubes, applicators, and transfer tube-
 R10 applicator interfaces.

R10 (3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C.,
 R10 to measure the output for one set of exposure conditions. The remaining
 R10 radiation measurements required in paragraph 64E-5.6411(2)(a), F.A.C., may be
 R10 made using a dosimetry system that indicates relative dose rates.

R10 (4) A licensee shall make full calibration measurements required by subsection
 R10 64E-5.6411(1), F.A.C., in accordance with published protocols accepted by
 R10 nationally recognized bodies.

- R10 (5) A licensee shall correct mathematically the outputs determined in paragraph
R10 64E-5.641(2)(a), F.A.C., for physical decay at intervals consistent with 1 percent
R10 physical decay.
- R10 (6) Full calibration measurements required by subsection 64E-5.6411(1), F.A.C., and
R10 physical decay corrections required by subsection 64E-5.641(5), F.A.C., shall be
R10 performed by the authorized medical physicist.
- R10 (7) In addition to the requirements for full calibrations for low dose-rate remote
R10 afterloader units in subsection 64E-5.6411(2), F.A.C., a licensee shall perform an
R10 autoradiograph of the source(s) to verify inventory and source(s) arrangement at
R10 intervals not exceeding 1 quarter.
- R10 (8) For low dose-rate remote afterloader units, a licensee may use measurements
R10 provided by the source manufacturer that are made in accordance with
R10 subsections 64E-5.6411(1)-(5), F.A.C.
- R10 (9) A licensee shall maintain a record of each remote afterloader unit calibration for
R10 three years. The record shall include the following:
- R10 (a) The date of the calibration;
- R10 (b) The manufacturer's name, model number, and serial number for both the
R10 remote afterloader unit and the source;
- R10 (c) The model numbers and serial numbers of the instruments used to
R10 calibrate the remote afterloader unit;
- R10 (d) The results and an assessment of the full calibrations.
- R10 (e) The results of the audiograph required for low dose-rate remote
R10 afterloaders; and
- R10 (f) The signature of the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..

R10 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.

R10 History: New 02-11-10.

R10 **64E-5.6412 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.**
(Entire section New)

- R10 (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical
R10 use shall perform full calibration measurements on each gamma stereotactic
R10 radiosurgery:
- R10 (a) Before the first medical use of the unit;
- R10 (b) 1. Before medical use whenever spot-check measurements indicate
R10 that the output differs by more than 5 percent from the output
R10 obtained at the last full calibration corrected mathematically for
R10 radioactive decay;

- R10 2. Before medical use following replacement of the source or following
R10 reinstallation of the gamma stereotactic radiosurgery unit in a new
R10 location;
- R10 3. Following any repair of the gamma stereotactic radiosurgery unit that
R10 includes removal of the sources or major repair of the components
R10 associated with the source assembly; and
- R10 (c) At intervals not exceeding 1 year, with the exception that relative helmet
R10 factors need only be determined before the first medical use of a helmet
R10 and following any damage to a helmet.
- R10 (2) Full calibration measurements of the gamma stereotactic radiosurgery unit shall
R10 include the determination of:
- R10 (a) The output within 3 percent;
- R10 (b) Relative helmet factors;
- R10 (c) Isocenter coincidence;
- R10 (d) Timer constancy and linearity over the range of use;
- R10 (e) On-off timers;
- R10 (f) Trunnion centricity;
- R10 (g) Treatment table retraction mechanism, using backup battery power or
R10 hydraulic backups with the unit off;
- R10 (h) Helmet microswitches;
- R10 (i) Emergency timing circuits; and
- R10 (j) Stereotactic frames and localizing devices (trunnions).
- R10 (3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C.,
R10 to measure the output for one set of exposure conditions. The remaining
R10 radiation measurements required in paragraph 64E-5.6412(2)(a), F.A.C., may be
R10 made using a dosimetry system that indicates relative dose rates.
- R10 (4) A licensee shall make full calibration measurements required by subsection
R10 64E-5.6412(1), F.A.C., in accordance with published protocols accepted by
R10 nationally recognized bodies.
- R10 (5) A licensee shall correct mathematically the outputs determined in paragraph
R10 64E-5.6412(2)(a), F.A.C., at intervals not exceeding 1 month for cobalt-60 and at
R10 intervals consistent with 1 percent physical decay for all other radionuclides.
- R10 (6) Full calibration measurements required by subsection 64E-5.6412(1), F.A.C., and
R10 physical decay corrections required by subsection 64E-5.6412(5), F.A.C., shall
R10 be performed by the authorized medical physicist.

- R10 (7) A licensee shall maintain a record of each gamma stereotactic radiosurgery unit
- R10 calibration for three years. The record shall include:
- R10 (a) The date of the calibration;
- R10 (b) The manufacturer's name, model number, and serial number for both the
- R10 gamma stereotactic radiosurgery unit and the source;
- R10 (c) The model numbers and serial numbers of the instruments used to
- R10 calibrate the gamma stereotactic radiosurgery unit;
- R10 (d) The results and an assessment of the full calibrations; and
- R10 (e) The signature of the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..

R10 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.

R10 History: New 02-11-10.

R10 **64E-5.642 Periodic Spot-Checks of Teletherapy Units.**

- (1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at least every month.
- (2) Spot-checks shall include the determination of:
 - (a) Timer constancy and timer linearity over the range of use;
 - (b) On-off error;
 - (c) The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - (d) The accuracy of all distance measuring and localization devices used for medical use;
 - (e) The output for one typical set of operating conditions; and
 - (f) The difference between the measurement made in paragraph 64E-5.642(2)(e), F.A.C., and the anticipated output, expressed as a percentage of the anticipated output, which is the value obtained at the last full calibration corrected mathematically for physical decay.
- (3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C., to make the spot-check required in paragraph 64E-5.642(2)(e), F.A.C.
- (4) A licensee shall perform spot-checks required by subsection 64E-5.642(1), F.A.C., following procedures established by the authorized medical physicist.
- (5) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days and promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification for 3 years.

- R10 (6) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility monthly and after each source installation.
- R10 (7) Safety spot-checks shall assure proper operation of:
- (a) Electrical interlocks at each teletherapy room entrance;
- (b) Electrical or mechanical stops installed to limit use of the primary beam of radiation, restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam on-off mechanism;
- R10 (c) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
- R10 (d) Viewing and intercom systems;
- (e) Treatment room doors from inside and outside the treatment room; and
- (f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.
- R10 (8) If the results of the checks required in subsection 64E-5.642(7), F.A.C., of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit.
- R10 (9) A licensee shall promptly repair any system identified in subsection 64E-5.642(7), F.A.C. that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.
- R10 (10) A licensee shall maintain a record of each spot-check required by 64E-5.642(1) and (6) for 3 years and a copy of the procedures required by subsection 64E-5.641(4), F.A.C., until the licensee no longer possesses the teletherapy unit. The record shall include:
- (a) The date of the spot-check;
- (b) The manufacturer's name, model number, and serial number for both the teletherapy unit and source;
- (c) The manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit;
- (d) The timer linearity and constancy;
- (e) The calculated on-off error;
- (f) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
- (g) The determined accuracy of each distance measuring or localization device;

(h) The difference between the anticipated output and the measured output;

(i) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors; and

R10 (j) The name of the individual who performed the periodic spot-check and the
 R10 signature of the authorized medical physicist who reviewed the record of
 R10 the spot check.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.761, Amended 02-11-10.

R10 **64E-5.6421 Periodic Spot-Checks for Remote Afterloader Units. (Entire section New)**

R10 (1) A licensee authorized to use a remote afterloader unit for medical use shall
 R10 perform the following spot-checks:

R10 (a) Before the first use of a high dose-rate, medium dose-rate, or pulsed
 R10 dose-rate remote afterloader unit on a given day;

R10 (b) Before each patient treatment with a low dose-rate remote afterloader unit;
 R10 and

R10 (c) After each source installation.

R10 (2) Spot-checks shall include the determination of:

R10 (a) Electrical interlocks at each remote afterloader unit room entrance;

R10 (b) Source exposure indicator lights on the remote afterloader unit, on the
 R10 control console, and in the facility;

R10 (c) Viewing and intercom systems in each high dose-rate, medium dose-rate,
 R10 and pulsed dose-rate remote afterloader facility;

R10 (d) Emergency response equipment;

R10 (e) Radiation monitors used to indicate the source position;

R10 (f) Timer accuracy;

R10 (g) Clock (date and time) in the unit's computer; and

R10 (h) Decayed source(s) activity in the unit's computer.

R10 (3) If the results of the checks required in subsection 64E-5.6421(2), F.A.C., of this
 R10 section indicate the malfunction of any system, a licensee shall lock the control
 R10 console in the off position and not use the unit except as may be necessary to
 R10 repair, replace, or check the malfunctioning system.

- R10 (4) A licensee shall perform spot-checks required by subsection 64E-5.6421(2),
R10 F.A.C., following procedures established by the authorized medical physicist.
- R10 (5) A licensee shall have the authorized medical physicist review the results of each
R10 spot-check within 15 days and promptly notify the licensee in writing of the
R10 results of each spot-check. The licensee shall keep a copy of each written
R10 notification for 3 years.
- R10 (6) A licensee shall retain a copy of the procedures required by subsection
R10 64E-5.6421(4), F.A.C., until the licensee no longer possesses the remote
R10 afterloader unit.
- R10 (7) A licensee shall maintain a record of each spot-check required by subsection
R10 64E-5.6421(2), F.A.C., for 3 years and a copy of the procedures required by
R10 subsections 64E-5.6421(4) and (5), F.A.C., until the licensee no longer
R10 possesses the remote afterloader unit. The record shall include:
- R10 (a) The date of the spot-check;
- R10 (b) The manufacturer's name, model number, and serial number for both the
R10 remote afterloader unit and source;
- R10 (c) An assessment of timer accuracy;
- R10 (d) Notations indicating the operability of each entrance door electrical
R10 interlock, radiation monitors, source exposure indicator lights, viewing and
R10 intercom systems, and clock and decayed source activity in the unit's
R10 computer; and
- R10 (e) The name of the individual who performed the periodic spot-check and the
R10 signature of the authorized medical physicist who reviewed the record of
R10 the spot-check.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..

R10 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.

R10 History: New 02-11-10.

R10 **64E-5.6422 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units**
(Entire section New)

- R10 (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical
R10 use shall perform the following spot-checks:
- R10 (a) Monthly;
- R10 (b) Before the first use of the unit on a given day; and
- R10 (c) After each source installation.
- R10 (2) Spot-checks shall include the determination of:
- R10 (a) Assure the proper operation of the:

- R10
R10 1. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
- R10
R10 2. Helmet microswitches;
- R10
R10 3. Emergency timing circuits; and
- R10
R10 4. Stereotactic frames and localizing devices (trunnions).
- R10 (b) Determine the following elements:
- R10
R10
R10 1. The output for one typical set of operating conditions measured with the dosimetry system described in subsection 64E-5.640(2), F.A.C.;
- R10
R10
R10
R10 2. The difference between the measurement made in subparagraph 64E-5.6422(2)(b)1, F.A.C., and the anticipated output, expressed as a percentage of the anticipated output value obtained at last full calibration corrected mathematically for physical decay;
- R10
R10 3. Source output against computer calculation;
- R10
R10 4. Timer accuracy and linearity over the range of use;
- R10
R10 5. On-off error; and
- R10
R10 6. Trunnion centricity.
- R10 (3) A licensee shall perform spot-checks required by subsection 64E-5.6422(1), F.A.C., following procedures established by the authorized medical physicist.
- R10 (4) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days and promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for 3 years
- R10 (5) To satisfy the requirements of paragraphs 64E-5.6422(1)(b) and (c), F.A.C., the licensee's spot-checks must assure proper operation of the following:
- R10 (a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
- R10 (b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
- R10 (c) Viewing and intercom systems;
- R10 (d) Timer termination;
- R10 (e) Radiation monitors used to indicate room exposures; and
- R10 (f) Emergency off buttons.

- R10 (6) If the results of the checks required in subsection 64E-5.6422(5), F.A.C., of this
R10 section indicate the malfunction of any system, a licensee shall lock the control
R10 console in the off position and not use the unit except as may be necessary to
R10 repair, replace, or check the malfunctioning system.
- R10 (7) A licensee shall arrange for the repair of any system identified in subsection
R10 64E-5.6422(2), F.A.C., that is not operating properly as soon as possible.
- R10 (8) A licensee shall maintain a record of each spot-check required by subsections
R10 64E-5.6422(2) and (5), F.A.C., for 3 years and a copy of the procedures required
R10 in subsections 64E-5.5422(2) and (3), F.A.C., until the licensee no longer
R10 possesses the gamma stereotactic radiosurgery unit. The record shall include:
- R10 (a) The date of the spot-check;
- R10 (b) The manufacturer's name, model number, and serial number for the
R10 gamma stereotactic radiosurgery unit;
- R10 (c) The manufacturer's name, model number and serial number of the
instrument used to measure the output of the gamma stereotactic
radiosurgery unit;
- R10 (d) The timer linearity and constancy;
- R10 (e) The calculated on-off error;
- R10 (f) A determination of trunnion centricity;
- R10 (g) The difference between the anticipated output and the measured output;
- R10 (h) An assessment of source output against computer calculations;
- R10 (i) Notations indicating the operability of radiation monitors, helmet
R10 microswitches, emergency timing circuits, emergency off buttons,
R10 electrical interlocks, source exposure indicator lights, viewing and intercom
R10 systems, timer termination, treatment table retraction mechanism, and
R10 stereotactic frames and localizing devices (trunnions); and
- R10 (j) The name of the individual who performed the periodic spot-check and the
R10 signature of the authorized medical physicist who reviewed the record of
R10 the spot-check.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..

R10 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.

R10 History: New 02-11-10.

R10 **64E-5.6423 Additional Technical Requirements for Mobile Remote Afterloader Units.**
R10 **(Entire section New)**

- R10 (1) A licensee providing mobile remote afterloader service for medical use shall
R10 perform the following:
- R10 (a) Check survey instruments before medical use at each address of use or
R10 on each day of use, whichever is more frequent; and
- R10 (b) Account for all sources before departure from a client's address of use.
- R10 (2) In addition to the periodic spot-checks required by Rule 64E-5.6421, F.A.C., a
R10 licensee authorized to use mobile afterloaders for medical use shall perform
R10 checks on each remote afterloader unit before use at each address of use. At a
R10 minimum, checks must be made to verify the operation of the following:
- R10 (a) Electrical interlocks on treatment area access points;
- R10 (b) Source exposure indicator lights on the remote afterloader unit, on the
R10 control console, and in the facility;
- R10 (c) Viewing and intercom systems;
- R10 (d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;
- R10 (e) Radiation monitors used to indicate room exposures;
- R10 (f) Source positioning (accuracy); and
- R10 (g) Radiation monitors used to indicate whether the source has returned to a
R10 safe shielded position.
- R10 (3) In addition to the requirements for checks in subsection 64E-5.6423(2), F.A.C., a
R10 licensee shall ensure overall proper operation of the remote afterloader unit by
R10 conducting a simulated cycle of treatment before use at each address of use.
- R10 (4) If the results of the checks required in subsection 64E-5.6423(2), F.A.C., indicate
R10 the malfunction of any system, a licensee shall lock the control console in the off
R10 position and not use the unit except as may be necessary to repair, replace, or
R10 check the malfunctioning system.
- R10 (5) The licensee shall keep a copy of each check for mobile remote afterloader unit
R10 required by subsection 64E-5.6423(2), F.A.C., for three years. The records shall
R10 include:
- R10 (a) The date of the check;
- R10 (b) The manufacturer's name, model number, and serial number of the
R10 remote afterloader unit;
- R10 (c) Notations accounting for all sources before the licensee departs from a
R10 facility;

R10 (d) Notations indicating the operability of each entrance door electrical
 R10 interlock, radiation monitors, source exposure indicator lights, viewing and
 R10 intercom system, applicators, source transfer tubes, and transfer tube
 R10 applicator interfaces, and source positioning accuracy; and

R10 (e) The signature of the individual who performed the check.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..

R10 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.

R10 History: New 02-11-10.

64E-5.643 Radiation Surveys for Teletherapy Facilities.

R2 (1) The licensee shall perform radiation surveys with an operable radiation survey
 R2 instrument calibrated as provided in Rule 64E-5.615, F.A.C., before medical use,
 R2 after each installation of a teletherapy source, and after making any change for
 R2 which an amendment is required by Rule 64E-5.636, F.A.C.

(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.

R2 (b) With the teletherapy source in the on position with the largest clinically
 R2 available treatment field and with a scattering phantom in the primary
 R2 beam of radiation, radiation levels in restricted areas shall be unlikely to
 R2 cause any occupationally exposed individuals to receive a dose in excess
 R2 of the limits specified in Rule 64E-5.304, F.A.C.; and radiation dose rates
 R2 of any individual member of the public in unrestricted areas shall not
 R2 exceed the limits specified in paragraph 64E-5.312(1)(c), F.A.C.

(2) If the results of the surveys required in subsection 64E-5.643(1), F.A.C., indicate
 any radiation levels in excess of the limits specified, the licensee shall lock the
 control in the off position and shall not use the unit:

(a) Except to repair, replace, or test the teletherapy unit, the teletherapy unit
 shielding, or the treatment room shielding; or

(b) Until the licensee has received a specific exemption from the department.

(3) A licensee shall maintain a record of the radiation measurements made following
 installation of a source for the duration of the license. The record shall include:

(a) The date of the measurements;

(b) The reason the survey is required;

(c) The manufacturer's name, model number and serial number of the
 teletherapy unit, the source, and the instrument used to measure radiation
 levels;

- (d) Each dose rate measured around the teletherapy source while in the off position and the average of all measurements;
 - (e) A plan of the areas surrounding the treatment room that were surveyed;
 - (f) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;
 - (g) The calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and
- R10 (h) The signature of the RSO or the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
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, F.S.
R10 History: New 8-25-91, Amended 1-1-994, Formerly 10D-91.762, Amended 10-8-00, Amended 02-11-10.

R10 **64E-5.644 Radiation Surveys for Remote Afterloader and Gamma Stereotactic**
R10 **Radiosurgery Facilities. (Entire section Changed)**

- R10 (1) The licensee shall perform radiation surveys with an operable radiation survey instrument calibrated as provided in Rule 64E-5.615, F.A.C., to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.
- R10 (2) The licensee shall make the survey specified in subsection 64E-5.644(1), F.A.C., at the installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- R10 (3) A licensee shall retain a record of the radiation surveys required by subsection 64E-5.644(1), F.A.C., for the duration of the license. These records shall include:
- (a) The date of the measurements;
 - (b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
 - (c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
 - (d) The signature of the RSO or authorized medical physicist who performed the test.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
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, F.S.
R10 History: New 8-25-91, Formerly 10D-91.763, Amended 02-11-10.

R10 **64E-5.645 Therapy-Related Computer Systems. (Entire section Changed)** The
 R10 licensee shall perform acceptance testing on the treatment planning system of therapy-related
 R10 computer systems in accordance with published protocols accepted by nationally recognized
 R10 bodies. An example of a nationally recognized body is the American Association of Physicists
 R10 in Medicine. At a minimum, the acceptance testing must include, as applicable, verification of
 R10 the following:

- R10 (1) The source-specific input parameters required by the dose calculation algorithm;
- R10 (2) The accuracy of dose, dwell time, and treatment time calculations at
 representative points;
- R10 (3) The accuracy of isodose plots and graphic displays;
- R10 (4) The accuracy of the software used to determine sealed source positions from
 R10 radiographic images; and
- R10 (5) The accuracy of electronic transfer of the treatment delivery parameters to the
 R10 treatment delivery unit from the treatment planning system.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.764, Amended 10-8-00, Amended 02-11-10.

64E-5.646 Reports of Teletherapy Surveys, Checks, Tests, and Measurements.

A licensee shall furnish a copy of the records required in Rules 64E-5.643, 64E-5.644, and 64E-5.645, F.A.C., and the output from the teletherapy source expressed as rads (grays) per hour at 1 meter from the source as determined during the full calibration required in Rule 64E-5.641, F.A.C., to the department within 30 days following completion of the action that initiated the record requirement.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

History: New 8-25-91, Formerly 10D-91.765.

64E-5.647 Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

- R10 (1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery
 R10 unit fully inspected and serviced during source replacement or at least every 5
 years, whichever comes first, to assure proper functioning of the source
 exposure mechanism.
- (2) This inspection and servicing shall only be performed by persons specifically
 licensed to do so by the department, an agreement state, or the U.S. Nuclear
 Regulatory Commission.

- (3) A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain:
- (a) The inspector's name;
 - R10 (b) The inspector's **radioactive materials** license number;
 - (c) The date of inspection;
 - R10 (d) The manufacturer's name and model number and serial number for both the **treatment** unit and source;
 - (e) A list of components inspected;
 - (f) A list of components serviced and the type of service;
 - (g) A list of components replaced; and
 - (h) The signature of the inspector.

R10 **Rulemaking** Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.766, **Amended 02-11-10**.

SUBPART I TRAINING AND EXPERIENCE REQUIREMENTS

R10 **64E-5.648 Radiation Safety Officer.** Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the RSO as provided in Rule 64E-5.605, F.A.C., to be an individual who: **(Entire section Changed)**

- R10 (1) **Is certified by a specialty board whose certification process has been recognized**
 R10 **by the NRC or an agreement state and who meets the requirements in**
 R10 **subsections 64E-5.648(4) and (5), F.A.C., of this section. (The names of board**
 R10 **certifications which have been recognized by the NRC or an agreement state will**
 R10 **be posted on the NRC's Web page at [http://www.nrc.gov/materials/miau/med-](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html)**
 R10 **use-toolkit/spec-board-cert.html.) To have its certification process recognized, a**
 R10 **specialty board shall require all candidates for certification to:**
- R10 (a) 1. **Hold a bachelor's or graduate degree from an accredited college or**
 R10 **university in physical science or engineering or biological science**
 R10 **with a minimum of 20 college credits in physical science;**
 - R10 2. **Have 5 or more years of professional experience in health physics**
 R10 **(graduate training may be substituted for no more than 2 years of**
 R10 **the required experience) including at least 3 years in applied health**
 R10 **physics; and**
 - R10 3. **Pass an examination administered by diplomates of the specialty**
 R10 **board, which evaluates knowledge and competence in radiation**
 R10 **physics and instrumentation, radiation protection, mathematics**
 R10 **pertaining to the use and measurement of radioactivity, radiation**
 R10 **biology, and radiation dosimetry; or**

- R10 (b) 1. Hold a master's or doctor's degree in physics, medical physics,
R10 other physical science, engineering, or applied mathematics from
R10 an accredited college or university;
- R10 2. Have 2 years of full-time practical training and/or supervised
R10 experience in medical physics either:
- R10 a. Under the supervision of a medical physicist who is certified
R10 in medical physics by a specialty board recognized by the
R10 NRC or an agreement state; or
- R10 b. In clinical nuclear medicine facilities providing diagnostic or
R10 therapeutic services under the direction of physicians who
R10 meet the requirements for authorized users in Rule
R10 64E-5.657, 64E-4.650 or 64E-5.660, F.A.C.;
- R10 3. Pass an examination, administered by diplomates of the
R10 specialty board, that assesses knowledge and competence
R10 in clinical diagnostic radiological or nuclear medicine physics
R10 and in radiation safety; or
- R10 (2) Have completed a structured educational program consisting of both:
- R10 (a) 200 hours of classroom and laboratory training in the following areas:
- R10 1. Radiation physics and instrumentation;
- R10 2. Radiation protection;
- R10 3. Mathematics pertaining to the use and measurement of
R10 radioactivity;
- R10 4. Radiation biology; and
- R10 5. Radiation dosimetry.
- R10 (b) One year of full-time radiation safety experience under the supervision of
R10 the individual identified as the RSO on a NRC or agreement state license
R10 or permit issued by a NRC master material licensee that authorizes similar
R10 type(s) of use(s) of radioactive material involving the following:
- R10 1. Shipping, receiving, and performing related radiation surveys;
- R10 2. Using and performing checks for proper operation of instruments
R10 used to determine the activity of dosages, survey meters, and
R10 instruments used to measure radionuclides;
- R10 3. Securing and controlling radioactive material;
- R10 4. Using administrative controls to avoid mistakes in the
R10 administration of radioactive material;

- R10 5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- R10 6. Using emergency procedures to control radioactive material; and
- R10 7. Disposing of radioactive material; or
- R10 (3) (a) Is a medical physicist who has been certified by a specialty board whose
R10 certification process has been recognized by the NRC or an agreement
R10 state under subsection 64E-5.656(1), F.A.C., and has experience in
R10 radiation safety for similar types of use of radioactive material for which
R10 the licensee is seeking the approval of the individual as RSO and who
R10 meets the requirements in subsections 64E-5.648(4) and (5), F.A.C., of
R10 this section; or
- R10 (b) Is an authorized user, authorized medical physicist, or authorized nuclear
R10 pharmacist identified on the licensee's license and has experience with the
R10 radiation safety aspects of similar types of use of radioactive material for
R10 which the individual has RSO responsibilities; and
- R10 (4) Have obtained written attestation, signed by a preceptor RSO, or residency
R10 program director who represents a consensus of residency program faculties (as
R10 long as at least one member of the residency program faculty is an authorized
R10 individual in the same category as designated by the applicant seeking
R10 authorized status) who meets the requirements in subsection 64E-5.648(5)
R10 and in subparagraphs 64E-5.648(1)(a)1., and 64E-5.648(1)(a)2., or
R10 64E-5.648(1)(b)1., and 64E-5.648(1)(b)2., or subsection 64E-5.648(2) or
R10 paragraph 64E-5.648(3)(a), F.A.C., of this section, and has demonstrated the
R10 ability to function independently as a RSO to fulfill the radiation safety related
R10 duties for a medical use licensee; and
- R10 (5) Has training in the radiation safety, regulatory issues, and emergency procedures
R10 for the types of use for which a licensee seeks approval. This training
R10 requirement may be satisfied by completing training that is supervised by a RSO,
R10 authorized medical physicist, authorized nuclear pharmacist, or authorized user,
R10 as appropriate, who is authorized for the type(s) of use for which the licensee is
R10 seeking approval.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
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, F.S.
R10 History: New 8-25-91, Formerly 10D-91.767, Amended 02-11-10.

64E-5.649 Training for Uptake, Dilution, or Excretion Studies. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a radiopharmaceutical listed in subsection 64E-5.626(1), F.A.C., to: **(Entire section Changed)**

- R10 (1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.649(3)(b), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
- R10 (a) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraph 64E-5.649(3)(a) and subparagraph 64E-5.649(3)(a)2., F.A.C., of this section; and
- R10 (b) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
- R10 (2) Be an authorized user under Rule 64E-5.650 or 64E-5.660, F.A.C., or equivalent agreement state requirements; or
- R10 (3) (a) Have completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include the following:
- R10 1. Classroom and laboratory training in the following areas:
- R10 a. Radiation physics and instrumentation;
- R10 b. Radiation protection;
- R10 c. Mathematics pertaining to the use and measurement of radioactivity;
- R10 d. Chemistry of radioactive material for medical use; and
- R10 2. Work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.649, 64E-5.650 or 64E-5.660, F.A.C., or equivalent agreement state requirements, involving the following:
- R10 a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- R10 b. Performing quality control procedures on instruments used to
R10 determine the activity of dosages and performing checks for
R10 proper operation of survey meters;
- R10 c. Calculating, measuring, and safely preparing patient or
R10 human research subject dosages;
- R10 d. Using administrative controls to prevent a medical event
R10 involving the use of unsealed radioactive material;
- R10 e. Using procedures to contain spilled radioactive material
R10 safely and using proper decontamination procedures; and
- R10 f. Administering dosages of radioactive drugs to patients or
R10 human research subjects.

- R10 (b) Have obtained written attestation, signed by a preceptor authorized user
R10 or a residency program director who represents a consensus of residency
R10 program faculties (as long as at least one member of the residency
R10 program faculty is an authorized individual in the same category
R10 designated by the applicant seeking authorized status) who meets the
R10 requirements in Rule 64E-5.657, 64E-5.649, 64E-5.650 or 64E-5.660,
R10 F.A.C., or equivalent agreement state requirements, that the individual has
R10 satisfactorily completed the requirements in paragraph
R10 64E-5.649(1)(a) or 64E-5.649(3)(a), F.A.C., of this section and has
R10 demonstrated the ability to function independently as an authorized user
R10 to fulfill the radiation safety related duties for medical uses authorized
R10 under subsection 64E-5.626(1), F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.769, Amended 02-11-10.

- R10 **64E-5.650 Training for Imaging and Localization Studies for Which a Written**
R10 **Directive Is Not Required.** Except as provided in Rule 64E-5.657, F.A.C., the licensee shall
R10 require the authorized user specified in subsection 64E-5.627(1), F.A.C., to:
(Entire section Changed)

- R10 (1) Be certified by a medical specialty board whose certification process has been
R10 recognized by the NRC or an agreement state and who meets the requirements
R10 in paragraph 64E-5.650(3)(b), F.A.C., of this section. (The names of board
R10 certifications which have been recognized by the NRC or an agreement state will
R10 be posted on the NRC's Web page at [http://www.nrc.gov/materials/miau/med-
R10 use-toolkit/spec-board-cert.html](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html).) To have its certification process recognized, a
R10 specialty board shall require all candidates for certification to:

- R10 (a) Complete 700 hours of training and experience in basic radionuclide
R10 handling techniques and radiation safety applicable to the medical use of
R10 unsealed radioactive material for imaging and localization studies that
R10 includes the topics listed in subparagraphs 64E-5.650(3)(a)1. and
R10 64E-5.650(3)(a)2., F.A.C., of this section; and

- R10 (b) Pass an examination, administered by diplomates of the specialty board,
R10 which assesses knowledge and competence in radiation safety,
R10 radionuclide handling, and quality control; or
- R10 (2) Be an authorized user under Rule 64E-5.660, F.A.C., and meet the requirements
R10 in sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C., or equivalent agreement state
R10 requirements; or paragraph 64E-5.650(3)(a), F.A.C.; or
- R10 (3) (a) Have completed 700 hours of training and experience, including a
R10 minimum of 80 hours of classroom and laboratory training, in basic
R10 radionuclide handling techniques applicable to the medical use of
R10 unsealed radioactive material for imaging and localization studies. The
R10 training and experience must include, at a minimum the following:
- R10 1. Classroom and laboratory training in the following areas:
 - R10 a. Radiation physics and instrumentation;
 - R10 b. Radiation protection;
 - R10 c. Mathematics pertaining to the use and measurement of
R10 radioactivity;
 - R10 d. Chemistry of radioactive material for medical use;
 - R10 e. Radiation biology; and
 - R10 2. Work experience, under the supervision of an authorized user who
R10 meets the requirements in Rule 64E-5.657, 64E-5.650 or sub-
R10 subparagraph 64E-5.650(3)(a)2.g., and Rule 64E-5.660, F.A.C., or
R10 equivalent agreement state requirements, involving the following:
 - R10 a. Ordering, receiving, and unpacking radioactive materials
R10 safely and performing the related radiation surveys;
 - R10 b. Performing quality control procedures on instruments used
R10 to determine the activity of dosages and performing checks
R10 for proper operation of survey meters;
 - R10 c. Calculating, measuring, and safely preparing patient or
R10 human research subject dosages;
 - R10 d. Using administrative controls to prevent a medical event
R10 involving the use of unsealed radioactive material;
 - R10 e. Using procedures to safely contain spilled radioactive material
R10 and using proper decontamination procedures;
 - R10 f. Administering dosages of radioactive drugs to patients or
R10 human research subjects; and

R10 g. Eluting generator systems appropriate for preparation of
 R10 radioactive drugs for imaging and localization studies,
 R10 measuring and testing the eluate for radionuclide purity, and
 R10 processing the eluate with reagent kits to prepare labeled
 R10 radioactive drugs; and

R10 (3) (b) Have obtained written attestation, signed by a preceptor authorized user
 R10 or a residency program director who represents a consensus of residency
 R10 program faculties (as long as at least one member of the residency
 R10 program faculty is an authorized individual in the same category
 R10 designated by the applicant seeking authorized status) who meets the
 R10 requirements in Rules 64E-5.657, 64E-5.650, 64E-5.660, and sub-
 R10 subparagraph 64E-5.650(3)(a)2.g., F.A.C., or equivalent agreement state
 R10 requirements, that the individual has satisfactorily completed the
 R10 requirements in paragraph 64E-5.650(1)(a) or 64E-5.650(3)(a) or
 R10 64E-5.650(3)(a), F.A.C., of this section and has demonstrated the ability to
 R10 function independently as an authorized user to fulfill the radiation safety
 R10 related duties for medical uses authorized under subsections
 R10 64E-5.626(1) and 64E-5.627(1), F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.770, Amended 02-11-10.

R10 **64E-5.651 Repealed 02-11-10 (See Rules 64E-5.660, 64E-5.661, 64E-5.662 & 64E-5.663)**

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.771, Repealed 02-11-10.

R10 **64E-5.652 Training for Use of Manual Brachytherapy Sources.** Except as
 R10 provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a
 R10 brachytherapy source specified in 64E-5.632, F.A.C., to: **(Entire section Changed)**

R10 (1) Be certified by a medical specialty board whose certification process has been
 R10 recognized by the NRC or an agreement state, and who meets the requirements
 R10 in paragraph 64E-5.652(2)(c), F.A.C., of this section. (The names of board
 R10 certifications which have been recognized by the NRC or an agreement state will
 R10 be posted on the NRC's Web page at [http://www.nrc.gov/materials/miau/med-
 R10 use-toolkit/spec-board-cert.html](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html).) To have its certification process recognized, a
 R10 specialty board shall require all candidates for certification to:

R10 (a) Successfully complete a minimum of 3 years of residency training in a
 R10 radiation oncology program approved by the Residency Review
 R10 Committee of the Accreditation Council for Graduate Medical Education or
 R10 the Royal College of Physicians and Surgeons of Canada or the
 R10 Committee on Post-Graduate Training of the American Osteopathic
 R10 Association; and

R10 (b) Pass an examination, administered by diplomates of the specialty board,
 R10 that tests knowledge and competence in radiation safety, radionuclide
 R10 handling, treatment planning, quality assurance, and clinical use of manual
 R10 brachytherapy; or

- R10 (2) (a) Have completed a structured educational program in basic radionuclide
R10 handling techniques applicable to the use of manual brachytherapy
R10 sources that includes-
- R10 1. 200 hours of classroom and laboratory training in the following
R10 areas:
- R10 a. Radiation physics and instrumentation;
- R10 b. Radiation protection;
- R10 c. Mathematics pertaining to the use and measurement of
R10 radioactivity; and
- R10 d. Radiation biology; and
- R10 2. 500 hours of work experience, under the supervision of an
R10 authorized user who meets the requirements in Rule 64E-5.657 or
R10 64E-5.652, F.A.C., or equivalent agreement state requirements at a
R10 medical institution, clinic, or private practice facility, involving the
R10 following:
- R10 a. Ordering, receiving, and unpacking radioactive materials
R10 safely and performing the related radiation surveys;
- R10 b. Checking survey meters for proper operation;
- R10 c. Preparing, implanting, and removing brachytherapy sources;
- R10 d. Maintaining running inventories of material on hand;
- R10 e. Using administrative controls to prevent a medical event
R10 involving the use of radioactive material;
- R10 f. Using emergency procedures to control radioactive material;
R10 and
- R10 (b) Have completed 3 years of supervised clinical experience in radiation
R10 oncology, under an authorized user who meets the requirements in Rule
R10 64E-5.657 or 64E-5.652, F.A.C., or equivalent agreement state
R10 requirements, as part of a formal training program approved by the
R10 Residency Review Committee for Radiation Oncology of the Accreditation
R10 Council for Graduate Medical Education or the Royal College of
R10 Physicians and Surgeons of Canada or the Committee on Postdoctoral
R10 Training of the American Osteopathic Association. This experience may
R10 be obtained concurrently with the supervised work experience required by
R10 subparagraph 64E-5.652(2)(a)2., F.A.C., of this section; and

R10 (c) Have obtained written attestation, signed by a preceptor authorized user
 R10 or a residency program director who represents a consensus of residency
 R10 program faculties (as long as at least one member of the residency
 R10 program faculty is an authorized individual in the same category
 R10 designated by the applicant seeking authorized status) who meets the
 R10 requirements in Rule 64E-5.657 or 64E-5.652, F.A.C., or equivalent
 R10 agreement state requirements, that the individual has satisfactorily
 R10 completed the requirements in paragraph 64E-5.652(1)(a) or
 R10 64E-5.652(2)(a) and 64E-5.652(2)(b), F.A.C., of this section and have
 R10 demonstrated the ability to function independently as an authorized user
 R10 to fulfill the radiation safety related duties for medical uses of manual
 R10 brachytherapy sources authorized under Rule 64E-5.632, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.772, Amended 02-11-10.

64E-5.653 Training for Ophthalmic Use of Strontium 90. Except as provided in
 64E-5.657, the licensee shall require the authorized user of only strontium 90 for ophthalmic
 R10 radiotherapy to: **(Entire section Changed)**

R10 (1) Be authorized user under Rule 64E-5.652, F.A.C., or equivalent agreement state
 R10 requirements; or

R10 (2) (a) Have completed 24 hours of classroom and laboratory training applicable
 R10 to the medical use of strontium-90 for ophthalmic radiotherapy. The
 R10 training must include the following:

R10 1. Radiation Protection and instrumentation;

R10 2. Radiation Protection;

R10 3. Mathematics pertaining to the use and measurement of
 radioactivity; and

R10 4. Radiation biology; and

R10 (b) Have supervised clinical training in ophthalmic radiotherapy under the
 R10 supervision of an authorized user at a medical institution, clinic, or private
 R10 practice that includes the use of strontium-90 for the ophthalmic treatment
 R10 of five individuals. This supervised clinical training must involve the
 R10 following:

1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

R10 4. Follow-up and review of each individual's case history; and

R10 (c) Have obtained written attestation, signed by a preceptor authorized user
 R10 or a residency program director who represents a consensus of residency
 R10 program faculties (as long as at least one member of the residency
 R10 program faculty is an authorized individual in the same category
 R10 designated by the applicant seeking authorized status) who meets the
 R10 requirements in Rule 64E-5.657 or 64E-5.652, 64E-5.653, F.A.C., or
 R10 equivalent agreement state requirements, that the individual has
 R10 satisfactorily completed the requirements in paragraphs 64E-5.653(2)(a)
 R10 and 64E-5.653(2)(b), F.A.C., of this section and have demonstrated the
 R10 ability to function independently as an authorized user to fulfill the
 R10 radiation safety related duties for a medical use licensee authorized for
 R10 strontium-90 for ophthalmic use.

R10 **Rulemaking** Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
 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, F.S.
 R10 History: New 8-25-91, Formerly 10D-91.773, Amended 02-11-10.

64E-5.654 Training for Use of Sealed Sources for Diagnosis. Except as provided
 in 64E-5.657, the licensee shall require the authorized user of a sealed source in a device
 R10 specified in 64E-5.631, F.A.C., to: **(Entire section Changed)**

- R10 (1) Be certified by a specialty board whose certification process includes all of the
 R10 requirements in subsections 64E-5.654(2) and (3), F.A.C., of this section and
 R10 whose certification has been recognized by the NRC or an agreement state.
 R10 (The names of board certifications which have been recognized by the NRC or
 R10 an agreement state will be posted on the NRC's Web page at
 R10 <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>); or
- R10 (2) Have completed 8 hours of classroom and laboratory training in basic
 R10 radionuclide handling techniques specifically applicable to the use of the device.
 R10 The training must include the following:
 - R10 (a) Radiation physics and instrumentation;
 - R10 (b) Radiation protection;
 - R10 (c) Mathematics pertaining to the use and measurement of radioactivity; and
 - R10 (d) Radiation biology; and
- R10 (3) Have completed training in the use of the device for the uses requested.

R10 **Rulemaking** Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
 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, F.S.
 R10 History: New 8-25-91, Formerly 10D-91.774, Amended 02-11-10.

R10 **64E-5.655 Training for Use of Remote Afterloader Units, Teletherapy Units, and**
R10 **Gamma Stereotactic Radiosurgery Units.** Except as provided in 64E-5.657, the licensee
R10 shall require the authorized user of a sealed source specified in 64E-5.634, F.A.C., to:

R10 (1) Be certified by a medical specialty board whose certification process has been
R10 recognized by the NRC or an agreement state and who meets the requirements
R10 in paragraph 64E-5.655(2)(c) and subsection 64E-5.655(3), F.A.C., of this
R10 section. (The names of board certifications which have been recognized by the
R10 NRC or an agreement state will be posted on the NRC's Web page at
R10 <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To
R10 have its certification process recognized, a specialty board shall require all
R10 candidates for certification to:

R10 (a) Successfully complete a minimum of 3 years of residency training in a
R10 radiation therapy program approved by the Residency Review Committee
R10 of the Accreditation Council for Graduate Medical Education or the Royal
R10 College of Physicians and Surgeons of Canada or the Committee on Post-
R10 Graduate Training of the American Osteopathic Association; and

R10 (b) Pass an examination, administered by diplomates of the specialty board,
R10 which tests knowledge and competence in radiation safety, radionuclide
R10 handling, treatment planning, quality assurance, and clinical use of
R10 stereotactic radiosurgery, remote afterloaders and external beam therapy;
R10 or

R10 (2) (a) Have completed a structured educational program in basic radionuclide
R10 techniques applicable to the use of a sealed source in a therapeutic
R10 medical unit that includes the following:

R10 1. 200 hours of classroom and laboratory training in the following
R10 areas:

R10 a. Radiation physics and instrumentation;

R10 b. Radiation protection;

R10 c. Mathematics pertaining to the use and measurement of
R10 radioactivity; and

R10 d. Radiation biology; and

R10 2. 500 hours of work experience, under the supervision of an
R10 authorized user who meets the requirements in Rule 64E-5.657 or
R10 64E-5.655, F.A.C., or equivalent agreement state requirements at a
R10 medical institution, clinic, or private practice facility, involving the
R10 following:

R10 a. Reviewing full calibration measurements and periodic spot-
R10 checks;

R10 b. Preparing treatment plans and calculating treatment doses
R10 and times;

- R10 c. Using administrative controls to prevent a medical event
- R10 involving the use of radioactive material;
- R10 d. Implementing emergency procedures to be followed in the
- R10 event of the abnormal operation of the medical unit or
- R10 console;
- R10 e. Checking and using survey meters;
- R10 f. Selecting the proper dose and how it is to be administered;
- R10 and

R10 (b) Have completed 3 years of supervised clinical experience in radiation

R10 therapy, under an authorized user who meets the requirements in Rule

R10 64E-5.657 or 64E-5.655, F.A.C., or equivalent agreement state

R10 requirements as part of a formal training program approved by the

R10 Residency Review Committee for Radiation Oncology of the Accreditation

R10 Council for Graduate Medical Education or the Royal College of

R10 Physicians and Surgeons of Canada or the Committee on Postdoctoral

R10 Training of the American Osteopathic Association. This experience may

R10 be obtained concurrently with the supervised work experience required by

R10 subparagraph 64E-5.655(2)(a)2., F.A.C., of this section; and

R10 (c) Have obtained written attestation that the individual has satisfactorily

R10 completed the requirements in paragraph 64E-5.655(1)(a) or

R10 64E-5.655(2)(a) and 64E-5.655(2)(b) and subsection 64E-5.655(3),

R10 F.A.C., of this section, and have demonstrated the ability to function

R10 independently as an authorized user to fulfill the radiation safety related

R10 duties for a medical use licensee for each type of therapeutic medical unit

R10 for which the individual is requesting authorized user status. The written

R10 attestation must be signed by a preceptor authorized user or a residency

R10 program director who represents a consensus of residency program

R10 faculties (as long as at least one member of the residency program faculty

R10 is an authorized individual in the same category designated by the

R10 applicant seeking authorized status) who meets the requirements in Rule

R10 64E-5.657 or 64E-5.655, F.A.C., or equivalent agreement state

R10 requirements for an authorized user for each type of therapeutic medical

R10 unit for which the individual is requesting authorized user status; and

R10 (3) Have received training in device operation, safety procedures, and clinical use for

R10 the type(s) of use for which authorization is sought. This training requirement

R10 may be satisfied by satisfactory completion of a training program provided by the

R10 vendor for new users or by receiving training supervised by an authorized user or

R10 authorized medical physicist, as appropriate, who is authorized for the type(s) of

R10 use for which the individual is seeking authorization.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
 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, F.S.
 R10 History: New 8-25-91, Formerly 10D-91.775, Amended 02-11-10.

R10 **64E-5.656 Training for an Authorized Medical Physicist.** Except as provided in
R10 Rule 64E-5.657, F.A.C., the licensee shall require the authorized medical physicist to:
(Entire section Changed)

- R10 (1) Be certified by a specialty board whose certification process has been
R10 recognized by the NRC or an agreement state and who meets the requirements
R10 in paragraph 64E-5.656(2)(b) and subsection 64E-5.656(3), F.A.C., of this
R10 section. (The names of board certifications which have been recognized by the
R10 NRC or an agreement state will be posted on the NRC's Web page at
R10 <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To
R10 have its certification process recognized, a specialty board shall require all
R10 candidates for certification to:
- R10 (a) Hold a master's or doctor's degree in physics, medical physics, other
R10 physical science, engineering, or applied mathematics from an accredited
R10 college or university;
- R10 (b) Have 2 years of full-time practical training and/or supervised experience in
R10 medical physics:
- R10 1. Under the supervision of a medical physicist who is certified in
R10 medical physics by a specialty board recognized by the NRC or an
R10 agreement state; or
- R10 2. In clinical radiation facilities providing high-energy, external beam
R10 therapy (photons and electrons with energies greater than or equal
R10 to 1 million electron volts) and brachytherapy services under the
R10 direction of physicians who meet the requirements for authorized
R10 users in Rule 64E-5.657, 64E-5.652 or 64E-5.655, F.A.C.; and
- R10 (c) Pass an examination, administered by diplomates of the specialty board,
R10 that assesses knowledge and competence in clinical radiation therapy,
R10 radiation safety, calibration, quality assurance, and treatment planning for
R10 external beam therapy, brachytherapy, and stereotactic radiosurgery; or
- R10 (2) (a) Hold a master's or doctor's degree in physics, medical physics, other
R10 physical science, engineering, or applied mathematics from an accredited
R10 college or university; and has completed 1 year of full-time training in
R10 medical physics and an additional year of full-time work experience under
R10 the supervision of an individual who meets the requirements for an
R10 authorized medical physicist for the type(s) of use for which the individual
R10 is seeking authorization. This training and work experience must be
R10 conducted in clinical radiation facilities that provide high-energy, external
R10 beam therapy (photons and electrons with energies greater than or equal
R10 to 1 million electron volts) and brachytherapy services and must include:

- R10 1. Performing sealed source leak tests and inventories;
- R10 2. Performing decay corrections;
- R10 3. Performing full calibration and periodic spot checks of external
R10 beam treatment units, stereotactic radiosurgery units, and remote
R10 afterloading units as applicable; and
- R10 4. Conducting radiation surveys around external beam treatment
R10 units, stereotactic radiosurgery units, and remote afterloading units
R10 as applicable; and
- R10 (b) Have obtained written attestation that the individual has satisfactorily
R10 completed the requirements in subsection 64E-5.656(3) and paragraphs
R10 64E-5.656(1)(a) and (b) or 64E-5.656(2)(a) and subsection 64E-5.656(3),
R10 F.A.C., of this section, and have demonstrated the ability to function
R10 independently as an authorized medical physicist to fulfill the radiation
R10 safety related duties for each type of therapeutic medical unit for which the
R10 individual is requesting authorized medical physicist status. The written
R10 attestation must be signed by a preceptor authorized user or a residency
R10 program director who represents a consensus of residency program
R10 faculties (as long as at least one member of the residency program faculty
R10 is an authorized individual in the same category designated by the
R10 applicant seeking authorized status) who meets the requirements in Rule
R10 64E-5.656 or 64E-5.657, F.A.C., or equivalent agreement state
R10 requirements, for an authorized medical physicist for each type of
R10 therapeutic medical unit for which the individual is requesting authorized
R10 medical physicist status; and
- R10 (3) Have training for the type(s) of use for which authorization is sought that includes
R10 hands-on device operation, safety procedures, clinical use, and the operation of
R10 a treatment planning system. This training requirement may be satisfied by
R10 satisfactorily completing either a training program provided by the vendor or by
R10 training supervised by an authorized medical physicist authorized for the type(s)
R10 of use for which the individual is seeking authorization.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
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, F.S.
R10 History: New 8-25-91, Formerly 10D-91.776, Amended 02-11-10.

R10 **64E-5.657 Training for Experienced RSO, Teletherapy or Medical Physicist,**
 R10 **Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized**
 R10 **Nuclear Pharmacist. (Entire section Changed)**

R10 (1) (a) An individual identified as a RSO, a teletherapy or medical physicist, or a
 R10 nuclear pharmacist on a NRC or agreement state license or a permit
 R10 issued by a NRC or agreement state broad scope licensee or master
 R10 material license permit or by a master material license permittee of broad
 R10 scope, need not comply with the training requirements of Rule
 R10 64E-5.648, 64E-5.656 or 64E-5.659, F.A.C., respectively.

R10 (b) An individual identified as a RSO, an authorized medical physicist, or an
 R10 authorized nuclear pharmacist on a NRC or agreement state license or a
 R10 permit issued by a NRC or agreement state broad scope licensee or
 R10 master material license permit or by a master material license permittee of
 R10 broad scope, need not comply with the training requirements of Rule
 R10 64E-5.648, 64E-5.656 or 64E-5.659, F.A.C., respectively.

R10 (2) Physicians, dentists, or podiatrists identified as authorized users for the medical
 R10 use of radioactive material on a license issued by the NRC or agreement state, a
 R10 permit issued by a NRC master material licensee, a permit issued by a NRC or
 R10 agreement state broad scope licensee, or a permit issued by a NRC master
 R10 material license broad scope permittee who perform only those medical uses for
 R10 which they were authorized, need not comply with the training requirements of
 R10 Rule 64E-5.649, 64E-5.650, 64E-5.660, 64E-5.661, 64E-5.662, 64E-5.663,
 R10 64E-5.652, 64E-5.653, 64E-5.654 or 64E-5.655, F.A.C.

R10 (3) Individuals who need not comply with training requirements as described in this
 R10 section may serve as preceptors for, and supervisors of, applicants seeking
 R10 authorization on department radioactive materials licenses for the same uses for
 R10 which these individuals are authorized.

R10 Rulemaking Authority: 404.051, 404.061, 404.071, F.S.

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

R10 History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.777, Amended 02-11-10.

64E-5.658 Recentness of Training. The training and experience specified in
 R10 Rules 64E-5.648, 64E-5.649, 64E-5.650, 64E-5.652, 64E-5.653, 64E-5.654, 64E-5.655, 64E-
 R10 5.656, 64E-5.657, 64E-5.659, 64E-5.660, 64E-5.661, 64E-5.662 and 64E-5.663, F.A.C., shall
 R10 have been obtained within the 7 years preceding the date of application or the individual shall
 R10 have had related continuing education or experience since the required training and
 R10 experience was completed and within the 7 years preceding the date of application.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

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, F.S.

R10 History: New 8-25-91, Formerly 10D-91.779, Amended 02-11-10.

R10 **64E-5.659 Training for an Authorized Nuclear Pharmacist.** Except as provided in Rule
R10 64E-5.657, F.A.C., the licensee shall require the authorized nuclear pharmacist to:
(Entire section New)

- R10 (1) Be certified by a specialty board whose certification process has been
R10 recognized by the NRC or an agreement state and who meets the requirements
R10 in paragraph 64E-5.659(2)(b), F.A.C., of this section. (The names of board
R10 certifications which have been recognized by the NRC or an agreement state will
R10 be posted on the NRC's Web page at [http://www.nrc.gov/materials/miau/med-
R10 use-toolkit/spec-board-cert.html](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html).) To have its certification process recognized, a
R10 specialty board shall require all candidates for certification to:
- R10 (a) Have graduated from a pharmacy program accredited by the American
R10 Council on Pharmaceutical Education (ACPE) or have passed the Foreign
R10 Pharmacy Graduate Examination Committee (FPGEC) examination;
- R10 (b) Hold a current, active license to practice pharmacy;
- R10 (c) Provide evidence of having acquired at least 4000 hours of
R10 training/experience in nuclear pharmacy practice. Academic training may
R10 be substituted for no more than 2000 hours of the required training and
R10 experience; and
- R10 (d) Pass an examination in nuclear pharmacy administered by diplomats of
R10 the specialty board, that assess knowledge and competency in
R10 procurement, compounding, quality assurance, dispensing, distribution,
R10 health and safety, radiation safety, provision of information and
R10 consultation, monitoring patient outcomes, research and development; or
- R10 (2) (a) Have completed 700 hours in a structured educational program consisting
R10 of both:
- R10 1. 200 hours of classroom and laboratory training in the following
R10 areas:
- R10 a. Radiation physics and instrumentation;
- R10 b. Radiation protection;
- R10 c. Mathematics pertaining to the use and measurement of
R10 radioactivity;
- R10 d. Chemistry of radioactive material for medical use; and
- R10 e. Radiation biology; and

- R10 2. Supervised practical experience in a nuclear pharmacy involving:
- R10 a. Shipping, receiving, and performing related radiation
R10 surveys;
- R10 b. Using and performing checks for proper operation of
R10 instruments used to determine the activity of dosages,
R10 survey meters, and, if appropriate, instruments used to
R10 measure alpha or beta-emitting radionuclides;
- R10 c. Calculating, assaying, and safely preparing dosages for
R10 patients or human research subjects;
- R10 d. Using administrative controls to avoid medical events in the
R10 administration of radioactive material; and
- R10 e. Using procedures to prevent or minimize radioactive
R10 contamination and using proper decontamination
R10 procedures; and
- R10 (b) Have obtained written attestation, signed by a preceptor authorized user
R10 or a residency program director who represents a consensus of residency
R10 program faculties (as long as at least one member of the residency
R10 program faculty is an authorized individual in the same category
R10 designated by the applicant seeking authorized status) who meets the
R10 requirements in paragraphs 64E-5.659(1)(a), 64E-5.659(1)(b) and
R10 64E-5.659(1)(c) or 64E-5.659(2)(a), F.A.C., of this section and have
R10 demonstrated the ability to function independently as an authorized
R10 nuclear pharmacist to fulfill the radiation safety related duties for a medical
R10 use licensee.
- R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
R10 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.
R10 History-New 02-11-10

R10 **64E-5.660 Training for Use of Unsealed Radioactive Material for Which a Written**
R10 **Directive Is Required in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C.** Except as
R10 provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of unsealed
R10 radioactive materials specified in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., which
R10 require a written directive to: **(Entire section New)**

- R10 (1) Be certified by a medical specialty board whose certification process has been
R10 recognized by the NRC or an agreement state and who meets the requirements
R10 in sub-subparagraphs 64E-5.660(2)(a)2.g. and paragraph 64E-5.660(2)(b),
R10 F.A.C., of this section. (Specialty boards whose certification processes have
R10 been recognized by the NRC or an agreement state will be posted on the NRC's
R10 Web page at [http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html)
R10 [cert.html](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html).) To be recognized, a specialty board shall require all candidates for
R10 certification to:
- R10 (a) Successfully complete residency training in a radiation therapy or nuclear
R10 medicine training program or a program in a related medical specialty.
R10 These residency training programs must include 700 hours of training and
R10 experience as described in subparagraph 64E-5.660(2)(a)1. through sub-
R10 subparagraph 64E-5.660(2)(a)2.e., F.A.C., of this section. Eligible training
R10 programs must be approved by the Residency Review Committee of the
R10 Accreditation Council for Graduate Medical Education, the Royal College
R10 of Physicians and Surgeons of Canada, or the Committee on Post-
R10 Graduate Training of the American Osteopathic Association; and
- R10 (b) Pass an examination, administered by diplomats of the specialty board,
R10 which tests knowledge and competence in radiation safety, radionuclide
R10 handling, quality assurance, and clinical use of unsealed radioactive
R10 material for which a written directive is required; or
- R10 (2) (a) Have completed 700 hours of training and experience, including a
R10 minimum of 200 hours of classroom and laboratory training, in basic
R10 radionuclide handling techniques applicable to the medical use of
R10 unsealed radioactive material requiring a written directive. The training
R10 and experience must include the following:
- R10 1. Classroom and laboratory training in the following areas:
- R10 a. Radiation physics and instrumentation;
- R10 b. Radiation protection;
- R10 c. Mathematics pertaining to the use and measurement of
R10 radioactivity;
- R10 d. Chemistry of radioactive material for medical use; and
- R10 e. Radiation biology; and

- R10 2. Work experience, under the supervision of an authorized user who
R10 meets the requirements in Rule 64E-5.657 or 64E-5.660, F.A.C., or
R10 equivalent agreement state requirements. A supervising authorized
R10 user, who meets the requirements in subsection
R10 64E-5.660(2), F.A.C., must also have experience in administering
R10 dosages in the same dosage category or categories (i.e., sub-
R10 subparagraph 64E-5.660(2)(a)2.g., F.A.C.) as the individual
R10 requesting authorized user status. The work experience must
R10 involve the following:
- R10 a. Ordering, receiving, and unpacking radioactive materials
R10 safely and performing the related radiation surveys;
- R10 b. Performing quality control procedures on instruments used
R10 to determine the activity of dosages, and performing checks
R10 for proper operation of survey meters;
- R10 c. Calculating, measuring, and safely preparing patient or
R10 human research subject dosages;
- R10 d. Using administrative controls to prevent a medical event
R10 involving the use of unsealed radioactive material;
- R10 e. Using procedures to contain spilled radioactive material
R10 safely and using proper decontamination procedures;
- R10 f. Performing checks for proper operation of survey meters;
R10 and
- R10 g. Administering dosages of radioactive drugs to patients or
R10 human research subjects involving a minimum of three
R10 cases in each of the following categories for which the
R10 individual is requesting authorized user status as listed
R10 below:
- R10 (I) Oral administration of less than or equal to
R10 1.22 gigabecquerels (33 millicuries) of sodium iodide
R10 I-131, for which a written directive is required or sub-
R10 sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.;
- R10 (II) Oral administration of greater than 1.22
R10 gigabecquerels (33 millicuries) of sodium iodide I-131;
- R10 (III) Parenteral administration of any beta emitter, or a
R10 photon-emitting radionuclide with a photon energy
R10 less than 150 keV, for which a written directive is
R10 required; and/or
- R10 (IV) Parenteral administration of any other radionuclide,
R10 for which a written directive is required; and

R10 (b) Have obtained written attestation that the individual has satisfactorily
 R10 completed the requirements in paragraphs 64E-5.660(1)(a) and
 R10 subparagraph 64E-5.660(2)(a)2.g., or paragraph 64E-5.660(2)(a), F.A.C.,
 R10 of this section, and have demonstrated the ability to function
 R10 independently as an authorized user to fulfill the radiation safety related
 R10 duties for a medical use licensee authorized under Rule 64E-5.626,
 R10 64E-5.627 or 64E-5.630, F.A.C., that require a written directive. Have
 R10 obtained written attestation, signed by a preceptor authorized user or a
 R10 residency program director who represents a consensus of residency
 R10 program faculties (as long as at least one member of the residency
 R10 program faculty is an authorized individual in the same category
 R10 designated by the applicant seeking authorized status) who meets the
 R10 requirements in Rule 64E-5.657 or 64E-5.660, F.A.C., or equivalent
 R10 agreement state requirements. The preceptor authorized user, who meets
 R10 the requirements in subsection 64E-5.660(2), F.A.C., must have
 R10 experience in administering dosages in the same dosage category or
 R10 categories specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II),
 R10 F.A.C., as the individual requesting authorized user status.

R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.

R10 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.

R10 History-New 02-11-10

R10 **64E-5.661 Training for the Oral Administration of Sodium Iodide I-131 Requiring a**
 R10 **Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33**
 R10 **Millicuries).** Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an
 R10 authorized user for the oral administration of sodium iodide I-131 requiring a written directive in
 R10 quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to: **(Entire section New)**

R10 (1) Be certified by a medical specialty board whose certification process includes all
 R10 of the requirements in paragraphs 64E-5.661(3)(a) and 64E-5.661(3)(b), F.A.C.,
 R10 of this section and whose certification process has been recognized by the NRC
 R10 or an agreement state and who meets the requirements in paragraph 64E-
 R10 5.661(3)(c), F.A.C., of this section. (The names of board certifications which
 R10 have been recognized by the NRC or an agreement state will be posted on the
 R10 NRC's Web page at [http://www.nrc.gov/materials/miau/med-use-toolkit/spec-](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html)
 R10 [board-cert.html](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html).); or

R10 (2) Be an authorized user under Rule 64E-5.660, F.A.C., or uses listed in sub-sub-
 R10 subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), or Rule 64E-
 R10 5.662, F.A.C., or equivalent agreement state requirements; or

R10 (3) (a) Has successfully completed 80 hours of classroom and laboratory training,
 R10 applicable to the medical use of sodium iodide I-131 for procedures
 R10 requiring a written directive. The training must include the following:

R10 1. Radiation physics and instrumentation;

R10 2. Radiation protection;

R10 3. Mathematics pertaining to the use and measurement of
 R10 radioactivity;

- R10 4. Chemistry of radioactive material for medical use; and
- R10 5. Radiation biology; and
- R10 (b) Have work experience, under the supervision of an authorized user who
R10 meets the requirements in Rule 64E-5.657, 64E-5.660, 64E-5.661 or
R10 64E-5.662, F.A.C., or equivalent agreement state requirements. A
R10 supervising authorized user who meets the requirements in subsection
R10 64E-5.660(2), F.A.C., must also have experience in administering
R10 dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or
R10 64E-5.660(2)(a)2.g.(II), F.A.C. The work experience must involve the
R10 following:
- R10 1. Ordering, receiving, and unpacking radioactive materials safely and
R10 performing the related radiation surveys;
 - R10 2. Performing quality control procedures on instruments used to
R10 determine the activity of dosages and performing checks for proper
R10 operation of survey meters;
 - R10 3. Calculating, measuring, and safely preparing patient or human
R10 research subject dosages;
 - R10 4. Using administrative controls to prevent a medical event involving
R10 the use of radioactive material;
 - R10 5. Using procedures to contain spilled radioactive material safely and
R10 using proper decontamination procedures; and
 - R10 6. Administering dosages to patients or human research subjects, that
R10 includes at least 3 cases involving the oral administration of less
R10 than or equal to 1.22 gigabecquerels (33 millicuries) of sodium
R10 iodide I-131; and
- R10 (c) Have obtained written attestation that the individual has satisfactorily
R10 completed the requirements in paragraphs 64E-5.661(3)(a) and
R10 64E-5.661(3)(b), F.A.C., of this section, and have demonstrated the ability
R10 to function independently as an authorized user to fulfill the radiation
R10 safety related duties for a medical use licensee that required a written
R10 directive under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C. Have
R10 obtained written attestation, signed by a preceptor authorized user or a
R10 residency program director who represents a consensus of residency
R10 program faculties (as long as at least one member of the residency
R10 program faculty is an authorized individual in the same category
R10 designated by the applicant seeking authorized status) who meets the
R10 requirements in Rule 64E-5.657, 64E-5.660, 64E-5.661 or 64E-5.662,
R10 F.A.C., or equivalent agreement state requirements. A preceptor
R10 authorized user, who meets the requirement in subsection 64E-5.660(2),
R10 F.A.C., must also have experience in administering dosages as specified
R10 in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II),
R10 F.A.C.

R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.

R10 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.

R10 History-New 02-11-10

R10 **64E-5.662 Training for the Oral Administration of Sodium Iodide I-131 Requiring a**
R10 **Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries).** Except
R10 as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the
R10 oral administration of sodium iodide I-131 requiring a written directive in quantities greater than
R10 1.22 Gigabecquerels (33 millicuries), to: **(Entire section New)**

R10 (1) Be certified by a medical specialty board whose certification process includes all
R10 of the requirements in paragraphs 64E-5.662(3)(a) and 64E-5.662(3)(b), F.A.C.,
R10 of this section, and whose certification has been recognized by the NRC or an
R10 agreement state, and who meets the requirements in paragraph 64E-5.662(3)(c),
R10 F.A.C., of this section. (The names of board certifications which have been
R10 recognized by the NRC or an agreement state will be posted on the NRC's Web
R10 page at [http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html)
R10 [cert.html](http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html).); or

R10 (2) Be an authorized user under Rule 64E-5.660, F.A.C., for uses listed in sub-sub-
R10 subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C., or equivalent agreement state
R10 requirements; or

R10 (3) (a) Have successfully completed 80 hours of classroom and laboratory
R10 training, applicable to the medical use of sodium iodide I-131 for
R10 procedures requiring a written directive. The training must include:

R10 1. Radiation physics and instrumentation;

R10 2. Radiation protection;

R10 3. Mathematics pertaining to the use and measurement of
R10 radioactivity;

R10 4. Chemistry of radioactive material for medical use; and

R10 5. Radiation biology; and

R10 (b) Have work experience, under the supervision of an authorized user who
R10 meets the requirements in Rules 64E-5.657, 64E-5.660 or 64E-5.662,
R10 F.A.C., or equivalent agreement state requirements. A supervising
R10 authorized user, who meets the requirements in subsection 64E-5.660(2),
R10 F.A.C., must also have experience in administering dosages as specified
R10 in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C. The work
R10 experience must involve the following:

R10 1. Ordering, receiving, and unpacking radioactive materials safely and
R10 performing the related radiation surveys;

R10 2. Performing quality control procedures on instruments used to
R10 determine the activity of dosages and performing checks for proper
R10 operation of survey meters;

R10 3. Calculating, measuring, and safely preparing patient or human
R10 research subject dosages;

- R10 4. Using administrative controls to prevent a medical event involving
R10 the use of radioactive material;
- R10 5. Using procedures to contain spilled radioactive material safely and
R10 using proper decontamination procedures; and
- R10 6. Administering dosages to patients or human research subjects, that
R10 includes at least 3 cases involving the oral administration of greater
R10 than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;
R10 and
- R10 (c) Have obtained written attestation that the individual has satisfactorily
R10 completed the requirements in paragraphs 64E-5.662(3)(a) and
R10 64E-5.662(3)(b), F.A.C., of this section, and have demonstrated the ability
R10 to function independently as an authorized user to fulfill the radiation
R10 safety related duties for a medical use licensee authorized under Rule
R10 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., that require written directives.
R10 Have obtained written attestation, signed by a preceptor authorized user
R10 or a residency program director who represents a consensus of residency
R10 program faculties (as long as at least one member of the residency
R10 program faculty is an authorized individual in the same category
R10 designated by the applicant seeking authorized status) who meets the
R10 requirements in Rule 64E-5.657 or 64E-5.660, 64E-5.662, F.A.C., or
R10 equivalent agreement state requirements. A preceptor authorized user,
R10 who meets the requirements in subsection 64E-5.660(2), F.A.C., must
R10 also have experience in administering dosages as specified in sub-sub-
R10 subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.

R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.

R10 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.

R10 History-New 02-11-10

R10 **64E-5.663 Training for the Parenteral Administration of Unsealed Radioactive Material**
R10 **Requiring a Written Directive.** Except as provided in Rule 64E-5.657, F.A.C., the licensee
R10 shall require an authorized user for the parenteral administration requiring a written directive,
R10 to: **(Entire section New)**

- R10 (1) Be an authorized user under Rule 64E-5.660, F.A.C., for uses listed in sub-sub-
R10 subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C., or
R10 equivalent agreement state requirements; or
- R10 (2) Be an authorized user under Rule 64E-5.652 or 64E-5.655, F.A.C., or equivalent
R10 agreement state requirements and who meets the requirements in subsection
R10 64E-5.663(4), F.A.C. of this section; or
- R10 (3) Be certified by a medical specialty board whose certification process has been
R10 recognized by the NRC or an agreement state under Rule 64E-5.652 or
R10 64E-5.655, F.A.C., and who meets the requirements in subsection 64E-5.663(4),
R10 F.A.C., of this section.

- R10 (4) (a) Have successfully completed 80 hours of classroom and laboratory
R10 training, applicable to parenteral administrations, for which a written
R10 directive is required, of any beta emitter, or any photon-emitting
R10 radionuclide with a photon energy less than 150 keV, and/or parenteral
R10 administration of any other radionuclide for which a written directive is
R10 required. The training must include the following:
R10
- R10 1. Radiation physics and instrumentation;
 - R10 2. Radiation protection;
 - R10 3. Mathematics pertaining to the use and measurement of
R10 radioactivity;
 - R10 4. Chemistry of radioactive material for medical use; and
 - R10 5. Radiation biology; and
- R10 (b) Have work experience, under the supervision of an authorized user who
R10 meets the requirements in Rule 64E-5.657, 64E-5.660 or 65E-5.663,
R10 F.A.C., or equivalent agreement state requirements, in the parenteral
R10 administration, for which a written directive is required, of any beta emitter,
R10 or any photon-emitting radionuclide with a photon energy less than
R10 150 keV, and/or parenteral administration of any other radionuclide for
R10 which a written directive is required. A supervising authorized user who
R10 meets the requirements in Rule 64E-5.660, F.A.C., or equivalent
R10 agreement state requirements, must have experience in administering
R10 dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or
R10 64E-5.660(2)(a)2.g.(IV), F.A.C., or equivalent agreement state
R10 requirements. The work experience must involve the following:
- R10 1. Ordering, receiving, and unpacking radioactive materials safely,
R10 and performing the related radiation surveys;
 - R10 2. Performing quality control procedures on instruments used to
R10 determine the activity of dosages, and performing checks for proper
R10 operation of survey meters;
 - R10 3. Calculating, measuring, and safely preparing patient or human
R10 research subject dosages;
 - R10 4. Using administrative controls to prevent a medical event involving
R10 the use of unsealed radioactive material;
 - R10 5. Using procedures to contain spilled radioactive material safely, and
R10 using proper decontamination procedures; and

R10 6. Administering dosages to patients or human research subjects, that
 R10 include at least 3 cases involving the parenteral administration, for
 R10 which a written directive is required, of any beta emitter, or any
 R10 photon-emitting radionuclide with a photon energy less than
 R10 150 keV and/or at least 3 cases involving the parenteral
 R10 administration of any other radionuclide, for which a written
 R10 directive is required; and

R10 (c) Have obtained written attestation that the individual has satisfactorily
 R10 completed the requirements in subsection 64E-5.663(2) or 64E-5.663(3),
 R10 F.A.C., of this section, and have demonstrated the ability to function
 R10 independently as an authorized user to fulfill the radiation safety related
 R10 duties for a medical use licensee authorized for the parenteral
 R10 administration of unsealed radioactive material requiring a written
 R10 directive. Have obtained written attestation, signed by a preceptor
 R10 authorized user or a residency program director who represents a
 R10 consensus of residency program faculties (as long as at least one member
 R10 of the residency program faculty is an authorized individual in the same
 R10 category designated by the applicant seeking authorized status) who
 R10 meets the requirements in Rule 64E-5.657, 64E-5.660 or 65E-5.663,
 R10 F.A.C., or equivalent agreement state requirements. A preceptor
 R10 authorized user, who meets the requirements in Rule 64E-5.660, F.A.C.,
 R10 must have experience in administering dosages as specified in sub-sub-
 R10 subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C.

R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.

R10 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.

R10 History-New 02-11-10

R10 **SUBPART J**
R10 **OTHER MEDICAL USES OR RADIOACTIVE MATERIAL OR RADIATION FROM**
R10 **RADIOACTIVE MATERIAL**

R10 **64E-5.664 Other Medical Uses of Radioactive Material or Radiation From Radioactive**
R10 **Material** . A licensee may use radioactive materials or a radiation source from radioactive
R10 materials approved for medical use which is not specifically addressed in Rule 64E-5.626,
R10 64E-5.627, 64E-5.630, 64E-5.631, 64E-5.632 or 64E-5.634, F.A.C., provided the following are
R10 satisfied: **(Entire section New)**

R10 (1) The applicant or licensee has received written approval from the department in a
R10 license or license amendment and uses the material in accordance with the
R10 regulations and specific license conditions the department considers necessary
R10 for the medical use of the material;

R10 (2) The applicant or licensee has submitted the information required by
R10 Rules 64E-5.207 and 64E-5.208, F.A.C.; and

R10 (3) The licensee shall provide specific information on the following:

R10 (a) Radiation safety precautions and instruction;

R10 (b) Methodology for measuring dosages or doses to be administered to
R10 patients or human research subjects;

R10 (c) Calibration, maintenance, and repair of instruments and equipment
R10 necessary for radiation safety; and

R10 (d) Security of radioactive materials, training or experience of individuals
R10 involved in these uses or other information not specified in paragraph
R10 64E-5.665(3)(a)(b) or (c), F.A.C.

R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.

R10 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.

R10 History-New 02-11-10

**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 VII

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

64E-5.701 Equipment Requirements.

- (1) Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant may apply to the department for an exemption from the requirement of a safety device. Such application shall include:
 - (a) A description of the various safety devices that have been evaluated;
 - (b) The reason each of these devices cannot be used; and
 - (c) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that the operator and others in the area will be informed of the absence of safety devices.
- (2) Warning Devices.
 - (a) Open-beam configurations shall be provided with a readily discernible indication of:
 1. X-ray tube on-off status located near the radiation source housing, if the primary beam is controlled in this manner; or
 2. Shutter open-closed status located near each port on the radiation source housing, if the primary beam is controlled in this manner.
 - (b) Warning devices shall be labeled so that their purpose is easily identified.
 - (c) Warning devices shall have fail-safe characteristics.
- (3) Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.
- (4) Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:
 - (a) "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the x-ray source housing; and
 - (b) "CAUTION RADIATION -- THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube.

- (5) Shutters. On open-beam configurations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.
- (6) Warning Lights. An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, having fail-safe characteristics, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized.
- (7) Radiation Source Housing. Each x-ray tube housing installed after the effective date of these regulations shall be so constructed that, with all shutters closed, the leakage radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 mrem (0.025 mSv) in any given hour at any specified tube rating.
- (8) Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem (2.5 uSv) in any given hour.

Specific Authority: 404.051, 404.141, 404.22, F.S.
Law Implemented: 404.051(1)(4)(6), 404.141, 404.22, F.S.
History: New July 17, 1985, Formerly 10D-91.803.

64E-5.702 Area Requirements.

- (1) Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 64E-5.312. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.
- (2) Surveys.
 - (a) Radiation surveys, as required by 64E-5.314, of all analytical x-ray systems sufficient to show compliance with (1), above, shall be performed:
 1. Upon installation of the equipment and at least once every 12 months thereafter;
 2. Following any change in the initial arrangement, number or type of local components in the system;
 3. Following any maintenance requiring the disassembly or removal of a local component of the system;

4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;
 5. Any time a visual inspection of the local components of the system reveals an abnormal condition; and
 6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 64E-5.312.
- (b) Radiation survey measurements shall not be required if a registrant can demonstrate compliance with (1), above, to the satisfaction of the department.
- (3) Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION -- X-RAY EQUIPMENT", or words having a similar intent.

Specific Authority: 404.051, 404.141, 404.22, F.S.

Law Implemented: 404.051(1)(4)(6), 404.141, 404.22, F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.804.

64E-5.703 Operating Requirements.

- (1) Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained the written approval of the radiation safety officer.
- (2) Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the written approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing.
- (3) Repair or Modification of X-ray Tube Systems. Except as specified in (2), above, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops shall be performed without first ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

Specific Authority: 404.051, 404.081, 404.22, F.S.

Law Implemented: 404.051(1)(4)(6), 404.081(1), 404.22, F.S.

History: New July 17, 1985, Formerly 10D-91.805.

64E-5.704 Personnel Requirements.

- (1) Instruction. No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instruction in and demonstrated competence as to:
 - (a) Identification of radiation hazards associated with the use of the equipment;
 - (b) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
 - (c) Proper operating procedures for the equipment;
 - (d) Symptoms of an acute localized overexposure; and
 - (e) Proper procedures for reporting an actual or suspected overexposure.
- (2) Personnel Monitoring.
 - (a) Finger or wrist dosimetric devices shall be provided to and shall be used by:
 1. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
 2. Personnel maintaining analytical x-ray equipment, if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.
 - (b) Reported dose values shall not be used for the purpose of determining compliance with 64E-5.304 unless evaluated by a qualified person, as defined in 64E-5.501(61).

Specific Authority: 04.051, 404.22, F.S.

Law Implemented: 404.051(1)(4), 404.22, F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.806.

**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 VIII

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL PARTICLE ACCELERATORS

SUBPART A REGISTRATION PROCEDURE

64E-5.801 Registration Requirements.

- (1) No person shall receive, possess, use, transfer, or acquire a particle accelerator facility or a particle accelerator except as authorized by a registration certificate issued by the department pursuant to these rules.
- (2) Application for registration shall be made on DH Form 1107, which is incorporated by reference herein effective July 17, 1989 furnished by the department, and shall contain all information required by the form and accompanying instructions. Part V contains rules concerning registration and the payment of registration fees.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(9), 404.22(1), F.S.

History: New July 17, 1985, Amended May 15, 1996, Formerly 10D-91.902.

64E-5.802 General Requirements for the Issuance of a Registration Certificate for Particle Accelerators. A registration application for acquisition and use of a particle accelerator or particle accelerator facility will be approved only if the department determines that:

- (1) The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this part and Parts III and IX in such a manner as to minimize danger to public health and safety or property;
- (2) The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;
- (3) The issuance of the registration certificate will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 64E-5.803;
- (4) The applicant has appointed a radiation safety officer;
- (5) The applicant or the applicant's staff have substantial experience in the use of particle accelerators and training sufficient to properly use the accelerator for accomplishment of the intended objectives; and
- (6) The applicant has a radiation safety training program for operators of particle accelerators.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(8)(9), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.903.

64E-5.803 Particle Accelerators for Therapeutic Use on Humans. In addition to the general registration requirements set forth in 64E-5.802, accelerators used for treatment of humans will be registered only if the department determines that:

- (1) The applicant agrees to appoint a medical committee of at least two physicians, one of whom is expert in radiation therapy, plus a person experienced in depth dose calculations and radiation protection, for the purpose of evaluating and approving all proposed uses involving exposure of human beings;
- (2) Persons designated on the application as the authorized users have had training and experience in treatment of humans utilizing radiations of the type and at energies near those produced by the accelerator to be employed;
- (3) Individuals designated on the registration application as authorized users are physicians, as defined in 64E-5.101; and
- (4) The applicable provisions of 64E-5.508 are met.

Specific Authority: 404.051, 404.081, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.081(1), 404.141, 404.051(1)(4)(8)(9), 404.22(1), F.S.

History: New July 17, 1985, Amended August 29, 1994, Formerly 10D-91.904.

(Space intentionally left blank)

SUBPART B
RADIATION SAFETY REQUIREMENTS
FOR THE USE OF PARTICLE ACCELERATORS

64E-5.804 Limitations.

- (1) The registrant shall not permit any person to act as a particle accelerator operator until such person:
 - (a) Has been instructed in accelerator radiation safety and has demonstrated an understanding thereof;
 - (b) Has received copies of and instructions in this part and the applicable requirements of Parts III and IX, pertinent registration conditions and the registrant's operating and emergency procedures, and has demonstrated an understanding thereof; and
 - (c) Has demonstrated competence to use the particle accelerator, related equipment and survey instruments which will be employed in assignment.
- (2) The radiation safety officer shall have the authority to terminate the operations at a particular accelerator facility if such action is deemed necessary to protect health and minimize danger to public health and safety or property.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.906.

64E-5.805 Shielding and Safety Design Requirements.

- (1) A radiological physicist, as defined in Rule 64E-5.501, F.A.C., shall be consulted in the design of each particle accelerator installation and shall be responsible for specification of barrier materials and thicknesses. Plans and specifications, along with assumptions and calculations on which the shielding design is based, shall be filed with the department.
- (2) Each particle accelerator installation shall be provided with the primary and secondary barriers necessary to comply with 64E-5.304 and 64E-5.312.
- (3) A qualified person, as defined in Rule 64E-5.501, F.A.C., not necessarily the consultant involved in the design, shall be engaged to perform a radiation survey of the facility when the accelerator is first capable of producing radiation, and such survey shall include measurements of all types of radiation produced under all modes of operation at maximum operating potential.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6), 404.22(1), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.907.

64E-5.806 Particle Accelerator Controls and Interlock Systems.

- (1) Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

- (2) All entrances into a target room or other high radiation area shall be provided with interlocks that shut down the machine under conditions of barrier penetration.
- (3) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped, and lastly at the main control console. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 64E-5.304, 64E-5.310 and 64E-5.312.
- (4) Each safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.
- (5) All safety interlocks shall function to the extent that any defect or component failure in an interlock system will either prevent operation of the accelerator or will produce a conspicuous audible signal or flashing warning light both at the control and at the barrier involved. Warning signals, where employed, shall not be disconnected or otherwise disabled, but shall continue to produce the warning signal during accelerator operation until the interlock has been restored to proper operation. Any failure of the warning system shall prevent operation of the accelerator.
- (6) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.22(1), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.908.

64E-5.807 Warning Devices.

- (1) All locations designated as high radiation areas, and all entrances to such locations shall be equipped with easily observable warning lights that operate when and only when radiation is being produced.
- (2) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and in any adjacent radiation areas.
- (3) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with 64E-5.322 and 64E-5.323.

Specific Authority: 404.051, 404.022, F.S.

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

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.909.

64E-5.808 Operating Procedures.

- (1) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.
- (2) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency or test situation.
- (3) All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed 1 month. Results of such tests shall be maintained for inspection by the department at the accelerator facility.
- (4) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and available to the operator at each accelerator facility and maintained for inspection by the department.
- (5) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:
 - (a) Authorized by the radiation safety committee or radiation safety officer;
 - (b) Recorded in a permanent log and notice posted at the accelerator control console; and
 - (c) Terminated as soon as possible.
- (6) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

Specific Authority: 404.051, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081(1), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.910.

64E-5.809 Radiation Monitoring Requirements.

- (1) At each particle accelerator facility capable of producing radioactive materials by activation, the registrant shall provide appropriate portable monitoring equipment which is operable and has been calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation each day of use and calibrated at intervals not to exceed 12 months and after each servicing or repair.
- (2) A radiation survey shall be performed and documented by a qualified person, as defined in 64E-5.501(61), when changes have been made in shielding, operation, or equipment within the facility or in the occupancy of adjacent areas.

- (3) Radiation levels in all high radiation areas shall be continuously monitored. The monitoring device shall be electrically independent of the accelerator control and interlock systems and capable of providing a visual or audible alarm at the entrance to high radiation areas, and other appropriate locations, so that people entering or present become aware of the existence of the hazard. A remote readout shall be located at the control panel when the production of radioactive materials by activation could cause a high radiation area.
- (4) Area monitors designed and intended to display the exposure rate shall be calibrated at intervals not to exceed 1 year and after each servicing and repair.
- (5) Whenever applicable, surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.
- (6) Whenever applicable, smear surveys shall be made to determine the degree of contamination in target and other pertinent areas
- (7) All area surveys shall be made in accordance with the written procedures established by a qualified person, as defined in 64E-5.501(61), or the radiation safety officer of the particle accelerator facility.
- (8) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility for inspection by the department for 3 years.

Specific Authority: 404.051, 404.061, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(1), 404.081(1), 404.22, F.S.

History: New July 17, 1985, Formerly 10D-91.911.

64E-5.810 Ventilation Systems.

- (1) Means shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to concentrations in excess of the limits specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I., Column 3.
- (2) A registrant shall not vent, release or otherwise discharge airborne radioactive material to an uncontrolled area in concentrations which exceed the limits specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I., Column 3, except as authorized pursuant to 64E-5.329. For purposes of this paragraph, concentrations may be averaged over a period not greater than 1 year. Every reasonable effort should be made to maintain releases of radioactive material to uncontrolled areas, as far below these limits as reasonably achievable.

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

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

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.912.

**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 IX

NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

64E-5.901 Posting of Notices to Workers.

- (1) Each licensee or registrant shall post current copies of the following documents:
 - (a) The regulations in this part and in Part III;
 - (b) The license, conditions or documents incorporated into the license by reference and amendments thereto;
 - (c) The operating procedures applicable to activities under the license or registration;
 - (d) Any notice of violation involving radiological working conditions, proposed imposition of administrative penalties, or order issued pursuant to Part I, and any response from the licensee or registrant;
 - (e) The certificate of registration; and
 - (f) The emergency procedures applicable to activities conducted under the license or registration.

R5 (2) If posting of a document specified in paragraphs (a), (b), and (c) above is not physically practical, the licensee or registrant may post a notice which describes the document and states where it may be examined. The documents specified in paragraphs (d), (e) and (f) above must be posted in their entirety.

R5 (3) "Notice to Employees 3/01", which is herein incorporated by reference and which is available from the department, shall be posted by each licensee or registrant as required by these regulations.

(4) Department documents posted pursuant to 64E-5.901(1)(d) shall be posted within 5 working days after receipt of the documents from the department; the licensee's or registrant's response, if any, shall be posted within 5 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

(5) Documents, notices, or forms shall be posted to permit workers to observe them on the way to or from work, shall be conspicuous, and shall be replaced if defaced or altered.

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

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

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

Amended May 15, 1996, Formerly 10D-91.1002, Amended December 19, 2001.

R5

64E-5.902 Instructions to Workers.

- R1
R1
- (1) All individuals who in the course of employment are likely to receive an occupational dose in excess of 100 millirem (1 mSv) in a year:
- (a) Shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's facility;
 - (b) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, in precautions or procedures to minimize exposures, and in the purposes and functions of protective devices employed;
 - (c) Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;
 - (d) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, and licenses or unnecessary exposure to radiation or radioactive material;
 - (e) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
 - (f) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 64E-5.903.
- R1
R1
R1
R1
R1
- (2) In determining those individuals subject to the requirements of (1), above, licensees or registrants shall consider assigned activities during normal and abnormal situations involving exposure to sources of radiation or radioactive material that reasonably can be expected to occur during the life of the licensee's or registrant's facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

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

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

R1 History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.1003, Amended May 18, 1998.

64E-5.903 Notification and Reports to Individuals.

- (1) Licensees or registrants for which personnel monitoring is required shall prepare a report as specified in this section of the radiation exposure data for each affected individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of the individual. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to Part III. Each notification and report shall:
 - (a) Be in writing;
 - (b) Include appropriate identifying data such as the name of the licensee or registrant and the name of the individual;
 - (c) Include the individual's exposure information; and
 - (d) Contain the following statement: "This report is furnished to you under the provisions of the Florida Department of Health regulation entitled Chapter 64E-5, Control of Radiation Hazards. You should preserve this report for future reference."
- (2) Each licensee or registrant for which personnel monitoring is required shall furnish each worker annually a written copy of the report specified in (1), above, of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to Part III. The licensee or registrant shall maintain records that the report was furnished for 3 years.
- (3) Each licensee or registrant shall furnish to the worker upon termination of employment a written report as specified in (1), above, of the worker's exposure to radiation received by that worker from operations of the licensee or registrant. Such report shall be furnished within 30 days from the time of termination of employment or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover each calendar quarter in which the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated. The licensee or registrant shall maintain records that the report was furnished for 3 years.
- (4) When a licensee or registrant is required pursuant to Part III to report to the department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the department.

- (5) At the request of a worker who is terminating employment in a given calendar quarter with the licensee or registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's or registrant's facility in that calendar quarter, each licensee or registrant shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.

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

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

History: New July 17, 1985, Amended May 12, 1993, Formerly 10D-91.1004.

64E-5.904 Presence of Representatives of Licensees or Registrants and Workers During Inspection.

- (1) Each licensee or registrant shall afford to the department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises and records pursuant to these regulations.
- (2) During an inspection, department inspectors may consult privately with workers as specified in this part. The licensee or registrant may accompany department inspectors during other phases of an inspection.
- (3) If, at the time of inspection, an individual has been authorized by the workers to represent them during department inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.
- (4) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in this part.
- (5) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection; however, only one workers' representative at a time may accompany the inspectors.
- (6) With approval of the licensee or registrant or the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, such as a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany department inspectors during the inspection of physical working conditions.

- (7) Notwithstanding the other provisions of this section, department inspectors are authorized to refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

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

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1005.

64E-5.905 Consultation with Workers During Inspections.

- (1) Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.
- (2) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused a violation of the Act, these regulations, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 64E-5.906(1).
- (3) The provisions of (2), above, shall not be interpreted as authorization to disregard instructions pursuant to 64E-5.902.

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

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1006.

64E-5.906 Request by Workers for Inspections.

- (1) Any worker or representative of workers believing that a violation of the Act, these regulations or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the department. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the department no later than at the time of inspection.

- (2) If, upon receipt of such notice, the department determines that the complaint meets the requirements set forth in this section and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

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

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1007.

64E-5.907 Inspections Not Warranted; Informal Review.

- (1) If the department determines, with respect to a complaint under this part, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the department shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the department. The department will provide the licensee or registrant with a copy of such statement by certified mail. The licensee or registrant may submit an opposing written statement of position with the department. The department will provide the complainant with a copy of such statement by certified mail.
- (2) Upon the request of the complainant, the department may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the department shall affirm, modify, or reverse the previous determination of the department and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.
- (3) If the department determines that an inspection is not warranted because the requirements of 64E-5.906(1) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 64E-5.906(1).

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

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1008.

PART X ENVIRONMENTAL RADIATION STANDARDS
SUBPART A RADIATION STANDARDS FOR BUILDINGS

64E-5.1001.. Standards..... X-1

SUBPART B ENVIRONMENTAL MONITORING

64E-5.1002.. Monitoring Requirements..... X-1

R8 64E-5.1003.. Monitoring Fees X-2

PART X

ENVIRONMENTAL RADIATION STANDARDS

Subpart A

ENVIRONMENTAL RADIATION STANDARDS

64E-5.1001 Standards.

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

Specific Authority: 404.051, 404.056, F.S.

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

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

Subpart B

ENVIRONMENTAL MONITORING

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

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

Specific Authority: 404.051, 404.056, F.S.

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

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

64E-5.1003 Monitoring Fees.

- (1) The costs incurred by the department and the subsequent fees associated with the monitoring program shall be annually prorated on the basis of the total number of measurements to be made on land proposed to be mined and land proposed to be reclaimed, excluding bodies of water.
- (2) The annual fees paid by the mining companies shall be calculated by the following method:
 - R8 (a) Gamma radiation exposure measurements will be made at the rate of one per acre. An annual fee of \$11.63 per measurement shall be assessed the mining company by the department.
 - R8 (b) Soil characterization measurements will be made at the rate of one per 20 acres. An annual fee of \$496.00 per each 20 acres measured shall be assessed the mining company by the department.
 - R8 (c) Air monitoring measurements will be assessed at the rate of \$255.75 per measurement. The department shall prorate the cost of air monitoring measurements among the mining companies based on their share of the total acreage to be mined and reclaimed each year. The department will conduct no more than 272 air monitoring measurements per year for all mining companies for which a fee will be assessed.
 - (d) Surface and ground water monitoring measurements will be assessed at the rate of \$300.00 per measurement. The department shall prorate the cost of water monitoring among the mining companies based on their share of the total acreage to be mined and reclaimed each year. The department will analyze no more than 160 water samples per year for all mining companies for which a fee will be assessed.
- (3) The department shall bill each affected company by March for activities which are planned for the following July through December time period. The department shall bill each affected company by September for activities which are planned for the following January through June time period. Each mining company shall remit the fee to the department within 60 days of the billing date.
- (4) Overpayments or underpayments from an affected company will be reconciled by the department on an annual basis.

Specific Authority: 404.022, 404.051, 404.056, 404.131, F.S.

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

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

R8

PART XI RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS

R1	64E-5.1101Prohibitions.....	XI-1
SUBPART A EQUIPMENT CONTROL			
	64E-5.1102Storage and Transportation Precautions	XI-2
R2	64E-5.1103Radiation Survey Instruments	XI-2
R6	64E-5.1104Leak Testing of Sealed Sources.....	XI-3
	64E-5.1105 Quarterly Inventory	XI-4
	64E-5.1106Utilization Records.....	XI-4
R6	64E-5.1107Design, Performance and Certification Criteria for Sealed Sources Used in Downhole Operations	XI-4
R6	64E-5.11071	..Uranium Sinker Bars	XI-5
R8	64E-5/11072	..Energy Compensation Source.....	XI-6
R6	64E-5.11073	..Tritium Neutron Generator Target Source	XI-6
	64E-5.1108 Labeling	XI-6
	64E-5.1109 Inspection and Maintenance.....	XI-7
SUBPART B REQUIREMENTS FOR PERSONNEL SAFETY			
	64E-5.1110 Training Requirements	XI-7
	64E-5.1111 Operating and Emergency Procedures	XI-8
R6	64E-5.1112 Personnel Monitoring.....	XI-9
SUBPART C PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER OPERATIONS			
	64E-5.1113 Security	XI-9
	64E-5.1114 Handling Tools.....	XI-9
	64E-5.1115 Subsurface Tracer Studies	XI-9
SUBPART D RADIATION SURVEYS AND RECORDS			
	64E-5.1116 Radiation Surveys	XI-10
	64E-5.1117 Documents and Records Required at Field Stations	XI-11
	64E-5.1118 Documents and Records Required at Temporary Jobsites	XI-11
SUBPART E NOTIFICATION			
R6	64E-5.1119 Notification of Incidents, Abandonment and Lost Sources	XI-12
R6	64E-5.1120 Subjects To Be Included in Training Courses For Logging Supervisors	XI-14

PART XI

RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

64E-5.1101 Prohibitions.

- (1) No licensee shall perform wireline service operations with a sealed source unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor or land owner that:
 - (a) In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and
 - (b) In the event a decision is made to abandon the sealed source downhole, the requirements of 64E-5.1119 shall be met.
- (2) No registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of Part III, as applicable, are met.

Specific Authority: 404.051, 404.061, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1203.

Space Intentionally Left Blank

SUBPART A EQUIPMENT CONTROL

64E-5.1102 Storage and Transportation Precautions.

- (1) Each sealed source of radioactive material shall be provided with a storage or transport container. The container shall be provided with a lock or tamper seal to prevent unauthorized removal of, or exposure to, the source of radiation.
- (2) Sealed sources of radioactive material shall be stored in a manner which will minimize danger from explosion and fire.
- (3) Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

Specific Authority: 404.051, 404.061, F.S.

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

History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.1204.

64E-5.1103 Radiation Survey Instruments.

- R2
- R2
- R2
- (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)** per hour through at least 50 milliroentgens **(0.5 mSv)** per hour.
 - (2) Radiation survey instruments used to establish dose rates shall be calibrated:
 - (a) At energies and geometries appropriate for use;
 - (b) At intervals not to exceed 6 months, and after each instrument servicing;
 - (c) Such that accuracy within plus or minus 20 percent can be demonstrated; and
 - (d) For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points.
 - (3) Records of survey instrument calibrations shall be maintained for 3 years after the calibration date for inspection by the department.

Specific Authority: 404.051, 404.061, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.081(1), 404.22, F.S.

History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.1205, **Amended October 8, 2000.**

R2

64E-5.1104 Leak Testing of Sealed Sources.

(1) Requirements. Each licensee using sealed sources containing radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department for 3 years after the leak test is performed or until transfer or disposal of the sealed source.

R6 (2) Method of Testing. Tests for leakage shall be performed only by persons
R6 specifically authorized to perform such tests by the department, the U.S. Nuclear
R6 Regulatory Commission, an agreement state, or a licensing state using a leak
R6 test kit or method approved by the department, the U.S. Nuclear Regulatory
R6 Commission, an Agreement State, or a Licensing State. . The test sample shall
be taken from the nearest accessible point to the sealed source where
contamination might accumulate. The test sample shall be analyzed for
radioactive contamination, and the analysis shall be capable of detecting the
presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

R6 (3) Test frequency.

R6 (a) Each sealed source except an energy compensation source or ECS
containing radioactive material shall be tested at intervals not to exceed 6
months. In the absence of a certificate from a transferor indicating that a
R6 test has been made within the 6 months before the transfer, the sealed
R6 source shall not be used until tested. If, for any reason, it is suspected
that a sealed source may be leaking, it shall be removed from service
immediately and tested for leakage as soon as practical.

R6 (b) Each ECS that is not exempt from testing as specified in subsection 64E-
R6 5.1104(5), F.A.C., below, shall be tested at intervals not to exceed 3
R6 years. In the absence of a certificate from a transferor that a test has been
R6 made within the 3 years before transfer, the ECS shall not be used until
R6 tested.

R6 (4) Removal of Leaking or Contaminated Sources from service. . If the test specified
R6 in subsection (3), above, reveals the presence of 0.005 microcurie (185 Bq) or
R6 more of removable radioactive material , the licensee shall remove the sealed
R6 source from service immediately and shall cause it to be decontaminated,
R6 repaired, or disposed of by a person licensed by the department, the U.S.
R6 Nuclear Regulatory Commission, an Agreement State, or a Licensing State to
R6 perform these functions. The licensee shall check the equipment associated with
the leaking source for radioactive contamination, and if contaminated, have it
decontaminated or disposed of in accordance with these regulations. A report
describing the equipment involved, the test results, any contamination which
resulted from the leaking source, and corrective action taken shall be filed with
the department within 5 days of receiving the test results.

(5) Exemptions. The following sources are exempted from the periodic leak test requirements of 64E-5.1104(1) through (4):

(a) Hydrogen 3 sources;

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

Specific Authority: 404.022, 404.051(1)(4), 404.061, 404.081(1), F.S.

Law Implemented: 404.022, 404.051(1)(5), 404.061(2), F.S.

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

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

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), 404.081(1), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1206.

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

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

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

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

History: New July 17, 1985, Formerly 10D-91.1207.

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

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

- R6 (2) A licensee can use a sealed source manufactured on or before July 14, 1989, in well logging applications if it meets the requirements of USASI N5.10 – 1968, "Classification of Sealed Radioactive Sources", which is herein incorporated by reference and available from the Department, or the requirements specified in subsections (3) and (4), below. .
- R6 (3) A licensee can use a sealed source manufactured after July 14, 1989, in well logging applications if it meets the oil-well logging requirements specified in ANSI/HPS N43.6 – 1997, "Sealed Radioactive Sources – Classification", which is herein incorporated by reference and available from the Department. .
- R6 (4) A licensee can use a sealed source manufactured after July 14, 1989, in well logging applications if:
 - R6 (a) The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:
 - R6 1. Temperature. The test source is held at -40° C for 20 minutes, 600° C for 1 hour, and then subjected to a thermal shock test with a temperature drop from 600° C to 20° C within 15 seconds.
 - R6 2. Impact test. A 5 kg steel hammer 2.5 cm in diameter is dropped from a height of 1 m onto the test source.
 - R6 3. Vibration test. The test source is subjected to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.
 - R6 4. Puncture test. A 1 gram hammer and 0.3 cm diameter pin is dropped from a height of 1 m onto the test source.
 - R6 5. Pressure test. The test source is subjected to an external pressure of 24,600 pounds per square inch absolute (1.695 x 10⁷ pascals).
 - R6 (5) The requirements of subsection (1) through (4), above, do not apply to sealed sources that contain licensed material in gaseous form.
 - R6 (6) The requirements of subsections (1) through (4), above, do not apply to ECSs. ECSs shall be registered with the department as specified in subsection 64E-5.210(14), F.A.C., the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State

Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S.
 Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.071(1), 404.081(1), F.S.
 R6 History: New July 17, 1985, Formerly 10D-91.1208m Amended September 28, 2006

R6 **64E-5.11071 Uranium sinker bars.** The licensee can use a uranium sinker bar
 R6 in well logging applications only if it is legibly impressed with the words
 R6 "CAUTION – RADIOACTIVE – DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES
 R6 (OR COMPANY NAME) IF FOUND.

R6 Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S.
 R6 Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.071(1), 404.081(1), F.S.
 R6 History: New September 28, 2006

R6 **64E-5.11072 Energy Compensation Source.** The licensee can use an ECS that
R6 is contained within a logging tool or other tool components only if the ECS contains 100
R6 microcuries (3.7 MBq) or less of licensed material

R6 (1) For well logging applications with a surface casing for protecting fresh water
R6 aquifers, use of the ECS is subject only to the requirements specified in Rules
R8 64E-5.1104, 64E-5.1105, and 64E-5.1106, F.A.C., above.

R6 (2) For well logging applications without a surface casing for protecting fresh water
R6 aquifers, use of the ECS is subject only to the requirements specified in Rules
R6 64E-5.1101, 64E-1104, 64E-5.1105, 64E-5.1106, 64E-5.1119(5), and 64E-5.343
R6 through 64E-5.349, F.A.C.

R6 Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S.
R6 Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.071(1), 404.081(1), F.S.
R8 History: New September 28, 2006, Amended February 28, 2008.

R6 **64E-5.11073 Tritium Neutron Generator Target Source.**

R6 (1) Use of a tritium neutron generator target source containing quantities not
R6 exceeding 30 curies (1,110 MBq) and in a well with a surface casing to protect
R6 fresh water aquifers is not subject to the requirements specified in Rules
R6 64E-5.1101, 64E-5.1107, 64E-5.1119(5), and 64E-5.343 through 64E-5.349,
R6 F.A.C.

R6 (2) Use of a tritium neutron generator target source containing more than 30 curies
R6 (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers
R6 is not subject to the requirements specified in Rule 64E-5.1107, F.A.C.

R6 Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S.
R6 Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.071(1), 404.081(1), F.S.
R6 History: New September 28, 2006

64E-5.1108 Labeling.

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

DANGER (OR "CAUTION")
RADIOACTIVE

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

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

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

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

64E-5.1109 Inspection and Maintenance.

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

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

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

History: New July 17, 1985, Formerly 10D-91.1210.

SUBPART B REQUIREMENTS FOR PERSONNEL SAFETY

64E-5.1110 Training Requirements.

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

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

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), 404.081(1), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1211.

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

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

Specific Authority: 404.051, 404.061, 404.081, 404.20, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.081(1), 404.20(1), 404.22, F.S.

History: New July 17, 1985, Formerly 10D-91.1212.

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

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

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

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

SUBPART C PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER OPERATIONS

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

Specific Authority: 404.051, 404.061, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4), 404.061(2), F.S.

History: New July 17, 1985, Amended August 29, 1994, Formerly 10D-91.1214.

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

Specific Authority: 404.051, 404.061, F.S.

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

History: New July 17, 1985, Formerly 10D-91.1215.

64E-5.1115 Subsurface Tracer Studies.

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

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

Specific Authority: 404.051, 404.061, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4), 404.061(2), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.1216.

SUBPART D RADIATION SURVEYS AND RECORDS

64E-5.1116 Radiation Surveys.

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

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.071(1), 404.081(1), 404.20(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1217.

64E-5.1117 Documents and Records Required at Field Stations. Each licensee or registrant shall maintain, for inspection by the department, the following documents and records for the specific devices and sources used at the field station:

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

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

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), 404.081(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1218.

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

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

Specific Authority: 404.051, 404.061, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(11), 404.061(2), 404.081(1), 404.22, F.S.

History: New July 17, 1985, Amended May 15, 1996, Formerly 10D-91.1219.

SUBPART E NOTIFICATION

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

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

R6
R6
R6
R6
R6
R6

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

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

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

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

R6 History: New July 17, 1985, Formerly 10D-91.1220., **Amended September 28, 2006.**

64E-5.1120 Subjects To Be Included In Training Courses For Logging

Supervisors. The following subjects must be included in training courses for logging supervisors.

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

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

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

Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.081(1), 404.22, F.S.

History: New July 17, 1985, Formerly 10D-91.1221.

Page Intentionally left Blank

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

R10 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-4

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**

R6 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 Gases..... XIII-10

64E-5.1318.... Instrumentation..... XIII-10

64E-5.1319.... Contamination Control Program XIII-11

R10 64E-5.1320.... Bioassay Program XIII-13

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 Material. The rules in this part establish radiation safety requirements for licensees possessing or using sealed or unsealed sources of radioactive materials not otherwise specified in a license or addressed in these rules. The requirements of this part are in addition to and not in substitution for other applicable requirements of these rules. Licenses of broad scope are exempt from the requirements of Rule 64E-5.1313, subsections 64E-5.1318(2), and 64E-5.1319(1), (2), (3) and (4), F.A.C. **Except for Rule 64E-5.1320, F.A.C.,** the requirements of this part do not apply to persons licensed as specified in Parts IV, VI, and XI. General licensees as specified in subsections 64E-5.206(7) and (8), F.A.C., are exempt from the requirements of this part.

R10 **Rulemaking** Authority: 404.051, 404.061, F.S.

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

R10 History: New 5-12-93, Amended 5-15-96, Formerly 10D-91.1401, **Amended 02-11-10.**

SUBPART A GENERAL REQUIREMENTS

64E-5.1302 Operating and Emergency Procedures. The licensee's operating and emergency procedures shall be posted in accordance with 64E-5.901 and shall accompany portable devices at all times. The procedures shall include instructions in the following as applicable to the type of use:

- (1) The uses of sources of radiation so that exposures are maintained as low as reasonably achievable and no individual is likely to be exposed to radiation doses in excess of the standards in Part III;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods and occasions for locking and securing sources of radiation;
- (4) Personnel monitoring and the use of personnel monitoring equipment;
- (5) Minimizing exposure of individuals in the event of an accident;
- (6) Notifying proper personnel in the event of damage, loss, theft, or accident involving sources of radiation;
- (7) General guidelines for the safe handling and use of unsealed sources of radioactive materials;
- (8) Maintenance of records;
- (9) Procedures for picking up, receiving and opening packages containing radioactive materials; and

- (10) The transportation of radioactive sources to temporary job sites, including the packaging, marking, labeling and placing of such sources in vehicles, placarding of vehicles, securing the sources during transportation and possessing proper shipping papers and emergency response information.

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

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

History: New May 12, 1993, Amended January 1, 1994, Amended May 15, 1996, Formerly 10D-91.1403.

64E-5.1303 Leak Test Requirements for Possession of Sealed Sources.

- (1) A licensee in possession of a sealed source shall assure that:
 - (a) The sealed source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the sealed source was tested semiannually before transfer to the licensee;
 - (b) The sealed source is tested for leakage at least semiannually or at intervals approved by the department;
 - (c) Leak tests are capable of detecting 0.005 microcurie (185 Bq) of radioactive material on the test sample, or, in the case of radium, the escape of radon of 0.001 microcurie (37 Bq) each 24 hours;
 - (d) Test samples are taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate; and
 - (e) Device test samples are taken when the sealed source is in the off or shielded position.
 - (f) Leak tests are analyzed by individuals who are licensed by the department, U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform leak test services.
- (2) A licensee shall retain leak test records for 3 years. The records shall contain the manufacturer's name, the model and serial numbers of each sealed source tested, the identity of each sealed source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), the date of the test, and the signature of the radiation safety officer or designee.

- (3) If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:
- (a) Immediately withdraw the sealed source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with these regulations; and
 - (b) File a report with the department within 5 days of receiving the leak test results describing the equipment involved, the test results, and the action taken.
- (4) A leak test is not required on the following sealed sources:
- (a) Sealed sources containing only radioactive material with a half-life of less than 30 days;
 - (b) Sealed sources containing only radioactive material as a gas;
 - (c) Sealed sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; and
 - (d) Sealed sources that are listed on a department license for storage only. The licensee shall test each such sealed source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.
- (5) The department is authorized to approve leak test frequencies other than semiannually. Criteria used to determine these frequencies include:
- (a) The isotope and activity;
 - (b) The requested usage;
 - (c) The environmental hazards to which the sealed sources may potentially be exposed;
 - (d) The manufacturer's recommended frequency; and
 - (e) Specific information on the sealed source or device provided by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, including:
 - 1. Sealed Source and Device Registry sheets;
 - 2. Naturally Occurring or Accelerator Produced Radioactive Materials Sealed Source and Device Registry sheets.

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-91.1404.

64E-5.1304 Inventory Requirements. A licensee who possesses sealed sources shall conduct a physical inventory of all such sealed sources semiannually unless another interval is specified in the license. Inventory records shall be retained for 3 years. Inventory records shall contain the following:

- (1) The model and serial number of each sealed source;
- (2) The identity of each sealed source radionuclide and its estimated activity;
- (3) The location of each sealed source;
- (4) The date of the inventory; and
- (5) The signature of the radiation safety officer or designee.

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-91.1405.

64E-5.1305 Training Requirements, Authority, Duties and Responsibilities of the Radiation Safety Officer.

- (1) The licensee shall appoint a radiation safety officer with the authority to fulfill the duties and responsibilities listed in this part.
- (2) The radiation safety officer shall have sufficient training and experience with radioactive materials to be a user of the requested licensed materials, unless otherwise specified in the license. This training shall include practical experience in the safe use of radioactive materials and knowledge of procedures, facilities and equipment.
- (3) The duties and responsibilities of the radiation safety officer shall include the following:
 - (a) Ensure that all terms and conditions of the license and these regulations are complied with;
 - (b) Ensure that the sealed sources are leak tested timely and as prescribed by the manufacturer or by the license;
 - (c) Ensure that radioactive materials are used only by individuals who are authorized by the license and that all individuals wear required personnel monitoring equipment;
 - (d) Maintain all records required by the license and these regulations. These records shall include personnel monitoring records, leak test records, inventory records, training records for users and receipt, transfer and disposal records;
 - (e) Ensure that radioactive materials are properly secured against unauthorized access or removal;

- (f) Serve as a contact with the department for events such as the loss, theft or damage of radioactive material; and
- (g) Ensure that all users read and understand the licensee's emergency, operating and radiation safety procedures.

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-91.1406.

64E-5.1306 Opening Sealed Sources. Unless otherwise specifically licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such services, the licensee shall not open sealed sources.

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-91.1407.

64E-5.1307 Training Requirements for Authorized Users.

- (1) Radioactive materials shall be used by individuals who are qualified by training and experience to protect public health, safety and the environment. A description of this training must be submitted and approved by the department and include the following:
 - (a) Principles and fundamentals of radiation protection and safety practices related to the use of radioactive materials, including ALARA principles;
 - (b) Radioactivity measurements;
 - (c) Use of radiation detection instruments and monitoring techniques;
 - (d) Biological effects of radiation;
 - (e) Transportation of radioactive materials;
 - (f) Practical experience with the use of radioactive materials; and
 - (g) Licensee's operating and emergency procedures.
- (2) For licensees who propose to train their own personnel to be authorized users, the following must be provided to and approved by the department:
 - (a) Instructor qualifications, including training and experience with radioactive materials specifically relating to the topics of instruction;
 - (b) A detailed training program, including duration of training for each of the topics listed in (1) of this section;
 - (c) The method of testing the knowledge of students, such as a written and practical examination, and whether the examination is open or closed book; and

- (d) If an examination is used, the passing score, method of retesting students who do not pass and an example of the examination with the correct answers indicated.
- (3) Records of training shall be maintained during the employment of the individual or 5 years, whichever is greater.
- (4) Unless otherwise specified in the license, a licensee's authorized user training program is not transferable to another licensee.

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-91.1409.

64E-5.1308 Additional Requirements for General Licenses. Specific licensees authorized for a general license described in 64E-5.205(4), 64E-5.206(1), 64E-5.206(4) or 64E-5.206(6), shall comply with the regulations that are applicable to that general license and 64E-5.1304 and 64E-5.1305. Specific licensees authorized for the general license in 64E-5.205(4), or possess generally licensed devices described in 64E-5.206(1) or (4) are not required to remit the annual fees specified in 64E-5.204(1)(c)1., 2., or 5.

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-91.1410.

64E-5.1309 Training for Current Authorized Users. Individuals who are authorized users on a department, U.S. Nuclear Regulatory Commission, agreement state or licensing state license on May 12, 1993 who perform only those procedures for which they are authorized on that date need not comply with the training requirements in 64E-5.1307, 64E-5.1312 and 64E-5.1313.

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-91.1411.

64E-5.1310 Personnel Monitoring.

- R2 (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 a film badge, **OSLD**, or a TLD.
- R2 (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 a film badge, **OSLD**, or a TLD.
- (3) Licensees who use iodine 125, iodine 131, hydrogen 3, uranium 234, uranium 235 or uranium 238 and are required to have a bioassay program must submit a description of their bioassay program for approval by the department.

- R2 (4) A whole body film badge, OSLD, or TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of any gamma-emitting isotope with a gamma ray energy greater than 50 kiloelectron volts or the use of any beta-emitting isotope with a maximum beta energy of 300 kiloelectron volts or more.
- R2 (5) An extremity film badge or, OSLD, TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of 1,000 microcuries (37 MBq) or more of beta-emitting isotopes with a maximum beta energy of 1,000 kiloelectron volts or more in any month or by any individual who receives a dose of 40 millirem (400 μSv) or more on a whole body film badge, OSLD, or TLD for 2 consecutive months.
- R2 (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, F.S.
 Law Implemented 404.022, 404.051(1), (4), (6), (10), 404.061(2), 404.081(1)(2), F.S.
 R2 History--New May 15, 1996, Formerly 10D-91.1411, Amended October 8, 2000.

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

64E-5.1311 Storage, Security and Transportation Precautions

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

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.
 R6 History: New May 12, 1993, Formerly 10D-91.1412, Amended September 28, 2006.

64E-5.1312 Training and User Requirements.

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

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

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

History: New May 12, 1993, Formerly 10D-91.1415.

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

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

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

- (3) Documentation of training for each user must be maintained for the duration of employment or 5 years, whichever is greater.
- (4) Sealed sources in fixed devices may be used by individuals under the supervision of an authorized user. An authorized user must be available at all times when sealed sources in fixed devices are being used.
- (5) Installations, maintenance or service, initial radiation surveys, relocations or removal from service may be performed by individuals who are under the direct supervision and in the physical presence of an individual who is an authorized user for these operations.

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-91.1418.

64E-5.1314 Possession of Survey Instruments. A licensee authorized to perform installations, maintenance or service, initial radiation surveys, relocations or removal from service of sealed sources in fixed devices shall possess portable radiation survey instruments with a range from 1 millirem (10 μ Sv) per hour to 200 millirem (2 mSv) per hour. The instruments shall be operable and calibrated as provided in 64E-5.314.

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, Amended January 1, 1994, Formerly 10D-91.1419.

64E-5.1315 Additional Requirements. A licensee must post and provide to personnel lock-out procedures that prevent employees from entering the radiation beam during maintenance, repairs, or other work in, on, or around a bin, tank, hopper or pipe on which a device is mounted. The department is authorized to require a physical barrier around certain types of devices where the possibility exists that an individual could be exposed to the beam of radiation.

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-91.1420.

SUBPART D REQUIREMENTS FOR POSSESSION AND USE OF UNSEALED SOURCES OF RADIOACTIVE MATERIALS

64E-5.1316 General Rules for the Safe Use of Unsealed Sources of Radioactive Materials. The licensee shall assure that all individuals who handle unsealed sources of radioactive materials comply with the following, unless otherwise specified in the license:

- (1) Laboratory coats or other protective clothing are worn at all times in areas where radioactive materials are used;
- (2) Disposable gloves are worn at all times while handling radioactive materials;
- (3) Eating, drinking, smoking, or applying cosmetics in any area where radioactive material is stored or used is prohibited;

- (4) Storing food, drinks, or personal effects in areas where radioactive material is stored or used is prohibited;
- (5) If applicable, personnel monitoring devices are worn at all times while in areas where radioactive materials are used or stored;
- (6) Radioactive waste is disposed of only in designated, labeled, and properly shielded receptacles; and
- (7) Radioactive materials are confined in clearly labeled appropriate containers.

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-91.1422.

64E-5.1317 Storage and Control of Volatiles and Gases.

- (1) A licensee shall store volatile radioactive materials and radioactive gases in the shippers' radiation shield and container or an equivalent shield and container.
- (2) Unless otherwise specified in the license, a licensee shall store and use radioactive volatiles and gases in a properly functioning glove box or fume hood that will maintain airborne concentrations within the limits prescribed by State of Florida Bureau of Radiation Control, ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 2 and Table II, Column 1.
- (3) Unless otherwise specified in the license, the glove box or fume hood shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the volatile or gas.

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, Amended January 1, 1994, Formerly 10D-91.1423.

64E-5.1318 Instrumentation

- (1) The licensee shall have instruments available to detect radioactive materials listed on the license, unless otherwise authorized by the department. Instrumentation shall be sensitive enough to detect activities required for adequate contamination control described in this part.
- (2) The licensee must submit a description of the equipment and procedures to be followed in measuring contamination for departmental approval. These procedures shall include the following:
 - (a) Type of instrument detection system used, such as a Geiger-Mueller or scintillation detector with a scaler, single or multichannel analyzer, and type of radiation detected;
 - (b) Background counting times and average background counts;
 - (c) Sample counting times;

- (d) Instrument efficiency and calculation of efficiency determination;
 - (e) Instrument's lower limit of detection using the sample counting time and the isotope and activity of calibration standards;
 - (f) Sample calculation converting counting results into activity or activity per unit time, if applicable; and
 - (g) Frequency of instrument calibration.
- (3) If portable radiation survey instruments are used to determine compliance with the contamination control action levels described in this part, the instruments shall be operable and calibrated as provided in 64E-5.314.

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, Amended January 1, 1994, Formerly 10D-91.1425.

64E-5.1319 Contamination Control Program. The licensee shall establish and submit for department approval a contamination control program to limit the spread of unsealed sources of radioactive materials. This program shall include contamination action levels, corresponding actions taken if these levels are exceeded, frequency of measurement and maintenance of records.

- (1) Unless otherwise specified in the license, the licensee shall perform the following:
- (a) A survey with a radiation survey instrument shall be completed at the end of each day of use or receipt of all areas where radioactive materials are used or received.
 - (b) A weekly survey with a radiation survey instrument shall be completed of all areas where radioactive materials or radioactive waste are stored.
 - (c) A wipe survey shall be completed for removable contamination weekly during weeks of use of all areas where radioactive materials or waste are routinely used or stored.
 - (d) Surveys required by (1)(a)(b) and (f) of this section shall be completed with an instrument capable of measuring dose rates as low as 0.1 millirem (1 μ Sv) per hour, if applicable.
 - (e) A wipe survey shall be completed for removable contamination at the end of each day of use of all areas where radioactive materials are routinely used if the radioactive materials authorized by the license are not detectable with instruments described in (1)(d) above.
 - (f) Monitoring shall be performed of individuals for contamination prior to leaving the restricted area.
 - (g) The radiation safety officer shall be notified if the contamination detected during the surveys required by this section exceeds the action levels specified in (2), below.

- (2) Unless otherwise specified in the license, the licensee shall take the following actions if the corresponding action levels are exceeded:
- (a) Follow decontamination procedures and resurvey to determine effectiveness of decontamination efforts if the action levels are exceeded when conducting surveys described in (1)(a)(b) or (f) above;
 - (b) Follow emergency procedures if the radiation detected during the survey required in (1)(f) of this section is above action levels; and
 - (c) Follow decontamination procedures and resurvey to determine effectiveness of decontamination efforts if the action levels listed below are exceeded for the survey required in (1)(c) or (e) above;
 - 1. 100 dpm per 100 square centimeters of any alpha-emitting radioactive materials not listed in this section;
 - 2. 1,000 dpm per 100 square centimeters of any beta- or gamma-emitting radioactive materials not listed in this section;
 - 3. 50 dpm per 100 square centimeters of any transuranic;
 - 4. 2,000 dpm per 100 square centimeters of uranium; or
 - 5. 2,000 dpm per 100 square centimeters of any radioactive material with a half-life of less than 80 hours.
- (3) The licensee shall retain a record of each survey required by this section for 3 years. These records shall include:
- (a) The date of the survey;
 - (b) An annotated diagram of each area surveyed;
 - (c) Background levels;
 - (d) Measured dose rates, keyed to the diagram, expressed in millirem (microsieverts) per hour or the removable contamination, keyed to the diagram, expressed in dpm per 100 square centimeters, or counts per minute if performed with a radiation survey instrument, with the action level described in (2)(a) of this section;
 - (e) The serial number and model number of the instrument used to make the survey or analyze the samples; and
 - (f) The initials of the person who performed the survey.
- (4) Records of surveys described in (1)(f) need not be recorded unless the action level described in (2)(a) of this section is exceeded.

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-91.1426.

R10 **64E-5.1320 Bioassay Program.** The licensee shall establish and submit for
 R10 department approval a bioassay program used to evaluate internal doses. At a minimum an
 R10 acceptable program shall include the following action levels for organ uptakes, corresponding
 R10 actions taken if these levels are exceeded, frequency of measurement and maintenance of
 R10 records.

R10 (1) Routine bioassay is required when an individual handles in open form unsealed
 R10 quantities of radioactive iodine that exceed those shown in the table 1 below.
 R10 The quantities shown apply to both the quantity handled at any one time or
 R10 integrated as the total amount of activity introduced into a process by an
 R10 employee over any 3-month period.

R10

TABLE 1		
I-125 or I-131 Activity Handled in Unsealed Form Requiring Bioassay		
Type of Operation	Volatile or Dispersible	Bound to Nonvolatile Agent
Processes in open room or bench, with possible escape of iodine from process vessels	1.0 mCi (37 MBq)	1.0 mCi (37 MBq)
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	1.0 mCi (37 MBq)	10.0 mCi (370 MBq)
Processed carried out within glove boxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	10.0 mCi (370 MBq)	100.0 mCi (3700 MBq)

R10 (a) A bioassay shall be taken within 72 hours of initial use of radioiodine and
 R10 every 2 weeks thereafter. When radioiodine use is on an infrequent basis
 R10 (less than every 2 weeks), a bioassay shall be taken within 10 days of the
 R10 last day of use.

R10 (b) If the thyroid burden at the time of measurement exceeds 0.12 microcurie
 R10 (4.44 KBq) of iodine 125 or 0.04 microcurie (1.48 KBq) of iodine 131, the
 R10 following actions shall be taken:

- R10 1. An investigation of the operations involved, including air and other
 R10 facility surveys, shall be carried out to determine the cause(s);
- R10 2. Corrective actions that will eliminate or lower the potential for
 R10 further exposures shall be implemented;
- R10 3. A repeat bioassay shall be taken within 2 weeks of the previous
 R10 measurement and shall be evaluated within 24 hours after the
 R10 measurement in order to confirm the presence of internal
 R10 radioiodines; and

R10 4. Notification reports must be provided as required by Rules
 R10 64E-5.345, and 64E-5.347, F.A.C., or as required by conditions of
 R10 the license; and

R10 (c) A record of each bioassay shall be maintained for inspection by the
 R10 department in an auditable form for 3 years and shall include the date of
 R10 the bioassay, the name of the individual, and the thyroid burden at the
 R10 time of the measurement.

R10 (2) Routine bioassay is required when an individual handles in open form unsealed
 R10 quantities of tritium that exceed those shown in table 2 below. The quantities
 R10 shown apply to both the quantity handled at any one time or integrated as the
 R10 total amount of activity introduced into a process by an employee over a 1-month
 R10 period.

R10

TABLE 2		
Tritium Activity Handled in Levels or Concentrations Requiring Bioassay		
Type of Operation	HTO and Other Tritiated Compounds (Including Nucleotide Precursors)	Tritium (HT or T) Gas in Sealed Process Vessels
Processes in open room or bench with possible escape of tritium from process vessels	0.1 Ci (3.70 GBq)	100 Ci (3.7 TBq)
Processes with possible escape of tritium carried out within a fume hood of adequate design, face velocity, and performance reliability	1 Ci (37 GBq)	1,000 Ci (37 TBq)
Processes carried out within glove boxes that are ordinarily closed but with possible release of tritium ¹ from process vessels and occasional exposure to contaminated box and leakage	10 Ci (370 GBq)	10,000 Ci (370 TBq)

R10 (a) A bioassay shall be taken within 72 hours of initial use of tritium and every
 R10 2 weeks thereafter. When work with tritium is on an infrequent basis (less
 R10 frequent than every 2 weeks), a bioassay shall be taken within 10 days of
 R10 the last day of use.

R10 (b) If the urinary tritium concentration exceed 5 microcuries (185 KBq) per liter
 R10 at the time of the measurement the following actions shall be taken:

R10 1. An investigation of the operations involved, including air and other
 R10 facility surveys, shall be carried out to determine the cause(s);

R10 2. Corrective actions that will eliminate or lower the potential for
 R10 further exposures shall be implemented;

- R10 3. A repeat bioassay shall be taken within 1 week of the previous
R10 measurement and shall be evaluated within 1 week after the
R10 measurement. Internal dose commitments shall be estimated using
R10 at least two bioassays and other survey data, including the
R10 probable times of intake of tritium; and
- R10 4. Notification reports must be provided as required by Rules
R10 64E-5.345, and 64E-5.347, F.A.C., or as required by conditions of
R10 the license; and
- R10 (c) A record of each bioassay shall be maintained for inspection by the
R10 department in an auditable form for 3 years and shall include the date of
R10 the bioassay, the name of the patient, and the urinary tritium concentration
R10 at the time of the measurement.

R10 Rulemaking Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081 FS.

R10 Law Implemented: 404.022, 404.042, 404.051(1), (4), (6), (9), (10), 404.061(2), (3), 404.071(1), 404.081(1) FS..

R10 History: New 02-11-10

Page Left Blank Intentionally for Page Numbering

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

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

64E-5.1416.... Training	XIV-15
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 XIV

LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

SUBPART A GENERAL PROVISIONS

64E-5.1401 Irradiators.

- (1) This part contains requirements for licenses authorizing the use of sealed sources containing radioactive materials in irradiators to irradiate objects or material. This part also contains radiation safety requirements for operating irradiators.
- (2) The rules in this part apply to panoramic irradiators which have either dry or wet storage of radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators covered by the rules in this part are those whose radiation dose rates exceed 500 rads (5 grays) per hour at 1 meter from the radioactive sealed sources in air or in water.
- (3) The rules in this part do not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel. This part also does not apply to radioactive material used for medical radiology, teletherapy, industrial radiography, gauging, calibration of radiation instruments, or open-field agricultural irradiations.
- (4) The requirements of this part are in addition to other applicable requirements of these rules.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1501.

64E-5.1402 Definitions.

- (1) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within a capsule which is sealed within another capsule.
- (2) "Irradiator" means a facility which uses radioactive sealed sources to irradiate objects or materials and in which radiation dose rates exceeding 500 rads (5 grays) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

- (3) "Irradiator operator" means an individual who successfully completed the training and testing specified in 64E-5.1416 and who is authorized by the licensee and approved by the department to operate the irradiator without a supervisor present.
- (4) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiation occurs in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced to perform irradiations.
- (5) "Panoramic irradiator" means an irradiator in which the irradiation occurs in air in areas potentially accessible to personnel. The term includes beam-type irradiators.
- (6) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiation occurs in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.
- (7) "Pool irradiator" means an irradiator in which the sources are stored or used in a pool of water, including panoramic wet-source-storage irradiators and underwater irradiators.
- (8) "Product conveyor system" means a system to move the product to be irradiated to, from, and within the area where irradiation occurs.
- (9) "Radiation room" means a shielded room in which irradiation occurs. Underwater irradiators do not have radiation rooms.
- (10) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent as designated by the U.S. Geological Survey.
- (11) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and personnel cannot access the sealed source or the space subject to irradiation without entering the pool.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1502.

SUBPART B
SPECIFIC LICENSING REQUIREMENTS

64E-5.1403 Specific License for Large Irradiators. An application for a specific license to use sealed sources in a large irradiator shall be made as specified in 64E-5.207. A separate license is required for each large irradiator, radiation room or underwater irradiator. The department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

- (1) The applicant must satisfy the general requirements specified in 64E-5.208 and the requirements contained in this part.
- (2) The applicant must describe training for irradiator operators which includes the following:
 - (a) At least 40 hours of classroom training;
 - (b) At least 160 hours of on-the-job or simulator training;
 - (c) Safety reviews;
 - (d) The means the applicant will use to evaluate the operator's knowledge and understanding of and ability to comply with the department's rules and licensing requirements and the applicant's operating and emergency procedures; and
 - (e) The minimum qualifications of personnel who provide training.
- (3) The applicant shall submit an outline or summary of the written operating and emergency procedures specified in 64E-5.1417. The outline or summary must include important radiation safety aspects of the procedures.
- (4) The applicant shall describe the radiation safety responsibilities and authority of the radiation safety officer and other management personnel and specify who has the authority to stop unsafe operations. The applicant also shall describe the qualifications required of the radiation safety officer.
- (5) The applicant shall submit a description of the access control systems required by 64E-5.1406, the radiation monitors required by 64E-5.1409, the method to detect leaking sources required by 64E-5.1420, including the sensitivity of the method, and a diagram of the facility which shows the position of all required interlocks and radiation monitors.
- (6) The applicant shall assure that any radioactive source not used in the irradiation process shall be removed from the irradiator pool and disposed of or returned to the manufacturer unless otherwise approved by the department.

- (7) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the department for approval. The procedures must include the following:
- (a) Instruments to be used;
 - (b) Methods of performing the analysis; and
 - (c) Pertinent experience of individuals who analyze the samples.
- (8) If licensee personnel load or unload sources, the applicant shall describe the qualifications of the personnel and the procedures to be used. If the applicant contracts for source loading or unloading, the loading or unloading must be done by an organization licensed by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to load or unload irradiator sources.
- (9) The applicant shall perform operational tests on the following to ensure proper functioning of all equipment and safety devices before the irradiator is loaded with sources:
- (a) Interlock and radiation safety systems;
 - (b) Pool integrity and plumbing;
 - (c) Source rack mechanical positioning system;
 - (d) Source rack movement and position sensing systems;
 - (e) Source rack electrical control system;
 - (f) Uninterruptable electrical power supply for radiation monitoring warning systems;
 - (g) Fire protection system;
 - (h) Emergency systems for returning a stuck source rack into the pool;
 - (i) Systems used for transferring sources to and from transport vehicles; and
 - (j) Product conveyor system.
- (10) The applicant shall describe the operational inspection and maintenance program, including the frequency of operational checks required by 64E-5.1421.
- (11) The roof plug opening or removable shielding providing access for the loading and removal of sources shall be large enough to accommodate the largest applicable transportation cask.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1503.

64E-5.1404 Start of Construction.

- (1) The applicant shall not begin construction of a new irradiator before sending a license application to the department for the irradiator. As used in this paragraph, the term "construction" includes the construction of any portion of the permanent facility on the site but does not include:
 - (a) Engineering and design work;
 - (b) Purchase of the site;
 - (c) Site surveys or soil testing;
 - (d) Site preparation;
 - (e) Site excavation;
 - (f) Construction of warehouse structures; and
 - (g) Other similar tasks.
- (2) Site requirements for an irradiator include geological, radiological and hydrological testing to ensure a stable environment before construction begins. Records of the results of the siting requirements shall be maintained for the life of the facility.
- (3) Any activities undertaken before the issuance of a license will be entirely at the risk of the applicant and will have no bearing on the issuance of a license.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1504.

SUBPART C**DESIGN AND PERFORMANCE REQUIREMENTS FOR LARGE IRRADIATORS****64E-5.1405 Performance Criteria for Sealed Sources.**

- (1) The licensee shall assure that sealed sources installed after August 14, 1996 meet the requirements of this section. A prototype of the sealed source must be leak tested and found leak-free after each of the following tests:
 - (a) Temperature. The test source must be held at minus 40 degrees Celsius for 20 minutes, 600 degrees Celsius for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600 degrees Celsius to 20 degrees Celsius within 15 seconds.
 - (b) Pressure. The test source must be subjected twice to an external pressure of 290 pounds per square inch absolute for at least 5 minutes.
 - (c) Impact. A 2 kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

- (d) Vibration. The test source must be subjected three times for 10 minutes each time to a range of vibration from 25 Hertz to 500 Hertz at 5 times the acceleration of gravity for 30 minutes. Each test source must be vibrated for 30 minutes at each resonant frequency found.
 - (e) Puncture. A 50 gram weight and pin, 0.3 centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.
 - (f) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2,000 newtons at its center equidistant from two support cylinders. The distance between the support cylinders is 10 times the minimum cross-sectional dimension of the source.
- (2) Sealed sources installed after August 14, 1996 must be doubly encapsulated, the isotope or isotope and matrix contained within the sealed sources must be as nondispersible and insoluble as practical or rendered insoluble in water if the source is used in a wet-source-storage or wet-source-change irradiator and must satisfy the requirements specified in 64E-5.210(14).

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1505.

64E-5.1406 Access Control.

- (1) Panoramic irradiators shall not be operated unless the following are met:
- (a) Each entrance to a radiation room must have a door or other physical barrier to prevent inadvertent entry of personnel while the sources are exposed. Product conveyor systems can serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if any door or barrier to the radiation room is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The primary entry door must have a lock which is operated by the same key used to control source movement. The doors and barriers must not prevent any individual in the radiation room from leaving.
 - (b) Each entrance to a radiation room must have an independent backup access control to detect personnel entry while the sources are exposed if the primary access control fails. Entry while the sources are exposed must cause the sources to return to their fully shielded position and also must activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm also must alert at least one other individual of the entry who is on site and who is trained to render or summon assistance promptly.

- (c) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when the monitor detects high radiation levels. The monitor must generate audible and visible alarms if high radiation levels are detected when personnel entry is attempted. The monitor can be located in the entrance or maze but not in the direct radiation beam.
- (d) Before sources move from their shielded position, the source control automatically must activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.
- (e) Each radiation room must have a clearly visible and readily accessible control which will allow an individual in the room to return the sources to their fully shielded position.
- (f) Each radiation room must contain a control which allows the sources to move from the shielded position only if the control has been activated and the door or barrier to the radiation room subsequently has been closed within a preset time.
- (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 Rule 64E-5.323, F.A.C. Panoramic irradiators also must be posted as required by Rule 64E-5.323, F.A.C. The sign can be removed, covered, or otherwise made inoperative when the sources are shielded fully.
- (h) If the radiation room has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement can be met by interlocks which prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

R2
R2
R2

- (2) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management shall have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual, not necessarily on site, who is prepared to respond or summon assistance.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

R2 History: New August 14, 1996, Formerly 10D-91.1506, **Amended October 8, 2000.**

64E-5.1407 Shielding.

- (1) The radiation dose rate in areas which normally are occupied during operation of a panoramic irradiator must not exceed 2 millirem (0.02 millisievert) per hour at 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Areas where the radiation dose rates exceed 2 millirem (0.02 millisievert) per hour must be locked, roped off, or posted to prevent access and not entered without written approval or in the physical presence of the radiation safety officer or his designee.
- (2) The radiation dose at 30 centimeters over the pool of a pool irradiator when the source is in the fully shielded position must not exceed 2 millirem (0.02 millisievert) per hour.
- (3) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator must not exceed 2 millirem (0.02 millisievert) per hour and at 5 centimeters from the shield must not exceed 20 millirem (0.02 millisievert) per hour.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1507.

64E-5.1408 Fire Protection.

- (1) The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must become fully shielded automatically and the air handling systems within the radiation room must be disabled automatically if a fire is detected.
- (2) The radiation room at a panoramic irradiator must be equipped with a fire suppression or extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1508.

64E-5.1409 Radiation Monitors.

- (1) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radiation sources which are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.
- (2) For pool irradiators, the licensee shall provide a means to detect radioactive contamination in pool water each day the irradiator operates. The means can be either an on-line radiation monitor on the pool water purification system or an analysis of pool water. If the licensee uses an on-line radiation monitor, the detection of above normal background radiation levels must activate the alarm. The alarm set-point must be set as low as practical but high enough to avoid false alarms. If a false alarm due to background radiation occurs, the alarm set-point must be increased. Activation of the alarm must cause the water purification system to shut off automatically. However, the licensee can reset the alarm set-point to a higher level if necessary to operate the pool purification system to clean up contamination in the pool as provided specifically in written emergency procedures.
- (3) Underwater irradiators which are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm can have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1509.

64E-5.1410 Control of Source Movement.

- (1) The mechanism which moves the sources of a panoramic irradiator must require a key to operate. Operation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key shall be available for use at any time and only operators or facility management can possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock must be designed so that the key cannot be removed if the source is in an unshielded position. The door to the radiation room must require the same key. The key must be in the possession of a person entering the radiation room.
- (2) The console of a panoramic irradiator must have a source position indicator which indicates when the sources are in the fully shielded position, when they are in transit, and when they are exposed.

- (3) The control console of a panoramic irradiator must have a control which promptly returns the sources to the shielded position.
- (4) Each control for a panoramic irradiator must be labeled clearly as to its function.
- (5) Controls for a panoramic irradiator must be color-coded or illuminated as follows:
 - (a) Red represents emergency or critical information;
 - (b) Yellow or orange represents caution, no emergency but some function taking place to be aware of; and
 - (c) Green or blue represents normal or safe functioning or information.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1510.

64E-5.1411 Irradiator Pools.

- (1) For licenses initially issued after August 14, 1996, irradiator pools must possess a watertight stainless steel liner or a liner metallurgically compatible with other components in the pool or be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination and must include a means of safely storing sources during repairs of the pool.
- (2) For licenses initially issued after August 14, 1996, irradiator pools must have no penetration more than 0.5 meter below the normal low water level which could allow water to drain out of the pool. Pipes which have intakes more than 0.5 meter below the normal low water level must have siphon breakers to prevent the siphoning of the pool.
- (3) A means must be provided to replenish water losses from the pool.
- (4) An audible and visible indicator must be provided to indicate if the pool water level is below the normal low water level or above the normal high water level.
- (5) Irradiator pools must be equipped with a purification system designed to maintain the water during normal operation at a level of conductance not exceeding 20 microsiemens per centimeter and with a clarity so the sources can be seen clearly.
- (6) A physical barrier such as a railing or cover must be used around irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier can be removed during maintenance, inspection, and service operations.
- (7) If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools must not exceed 2 millirem (0.02 millisievert) per hour.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1511.

64E-5.1412 Source Rack Protection. If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism which moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism. A collision alarm system on the protective barrier must cause an alarm at the control console notifying the operator that a collision between the barrier and product conveyor has occurred.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1512.

64E-5.1413 Power Failures.

- (1) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must return automatically to the shielded position.
- (2) The lock on the door of the radiation room of a panoramic irradiator must not be deactivated by a power failure.
- (3) During a power failure, the area around the pool of an irradiator shall not be entered without using an operable and calibrated radiation survey meter.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1513.

64E-5.1414 Design Requirements. Irradiators whose construction begins after August 14, 1996 must meet the design requirements of this section. The requirements must be met before the start of the construction of the specific component, but do not have to be met before submitting a license application. After construction of the irradiator is completed, the licensee must submit to the department copies of as-built construction drawings signed by the architect and the licensee.

- (1) Panoramic irradiators shall meet the following design requirements:
 - (a) Shielding. The licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and shall design the walls, wall penetrations, and entrance ways to meet the radiation shielding requirements of 64E-5.1407. If the irradiator will use more than 2×10^{17} becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.
 - (b) Foundations. The licensee shall design the foundation with consideration given to soil characteristics to ensure it is adequate to support the weight of the facility.

- (c) Source Rack. The licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables or alternate means of support will not cause loss of integrity of sealed sources. The licensee shall review the design of the mechanism which moves the sources to assure that the likelihood of a stuck source is low and that if the rack sticks it can be freed without causing radiation overexposure of personnel.
 - (d) Access Control. The licensee shall verify from the design and logic diagram that the access control system will meet the requirements of 64E-5.1406.
 - (e) Fire Protection. The licensee shall verify that the number, design, locations and spacing of the smoke and heat detectors and extinguishing system are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.
 - (f) Source Return. The licensee shall verify that the source rack will be returned automatically to the fully shielded position if off-site power is lost for more than 10 seconds. If a component of the return mechanism fails, the design must allow for accomplishing the return without causing radiation overexposures of personnel.
 - (g) Seismicity. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to seismic requirements of an appropriate source such as American Concrete Institute Standard 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes.
 - (h) Wiring. The licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.
- (2) Pool irradiators shall meet the following design requirements:
- (a) Pool Integrity. The licensee shall design the pool to assure that it is leak-resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all penetrations meet the requirements of 64E-5.1411(2), and that metal components are metallurgically compatible with other components in the pool.

- (b) Water Handling System. The licensee shall design the water purification system to meet the requirements of 64E-5.1411(5). The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored. The licensee shall design the water chiller system so that it shall compensate adequately for the amount of heat generated by the sealed sources. The water handling system must have remote controls capable of safely operating a contaminated system.
 - (c) Source rack. The licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. The lift mechanisms for the source rack and source transport cask must be of designed working and breaking strength to lift safely a source transport cask and sources into and out of the irradiator pool.
- (3) All irradiators shall meet the following design requirements:
- (a) Radiation Monitors. The licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 64E-5.1409(1). The licensee shall verify that the product conveyor will stop before a source on the product conveyor causes a radiation overexposure. For pool irradiators, the licensee shall verify that the radiation monitor on the water purification system is located near the area in which elevated radiation levels will be expected.
 - (b) Product carriers. For irradiators using product carriers, the design of the carrier shall prevent the carrier from opening or coming into contact with the source rack or protective barrier. The design shall be submitted to the department for approval.
 - (c) Floor penetrations. No floor penetrations, including expansion joints, floor joints and drains, shall allow the uncontrolled release of water from the radiation room that has not been analyzed for its radioactive content.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1514.

64E-5.1415 Construction Control. The requirements of this section must be met before loading sources.

- (1) Panoramic irradiators shall meet the following construction requirements:
 - (a) **Shielding.** The licensee shall monitor the construction of the shielding to verify that it meets design specifications and generally accepted building code requirements for reinforced concrete.
 - (b) **Foundations.** The licensee shall monitor the construction of the foundations to verify that they meet design specifications.
 - (c) **Source Rack.** The licensee shall test the movement of the source racks for proper operation before source loading. Testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in 64E-5.1412 and 64E-5.1414(3)(b) are met for protection of the source racks and the mechanism which moves the rack. Testing must include any limit switches and interlocks used to protect the source rack and the mechanism which moves the rack from moving product carriers.
 - (d) **Access Control.** The licensee shall test the access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.
 - (e) **Fire Protection.** The licensee shall verify the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to become fully shielded automatically. The licensee also shall verify the operability of the fire suppression or extinguishing system.
 - (f) **Source Return.** The licensee shall demonstrate that the source racks can be returned to their fully shielded position without off-site power.
 - (g) **Computer Systems.** If a computer is used to control the access control system, the licensee shall demonstrate that the computer and the access control system will operate as planned if off-site power is lost by attempting to defeat the access control system in as many ways as possible. The computer must have suitable security features which prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.
 - (h) **Wiring.** The licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

- (2) Pool irradiators shall meet the following construction requirements:
- (a) Pool Integrity. The licensee shall test the integrity of the pool and verify that the pool meets the design specifications. The licensee shall verify that penetrations and water intakes meet the requirements of 64E-5.1411(2).
 - (b) Water Handling System. The licensee shall verify that the water purification system, the conductivity meter and the water level alarms operate properly.
- (3) Radiation Monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and related alarms and interlocks required by 64E-5.1409(1). For pool irradiators, the licensee shall verify the proper operation of the radiation monitor on the water purification system and the related alarms and interlocks required by 64E-5.1409(2). For underwater irradiators, the licensee shall verify the proper operation of the pool monitor, alarms, and interlocks required by 64E-5.1409(3).

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1515.

SUBPART D OPERATION OF IRRADIATORS

64E-5.1416 Training.

- (1) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in the following:
- (a) The fundamentals of radiation protection applied to irradiators, including:
 - 1. The difference between external radiation and radioactive contamination;
 - 2. Units of radiation dose;
 - 3. The department's dose limits;
 - 4. Why large radiation doses must be avoided;
 - 5. How shielding and access controls prevent large doses;
 - 6. How an irradiator is designed to avoid contamination;
 - 7. The use of survey meters and personnel dosimeters;
 - 8. Other radiation safety features of an irradiator; and
 - 9. The basic function of the irradiator.

- (b) The requirements of this part and Part IX of these rules;
 - (c) The operation of the irradiator;
 - (d) Licensee operating and emergency procedures which the individual is responsible for performing; and
 - (e) Case histories of accidents or problems involving irradiators similar to those to be used by the individual.
- (2) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received, consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to operate the irradiator safely without supervision.
- (3) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job or simulator training in the use of the irradiator as described in the license application. The individual also shall demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.
- (4) The licensee shall conduct safety reviews and emergency drills as described below for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:
- (a) Changes in operating and emergency procedures since the last review;
 - (b) Changes in rules and license conditions since the last review;
 - (c) Reports on recent accidents, mistakes, or problems which have occurred at irradiators;
 - (d) Relevant results of inspection of operator safety performance;
 - (e) Relevant results of the facility's inspection and maintenance checks; and
 - (f) A drill to practice an emergency or abnormal event procedure.
- (5) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that rules, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

- (6) Individuals who will be permitted unescorted access to the irradiators but who have not received the training required for operators and the radiation safety officer shall be trained and tested in precautions they should take to avoid radiation exposure, procedures or parts of procedures in 64E-5.1418 which they are expected to perform or comply with, and the proper response to alarms required in this part. Tests can be oral.
- (7) Individuals who must be prepared to respond to alarms required by 64E-5.1406, 64E-5.1408, 64E-5.1409, 64E-5.1411, and 64E-5.1412 shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests can be oral.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1516.

64E-5.1417 Operating and Emergency Procedures.

- (1) The licensee shall have and follow written operating procedures for the following:
 - (a) Operation of the irradiator, including entering and leaving the radiation room;
 - (b) Use of personnel dosimeters;
 - (c) Surveying the shielding of panoramic irradiators;
 - (d) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
 - (e) Leak testing of sources;
 - (f) Inspection and maintenance checks required by 64E-5.1422;
 - (g) Loading, unloading, and repositioning sources, if to be performed by the licensee;
 - (h) Inspection of movable shielding required by 64E-5.1406(1)(h), if applicable; and
 - (i) Security precautions while sources are stored outside the radiation room. Sealed sources must be moved into the radiation room within 48 hours of receipt unless the department is notified in writing that extenuating circumstances do not allow for source loading within the prescribed 48 hour period.
- (2) The licensee shall have and follow emergency or abnormal event procedures for the following:
 - (a) Sources stuck in the unshielded position;
 - (b) Personnel overexposures;

- (c) A radiation alarm from the product exit portal monitor or pool monitor;
 - (d) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
 - (e) A low water level alarm, a high water level alarm, an abnormal water loss, or leakage from the source storage pool;
 - (f) A prolonged loss of electrical power;
 - (g) A fire alarm or explosion in the radiation room;
 - (h) An alarm indicating unauthorized entry into the radiation room, the area around the pool, or another alarmed area;
 - (i) Natural phenomena, including an earthquake, a hurricane, a tornado, flooding, sinkhole formation, or other phenomena; and
 - (j) The jamming of automatic conveyor systems or an alarm indicating a collision between the barrier and product conveyor.
- (3) The licensee can revise operating and emergency procedures only with departmental approval.
- (4) The licensee shall provide and coordinate current emergency procedures annually with the local police, fire department, and civil authorities, including notification of responsible individuals and places of emergency treatment.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1517.

64E-5.1418 Personnel Monitoring.

- R2 (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.
- R2
- R2
- R2
- R2
- (2) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which can be a pocket dosimeter. For groups of visitors, only two people are required to wear dosimeters. Date of entry, all names and total dose must be recorded. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response must be done at least annually. Acceptable dosimeters must read within 30 percent of the true radiation dose.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
R2 History: New August 14, 1996, Formerly 10D-91.1518, Amended October 8, 2000.

64E-5.1419 Radiation Surveys.

- (1) Before the facility starts operation, the following radiation surveys must be performed:
 - (a) A radiation survey of the area above the pool after the sources are loaded and in the shielded position; and
 - (b) A survey of the area outside the shielding of the radiation room of a panoramic irradiator with the sources in the exposed position.
- (2) If the surveys indicate that radiation levels specified in 64E-5.1407 are exceeded, the shielding must be repaired to comply with the dose rate requirement in 64E-5.1407 before operation of the facility can start.
- (3) Radiation surveys described in (1) above must be performed after new sources are loaded and after any modifications which might increase dose rates are made to the radiation room, shielding or structure and at intervals not to exceed 3 years.
- (4) Portable radiation survey meters used to meet the requirements of paragraphs (1) and (3) of this section and the requirements of 64E-5.1413(3) and 64E-5.1424(1) must be calibrated at least annually to an accuracy of 20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.
- (5) Water from the irradiator pool or other potentially contaminated liquids and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table II, Column 2, or Table III, as applicable. The lower limit of detection for the measurements must be below those concentrations.
- (6) Resins to be released for unrestricted use must be monitored before release in an area with a background level less than 0.05 millirem (0.0005 millisievert) per hour. The resins can be released only if the survey does not detect radiation levels above background radiation levels. The survey meter must be capable of detecting radiation levels of 0.05 millirem (0.0005 millisievert) per hour.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1519.

64E-5.1420 Detection of Leaking or Contaminated Sources.

- (1) Each dry-source-storage sealed source must be tested for leakage at least every 6 months using a leak test kit or a method approved by the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state. The analysis must be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material and must be performed by a person approved by the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state to perform the analysis.
- (2) For pool irradiators, the pool water must be checked for contamination each day the irradiator operates. The check must be done by using an on-line radiation monitor on a pool water circulating system as described in 64E-5.1410(2) or by analysis of pool water. If a check for contamination is done by analysis of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical but high enough to avoid false alarms. The licensee can reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.
- (3) The licensee shall have written procedures and equipment available for the detection, isolation and removal of leaking sources.
- (4) If a leaking source is detected, the licensee shall remove the leaking source from service and have it decontaminated, repaired, or disposed of by a licensee of the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state authorized to perform these functions. The licensee shall check its personnel, equipment, facilities, and irradiated product promptly for radioactive contamination. No product shall be shipped until the product has been checked and found free of contamination. If a product has been shipped that could have been contaminated inadvertently, the licensee shall arrange to locate and survey that product for contamination. If any personnel are contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall have them decontaminated or disposed of by a licensee of the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state authorized to perform these functions. If the pool water is contaminated, the licensee shall clean the pool water until the contamination levels do not exceed the appropriate concentration in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table II, Column 2.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1520.

64E-5.1421 Inspection and Maintenance.

- (1) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:
 - (a) Operation of each aspect of the access control system required by 64E-5.1406;
 - (b) Functioning of the source position indicator required by 64E-5.1410(2);
 - (c) Operation of the radiation monitor on the pool water purification system using a radioactive check source to detect radioactive contamination in pool water as required by 64E-5.1409(2);
 - (d) Operation of the over-pool radiation monitor at underwater irradiators as required by 64E-5.1409(3).
 - (e) Operation of the product exit monitor required by 64E-5.1409(1);
 - (f) Operation of the emergency source return control required by 64E-5.1410(3);
 - (g) Leak-tightness of systems through which pool water circulates (visual inspection);
 - (h) Operation of the heat and smoke detectors and extinguisher system required by 64E-5.1408 but without turning on extinguishers;
 - (i) Operation of the means of pool water replenishment required by 64E-5.1411(3);
 - (j) Operation of the visible indicator of low and high pool water level required by 64E-5.1411(4);
 - (k) Operation of the intrusion alarm required by 64E-5.1406(2);
 - (l) Functioning and wear on the system, mechanisms, and cables used to raise and lower sources;
 - (m) Condition of the barrier to prevent products from hitting the sources or source mechanism and the operation of the collision alarm system, as required by 64E-5.1412;
 - (n) Amount of water added to the pool to determine if the pool is leaking;
 - (o) Electrical wiring on required safety systems for radiation damage;
 - (p) Pool water conductivity measurements and analysis as required by 64E-5.1422;
 - (q) Condition of the product carriers; and

- (r) Operation of the siphon breakers in the pool plumbing.
- (2) Malfunction and defects found during inspection and maintenance checks must be repaired without undue delay.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1521.

64E-5.1422 Pool Water Purity.

- (1) Pool water purification systems must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.
- (2) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1522.

64E-5.1423 Attendance During Operation.

- (1) An operator and at least one other individual trained and prepared to render or summon assistance promptly if the access control alarm sounds shall be present on site whenever a panoramic irradiator is operated using an automatic product conveyor system and whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.
- (2) At an underwater irradiator, an operator must be present whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in 64E-5.1416(6) and (7). Static irradiation can be performed without a person present at the facility only if the personnel access barrier around the pool is locked to prevent unauthorized entry and all required alarms are operable.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1523.

64E-5.1424 Entering and Leaving the Radiation Room.

- (1) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source before entry. The response of the survey meter to the radiation check source must be consistent and reproducible.
- (2) Before exiting from and locking the door to the radiation room of a panoramic irradiator before a planned irradiation, the irradiator operator shall perform the following:
 - (a) Inspect visually the entire radiation room to verify that no one else is in it; and
 - (b) Activate a control in the radiation room which permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.
 - (c) During a power failure, the area around the pool of an underwater irradiator cannot be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 64E-5.1409(3) is operating with backup power.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1524.

64E-5.1425 Irradiation of Explosive or Highly Flammable Materials.

- (1) Irradiation of explosive materials is prohibited unless the licensee has received prior written authorization from the department. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.
- (2) Irradiation of more than small quantities of highly flammable material with a flash point below 140 degrees Fahrenheit is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the department. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1525.

SUBPART E
RECORDS AND REPORTS

64E-5.1426 **Records and Retention Periods.**

- (1) The licensee shall maintain the following records at the irradiator for the periods specified:
 - (a) A copy of the license application and the license authorizing the licensee to operate the facility until a new license is issued;
 - (b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of 64E-5.1416 until 3 years after the individual terminates work;
 - (c) Records of the annual evaluation of the safety performance of irradiator operators required by 64E-5.1416(5) for 3 years after the evaluation;
 - (d) An up-to-date copy of the operating and emergency procedures required by 64E-5.1417 until superseded or the department terminates the license;
 - (e) Personnel monitoring results required by 64E-5.1418 until the department terminates the license;
 - (f) Records of radiation surveys required by 64E-5.1420 for 3 years from the date of the survey;
 - (g) Records of radiation survey meter calibrations required by 64E-5.1419 and pool water conductivity meter calibrations required by 64E-5.1422(2) until 3 years from the date of the calibration;
 - (h) Records of the results of leak tests required by 64E-5.1420 and the results of contamination checks required by 64E-5.1420(2) for 3 years from the date of the leak tests;
 - (i) Records of inspection and maintenance checks required by 64E-5.1421 for 3 years;
 - (j) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed;
 - (k) Records of the receipt, transfer and disposal of all licensed sealed sources as required by 64E-5.103.
 - (l) An inventory of all licensed sealed sources until the irradiator is decommissioned. The inventory must include for each sealed source the following:
 1. The date received;

2. The person from whom it was received;
 3. The model of the source;
 4. The serial number of the source;
 5. The radionuclide in the source;
 6. The activity of the source as supplied from the manufacturer and the date of the assigned activity;
 7. An up-to-date location of the source;
 8. Information on leaking or damaged sources and any actions taken to decontaminate or repair those sources;
 9. The date disposed of; and
 10. The person to whom the source was transferred.
- (m) Records on the design checks required by 64E-5.1414 and the construction control checks required by 64E-5.1415 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included;
- (n) Records of water added to the pool as required by 64E-5.1421(1)(n) for 3 years;
- (o) Records related to decommissioning the irradiator as required by 64E-5.214(4)(c)2.
- (p) Records of annual notification to local police, fire department and civil authorities of the current emergency procedures, responsible individuals and places of emergency treatment for 3 years;
- (q) Records of conductivity meter calibration as required by 64E-5.1422(2) for 3 years; and
- (r) Records of written approval of access to restricted areas as required by 64E-5.1407(1) for 3 years.
- (2) Records required by this section shall be available for inspection by the department.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1526.

64E-5.1427 Reports and Notifications.

- (1) In addition to the other reporting requirements in these rules, each licensee shall notify the department as soon as possible but not later than 4 hours after the discovery of the following events:
 - (a) Threats of violence or acts of terrorism against the operation of this facility;
 - (b) Fire or explosion in the radiation room;
 - (c) Detection of radiation by the product portal monitors;
 - (d) Detection of any radioactive contamination.
 - (e) Sources stuck in an unshielded position;
 - (f) Damage to source racks;
 - (g) Failure of the cable or drive mechanism used to move the source racks;
 - (h) Inoperability of the access control system;
 - (i) Structural damage to the pool liner or walls;
 - (j) Abnormal water loss or leakage from the source storage pool; or
 - (k) Pool water conductivity exceeding 100 microsiemens per centimeter.
- (2) The licensee must submit a written report within 30 days for any reports required by paragraph (1) above. The report must describe the event, what caused the event to the extent known, and corrective actions to prevent recurrence taken up to the time the report is made.
- (3) The licensee shall notify individuals of their exposure to radiation or radioactive materials as required by 64E-5.903.
- (4) The licensee shall notify the department at least 14 days before a source loading or unloading.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1527.

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

R8	64E-5.1501....Purpose and Scope	XV-1a
R8	64E-5.1502....Transportation of Radioactive Material	XV-1a
	64E-5.1503....Exemptions.....	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
R7	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.To 10 CFR Part 71 Determination of A ₁ , and A ₂ Values.....	XV-11
	TABLE A-1A ₁ and A ₂ Values for Radionuclides	XV-13
	TABLE A-2Relationship Between A ₁ and E _{max} for Beta Emitters.....	XV-31
	TABLE A-3.....Relationship Between A ₃ for Alpha Emitters and the Atomic Number of the Radionuclide	XV-31
	TABLE A-4Activity - Mass Relationships for Uranium/Thorium	XV-32

ATTACHMENTS

	ALIs, DACs, and Effluent Concentrations May 2006	Attachments Page-1
R6	Protection Factors for Respirators May 1006	Attachments Page-63
R2	Radioactive Material Requiring Labeling May 2000.....	Attachments Page-68
	Occupational Exposure Record for a Monitoring Period DH Form 1622 Edition 05/1997	Attachments Page-81
	Cumulative Occupational Exposure History DH Form 1623 Edition 05/1997	Attachments Page-84
	Certificate - Disposition of Radioactive Materials DH Form 1059 Edition 05/1997	Attachments Page-87
	Radioactive Materials License Application -- Non-Human Use	
R10	Radioactive Materials License Application Non-Human Use Form DH-1054 12/09	Attachments Page 89
R5	Notice to Employees DH Form 1081 3/01.....	Attachments Page 93
R1	Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997	Attachments page 95
R7	Transfers of Industrial Devices Report 04/2007	
R7	Radiation Machine Facility Registration DH 1107 03/07	
R10	Radioactive Materials License Application Human Use Form DH-1322 12/09	
R10	Federal Policy for the Protection of Human Subjects (Federal Policy) as described in 45 CFR Part 46 dated 11/9/2009 (See 64E-5.601)	

PART XV

TRANSPORTATION OF RADIOACTIVE MATERIALS

R8 64E-5.1501 Purpose and Scope.

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

Specific Authority: 404.051, 404.20, F.S.

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

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

64E-5.1502 Transportation of Radioactive Material.

- (1) No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general license or specific license issued by the department or as exempted in 64E-5.1503.
- (2) Each licensee who transports radioactive material outside of the confines of his facility or other place of use, or who offers radioactive material to a carrier for transport shall:
- R6 (a) Comply with the **current** applicable requirements, appropriate to the mode
R8 of transport, of **49 CFR Parts 107, 171-180, 383, 390-397** published on
R8 10/01/2007, and 10 C.F.R. Part 71 published on 01/01/2007.
- (b) Establish procedures for safely opening and closing packages in which radioactive material is transported and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and
- (c) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

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

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

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

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

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

64E-5.1503 Exemptions.

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

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

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

History: New July 17, 1985, Formerly 10D-91.2004.

64E-5.1504 General Licenses for Carriers.

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

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

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

History: New July 17, 1985, Formerly 10D-91.2005.

64E-5.1505 Routine Determinations. Prior to each shipment of radioactive material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this part and of the license. The licensee shall determine that:

- (1) The package is proper for the contents to be shipped;
- (2) The package is in an unimpaired physical condition except for superficial defects such as marks or dents;
- (3) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;
- (4) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;
- (5) Any pressure relief device is operable and set in accordance with written procedures;
- (6) The package has been loaded and closed in accordance with written procedures;
- (7) Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified by the U.S. Nuclear Regulatory Commission;
- (8) The level of nonfixed or removable radioactive contamination on the external surfaces of each package presented for shipment is as low as reasonably achievable and shall not exceed the applicable levels specified in the regulations of the U.S. Department of Transportation, 49 CFR 173.443; and
- (9) The external radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in the regulations of the U.S. Department of Transportation, 49 CFR 173.441.

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

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

History: New July 17, 1985, Formerly 10D-91.2006.

64E-5.1506 Advance Notification of Shipment of Certain Quantities of Radioactive Waste.

- (1) In addition to the notification requirements of 64E-5.1508, prior to the transport of certain quantities of radioactive waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of certain quantities of radioactive waste to a carrier for transport, each licensee shall provide advance notification of such transport in writing to the governor, or governor's designee, of each state through which the waste will be transported. A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555.

- (2) Such advance notification is required only when:
- (a) The radioactive waste is required to be in Type B packaging for transportation;
 - (b) The radioactive waste is being transported to, through, or across state boundaries to a disposal site or to a collection point for transport to a disposal site;
 - (c) The quantity of licensed material in a single package exceeds:
 - 1. Five thousand curies (185 TBq) of special form radionuclides; or
 - 2. Five thousand curies (185 TBq) of uncompressed gases of argon 41, krypton 85m, krypton 87, xenon 131m, or xenon 135; or
 - 3. Fifty thousand curies (1.85 PBq) of argon 37, or of uncompressed gases of krypton 85 or xenon 133, or of hydrogen 3 as a gas, as luminous paint, or adsorbed on solid material; or
 - 4. Twenty curies (740 GBq) of other nonspecial form radionuclides for which A_2 is less than or equal to 4 curies (148 GBq); or
 - 5. Two hundred curies (7.4 TBq) of other nonspecial form radionuclides for which A_2 is greater than 4 curies (148 GBq); and
 - (d) The quantity of spent nuclear fuel is less than that subject to advance notification requirements of 10 CFR Part 73.
- (3) Each advance notification required by (1) shall contain the following information:
- (a) The name, address, and telephone number of the generator, carrier and receiver of the radioactive waste shipment;
 - (b) A description of the radioactive waste contained in the shipment as required by the regulations of the U.S. Department of Transportation;
 - (c) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;
 - (d) The 7-day period during which arrival of the shipment at state boundaries is estimated to occur;
 - (e) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and
 - (f) A point of contact with a telephone number for current shipment information.

- (4) The notification required by 64E-5.1506(1) shall be made in writing to the office of each appropriate governor or governor's designee and to the department. A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee, at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 1 year for inspection by the department.
- (5) The licensee shall notify each appropriate governor, or governor's designee, and the department of any changes to schedule information provided pursuant to 64E-5.1506(1). Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate states. The licensee shall maintain for 1 year for inspection by the department a record of the name of the individual contacted.
- (6) Each licensee who cancels a radioactive waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the department. A copy of the notice shall be retained by the licensee for 1 year for inspection by the department.

Specific Authority: 404.051, 404.061, 404.081, 404.141, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.061(2), 404.081(1), 404.141, 404.20(1), F.S.

History: New July 17, 1985, Formerly 10D-91.2007.

**64E-5.1507 Designation of Routes for Shipment of Radioactive Waste
Requiring Advanced Notification.**

- (1) The department may designate routes within the state of Florida for all shipments requiring advanced notification under 64E-5.1506. Factors that the department will consider in the designation of routes for shipments requiring advanced notifications are:
 - (a) Population density in the vicinity of available highways;
 - (b) Accident rates of available highways;
 - (c) Transit time;
 - (d) Time and day of the week during which the shipment is to occur; and
 - (e) Routes that may have been previously designated by other states.
- (2) In lieu of the department's designation of routes, the interstate highway system and limited access roadways are preferred for transportation of radioactive waste requiring advanced notification pursuant to 64E-5.1506.

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

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

History: New July 17, 1985, Formerly 10D-91.2008.

64E-5.1508 Inspection of Low-Level Radioactive Waste Shipments.

- (1) All persons licensed by the department to use, manufacture, produce, transfer, transport, receive, acquire, own, process or possess radioactive materials, as well as nuclear power plants licensed by the U.S. Nuclear Regulatory Commission, and who desire to ship radioactive waste, including radioactive waste requiring advance notification as specified in 64E-5.1506, to a low-level radioactive waste treatment, storage or disposal facility, shall notify the department no less than 48 hours prior to departure of the shipment. The notification shall be made in writing or by telephone.
 - (a) Each notification must contain the following information:
 1. The name, address and telephone number of the generator;
 2. The name and telephone number of the contact person, designated by the generator, with whom the department may make arrangements for the inspection;
 3. The name and telephone number of the carrier;
 4. The location of departure, if different from the address of the generator;
 5. The scheduled date and time of departure; and
 6. The proposed route to the low-level radioactive waste facility.
- (2) Upon notification from a licensee or nuclear power plant licensed by the U.S. Nuclear Regulatory Commission, the department shall dispatch an authorized representative to the licensee's facility to inspect the shipment of radioactive waste destined for a low-level radioactive waste treatment, storage or disposal facility. The inspection shall include:
 - (a) Surveys of the external radiation levels of the vehicle;
 - (b) Inspection of package integrity, bracing and blocking, if accessible;
 - (c) Verification of required package marking and labeling, if accessible;
 - (d) Verification of required vehicle placarding; and
 - (e) Examination of the shipping papers for compliance with the regulations of the U.S. Department of Transportation.
- (3) Licensees or nuclear power plants licensed by the U.S. Nuclear Regulatory Commission shall also provide the department's representative the following information or material during the course of inspection of the low-level radioactive waste shipment:
 - (a) Time of departure of shipment;

- (b) Proposed route of the shipment to the low-level radioactive waste facility;
- (c) Estimated time of arrival of the shipment at the low-level radioactive waste facility;
- (d) The carrier's name;
- (e) A complete and legible copy of the bill of lading; and
- (f) A complete and legible copy of the radioactive shipment manifest.
- (4) If the shipment of low-level radioactive waste is found to be in compliance with the regulations of the U.S. Department of Transportation, the department's representative shall affix his initials on the bill of lading and the shipment may then proceed to the low-level radioactive waste facility. If the shipment of low-level radioactive waste is found to be in violation of the regulations of the U.S. Department of Transportation by the department's representative, the licensee shall not allow the shipment to leave the boundaries of his facility until the violation is corrected and the department's representative affixes his initials on the bill of landing signifying the shipment is in compliance.
- (5) Licensees or nuclear power plant licensees of the U.S. Nuclear Regulatory Commission shall, within 72 hours of receiving notice of arrival of their shipment at its destination for unloading, notify the department of such arrival. The licensee shall also forward to the department within 2 weeks of receiving notice of the arrival of the shipment at a destination for unloading, records of receipt and any other records indicating that a shipment was found in violation of the low-level radioactive waste treatment, storage or disposal facility's or host state's rules or regulations.
- (6) Each generator of radioactive waste whose shipment is inspected by the department's representative will be billed quarterly by the department a fee of \$1.95 per cubic foot (0.02832 cubic meter) of waste shipped or \$150.00 per shipment inspected, whichever is greater. This quarterly billing will be paid to the department within 30 days of receipt of the bill.

R7

Specific Authority: 404.051, 404.061, 404.071, 404.20, F.S.

R7 Law Implemented: 404.022, 404.051, 404.061, 404.071, 404.20, F.S.

R7 History: New July 17, 1985, Amended July 5, 1988, Formerly 10D-91.2009, Amended August 16, 2007.

64E-5.1509**Permit Requirements.**

- (1) Any carrier who transports low-level radioactive waste destined for a low-level radioactive waste treatment, storage or disposal facility, prior to entrance into the state of Florida, shall obtain a permit from the department for transporting such waste into the state.
- (a) An application for a permit must contain the following information or material:

1. Name, address and telephone number of the carrier; and
 2. Certification statement that the carrier will comply with this part and the regulations of the U.S. Department of Transportation.
- (b) Each application for a permit must be accompanied by an annual fee of \$100. Permits shall be valid for 365 days following the date of issue. Permit fees are not refundable. Permits may not be transferred or assigned to another carrier.
- (2) (a) Before any shipment of low-level radioactive waste may be transported into or through the state, the permitted carrier shall give written or telephonic notice to the department not less than 48 hours prior to the date of the arrival of the shipment at the borders of the state. The carrier must provide the department with the following information in the notice:
1. The expected date and time the shipment will arrive at the borders of the state;
 2. The estimated time the shipment will remain in the state;
 3. An estimate of the radioisotopes contained within the shipment;
 4. An estimate of the total activity, in curies, contained within the shipment;
 5. An estimate of the total volume, in cubic feet, contained within the shipment; and
 6. The proposed route over which the shipment will be transported.
- (b) The carrier must immediately notify the department of any cancellations or changes of information provided in the prior notification, such as changes in the date of shipment arrival, the length of time the shipment will remain in the state, or the description or quantity of the radioactive waste contained within the shipment.
- (3) Any permit issued pursuant to 64E-5.1509(1), may be suspended if the department has reasonable cause to suspect that the continued shipment of low-level radioactive waste presents a hazard to the public health. Grounds for suspension of a permit may include failure to include the information requested pursuant to 64E-5.1509(2), falsification of information submitted on the application for a permit, or violation of Florida law or department regulations. Prior to the suspension of a permit, the holder of the permit shall be notified in writing that the permit will be suspended and that an opportunity for an administrative hearing will be provided, if requested in writing within 30 days of the receipt of the notice of the intent to suspend the permit. The department may remove the suspension at any time if the department determines that the suspected hazard no longer exists.

- (4) All applications for permits and prior notifications of impending shipments shall be addressed to the department as outlined in 64E-5.1513(2).

Specific Authority: 404.051, 404.061, 404.131, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.131(2)(3), 404.20(6)(7)(8), F.S.

History: New July 17, 1985, Formerly 10D-91.2010.

64E-5.1510

Air Transport of Plutonium. Notwithstanding the provisions of any general license and notwithstanding any exemptions stated directly in this part or included indirectly by citation of the U.S. Department of Transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air or offered to a carrier for air transport unless:

- (1) The plutonium is contained in a medical device designed for individual human application; or
- (2) The plutonium is contained in a material in which the specific activity is not greater than 0.002 microcuries (74 Bq) per gram of material and in which the radioactivity is essentially uniformly distributed; or
- (3) The plutonium is shipped in a single package containing no more than an A₂ quantity of plutonium in any isotope or form and is shipped in accordance with 64E-5.1502; or
- (4) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the U.S. Nuclear Regulatory Commission.

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

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

History: New July 17, 1985, Formerly 10D-91.2011.

64E-5.1511

Notification in the Event of Suspected or Real Breach of Containment. In addition to the reporting requirements of the U.S. Department of Transportation, any carrier transporting radioactive material in the state shall notify the department immediately in the event the carrier suspects or knows of a breach in the containment of the radioactive material being transported. Notification shall be made as described in 64E-5.1513(2).

Specific Authority: 404.051, 404.20, F.S.

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

History: New July 17, 1985, Formerly 10D-91.2012.

64E-5.1512 Inspections.

- (1) A department representative is authorized to inspect any record of persons engaged in the transportation of a radioactive material where such records reasonably relate to packaging, preparing for shipment and transporting radioactive material.
- (2) A department representative is authorized to enter upon and inspect the premises and transport vehicles of any person engaged in the transportation of radioactive material for the purpose of determining compliance with or violation of the provisions of section 404.20, Florida Statutes, and these regulations.
- (3) The department may investigate the cause and circumstances of every event in which notification was made pursuant to 64E-5.1511.

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

Law Implemented: 404.022, 404.051(1)(4)(12), 404.061(2), 404.071(1), 404.20(1)(2)(7)(8), F.S.

History: New July 17, 1985, Formerly 10D-91.2013.

64E-5.1513 Communications.

R1
R2

- (1) All communications concerning this part should be addressed to:
Department of Health, Bureau of Radiation Control, Bin #C21,
4052 Bald Cypress Way, Tallahassee, FL 32399-1741.
- (2) All notifications required to be made pursuant to 64E-5.1506, 64E-5.1508, 64E-5.1509 and 64E-5.1511 shall be addressed to:
Department of Health, Bureau of Radiation Control, Post Office Box 680069,
Orlando, Florida 32868-0069; telephone (407) 297-2095.
- (3) Immediate notification as required by 64E-5.1511 shall be made by telephone or telegraph.

Specific Authority: 404.042, 404.051, 404.20, F.S.

Law Implemented: 404.042, 404.051(1)(4)(6)(11), 404.061(2), 404.081(1), 404.141, 404.20(1), F.S.

History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.2014.

Appendix A to Part 71 - Determination of A₁ and A₂

- I. Values of A₁ and A₂ for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A₁ or A₂ are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.
- II. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the determination of the values of A₁ and A₂ requires Commission approval, except that the values of A₁ and A₂ in Table A-2 may be used without obtaining Commission approval.
- III. In the calculations of A₁ and A₂ for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than 10 days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A₁ or A₂ value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than 10 days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.
- IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

- (a) For special form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_i \frac{B(i)}{A_1(i)} \quad \text{less than or equal to } 1$$

- (b) For normal form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_i \frac{B(i)}{A_2(i)} \quad \text{less than or equal to } 1$$

where B(i) is the activity of radionuclide i and A₁(i) and A₂(i) are the A₁ and A₂ values for radionuclide i, respectively.

Alternatively, an A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where $f(i)$ is the fraction of activity of nuclide i in the mixture and $A_1(i)$ is the appropriate A_1 value for nuclide i .

An A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where $f(i)$ is the fraction of activity of nuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide i .

- V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

Table A-1 A₁ and A₂ Values for Radionuclide

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Ac-225	Actinium(89)	0.6	16.2	1x10 ⁻²	0.270	2.1x10 ³	5.8x10 ⁴
Ac-227		40	1080	2x10 ⁻⁵	5.41x10 ⁻⁴	2.7	7.2x10 ¹
Ac-228		0.6	16.2	0.4	10.8	8.4x10 ⁴	2.2x10 ⁶
Ag-105	Silver(47)	2	54.1	2	54.1	1.1x10 ³	3.0x10 ⁴
Ag-108m		0.6	16.2	0.6	16.2	9.7x10 ⁻¹	2.6x10 ¹
Ag-110m		0.4	10.8	0.4	10.8	1.8x10 ²	4.7x10 ³
Ag-111		0.6	16.2	0.5	13.5	5.8x10 ³	1.6x10 ⁵
Al-26	Aluminum(13)	0.4	10.8	0.4	10.8	7.0x10 ⁻⁴	1.9x10 ⁻²
Am-241	Americium(95)	2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	1.3x10 ⁻¹	3.4
Am-242m		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	3.6x10 ⁻¹	1.0x10 ¹
Am-243		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	7.4x10 ⁻³	2.0x10 ⁻¹
Ar-37	Argon(18)	40	1080	40	1080	3.7x10 ³	9.9x10 ⁴
Ar-39		20	541	20	541	1.3x10 ⁰	3.4x10 ¹
Ar-41		0.6	16.2	0.6	16.2	1.5x10 ⁶	4.2x10 ⁷
Ar-42		0.2	5.41	0.2	5.41	9.6	2.6x10 ²
As-72	Arsenic(33)	0.2	5.41	0.2	5.41	6.2x10 ⁴	1.7x10 ⁶
As-73		40	1080	40	1080	8.2x10 ²	2.2x10 ⁴
As-74		1	27.0	0.5	13.5	3.7x10 ³	9.9x10 ⁴
As-76		0.2	5.41	0.2	5.41	5.8x10 ⁴	1.6x10 ⁶
As-77		20	541	0.5	13.5	3.9x10 ⁴	1.0x10 ⁶
At-211	Astatine(85)	30	811	2	54.1	7.6x10 ⁴	2.1x10 ⁶
Au-193	Gold(79)	6	162	6	162	3.4x10 ⁴	9.2x10 ⁵

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Au-194		1	27.0	1	27.0	1.5x10 ⁴	4.1x10 ⁵
Au-195		10	270	10	270	1.4x10 ²	3.7x10 ³
Au-196		2	54.1	2	54.1	4.0x10 ³	1.1x10 ⁵
Au-198		3	81.1	0.5	13.5	9.0x10 ³	2.4x10 ⁵
Au-199		10	270	0.9	24.3	7.7x10 ³	2.1x10 ⁵
Ba-131	Barium(56)	2	54.1	2	54.1	3.1x10 ³	8.4x10 ⁴
Ba-133m		10	270	0.9	24.3	2.2x10 ⁴	6.1x10 ⁵
Ba-133		3	81.1	3	81.1	9.4	2.6x10 ²
Ba-140		0.4	10.8	0.4	10.8	2.7x10 ³	7.3x10 ⁴
Be-7	Beryllium(4)	20	541	20	541	1.3x10 ⁴	3.5x10 ⁵
Be-10		20	541	0.5	13.5	8.3x10 ⁻⁴	2.2x10 ⁻²
Bi-205	Bismuth(83)	0.6	16.2	0.6	16.2	1.5x10 ³	4.2x10 ⁴
Bi-206		0.3	8.11	0.3	8.11	3.8x10 ³	1.0x10 ⁵
Bi-207		0.7	18.9	0.7	18.9	1.9	5.2x10 ¹
Bi-210m		0.3	8.11	3x10 ⁻²	0.811	2.1x10 ⁻⁵	5.7x10 ⁻⁴
Bi-210		0.6	16.2	0.5	13.5	4.6x10 ³	1.2x10 ⁵
Bi-212		0.3	8.11	0.3	8.11	5.4x10 ⁵	1.5x10 ⁷
Bk-247	Berkelium(97)	2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	3.8x10 ⁻²	1.0
Bk-249		40	1080	8x10 ⁻²	2.16	6.1x10 ¹	1.6x10 ³
Br-76	Bromine(35)	0.3	8.11	0.3	8.11	9.4x10 ⁴	2.5x10 ⁶
Br-77		3	81.1	3	81.1	2.6x10 ⁴	7.1x10 ⁵
Br-82		0.4	10.8	0.4	10.8	4.0x10 ⁴	1.1x10 ⁶
C-11	Carbon(6)	1	27.0	0.5	13.5	3.1x10 ⁷	8.4x10 ⁸
C-14		40	1080	2	54.1	1.6x10 ⁻¹	4.5

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Ca-41	Calcium(20)	40	1080	40	1080	3.1x10 ⁻³	8.5x10 ⁻²
Ca-45		40	1080	0.9	24.3	6.6x10 ²	1.8x10 ⁴
Ca-47		0.9	24.3	0.5	13.5	2.3x10 ⁴	6.1x10 ⁵
Cd-109	Cadmium(48)	40	1080	1	27.0	9.6x10 ¹	2.6x10 ³
Cd-113m		20	541	9x10 ⁻²	2.43	8.3x10 ⁰	2.2x10 ²
Cd-115m		0.3	8.11	0.3	8.11	9.4x10 ²	2.5x10 ⁴
Cd-115		4	108	0.5	13.5	1.9x10 ⁴	5.1x10 ⁵
Ce-139	Cerium(58)	6	162	6	162	2.5x10 ²	6.8x10 ³
Ce-141		10	270	0.5	13.5	1.1x10 ³	2.8x10 ⁴
Ce-143		0.6	16.2	0.5	13.5	2.5x10 ⁴	6.6x10 ⁵
Ce-144		0.2	5.41	0.2	5.41	1.2x10 ²	3.2x10 ³
Cf-248	Californium(98)	30	811	3x10 ⁻³	8.11x10 ⁻²	5.8x10 ¹	1.6x10 ³
Cf-249		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	1.5x10 ⁻¹	4.1
Cf-250		5	135	5x10 ⁻⁴	1.35x10 ⁻²	4.0	1.1x10 ²
Cf-251		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	5.9x10 ⁻²	1.6
Cf-252		0.1	2.70	1x10 ⁻³	2.70x10 ⁻²	2.0x10 ¹	5.4x10 ²
Cf-253		40	1080	6x10 ⁻²	1.62	1.1x10 ³	2.9x10 ⁴
Cf-254		3x10 ⁻³	8.11x10 ⁻²	6x10 ⁻⁴	1.62x10 ⁻²	3.1x10 ²	8.5x10 ³
Cl-36	Chlorine(17)	20	541	0.5	13.5	1.2x10 ⁻³	3.3x10 ⁻²
Cl-38		0.2	5.41	0.2	5.41	4.9x10 ⁶	1.3x10 ⁸
Cm-240	Curium(96)	40	1080	2x10 ⁻²	0.541	7.5x10 ²	2.0x10 ⁴
Cm-241		2	54.1	0.9	24.3	6.1x10 ²	1.7x10 ⁴
Cm-242		40	1080	1x10 ⁻²	0.270	1.2x10 ²	3.3x10 ³
Cm-243		3	81.1	3x10 ⁻⁴	8.11x10 ⁻³	1.9	5.2x10 ¹

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Cm-244		4	108.0	4x10 ⁻⁴	1.08x10 ⁻²	3.0	5.7x10 ¹
Cm-245		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	6.4x10 ⁻³	1.7x10 ⁻¹
Cm-246		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	1.1x10 ⁻²	3.1x10 ⁻¹
Cm-247		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	3.4x10 ⁻⁶	9.3x10 ⁻⁵
Cm-248		4x10 ⁻²	1.08	5x10 ⁻⁵	1.35x10 ⁻³	1.6x10 ⁻⁴	4.2x10 ⁻³
Co-55	Cobalt(27)	0.5	13.5	0.5	13.5	1.1x10 ⁵	3.1x10 ⁶
Co-56		0.3	8.11	0.3	8.11	1.1x10 ³	3.0x10 ⁴
Co-57		8	216	8	216	3.1x10 ²	8.4x10 ³
Co-58m		40	1080	40	1080	2.2x10 ⁵	5.9x10 ⁶
Co-58		1	27.0	1	27.0	1.2x10 ³	3.2x10 ⁴
Co-60		0.4	10.8	0.4	10.8	4.2x10 ¹	1.1x10 ³
Cr-51	Chromium(24)	30	811	30	811	3.4x10 ³	9.2x10 ⁴
Cs-129	Cesium(55)	4	108	4	108	2.8x10 ⁴	7.6x10 ⁵
Cs-131		40	1080	40	1080	3.8x10 ³	1.0x10 ⁵
Cs-132		1	27.0	1	27.0	5.7x10 ³	1.5x10 ⁵
Cs-134m		40	1080	9	243	3.0x10 ⁵	8.0x10 ⁶
Cs-134		0.6	16.2	0.5	13.5	4.8x10 ¹	1.3x10 ³
Cs-135		40	1080	0.9	24.3	4.3x10 ⁻⁵	1.2x10 ⁻³
Cs-136		0.5	13.5	0.5	13.5	2.7x10 ³	7.3x10 ⁴
Cs-137		2	54.1	0.5	13.5	3.2	8.7x10 ¹
Cu-64	Copper(29)	5	135	0.9	24.3	1.4x10 ⁵	3.9x10 ⁶
Cu-67		9	243	0.9	24.3	2.8x10 ⁴	7.6x10 ⁵
Dy-159	Dysprosium(66)	20	541	20	541	2.1x10 ²	5.7x10 ³
Dy-165		0.6	16.2	0.5	13.5	3.0x10 ⁵	8.2x10 ⁶

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Dy-166		0.3	8.11	0.3	8.11	8.6x10 ³	2.3x10 ⁵
Er-169	Erbium(68)	40	1080	0.9	24.3	3.1x10 ³	8.3x10 ⁴
Er-171		0.6	16.2	0.5	13.5	9.0x10 ⁴	2.4x10 ⁶
Es-253	Einsteinium(99) ^a	200	5400	2x10 ⁻²	5.4x10 ⁻¹	--	--
Es-254		30	811	3x10 ⁻³	8.11x10 ⁻²	--	--
Es-254m		0.6	16.2	0.4	10.8	--	--
Es-255		--	--	--	--	--	--
Eu-147	Europium(63)	2	54.1	2	54.1	1.4x10 ³	3.7x10 ⁴
Eu-148		0.5	13.5	0.5	13.5	6.0x10 ²	1.6x10 ⁴
Eu-149		20	541	20	541	3.5x10 ²	9.4x10 ³
Eu-150		0.7	18.9	0.7	18.9	6.1x10 ⁴	1.6x10 ⁶
Eu-152m		0.6	16.2	0.5	13.5	8.2x10 ⁴	2.2x10 ⁶
Eu-152		0.9	24.3	0.9	24.3	6.5	1.8x10 ²
Eu-154		0.8	21.6	0.5	13.5	9.8	2.6x10 ²
Eu-155		20	541	2	54.1	1.8x10 ¹	4.9x10 ²
Eu-156		0.6	16.2	0.5	13.5	2.0x10 ³	5.5x10 ⁴
F-18	Fluorine(9)	1	27.0	0.5	13.5	3.5x10 ⁶	9.5x10 ⁷
Fe-52	Iron(26)	0.2	5.41	0.2	5.41	2.7x10 ⁵	7.3x10 ⁶
Fe-55		40	1080	40	1080	8.8x10 ¹	2.4x10 ³
Fe-59		0.8	21.6	0.8	21.6	1.8x10 ³	5.0x10 ⁴
Fe-60		40	1080	0.2	5.41	7.4x10 ⁻⁴	2.0x10 ⁻²
Fm-255	Fermium(100) ^b	40	1080	0.8	21.6	--	--
Fm-257		10	270	8x10 ⁻³	2.16x10 ⁻¹	--	--
Ga-67	Gallium(31)	6	162	6	162	2.2x10 ⁴	6.0x10 ⁵

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Ga-68		0.3	8.11	0.3	8.11	1.5x10 ⁶	4.1x10 ⁷
Ga-72		0.4	10.8	0.4	10.8	1.1x10 ⁵	3.1x10 ⁶
Gd-146	Gadolinium(64)	0.4	10.8	0.4	10.8	6.9x10 ²	1.9x10 ⁴
Gd-148		3	81.1	3x10 ⁻⁴	8.11x10 ⁻³	1.2	3.2x10 ¹
Gd-153		10	270	5	135	1.3x10 ²	3.5x10 ³
Gd-159		4	108	0.5	13.5	3.9x10 ⁴	1.1x10 ⁶
Ge-68	Germanium(32)	0.3	8.11	0.3	8.11	2.6x10 ²	7.1x10 ³
Ge-71		40	1080	40	1080	5.8x10 ³	1.6x10 ⁵
Ge-77		0.3	8.11	0.3	8.11	1.3x10 ⁵	3.6x10 ⁶
H-3	Hydrogen(1) See T-Tritium						
Hf-172	Hafnium(72)	0.5	13.5	0.3	8.11	4.1x10 ¹	1.1x10 ³
Hf-175		3	81.1	3	81.1	3.9x10 ²	1.1x10 ⁴
Hf-181		2	54.1	0.9	24.3	6.3x10 ²	1.7x10 ⁴
Hf-182		4	108	3x10 ⁻²	0.811	8.1x10 ⁻⁶	2.2x10 ⁻⁴
Hg-194	Mercury(80)	1	27.0	1	27.0	1.3x10 ⁻¹	3.5
Hg-195m		5	135	5	135	1.5x10 ⁴	4.0x10 ⁵
Hg-197m		10	270	0.9	24.3	2.5x10 ⁴	6.7x10 ⁵
Hg-197		10	270	10	270	9.2x10 ³	2.5x10 ⁵
Hg-203		4	108	0.9	24.3	5.1x10 ²	1.4x10 ⁴
Ho-163	Holmium(67)	40	1080	40	1080	2.7	7.6x10 ¹
Ho-166m		0.6	16.2	0.3	8.11	6.6x10 ⁻²	1.8
Ho-166		0.3	8.11	0.3	8.11	2.6x10 ⁴	7.0x10 ⁵
I-123	Iodine(53)	6	162	6	162	7.1x10 ⁴	1.9x10 ⁶

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
I-124		0.9	24.3	0.9	24.3	9.3x10 ³	2.5x10 ⁵
I-125		20	541	2	54.1	6.4x10 ²	1.7x10 ⁴
I-126		2	54.1	0.9	24.3	2.9x10 ³	8.0x10 ⁴
I-129		Unlimited	Unlimited	Unlimited	Unlimited	6.5x10 ⁻⁶	1.8x10 ⁻⁴
I-131		3	81.1	0.5	13.5	4.6x10 ³	1.2x10 ⁵
I-132		0.4	10.8	0.4	10.8	3.8x10 ⁵	1.0x10 ⁷
I-133		0.6	16.2	0.5	13.5	4.2x10 ⁴	1.1x10 ⁶
I-134		0.3	8.11	0.3	8.11	9.9x10 ⁵	2.7x10 ⁷
I-135		0.6	16.2	0.5	13.5	1.3x10 ⁵	3.5x10 ⁶
In-111	Indium(49)	2	54.1	2	54.1	1.5x10 ⁴	4.2x10 ⁵
In-113m		4	108	4	108	6.2x10 ⁵	1.7x10 ⁷
In-114m		0.3	8.11	0.3	8.11	8.6x10 ²	2.3x10 ⁴
In-115m		6	162	0.9	24.3	2.2x10 ⁵	6.1x10 ⁶
Ir-189	Iridium(77)	10	270	10	270	1.9x10 ³	5.2x10 ⁴
Ir-190		0.7	18.9	0.7	18.9	2.3x10 ³	6.2x10 ⁴
Ir-192		1	27.0	0.5	13.5	3.4x10 ²	9.2x10 ³
Ir-193m		10	270	10	270	2.4x10 ³	6.4x10 ⁴
Ir-194		0.2	5.41	0.2	5.41	3.1x10 ⁴	8.4x10 ⁵
K-40	Potassium(19)	0.6	16.2	0.6	16.2	2.4x10 ⁻⁷	6.4x10 ⁻⁶
K-42		0.2	5.41	0.2	5.41	2.2x10 ⁵	6.0x10 ⁶
K-43		1.0	27.0	0.5	13.5	1.2x10 ⁵	3.3x10 ⁶
Kr-81	Krypton(36)	40	1080	40	1080	7.8x10 ⁻⁴	2.1x10 ⁻²
Kr-85m		6	162	6	162	3.0x10 ⁵	8.2x10 ⁶
Kr-85		20	541	10	270	1.5x10 ¹	3.9x10 ²

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Kr-87		0.2	5.41	0.2	5.41	1.0x10 ⁶	2.8x10 ⁷
La-137	Lanthanum(57)	40	1080	2	54.1	1.6x10 ⁻³	4.4x10 ⁻²
La-140		0.4	10.8	0.4	10.8	2.1x10 ⁴	5.6x10 ⁵
Lu-172	Lutetium(71)	0.5	13.5	0.5	13.5	4.2x10 ³	1.1x10 ⁵
Lu-173		8	216	8	216	5.6x10 ¹	1.5x10 ³
Lu-174m		20	541	8	216	2.0x10 ²	5.3x10 ³
Lu-174		8	216	4	108	2.3x10 ¹	6.2x10 ²
Lu-177		30	811	0.9	24.3	4.1x10 ³	1.1x10 ⁵
MFP	For mixed fission products, use formula for mixtures or Table A-2.						
Mg-28	Magnesium(12)	0.2	5.41	0.2	5.41	2.0x10 ⁵	5.4x10 ⁶
Mn-52	Manganese(25)	0.3	8.11	0.3	8.11	1.6x10 ⁴	4.4x10 ⁵
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	6.8x10 ⁻⁵	1.8x10 ⁻³
Mn-54		1	27.0	1	27.0	2.9x10 ²	7.7x10 ³
Mn-56		0.2	5.41	0.2	5.41	8.0x10 ⁵	2.2x10 ⁷
Mo-93	Molybdenum(42)	40	1080	7	189	4.1x10 ⁻²	1.1
Mo-99		0.6	16.2	0.5	13.5 ^c	1.8x10 ⁴	4.8x10 ⁵
N-13	Nitrogen(7)	0.6	16.2	0.5	13.5	5.4x10 ⁷	1.5x10 ⁹
Na-22	Sodium(11)	0.5	13.5	0.5	13.5	2.3x10 ²	6.3x10 ³
Na-24		0.2	5.41	0.2	5.41	3.2x10 ⁵	8.7x10 ⁶
Nb-92m	Niobium(41)	0.7	18.9	0.7	18.9	5.2x10 ³	1.4x10 ⁵
Nb-93m		40	1080	6	162	8.8	2.4x10 ²

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Nb-94		0.6	16.2	0.6	16.2	6.9x10 ⁻³	1.9x10 ⁻¹
Nb-95		1	27.0	1	27.0	1.5x10 ³	3.9x10 ⁴
Nb-97		0.6	16.2	0.5	13.5	9.9x10 ⁵	2.7x10 ⁷
Nd-147	Neodymium(60)	4	108	0.5	13.5	3.0x10 ³	8.1x10 ⁴
Nd-149		0.6	16.2	0.5	13.5	4.5x10 ⁵	1.2x10 ⁷
Ni-59	Nickel(28)	40	1080	40	1080	3.0x10 ⁻³	8.0x10 ⁻²
Ni-63		40	1080	30	811	2.1	5.7x10 ¹
Ni-65		0.3	8.11	0.3	8.11	7.1x10 ⁵	1.9x10 ⁷
Np-235	Neptunium(93)	40	1080	40	1080	5.2x10 ¹	1.4x10 ³
Np-236		7	189	1x10 ⁻³	2.70x10 ⁻²	4.7x10 ⁻⁴	1.3x10 ⁻²
Np-237		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	2.6x10 ⁻⁵	7.1x10 ⁻⁴
Np-239		6	162	0.5	13.5	8.6x10 ³	2.3x10 ⁵
Os-185	Osmium(76)	1	27.0	1	27.0	2.8x10 ²	7.5x10 ³
Os-191m		40	1080	40	1080	4.6x10 ⁴	1.3x10 ⁶
Os-191		10	270	0.9	24.3	1.6x10 ³	4.4x10 ⁴
Os-193		0.6	16.2	0.5	13.5	2.0x10 ⁴	5.3x10 ⁵
Os-194		0.2	5.41	0.2	5.41	1.1x10 ¹	3.1x10 ²
P-32	Phosphorus(15)	0.3	8.11	0.3	8.11	1.1x10 ⁴	2.9x10 ⁵
P-33		40	1080	0.9	24.3	5.8x10 ³	1.6x10 ⁵
Pa-230	Protactinium(91)	2	54.1	0.1	2.70	1.2x10 ³	3.3x10 ⁴
Pa-231		0.6	16.2	6x10 ⁻⁵	1.62x10 ⁻³	1.7x10 ⁻³	4.7x10 ⁻²
Pa-233		5	135	0.9	24.3	7.7x10 ²	2.1x10 ⁴
Pb-201	Lead(82)	1	27.0	1	27.0	6.2x10 ⁴	1.7x10 ⁶
Pb-202		40	1080	2	54.1	1.2x10 ⁻⁴	3.4x10 ⁻³

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Pb-203		3	81.1	3	81.1	1.1x10 ⁴	3.0x10 ⁵
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	4.5x10 ⁻⁶	1.2x10 ⁻⁴
Pb-210		0.6	16.2	9x10 ⁻³	0.243	2.8	7.6x10 ¹
Pb-212		0.3	8.11	0.3	8.11	5.1x10 ⁴	1.4x10 ⁶
Pd-103	Palladium(46)	40	1080	40	1080	2.8x10 ³	7.5x10 ⁴
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	1.9x10 ⁻⁵	5.1x10 ⁻⁴
Pd-109		0.6	16.2	0.5	13.5	7.9x10 ⁴	2.1x10 ⁶
Pm-143	Promethium(61)	3	81.1	3	81.1	1.3x10 ²	3.4x10 ³
Pm-144		0.6	16.2	0.6	16.2	9.2x10 ¹	2.5x10 ³
Pm-145		30	811	7	189	5.2	1.4x10 ²
Pm-147		40	1080	0.9	24.3	3.4x10 ¹	9.3x10 ²
Pm-148m		0.5	13.5	0.5	13.5	7.9x10 ²	2.1x10 ⁴
Pm-149		0.6	16.2	0.5	13.5	1.5x10 ⁴	4.0x10 ⁵
Pm-151		3	81.1	0.5	13.5	2.7x10 ⁴	7.3x10 ⁵
Po-208	Polonium(84)	40	1080	2x10 ⁻²	0.541	2.2x10 ¹	5.9x10 ²
Po-209		40	1080	2x10 ⁻²	0.541	6.2x10 ⁻¹	1.7x10 ¹
Po-210		40	1080	2x10 ⁻²	0.541	1.7x10 ²	4.5x10 ³
Pr-142	Praseodymium(59)	0.2	5.41	0.2	5.41	4.3x10 ⁴	1.2x10 ⁶
Pr-143		4	108	0.5	13.5	2.5x10 ³	6.7x10 ⁴
Pt-188	Platinum(78)	0.6	16.2	0.6	16.2	2.5x10 ³	6.8x10 ⁴
Pt-191		3	81.1	3	81.1	8.7x10 ³	2.4x10 ⁵
Pt-193m		40	1080	9	243	5.8x10 ³	1.6x10 ⁵
Pt-193		40	1080	40	1080	1.4	3.7x10 ¹
Pt-195m		10	270	2	54.1	6.2x10 ³	1.7x10 ⁵

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Pt-197m		10	270	0.9	24.3	3.7x10 ⁵	1.0x10 ⁷
Pt-197		20	541	0.5	13.5	3.2x10 ⁴	8.7x10 ⁵
Pu-236	Plutonium(94)	7	189	7x10 ⁻⁴	1.89x10 ⁻²	2.0x10 ¹	5.3x10 ²
Pu-237		20	541	20	541	4.5x10 ²	1.2x10 ⁴
Pu-238		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	6.3x10 ⁻¹	1.7x10 ¹
Pu-239		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	2.3x10 ⁻³	6.2x10 ⁻²
Pu-240		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	8.4x10 ⁻³	2.3x10 ⁻¹
Pu-241		40	1080	1x10 ⁻²	0.270	3.8	1.0x10 ²
Pu-242		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	1.5x10 ⁻⁴	3.9x10 ⁻³
Pu-244		0.3	8.11	2x10 ⁻⁴	5.41x10 ⁻³	6.7x10 ⁻⁷	1.8x10 ⁻⁵
Ra-223	Radium(88)	0.6	16.2	3x10 ⁻²	0.811	1.9x10 ³	5.1x10 ⁴
Ra-224		0.3	8.11	6x10 ⁻²	1.62	5.9x10 ³	1.6x10 ⁵
Ra-225		0.6	16.2	2x10 ⁻²	0.541	1.5x10 ³	3.9x10 ⁴
Ra-226		0.3	8.11	2x10 ⁻²	0.541	3.7x10 ⁻²	1.0
Ra-228		0.6	16.2	4x10 ⁻²	1.08	1.0x10 ¹	2.7x10 ²
Rb-81	Rubidium(37)	2	54.1	0.9	24.3	3.1x10 ⁵	8.4x10 ⁶
Rb-83		2	54.1	2	54.1	6.8x10 ²	1.8x10 ⁴
Rb-84		1	27.0	0.9	24.3	1.8x10 ³	4.7x10 ⁴
Rb-86		0.3	8.11	0.3	8.11	3.0x10 ³	8.1x10 ⁴
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	3.2x10 ⁻⁹	8.6x10 ⁻⁸
Rb (natural)		Unlimited	Unlimited	Unlimited	Unlimited	6.7x10 ⁶	1.8x10 ⁸
Re-183	Rhenium(75)	5	135	5	135	3.8x10 ²	1.0x10 ⁴
Re-184m		3	81.1	3	81.1	1.6x10 ²	4.3x10 ³
Re-184		1	27.0	1	27.0	6.9x10 ²	1.9x10 ⁴

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Re-186		4	108	0.5	13.5	6.9x10 ³	1.9x10 ⁵
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	1.4x10 ⁻⁹	3.8x10 ⁻⁸
Re-188		0.2	5.41	0.2	5.41	3.6x10 ⁴	9.8x10 ⁵
Re-189		4	108	0.5	13.5	2.5x10 ⁴	6.8x10 ⁵
Re (natural)		Unlimited	Unlimited	Unlimited	Unlimited	"8.9x10 ⁻¹⁰ "	2.4x10 ⁻⁸
Rh-99	Rhodium(45)	2	54.1	2	54.1	3.0x10 ³	8.2x10 ⁴
Rh-101		4	108	4	108	4.1x10 ¹	1.1x10 ³
Rh-102m		2	54.1	0.9	24.3	2.3x10 ²	6.2x10 ³
Rh-102		0.5	13.5	0.5	13.5	4.5x10 ¹	1.2x10 ³
Rh-103m		40	1080	40	1080	1.2x10 ⁶	3.3x10 ⁷
Rh-105		10	270	0.9	24.3	3.1x10 ⁴	8.4x10 ⁵
Rn-222	Radon(86)	0.2	5.41	4x10 ⁻³	0.108	5.7x10 ³	1.5x10 ⁵
Ru-97	Ruthenium(44)	4	108	4	108	1.7x10 ⁴	4.6x10 ⁵
Ru-103		2	54.1	0.9	24.3	1.2x10 ³	3.2x10 ⁴
Ru-105		0.6	16.2	0.5	13.5	2.5x10 ⁵	6.7x10 ⁶
Ru-106		0.2	5.41	0.2	5.41	1.2x10 ²	3.3x10 ³
S-35	Sulfur(16)	40	1080	2	54.1	1.6x10 ³	4.3x10 ⁴
Sb-122	Antimony(51)	0.3	8.11	0.3	8.11	1.5x10 ⁴	4.0x10 ⁵
Sb-124		0.6	16.2	0.5	13.5	6.5x10 ²	1.7x10 ⁴
Sb-125		2	54.1	0.9	24.3	3.9x10 ¹	1.0x10 ³
Sb-126		0.4	10.8	0.4	10.8	3.1x10 ³	8.4x10 ⁴
Sc-44	Scandium(21)	0.5	13.5	0.5	13.5	6.7x10 ⁵	1.8x10 ⁷
Sc-46		0.5	13.5	0.5	13.5	1.3x10 ³	3.4x10 ⁴
Sc-47		9	243	0.9	24.3	3.1x10 ⁴	8.3x10 ⁵

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Sc-48		0.3	8.11	0.3	8.11	5.5x10 ⁴	1.5x10 ⁶
Se-75	Selenium(34)	3	81.1	3	81.1	5.4x10 ²	1.5x10 ⁴
Se-79		40	1080	2	54.1	2.6x10 ⁻³	7.0x10 ⁻²
Si-31	Silicon(14)	0.6	16.2	0.5	13.5	1.4x10 ⁶	3.9x10 ⁷
Si-32		40	1080	0.2	5.41	3.9	1.1x10 ²
Sm-145	Samarium(62)	20	541	20	541	9.8x10 ¹	2.6x10 ³
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	8.5x10 ⁻¹⁰	2.3x10 ⁻⁸
Sm-151		40	1080	4	108	9.7x10 ⁻¹	2.6x10 ¹
Sm-153		4	108	0.5	13.5	1.6x10 ⁴	4.4x10 ⁵
Sn-113	Tin(50)	4	108	4	108	3.7x10 ²	1.0x10 ⁴
Sn-117m		6	162	2	54.1	3.0x10 ³	8.2x10 ⁴
Sn-119m		40	1080	40	1080	1.4x10 ²	3.7x10 ³
Sn-121m		40	1080	0.9	24.3	2.0	5.4x10 ¹
Sn-123		0.6	16.2	0.5	13.5	3.0x10 ²	8.2x10 ³
Sn-125		0.2	5.41	0.2	5.41	4.0x10 ³	1.1x10 ⁵
Sn-126		0.3	8.11	0.3	8.11	1.0x10 ⁻³	2.8x10 ⁻²
Sr-82	Strontium(38)	0.2	5.41	0.2	5.41	2.3x10 ³	6.2x10 ⁴
Sr-85m		5	135	5	135	1.2x10 ⁶	3.3x10 ⁷
Sr-85		2	54.1	2	54.1	8.8x10 ²	2.4x10 ⁴
Sr-87m		3	81.1	3	81.1	4.8x10 ⁵	1.3x10 ⁷
Sr-89		0.6	16.2	0.5	13.5	1.1x10 ³	2.9x10 ⁴
Sr-90		0.2	5.41	0.1	2.70	5.1	1.4x10 ²
Sr-91		0.3	8.11	0.3	8.11	1.3x10 ⁵	3.6x10 ⁶
Sr-92		0.8	21.6	0.5	13.5	4.7x10 ⁵	1.3x10 ⁷

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
T	Tritium(1)	40	1080	40 ^d	1080 ^d	3.6x10 ²	9.7x10 ³
Ta-178	Tantalum(73)	1	27.0	1	27.0	4.2x10 ⁶	1.1x10 ⁸
Ta-179		30	811	30	811	4.1x10 ¹	1.1x10 ³
Ta-182		0.8	21.6	0.5	13.5	2.3x10 ²	6.2x10 ³
Tb-157	Terbium(65)	40	1080	10	270	5.6x10 ⁻¹	1.5x10 ¹
Tb-158		1	27.0	0.7	18.9	5.6x10 ⁻¹	1.5x10 ¹
Tb-160		0.9	24.3	0.5	13.5	4.2x10 ²	1.1x10 ⁴
Tc-95m	Technetium(43)	2	54.1	2	54.1	8.3x10 ²	2.2x10 ⁴
Tc-96m		0.4	10.8	0.4	10.8	1.4x10 ⁶	3.8x10 ⁷
Tc-96		0.4	10.8	0.4	10.8	1.2x10 ⁴	3.2x10 ⁵
Tc-97m		40	1080	40	1080	5.6x10 ²	1.5x10 ⁴
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	5.2x10 ⁻⁵	1.4x10 ⁻³
Tc-98		0.7	18.9	0.7	18.9	3.2x10 ⁻⁵	8.7x10 ⁻⁴
Tc-99m		8	216	8	216	1.9x10 ⁵	5.3x10 ⁶
Tc-99		40	1080	0.9	24.3	6.3x10 ⁻⁴	1.7x10 ⁻²
Te-118	Tellurium(52)	0.2	5.41	0.2	5.41	6.8x10 ³	1.8x10 ⁵
Te-121m		5	135	5	135	2.6x10 ²	7.0x10 ³
Te-121		2	54.1	2	54.1	2.4x10 ³	6.4x10 ⁴
Te-123m		7	189	7	189	3.3x10 ²	8.9x10 ³
Te-125m		30	811	9	243	6.7x10 ²	1.8x10 ⁴
Te-127m		20	541	0.5	13.5	3.5x10 ²	9.4x10 ³
Te-127		20	541	0.5	13.5	9.8x10 ⁴	2.6x10 ⁶
Te-129m		0.6	16.2	0.5	13.5	1.1x10 ³	3.0x10 ⁴
Te-129		0.6	16.2	0.5	13.5	7.7x10 ⁵	2.1x10 ⁷

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Te-131m		0.7	18.9	0.5	13.5	3.0x10 ⁴	8.0x10 ⁵
Te-132		0.4	10.8	0.4	10.8	1.1x10 ⁴	3.0x10 ⁵
Th-227	Thorium(90)	9	243	1x10 ⁻²	0.270	1.1x10 ³	3.1x10 ⁴
Th-228		0.3	8.11	4x10 ⁻⁴	1.08x10 ⁻²	3.0x10 ¹	8.2x10 ²
Th-229		0.3	8.11	3x10 ⁻⁵	8.11x10 ⁻⁴	7.9x10 ⁻³	2.1x10 ⁻¹
Th-230		2	54.1	2x10 ⁻⁴	5.41x10 ⁻³	7.6x10 ⁻⁴	2.1x10 ⁻²
Th-231		40	1080	0.9	24.3	2.0x10 ⁴	5.3x10 ⁵
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	4.0x10 ⁻⁹	1.1x10 ⁻⁷
Th-234		0.2	5.41	0.2	5.41	8.6x10 ²	2.3x10 ⁴
Th (natural)		Unlimited	Unlimited	Unlimited	Unlimited	8.1x10 ⁻⁹	2.2x10 ⁻⁷
Ti-44	Titanium(22)	0.5	13.5	0.2	5.41	6.4	1.7x10 ²
Tl-200	Thallium(81.1)	0.8	21.6	0.8	21.6	2.2x10 ⁴	6.0x10 ⁵
Tl-201		10	270	10	270	7.9x10 ³	2.1x10 ⁵
Tl-202		2	54.1	2	54.1	2.0x10 ³	5.3x10 ⁴
Tl-204		4	108	0.5	13.5	1.7x10 ¹	4.6x10 ²
Tm-167	Thulium(69)	7	189	7	189	3.1x10 ³	8.5x10 ⁴
Tm-168		0.8	21.6	0.8	21.6	3.1x10 ²	8.3x10 ³
Tm-170		4	108	0.5	13.5	2.2x10 ²	6.0x10 ³
Tm-171		40	1080	10	270	4.0x10 ¹	1.1x10 ³
U-230	Uranium(92)	40	1080	1x10 ⁻²	0.270	1.0x10 ³	2.7x10 ⁴
U-232		3	81.1	3x10 ⁻⁴	8.11x10 ⁻³	8.3x10 ⁻¹	2.2x10 ¹
U-233		10	270	1x10 ⁻³	2.70x10 ⁻²	3.6x10 ⁻⁴	9.7x10 ⁻³
U-234		10	270	1x10 ⁻³	2.70x10 ⁻²	2.3x10 ⁻⁴	6.3x10 ⁻³
U-235		Unlimited	Unlimited	Unlimited	Unlimited	8.0x10 ⁻⁸	2.2x10 ⁻⁶

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
U-236		10	270	1x10 ⁻³	2.70x10 ⁻²	2.4x10 ⁻⁶	6.5x10 ⁻⁵
U-238		Unlimited	Unlimited	Unlimited	Unlimited	1.2x10 ⁻⁸	3.4x10 ⁻⁷
U (natural)		Unlimited	Unlimited	Unlimited	Unlimited	2.6x10 ⁻⁸	7.1x10 ⁻⁷
U (enriched 5% or less)		Unlimited	Unlimited	Unlimited	Unlimited	--	(see Table A-3)
U (enriched more than 5%)		10	270	1x10 ⁻³	2.70x10 ⁻²	--	(see Table A-3)
U (depleted)		Unlimited	Unlimited	Unlimited	Unlimited	--	(see Table A-3)
V-48	Vanadium(23)	0.3	8.11	0.3	8.11	6.3x10 ³	1.7x10 ⁵
V-49		40	1080	40	1080	3.0x10 ²	8.1x10 ³
W-178	Tungsten(74)	1	27.0	1	27.0	1.3x10 ³	3.4x10 ⁴
W-181		30	811	30	811	2.2x10 ²	6.0x10 ³
W-185		40	1080	0.9	24.3	3.5x10 ²	9.4x10 ³
W-187		2	54.1	0.5	13.5	2.6x10 ⁴	7.0x10 ⁵
W-188		0.2	5.41	0.2	5.41	3.7x10 ²	1.0x10 ⁴
Xe-122	Xenon(54)	0.2	5.41	0.2	5.41	4.8x10 ⁴	1.3x10 ⁶
Xe-123		0.2	5.41	0.2	5.41	4.4x10 ⁵	1.2x10 ⁷
Xe-127		4	108	4	108	1.0x10 ³	2.8x10 ⁴
Xe-131m		40	1080	40	1080	3.1x10 ³	8.4x10 ⁴
Xe-133		20	541	20	541	6.9x10 ³	1.9x10 ⁵
Xe-135		4	108	4	108	9.5x10 ⁴	2.6x10 ⁶
Y-87	Yttrium(39)	2	54.1	2	54.1	1.7x10 ⁴	4.5x10 ⁵
Y-88		0.4	10.8	0.4	10.8	5.2x10 ²	1.4x10 ⁴

Symbol of Radionuclide	Element and Atomic Number	A ₁	A ₁	A ₂	A ₂	Specific Activity	
		(TBq)	(Ci)	(TBq)	(Ci)	(TBq/g)	(Ci/g)
Y-90		0.2	5.41	0.2	5.41	2.0x10 ⁴	5.4x10 ⁵
Y-91m		2	54.1	2	54.1	1.5x10 ⁶	4.2x10 ⁷
Y-91		0.3	8.11	0.3	8.11	9.1x10 ²	2.5x10 ⁴
Y-92		0.2	5.41	0.2	5.41	3.6x10 ⁵	9.6x10 ⁶
Y-93		0.2	5.41	0.2	5.41	1.2x10 ⁵	3.3x10 ⁶
Yb-169	Ytterbium(70)	3	81.1	3	81.1	8.9x10 ²	2.4x10 ⁴
Yb-175		30	811	0.9	24.3	6.6x10 ³	1.8x10 ⁵
Zn-65	Zinc(30)	2	54.1	2	54.1	3.0x10 ²	8.2x10 ³
Zn-69m		2	54.1	0.5	13.5	1.2x10 ⁵	3.3x10 ⁶
Zn-69		4	108	0.5	13.5	1.8x10 ⁶	4.9x10 ⁷
Zr-88	Zirconium(40)	3	81.1	3	81.1	6.6x10 ²	1.8x10 ⁴
Zr-93		40	1080	0.2	5.41	9.3x10 ⁻⁵	2.5x10 ⁻³
Zr-95		1	27.0	0.9	24.3	7.9x10 ²	2.1x10 ⁴
Zr-97		0.3	8.11	0.3	8.11	7.1x10 ⁴	1.9x10 ⁶

^a International shipments of Einsteinium require multilateral approvals of A₁ and A₂ values.

^b International shipments of Fermium require multilateral approvals of A₁ and A₂ values.

^c 20 curies for Mo⁹⁹ for domestic use.

^d Also, for liquids only, a concentration limit of not greater than 1 TBq/liter (27 Curies/liter).

EDITOR'S NOTE: The specific activity in quotes for Rhenium (natural) in TBq/g and U-234 in TBq/g and Ci/g is calculated by the editor. These values were left blank in 10 CFR Part 71 Appendix A.

Table A-2 General Values for A₁ and A₂

Contents	A ₁		A ₂	
	(TBq)	(Ci)	(TBq)	(Ci)
Only beta- or gamma-emitting nuclides are known to be present	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available.	0.10	2.7	2x10 ⁻⁵	5.41x10 ⁻⁴

Table A-3 Activity-mass Relationships for Uranium

Uranium Enrichment* wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8x10 ⁻⁸	5.0x10 ⁻⁷
0.72	2.6x10 ⁻⁸	7.1x10 ⁻⁷
1.0	2.8x10 ⁻⁸	7.6x10 ⁻⁷
1.5	3.7x10 ⁻⁸	1.0x10 ⁻⁶
5.0	1.0x10 ⁻⁷	2.7x10 ⁻⁶
10.0	1.8x10 ⁻⁷	4.8x10 ⁻⁶
20.0	3.7x10 ⁻⁷	1.0x10 ⁻⁵
35.0	7.4x10 ⁻⁷	2.0x10 ⁻⁵
50.0	9.3x10 ⁻⁷	2.5x10 ⁻⁵
90.0	2.2x10 ⁻⁶	5.8x10 ⁻⁵
93.0	2.6x10 ⁻⁶	7.0x10 ⁻⁵
95.0	3.4x10 ⁻⁶	9.1x10 ⁻⁵

* The figures for uranium include representative values for the activity of the uranium-235 which is concentrated during the enrichment process.

TABLE A-4

ACTIVITY - MASS RELATIONSHIP FOR URANIUM/THORIUM

Thorium and Uranium Enrichment ¹ · wt % ²³⁵ U present	Specific Activity	
	Ci per G	g per Ci
0.45	5.0×10^{-7}	2.0×10^6
0.72 (natural)	7.06×10^{-7}	1.42×10^6
1.0	7.6×10^{-7}	1.3×10^6
1.5	1.0×10^{-6}	1.0×10^6
5.0	2.7×10^{-6}	3.7×10^5
10.0	4.8×10^{-6}	2.1×10^5
20.0	1.0×10^{-5}	1.0×10^5
35.0	2.0×10^{-5}	5.0×10^4
50.0	2.5×10^{-5}	4.0×10^4
90.0	5.8×10^{-5}	1.7×10^4
93.0	7.0×10^{-5}	1.4×10^4
95.0	9.1×10^{-5}	1.1×10^4
Natural Thorium	2.2×10^{-7}	4.6×10^6

1. The figures for uranium include representative values for the activity of the uranium 234 which is concentrated during the enrichment process. The activity for thorium includes the equilibrium concentration of thorium 228.

PART XVI ELECTRONIC BRACHYTHERAPY

R9 64E-5.1601....Definitions.....XVI-1
R9 64E-5.1602....Administrative Requirements.....XVI-2
R9 64E-5.1603....Training and Education.....XVI-4
R9 64E-5.1604 General Technical Requirements For
R9 Electronic Brachytherapy Facilities.....XVI-7

Rules 64E-5.1601 — 64E 5.1604 are effective March 12, 2009 and are designated as Revision 9 (R9).

PART XVI ELECTRONIC BRACHYTHERAPY

- R9 **64E-5.1601 Definitions.** The following definitions apply only in this part.
- R9 (1) “AAPM” means the American Association of Physicists in Medicine,
R9 www.aapm.org.
- R9 (2) “Authorized user” means a person who has met the requirements of subsection
R9 64E-5.1603(1), F.A.C.
- R9 (3) “Authorized medical physicist” means a person who has met the requirements of
R9 subsection 64E-5.1603(2), F.A.C.
- R9 (4) “Authorized operator” means a person who has met the requirements of
R9 subsection 64E-5.1603(3), F.A.C.
- R9 (5) “Electronic brachytherapy” means a method of radiation therapy using
R9 electrically-generated x-rays to deliver a radiation dose at a distance of up to a
R9 few centimeters by intracavitary, intraluminal or interstitial application, or by
R9 applications with the source in contact with the body surface or very close to the
R9 body surface.
- R9 (6) “Electronic brachytherapy device” or “device” means the system used to produce
R9 and deliver therapeutic radiation including the x-ray tube, the control mechanism,
R9 the cooling system, and the power source.
- R9 (7) “Electronic brachytherapy source” or “source” means the x-ray tube component
R9 used in an electronic brachytherapy device.
- R9 (8) “Medical event” means any event, except for an event that results from patient
R9 intervention, in which the administration of radiation results in:
- R9 (a) A total dose delivered that differs from the prescribed dose by 20 percent
R9 or more;
- R9 (b) A fractionated dose delivered that differs from the prescribed dose, for a
R9 single fraction, by 50 percent or more; or
- R9 (c) A dose to the wrong individual or the wrong treatment site.
- R9 (9) “Mobile electronic brachytherapy device” means a device which is transported
R9 from one address to be used at another address.
- R9 (10) “Portable shielding” means shielding that can be easily moved into the primary or
R9 secondary beam in order to reduce the radiation exposure to the patient,
R9 occupational worker or a member of the public.

R9 Specific Authority: 404.051(4), 404.20, F.S.
R9 Law Implemented: 404.031, 404.051, 404.22, F.S.
R9 History: New 03-12-2009

R9 **64E-5.1602 Administrative Requirements.**

R9 (1) Registration and Notification.

R9 (a) No electronic brachytherapy device may be used on a human without a
R9 current certificate of registration from the department.

R9 (b) An electronic brachytherapy device that is not operational and that is
R9 under the control of a registered vendor prior to final installation is exempt
R9 from the registration and fee requirements of this section.

R9 (c) A separate registration and radiation protection program are required for
R9 facilities for which one or more of the following applies:

R9 1. The facilities are not at the same physical address;

R9 2. The facilities are not under the same radiation safety program; or

R9 3. The facilities are not under the same management.

R9 (d) Each person who acquires an electronic brachytherapy device shall apply
R9 for registration of the radiation device with the department within 30 days
R9 after acquisition. Application for registration shall be on Form DH 1107,
R9 03/07, "Radiation Machine Facility Registration," as incorporated in sub-
R9 paragraph 64E-5.511(2)(a)1., F.A.C. The application must include the
R9 following documents:

R9 1. A list identifying the radiation safety officer and all authorized
R9 medical physicists, authorized operators, and authorized users
R9 except visiting authorized users, together with documentation of
R9 their training and education as described in Rule 64E-5.1603,
R9 F.A.C.;

R9 2. A copy of the most current record of surveys, calculations and
R9 quality assurance checks on each device;

R9 3. A current copy of the quality management program as described in
R9 subsection 64E-5.1604(3), F.A.C.;

R9 4. A current copy of the quality assurance program as described in
R9 subsection 64E-5.1604(4), F.A.C.; and

R9 5. A copy of the device manufacturer's U.S. Food and Drug
R9 Administration certification; and

- R9 6. Facility design information, which at a minimum must include:
 - R9 a. A diagram of the physical facility showing the location of the
R9 electronic brachytherapy treatment rooms;
 - R9 b. Whether the facility is a new structure or a modification to an
R9 existing structure; and
 - R9 c. The type and thickness of the portable shielding used for
R9 compliance and a procedure demonstrating the use of the
R9 shielding prior to treatment
- R9 (e) The registrant shall update the registration on file with the department
R9 within 30 days of any change to any information reported in paragraph
R9 64E-5.1602(1)(d), F.A.C.
- R9 (2) Installation, Maintenance or Repair.
 - R9 (a) Only a manufacturer’s representative registered as a vendor under
R9 subsection 64E-5.511(3), F.A.C., shall install an electronic brachytherapy
R9 device.
 - R9 (b) Only a manufacturer’s representative registered as a vendor under
R9 subsection 64E-5.511(3), F.A.C., or an authorized medical physicist shall
R9 adjust, repair, maintain, or service an electronic brachytherapy device in
R9 accordance with the manufacturer’s guidelines.
 - R9 (c) A registrant shall retain a record of the installation, maintenance,
R9 adjustment, service and repair of an electronic brachytherapy device for 5
R9 years.
- R9 (3) Fees. The registrant of an electronic brachytherapy device shall comply with the
R9 requirements of paragraph 64E-5.511(2)(b), F.A.C., and pay the fees for a
R9 medical accelerator unit.

Specific Authority: 404.051(4), 404.22, F.S.
Law Implemented: 404.051, 404.081(1), 404.22, F.S.
History: New 03-12-2009

64E-5.1603 Training And Education.

- R9 (1) Qualification of Authorized User.
- R9 (a) The registrant shall require the authorized user to be a physician who:
- R9 1. Is licensed by the department as a medical doctor or doctor of
R9 osteopathy;
- R9 2. Has completed a manufacturer's device-specific training as
R9 specified in subsection 64E-5.1603(5), F.AC.; and
- R9 3. Is certified in:
- R9 a. Radiation oncology or therapeutic radiology by the American
R9 Board of Radiology;
- R9 b. Radiation oncology by the American Osteopathic Board of
R9 Radiology;
- R9 c. Radiology, with specialization in radiotherapy, as a British
R9 "Fellow of the Faculty of Radiology" or "Fellow of the Royal
R9 College of Radiology"; or
- R9 d. Therapeutic radiology by the Canadian Royal College of
R9 Physicians and Surgeons.
- R9 (b) A physician shall not act as an authorized user for any electronic
R9 brachytherapy device until such time as said physician's training has been
R9 reviewed and approved by the department.
- R9 (2) Qualification of Authorized Medical Physicist.
- R9 (a) The registrant shall require the authorized medical physicist to be a
R9 person who:
- R9 1. Is currently licensed pursuant to Section 483.901, F.S., as a
R9 therapeutic radiological physicist; and
- R9 2. Has completed a manufacturer's device-specific training as
R9 specified in subsection 64E-5.1603(5), F.A.C.
- R9 (b) A medical physicist shall not act as an authorized medical physicist for any
R9 electronic brachytherapy device until such time as said physicist's training
R9 has been reviewed and approved by the department

- R9 (3) Qualification of Authorized Operator. A person, other than an authorized user,
R9 who operates an electronic brachytherapy device to apply ionizing radiation to a
R9 human, shall be:
 - R9 (a) Certified in accordance with the Chapter 468, Part IV, F.S., as a radiation
R9 therapy technologist; and
 - R9 (b) Have completed a manufacturer's device-specific training as specified in
R9 subsection 64E-5.1603(5), F.A.C.

- R9 (4) Qualification of Radiation Safety Officer. The registrant shall require the radiation
R9 safety officer to be a person who has completed a manufacturer's device specific
R9 training as specified in subsection 64E-5.1603(5), F.A.C., and be:
 - R9 (a) An authorized user or authorized medical physicist; or
 - R9 (b) A person certified by:
 - R9 1. The American Board of Radiology in Radiology, Diagnostic
R9 Radiology, Therapeutic Radiology, or Radiation Oncology;
 - V 2. The American Board of Health Physics in Comprehensive Health
Physics;
 - R9 3. The American Board of Radiology in Radiological Physics,
R9 Therapeutic Radiological Physics, or Medical Nuclear Physics;
 - R9 4. The American Board of Nuclear Medicine;
 - R9 5. The American Board of Science in Nuclear Medicine; or
 - R9 6. The American Board of Medical Physicists; or
 - R9 (c) A person who has completed classroom and laboratory training consisting
R9 of the following:
 - R9 1. One hundred hours of radiation physics and instrumentation;
 - R9 2. Thirty hours of radiation protection;
 - R9 3. Twenty hours of mathematics pertaining to the use and
R9 measurement of radiation;
 - R9 4. Twenty hours of radiation biology;
 - R9 5. Thirty hours of medical therapy training; and
 - R9 6. One year of full time experience in radiation safety at a medical
R9 institution under the supervision of the individual identified as the
R9 radiation safety officer.

- R9 (5) Manufacturer's Training. The registrant shall require training in electronic
R9 brachytherapy device operation, safety procedures, and US Food & Drug
R9 Administration-approved clinical uses. All training taken to satisfy this
R9 requirement must have been completed within the 7 years preceding the date of
R9 application. This training requirement must be approved by the department and
R9 must be satisfied by:
- R9 (a) Completion of a training program provided by the manufacturer; or
- R9 (b) Completion of a training program which is provided by an institution
R9 approved by the manufacturer; or
- R9 (c) Receiving training that is substantially equivalent to the manufacturer's
R9 training program from an authorized user or authorized medical physicist
R9 who is authorized to use the device on a department registration.
- R9 (6) Annual Training.
- R9 (a) The registrant shall provide radiation safety training, initially and at least
R9 annually, to all personnel providing patient care and treatment planning to
R9 patients.
- R9 (b) The training should include device operation, safety procedures and
R9 clinical use updates.
- R9 (7) Training Records. The registrant shall retain for three years a record of each
R9 individual receiving initial manufacturer's training and annual training.

R9 Specific Authority: 404.051(4), 404.22, F.S.
R9 Law Implemented: 404.051, 404.081(1), 404.22, F.S..
R9 History: New 03-12-2009.

64E-5.1604 General Technical Requirements For Electronic Brachytherapy Facilities.

- R9 (1) Radiation Surveys.
- R9 (a) The registrant shall ensure that a survey, as defined in subsection
R9 64E-5.101(151), F.A.C., of all new facilities and existing facilities not
R9 previously surveyed, is performed with an operable radiation
R9 measurement survey instrument according to the requirements of
R9 Part III of Chapter 64E-5, F.A.C.
- R9 (b) The survey shall be performed by, or under the direction of, an authorized
R9 medical physicist or radiation safety officer who shall determine and
R9 record whether radiation levels are in compliance with the dose limits of
R9 Part III of Chapter 64E-5, F.A.C. Portable shielding may be used to
R9 comply with these radiation dose limits. Such surveys shall be conducted
R9 with the electronic brachytherapy device controls, source position,
R9 portable shielding and site-specific scattering phantom all set so as to
R9 produce the highest radiation exposure level that could occur during
R9 treatment.
- R9 (c) The survey record shall include: the date of the measurements; the reason
R9 the survey is required; the manufacturer's name, model number and serial
R9 number of the electronic brachytherapy device; the instrument(s) used to
R9 measure radiation levels; a plan of the areas surrounding the treatment
R9 room that were surveyed; the measured dose rate at several points in
R9 each area expressed in microsieverts or millirems per hour; the calculated
R9 maximum level of radiation over a period of 1 week for each restricted and
R9 unrestricted area; and the signature of the individual responsible for
R9 conducting the survey.
- R9 (d) A survey shall also be performed prior to any subsequent medical use,
R9 when:
- R9 1. Making any change in the portable shielding;
- R9 2. Making any change in the location where the electronic
R9 brachytherapy device is used within the treatment room; or
- R9 3. Relocating the electronic brachytherapy device.
- R9 (e) The registrant shall maintain the record of each survey for the duration of
R9 the registration.
- R9 (2) Dosimetry Equipment.
- R9 (a) For electronic brachytherapy devices, the calibration of the dosimetry
R9 system shall be for the source and energy or energies in use according to
R9 a current published protocol from a nationally-recognized professional
R9 association with expertise in electronic brachytherapy, such as the AAPM.
R9 In the absence of such a published protocol, the manufacturer's current
R9 protocol shall be followed.

R9

R9
R9
R9

(b) The registrant shall have available for use a dosimetry system for quality assurance check measurements. The quality assurance check system may be the same system used to meet the requirement for calibration.

R9
R9
R9
R9
R9
R9
R9
R9

(c) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. Each record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared or compared; the names of the individuals who performed the calibration, intercomparison, or comparison, and; evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, an authorized medical physicist of record.

R9

(3) Quality Management Program.

R9
R9
R9
R9
R9

(a) Each registrant under this part shall establish and maintain a written quality management program to provide a high confidence that electronic brachytherapy devices will be used as directed by the authorized user. The quality management program must include written policies and procedures to meet the following objectives:

R9
R9
R9
R9
R9

1. Except where a delay to provide a written directive as defined in subsection 64E-5.101(173), F.A.C., would jeopardize the patient's health as specified in sub-paragraphs 64E-5.1604(3)(a)2. and 3., F.A.C., a written directive is prepared prior to administration of a therapeutic radiation dose;

R9
R9
R9
R9
R9
R9

2. An oral directive is only acceptable when a delay to provide a written directive would jeopardize the patient's health because of the emergent nature of the patient's condition. The information contained in the oral directive must be documented immediately in the patient's record and a written directive prepared within 24 hours of the oral directive;

R9
R9
R9
R9
R9
R9

3. An oral revision to an existing written directive is only acceptable when a delay to provide a written revision to an existing written directive would jeopardize the patient's health. The oral revision must be documented immediately in the patient's record and a revised written directive must be signed by the authorized user within 48 hours of the oral revision;

R9
R9
R9
R9
R9

4. A written directive that changes an existing written directive for any therapeutic radiation procedure is only acceptable if the revision is dated and signed by an authorized user prior to the administration of the therapeutic electronic brachytherapy dose, or the next electronic brachytherapy fractional dose;

R9
R9

5. The patient's identity is verified by more than one method as the individual named in the written directive prior to administration;

- R9
R9
6. The final plans of treatment and related calculations agree with the respective written directives;
- R9
7. Each administration agrees with the written directive; and
- R9
R9
8. Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.
- R9
R9
- (b) The registrant shall retain for 3 years each written directive in an auditable form.
- R9
R9
- (c) The registrant shall develop procedures for and conduct a review of the quality management program including an evaluation of the following:
- R9
R9
1. A representative sample of patient administrations within the review period, as described in a procedure submitted to the Department;
- R9
R9
2. All recordable events, as defined in subsection 64E-5.101(123), F.A.C., within the review period; and
- R9
R9
3. All medical events within the review period to verify compliance with all aspects of the quality management program.
- R9
R9
R9
R9
- (d) The review of the quality management program shall be conducted at intervals not to exceed 12 months. The registrant shall maintain a record of each dated review for inspection by the department in an auditable form for 3 years and shall include evaluations and findings of the review.
- R9
R9
R9
- (e) The registrant shall evaluate each of these reviews to determine the effectiveness of the quality management program and make modifications to meet the objectives of the program.
- R9
R9
R9
R9
R9
- (f) The registrant may make modifications to the quality management program to increase the program's efficiency as long as the program's effectiveness is not diminished. The registrant is required to submit any modifications to the quality management program to the department within 30 days after the modifications have been made.
- R9
R9
- (g) Within 30 days of discovery of each recordable event, as defined in subsection 64E-5.101(123), F.A.C., the registrant shall:
- R9
1. Assemble the relevant facts including the cause;
- R9
R9
2. Identify and implement any corrective action required to prevent recurrence; and
- R9
R9
3. Retain a record in an auditable form for 3 years of the relevant facts and any corrective action taken.
- R9
R9
- (h) Each registrant shall maintain records and reports of medical events until the termination of the registration.

- R9 (4) Quality Assurance Program.
- R9 (a) Each registrant shall develop and administer a written quality assurance
R9 program as a method of minimizing deviations from facility procedures and
R9 to document preventative measures taken prior to serious patient injury or
R9 medical event. The quality assurance program must include written
R9 procedures for performing:
- R9 1. Treatment planning, chart and treatment field parameters;
- R9 2. Patient simulation, verification of catheter placement and device
R9 exchange;
- R9 3. Dose calculation and review; and
- R9 4. Review of daily treatment records.
- R9 (b) Deviations from the prescribed treatment or from the facility's quality
R9 assurance and operating procedures shall be investigated and brought to
R9 the attention of the authorized user, authorized medical physicist and
R9 radiation safety officer.
- R9 (c) A review of the quality assurance program shall be conducted at intervals
R9 not to exceed 3 months and shall include all the deviations from the
R9 prescribed treatment. A signed record of each dated review shall be
R9 maintained for inspection by the department in an auditable form for 3
R9 years and shall include evaluations and findings of the review.
- R9 (5) Authority and Responsibilities.
- R9 (a) Radiation Safety Officer.
- R9 1. A registrant shall appoint a radiation safety officer responsible for
R9 implementing the radiation safety program. The registrant, through
R9 the radiation safety officer, shall ensure that radiation safety
R9 activities are performed in accordance with approved procedures
R9 and regulatory requirements in the daily operation of the electronic
R9 brachytherapy devices.
- R9 2. The radiation safety officer shall promptly investigate and
R9 implement corrective actions as necessary regarding:
- R9 a. Incidents as defined in Rule 64E-5.344, F.A.C.;
- R9 b. Reportable events as defined in Rule 64E-5.345, F.A.C.; and
- R9 c. Other deviations from approved radiation safety practice. A
R9 written report of these investigations and the corrective
R9 actions taken shall be given to management within 30 days
R9 of the incident, event or deviation.

-
- R9 3. The radiation safety officer shall implement written policies and
R9 procedures to:
- R9 a. Use electronic brachytherapy devices safely;
- R9 b. Perform radiation surveys whenever necessary;
- R9 c. Perform checks of survey instruments and other safety
R9 equipment;
- R9 d. Train personnel who work in or frequent areas where
R9 radiation is present; and
- R9 e. Keep a copy of all records and reports required by
R9 department regulations, a copy of these regulations, and a
R9 copy of each registration correspondence to the department,
R9 and the written policies and procedures required by the
R9 regulations.
- R9 4. The radiation safety officer shall review at least every 3 months the
R9 occupational radiation exposure records of all personnel working
R9 with radiation therapy devices.
- R9 (b) Authorized User. Authorized users shall:
- R9 1. Be physically present during the initiation of each patient treatment;
- R9 2. Be physically present during the continuation of each patient
R9 treatment or identify in writing a physician under the supervision of
R9 the authorized user who is trained in the operation of and
R9 emergency response for the device who will be physically present
R9 during the continuation of each patient treatment;
- R9 3. Personally review the patient's case to assure that the therapeutic
R9 radiation procedure is appropriate; and
- R9 4. Review the progress of the patient receiving therapy and modify the
R9 originally prescribed dose, if needed.
- R9 (c) Visiting Authorized User.
- R9 1. A registrant may permit any visiting authorized user to use an
R9 electronic brachytherapy device for medical use under the terms of
R9 the registrant's registration and radiation protection program for 60
R9 days each year if:
- R9 a. The visiting authorized user has the prior written permission
R9 of the registrant's management;

- R9
R9
R9
R9
R9
- b. The registrant has a copy of an electronic brachytherapy device registration issued by the department or another state that identifies the visiting authorized user by name as an authorized user for medical use of an electronic brachytherapy device; and
- R9
R9
R9
- c. The visiting authorized user performs only those procedures for which he is specifically authorized by the registration described in sub-subparagraph 64E-5.1604(5)(c)1.b., F.A.C.
2. A registrant shall retain copies of the records specified in subparagraph 64E-5.1604(5)(c)1., F.A.C., for 5 years after the last visit of the visiting authorized user.
- R9 (d) Authorized Medical Physicist. The authorized medical physicist shall:
- R9
R9
1. Be physically present during the initiation and continuation of each patient treatment.
- R9
2. Evaluate the output from the electronic brachytherapy source;
- R9
3. Generate the necessary dosimetry information;
- R9
R9
4. Review treatment calculations prior to initial treatment of any treatment site;
- R9
R9
5. Establish the quality assurance spot checks and review the data from those checks as required by the submitted procedures;
- R9
R9
6. Consult with the authorized user in treatment planning, as needed; and
- R9
R9
7. Perform calculations and assessments regarding patient treatments that may constitute medical events.
- R9 (6) Operating Procedures. The registrant shall ensure compliance with the following
R9 procedures
- R9 (a) An electronic brachytherapy device shall only be used as approved by the
R9 US Food and Drug Administration for human use.
- R9 (b) When not in operation, the electronic brachytherapy device shall be
R9 secured from unauthorized use.
- R9 (c) When a patient must be held in position for radiation therapy, mechanical
R9 supporting or restraining devices shall be used.
- R9 (d) A copy of the current operating and emergency procedures shall be kept
R9 in close proximity to the electronic brachytherapy device and easily
R9 accessible to the operator.

- R9 (e) No individual other than the patient shall be exposed during the treatment.
- R9 (f) The radiation safety officer or his/her designee, and an authorized user,
R9 shall be notified as soon as possible but no later than 24 hours after a
R9 patient's, or human research subject's, medical emergency or death;
- R9 (g) Only individuals approved by the authorized user, radiation safety officer,
R9 or authorized medical physicist shall be present in the treatment room
R9 during treatment and a written log shall be kept of all personnel present
R9 during treatment;
- R9 (h) Simultaneous operation of more than one radiation-producing device in a
R9 treatment room shall be prohibited; and
- R9 (i) The registrant shall develop, implement, and maintain written procedures
R9 for responding to any situation in which the operator is unable to complete
R9 the treatment in compliance with the written directive. These procedures
R9 must include:
- R9 1. Instructions for responding to equipment failures and the names of
R9 the individuals responsible for implementing corrective actions;
 - R9 2. The process for restricting access to, and posting of, the treatment
R9 area to minimize the risk of inadvertent exposure; and
 - R9 3. The names and telephone numbers of the authorized users, the
R9 authorized medical physicist, and the radiation safety officer to be
R9 contacted if the device operates abnormally.
- R9 (7) Possession of a Survey Instrument. Each facility location authorized to use an
R9 electronic brachytherapy device shall possess portable monitoring equipment. At
R9 a minimum, such equipment shall include a portable radiation measurement
R9 survey instrument capable of measuring dose rates over the range 0.1
R9 microsievert (0.01 millirem) per hour to 10 millisievert (1000 millirem) per hour.
R9 All survey instruments shall be operable and calibrated annually.
- R9 (8) Calibration.
- R9 (a) Validation of the electronic brachytherapy source output shall be
R9 performed by an authorized medical physicist.
 - R9 (b) Calibration validation measurements shall be made for each x-ray tube, or
R9 after any repair affecting the x-ray beam generation, or when indicated by
R9 the spot checks.
 - R9 (c) Calibration validation must include determination of:
 - R9 1. The output within 2% of the expected value, or determination of the
R9 output if there is no expected value;
 - R9 2. Timer accuracy and linearity over the typical range of use;

- R9 3. Proper operation of back-up exposure control devices;
- R9 4. Evaluation that the relative dose distribution about the source is
R9 within 5% of that expected; and
- R9 5. Source positioning accuracy to within 1 millimeter within the
R9 applicator;
- R9 (d) The validation of the output shall use a dosimetry system as described by
R9 the facility's procedures to measure the output. Such procedures shall
R9 use a current published protocol from a nationally-recognized professional
R9 association with expertise in electronic brachytherapy, such as the AAPM.
R9 In the absence of such a published protocol, the manufacturer's current
R9 protocol shall be followed.
- R9 (e) The registrant shall make calibration measurements required by this
R9 section according to a current published protocol from a nationally-
R9 recognized professional association with expertise in electronic
R9 brachytherapy, such as the AAPM. In the absence of such a published
R9 protocol, the manufacturer's current testing protocol shall be followed.
- R9 (9) Routine and Day-Of-Use Periodic Spot Checks for Electronic Brachytherapy
R9 Devices and Dosimetry Equipment.
- R9 (a) A registrant authorized to use electronic brachytherapy devices shall have
R9 a program to perform spot checks on each unit:
 - R9 1. At the beginning of each day of use of an electronic brachytherapy
R9 unit;
 - R9 2. Each time the unit is moved to a new room or site; and
 - R9 3. After each x-ray tube installation.
- R9 (b) The authorized medical physicist shall:
 - R9 1. Establish written procedures for performing the spot checks;
 - R9 2. Supervise the making of the spot checks and review the spot check
R9 results within 2 days of completion; and
 - R9 3. Notify the registrant in writing of any failures detected during the
R9 spot checks, within 24 hours of the identification of the spot check
R9 failure.
- R9 (c) The authorized user will prevent the clinical use of a malfunctioning device
R9 until the malfunction identified in the spot check has been evaluated and
R9 corrected or, if necessary, the equipment repaired.

- R9 (d) The spot checks must, at a minimum, assure proper operation of:
- R9 1. Radiation exposure indicator lights on the electronic brachytherapy
R9 device and on the control console; and
- R9 2. The integrity of all cables, catheters or parts of the device.
- R9 (e) Spot checks of dosimetry must include checks that the output of the
R9 electronic brachytherapy source falls within 3% of expected values, which
R9 include:
- R9 1. Output as a function of time, or output as a function of setting on a
R9 monitor chamber; and
- R9 2. Verification of the consistency of the dose distribution to within 3%
R9 of that found during calibration;
- R9 3. Validation of the operation of positioning methods to assure that the
R9 treatment dose exposes the intended location within 1 mm; and
- R9 4. Inspection of all treatment components (e.g., connecting guide
R9 tubes, transfer tubes, transfer-tube-applicator interfaces, treatment
R9 spacers) on the day of use for any imperfections.
- R9 (f) A registrant shall retain a record of each spot check for 3 years. The
R9 record shall include:
- R9 1. The date of the check;
- R9 2. The manufacturer's name, model number, and serial number of the
R9 electronic brachytherapy source;
- R9 3. Notations indicating the operability of electronic brachytherapy
R9 source exposure indicator lights, applicators, source-transfer tubes,
R9 transfer tube-applicator interfaces, and source-positioning
R9 accuracy; and
- R9 4. The name and signature of the individual who performed the check.
- R9 (10) Mobile Electronic Brachytherapy Devices. A registrant providing mobile
R9 electronic brachytherapy services shall:
- R9 (a) Check all survey instruments before medical use at each address of use
R9 and on each day of use;
- R9 (b) Account for the x-ray tube in the device before departure from the client's
R9 address; and
- R9 (c) Perform, at each location, all of the required periodic spot checks specified
R9 in subsection 64E-5.1604(9), F.A.C., to assure proper operation of the
R9 device.

R9 (11) Treatment Planning.

R9 (a) The authorized medical physicist shall perform acceptance testing on the
R9 treatment planning system of therapy-related computer systems according
R9 to a current published protocol from a nationally-recognized professional
R9 association with expertise in electronic brachytherapy, such as the AAPM.
R9 In the absence of such a published protocol, the manufacturer's current
R9 protocol shall be followed. At a minimum, the acceptance testing shall
R9 include verification of:

R9 1. The electronic brachytherapy source-specific input parameters
R9 required by the dose-calculation algorithm;

R9 2. The accuracy of dose, dwell-time, and treatment-time calculations
R9 at representative points;

R9 3. The accuracy of isodose plots and graphic displays;

R9 4. The accuracy of the software used to determine source positions
R9 from images; and

R9 5. If the treatment-planning system is different from the treatment-
R9 delivery system, the accuracy of electronic transfer of the
R9 treatment-delivery parameters to the treatment-delivery unit from
R9 the treatment-planning system.

R9 (b) The authorized medical physicist shall compare the position indicators in
R9 the applicator to the actual position of the source or planned dwell
R9 positions at the time of commissioning.

R9 (c) Prior to each patient treatment regimen, the authorized medical physicist
R9 shall confirm the accuracy of the treatment parameters and dose.

R9 Specific Authority: 404.051(4), 404.22, F.S.
R9 Law Implemented: 404.051, 404.081(1), 404.22, F.S..
R9 History: New 03-12-2009.

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL

**REQUIREMENTS FOR TRANSFERS OF
LOW-LEVEL RADIOACTIVE WASTE INTENDED
FOR DISPOSAL AT LICENSED LAND DISPOSAL
FACILITIES AND MANIFEST**

July, 1997

REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE INTENDED FOR DISPOSAL AT LICENSED LAND DISPOSAL FACILITIES AND MANIFEST

I. Manifest

A waste generator, collector, or processor who transports or offers for transportation low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility shall prepare a manifest reflecting information requested on applicable NRC Form 540 (3-95), Uniform Low-Level Radioactive Waste Manifest - Shipping Paper and NRC Form 541 (11-96), Uniform Low-Level Radioactive Waste Manifest - Container and Waste Description and, if necessary, NRC Form 542 (3-95), Uniform Low-Level Radioactive Waste Manifest - Manifest Index and Regional Compact Tabulation, which are herein incorporated by reference and which are available from the department. NRC Form 540 (3-95) and NRC Form 540A (3-95) shall be completed and physically shall accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Form 541 (11-96) and NRC Form 541A (3-95) and NRC Form 542 (3-95) and NRC Form 542A (3-95) can be completed, transmitted, and stored in electronic media able to produce legible, accurate, and complete records on the respective forms. Licensees are not required to comply with the manifesting requirements of this part when they ship:

- LLW for processing and expect its return for storage under their license before disposal at a licensed land disposal facility;
- LLW that is being returned to the licensee who is the waste generator or generator as defined in this part; or
- Radioactively contaminated material to a waste processor that becomes the processor's residual waste.

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix can be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

NRC Form 540 (3-95), NRC Form 540A (3-95), NRC Form 541 (11-96), NRC Form 541A (3-95), NRC Form 542 (3-95), and NRC Form 542A (3-95), and the accompanying instructions in hard copy can be obtained from the department.

This appendix includes information requirements of the Department of Transportation, as codified in 49 CFR Part 172. Information on hazardous, medical, or other waste required to meet Environmental Protection Agency regulations as codified in 40 CFR Parts 259, 261 or elsewhere is not addressed in this section and shall be provided on the required EPA forms. However, the required EPA forms shall accompany the Uniform Low-Level Radioactive Waste Manifest required by this rule.

As used in this appendix, the following definitions apply:

Chelating agent means amine polycarboxylic acids such as EDTA and DTPA, hydroxycarboxylic acids, and polycarboxylic acids such as citric acid, carboic acid, and glucinic acid.

Chemical description means a description of the principal chemical characteristics of a low-level radioactive waste.

Computer-readable medium means that the department's computer can transfer the information from the medium into its memory.

Consignee means the designated receiver of the shipment of low-level radioactive waste.

Decontamination facility means a facility operating under an NRC or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

Disposal container means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility. (Also see "high integrity container".) Note that for some shipments the disposal container could be the transport package.

EPA identification number means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

Generator means a licensee operating under an NRC or Agreement State license who is a waste generator or is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985, for example, waste generated as a result of decontamination or recycle activities.

High integrity container (HIC) means a container commonly designed to meet the structural stability requirements of 64E-5.333(9), F.A.C., and to meet Department of Transportation requirements for a Type A package.

Land disposal facility means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For the purposes of these regulations, a geologic repository as defined in 10 CFR Part 60 is not considered a land disposal facility.

NRC Form 540 (3-95), NRC Form 540A (3-95), NRC Form 541 (11-96), NRC Form 541A (3-95), NRC Form 542 (3-95), and NRC Form 542A (3-95) are official department forms referenced in this appendix. Licensees need not use originals of these department forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Form 540 (3-95), NRC Form 540A (3-95), NRC Form 541 (11-96), and NRC Form 541A (3-95), can be completed, transmitted, and stored in electronic media. The electronic media shall be able to produce legible, accurate, and complete records in the format of the uniform manifest.

Package means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations with its radioactive contents as presented for transport.

Physical description means the items called for on NRC Form 541 (11-96) to describe a low-level radioactive waste.

Residual waste means low-level radioactive waste resulting from processing or decontamination activities that cannot be separated easily into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Shipper means the waste generator, waste collector, or waste processor who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Shipping paper means NRC Form 540 (3-95) and, if required, NRC Form 540A (3-95), which includes the information required by DOT in 49 CFR part 172.

Source material has the same meaning as that given in 64E-5.101, F.A.C.

Special nuclear material has the same meaning as that given in 64E-5.101, F.A.C.

Uniform Low-Level Radioactive Waste Manifest or uniform manifest means the combination of NRC Form 540 (3-95), NRC Form 541 (11-96), and, if necessary, NRC Form 542 (3-95), and their respective continuation sheets as needed, or equivalent.

Waste collector means an entity operating under an NRC or Agreement State license whose principal purpose is to collect and consolidate waste generated by others and to transfer this waste without processing or repackaging the collected waste to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Waste description means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541 (11-96).

Waste generator means an entity operating under an NRC or Agreement State license who possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use and transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services can be a waste generator if the transfer of low-level radioactive waste from its facility is defined as residual waste.

Waste processor means an entity operating under an NRC or agreement state license whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Waste type means a waste within a disposal container having a unique physical description such as a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media.

Information Requirements

A. General Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;
2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for the manifested shipment; and
3. The name, address, and telephone number or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;
2. The total number of packages and disposal containers;
3. The total disposal volume and disposal weight in the shipment;
4. The total radionuclide activity in the shipment;
5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and
6. The total masses of U-233, U-235, and plutonium in special nuclear material and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;
2. A physical description of the disposal container, including the manufacturer and model of high integrity container;
3. The volume displaced by the disposal container;
4. The gross weight of the disposal container, including the waste;
5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;
6. A physical and chemical description of the waste;
7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight plus the identity of the principal chelating agent;
8. The approximate volume of waste within a container;
9. The sorbing or solidification media if any and the identity of the solidification media vendor and brand name;
10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types such as activated materials, contaminated equipment, mechanical filters, sealed sources or devices, and wastes in solidification or stabilization media, the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and
12. For wastes consigned to a disposal facility, the classification of the waste pursuant to 64E-5.333(1)-(8), F.A.C. Waste not meeting the structural stability requirements of 64E-5.333(9)(b), F.A.C. shall be identified.

D. Uncontainerized Waste Information

The shipper of radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;
2. A physical and chemical description of the waste;
3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight plus the identity of the principal chelating agent;
4. For waste consigned to a disposal facility, the classification of the waste pursuant to 64E-5.333(1)-(8), F.A.C. Waste not meeting the structural stability requirements of 64E-5.333(9)(b), F.A.C. shall be identified;
5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and
6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. The origin of the LLW resulting from a processor's activities can be attributable to one or more generators including "waste generators as defined in this part. It also applies to mixtures of wastes shipped in an uncontainerized form for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.
2. For heterogeneous mixtures of waste such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types such as activated materials, contaminated equipment, mechanical filters, sealed source or devices and wastes in solidification or stabilization media, the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:
 - (a) The volume of waste within the disposal container;
 - (b) A physical and chemical description of the waste including the solidification agent, if any;
 - (c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight plus the identity of the principal chelating agent;

(d) The sorbing or solidification media if any and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 64E-5.333(9)(b); and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are classified, described, packaged, marked, and labeled properly and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the department. By signing the certification, a collector is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1 through 9 of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4 through 9 of this section. A licensee shall:

1. Prepare all wastes so that the waste is classified according to 64E-5.333(1)-(8), F.A.C. and meets the waste characteristics requirements in 64E-5.333(9), F.A.C.;
2. Label each disposal container or transport package if potential radiation hazards preclude labeling of the individual disposal container of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with 64E-5.333(1)-(8), F.A.C.;
3. Conduct a quality assurance program to assure compliance with 64E-5.333(1)-(8), F.A.C. and 64E-5.333(9), F.A.C. The program shall include management evaluation of audits;
4. Prepare the manifest as required by this appendix;
5. Forward a copy or electronically transfer the manifest to the intended consignee so that receipt of the manifest precedes the LLW shipment or the manifests delivered to the consignee with the waste at the time the waste is transferred to the consignee;
6. Include NRC Form 540 (3-95) and NRC Form 540A (3-95) if required with the shipment regardless of the option chosen in paragraph A.5 of this section;
7. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540 (3-95);
8. Retain a copy of or electronically store the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 64E-5, F.A.C.; and
9. Conduct an investigation in accordance with paragraph E of this appendix for any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of NRC Form 540 (3-95);
2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that the manifest identifies the generator of that container of waste for each container of waste in the shipment;
3. Forward a copy or electronically transfer the manifest to the intended consignee so that either receipt of the manifest precedes the LLW shipment or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee;
4. Include NRC Form 540 (3-95) and NRC Form 540A (3-95) if required with the shipment regardless of the option chosen in paragraph B.3 of this section;
5. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540 (3-95);
6. Retain a copy of or electronically store the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 64E-5, F.A.C.;
7. Conduct an investigation for any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix as specified in paragraph E of this appendix; and
8. Notify the shipper and the department when any shipment or part of a shipment has not arrived within 60 days after receipt of an advance manifest unless notified by the shipper that the shipment has been canceled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of NRC Form 540 (3-95);
2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. The manifest shall identify the waste generators, the preprocessed waste volume, and the other information required in paragraph I.E. of this appendix for each container of waste in the shipment;
3. Prepare all wastes so that the waste is classified according to 64E-5.333(1)-(8), F.A.C., and meets the waste characteristics requirements in 64E-5.333(9), F.A.C.;
4. Label each package of waste to identify whether it is Class A waste, Class B waste or Class C waste as specified in 64E-5.333(1)-(8), F.A.C., and 64E-5.333(10), F.A.C.;
5. Conduct a quality assurance program to assure compliance with 64E-5.333(1)-(9), F.A.C. The program shall include management evaluation of audits;
6. Forward a copy or electronically transfer the manifest to the intended consignee so that either receipt of the manifest precedes the LLW shipment or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee;
7. Include NRC Form 540 (3-95) and NRC Form 540A (3-95) if required with the shipment regardless of the option chosen in paragraph C.6 of this section;

8. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540 (3-95);

9. Retain a copy of or electronically store the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 64E-5, F.A.C.;

10. Conduct an investigation in accordance with paragraph E of this appendix for any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix; and

11. Notify the shipper and the department when any shipment or part of a shipment has not arrived within 60 days after receipt of an advance manifest unless notified by the shipper that the shipment has been canceled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within 1 week of receipt by returning as a minimum a signed copy of NRC Form 540 (3-95) to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the manifest and materials received, copies or electronic transfer of affected forms shall be returned indicating the discrepancy.

2. Maintain copies of all completed manifests and electronically store the information required by (a) and (b) below until the department terminates the license:

(a) All information required in this appendix except shipper and carrier telephone numbers and shipper and consignee certifications; and

(b) Following receipt and acceptance of a shipment of radioactive waste, the date that the shipment is received at the disposal facility, the date of disposal of the waste, a traceable shipment manifest number, a description of any engineered barrier or structural overpack provided for disposal of the waste, the location of disposal at the disposal site, the containment integrity of the waste disposal containers as received, any discrepancies between materials listed on the manifest and those received, the volume of any pallets, bracing, or other shipping or onsite generated materials that are contaminated and are disposed of as contaminated or suspect materials, any evidence of leaking or damaged disposal containers or radiation or contamination levels in excess of limits specified in DOT and department regulations, brief description of any repackaging operations of any of the disposal containers included in the shipment, and any other information required by the department as a license condition.

3. Notify the shipper and the department when any shipment or part of a shipment has not arrived within 60 days after receipt of an advance manifest unless notified by the shipper that the shipment has been canceled.

E. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section shall:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the department. Each licensee who conducts a trace investigation shall file a written report with the department within 2 weeks of completion of the investigation.

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
ALIs, DACs AND EFFLUENT CONCENTRATIONS
July 1993

ATTACHMENT 1**ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE****Introduction**

For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity medial aerodynamic diameter (AMAD) of 1 μm , micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note:

The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^2 or 600, and 6E+0 represents 6×10^0 or 6.

Table I "Occupational Values"

Note that the columns in Table I captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs are the annual intakes of given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 5 rem (0.05 sievert), stochastic ALI, or (2) a committed dose equivalent of 50 rem (0.5 sievert) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body to 5 rem (0.05 sievert). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor W_T . This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of W_T are listed under the definition of "weighting factor" in 64E-5.101. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of $W_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI track --stomach, small intestine, upper large intestine, and lower large intestine -- are to be treated as four separate organs.

Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to the limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parenthesis. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;
 St. wall = stomach wall;
 Blad wall = bladder wall; and
 Bone surf = bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of the non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 50 rem (0.5 sievert) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the non-stochastic ALIs (ALI_{ns}) that contributed to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is the sum of (intake (in μCi) of each radionuclide/ ALI_{ns}) ≤ 1.0 . If there is an external deep dose contribution of H_d , then this sum must be less than $1 - (H_d/50)$, instead of ≤ 1.0 .

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentrations (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

$$\begin{aligned} \text{DAC} &= \text{ALI (in } \mu\text{Ci)} / (2000 \text{ hours per working year} \times 60 \text{ minutes/hour} \\ &\quad \times 2 \times 10^4 \text{ ml per minute}) \\ &= [\text{ALI} / 2.4 \times 10^9] \mu\text{Ci/ml,} \end{aligned}$$

where 2×10^4 milliliters is the volume of air breathed per minute at work by Reference Man under working conditions or light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply when the individual both ingest and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See 64E-5.219. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W or Class Y, the exposure may be evaluated as if it were a mixture or different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table II “Effluent Concentrations”

The columns in Table II captioned “Effluents,” “Air” and “Water” are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of 64E-5.312. The concentration values given in Columns 1 and 2 of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (0.5 millisievert).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentrations limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public.

For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional as they were in 10D-91.429.

The air concentrations values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9 , relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor 300 includes the following components: a factor of 50 to relate to the 5 rem (0.05 sievert) annual occupational dose limit of 0.1 rem limit for members of the public; and a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table I, Column 3 was divided by 219. The factor 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age consideration is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7 . The factor of 7.3×10^7 (ml) includes the following components: the factor of 50 and 2 described above and a factor of 7.3×10^5 (ml) which is the annual water intake of "Reference Man".

Note 2 provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

Table III "Release to Sewers"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in 64E-5.330. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by "Reference Man," and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a "Reference Man" during a year, would result in a committed effective dose equivalent of 0.5 rem (5 millisievert).

LIST OF ELEMENTS

Name	Symbol	Atomic Number	Name	Symbol	Atomic Number
Actinium	Ac	89	Mendelevium	Md	101
Aluminum	Al	13	Mercury	Hg	80
Americium	Am	95	Molybdenum	Mo	42
Antimony	Sb	51	Neodymium	Nd	60
Argon	Ar	18	Neptunium	Np	93
Arsenic	As	33	Nickel	Ni	28
Astatine	At	85	Niobium	Nb	41
Barium	Ba	56	Osmium	Os	76
Berkelium	Bk	97	Palladium	Pd	46
Beryllium	Be	4	Phosphorus	P	15
Bismuth	Bi	83	Platinum	Pt	78
Bromine	Br	35	Plutonium	Pu	94
Cadmium	Cd	48	Polonium	Po	84
Calcium	Ca	20	Potassium	K	19
Californium	Cf	98	Praseodymium	Pr	59
Carbon	C	6	Promethium	Pm	61
Cerium	Ce	58	Protactinium	Pa	91
Cesium	Cs	55	Radium	Ra	88
Chlorine	Cl	17	Radon	Rn	86
Chromium	Cr	24	Rhenium	Re	75
Cobalt	Co	27	Rhodium	Rh	45
Copper	Cu	29	Rubidium	Rb	37
Curium	Cm	96	Ruthenium	Ru	44
Dysprosium	Dy	66	Samarium	Sm	62
Einsteinium	Es	99	Scandium	Sc	21
Erbium	Er	68	Selenium	Se	34
Europium	Eu	63	Silicon	Si	14
Fermium	Fm	100	Silver	Ag	47
Fluorine	F	9	Sodium	Na	11
Francium	Fr	87	Strontium	Sr	38
Gadolinium	Gd	64	Sulfur	S	16
Gallium	Ga	31	Tantalum	Ta	73
Germanium	Ge	32	Technetium	Tc	43
Gold	Au	79	Tellurium	Te	52
Hafnium	Hf	72	Terbium	Tb	65
Holmium	Ho	67	Thallium	Tl	81
Hydrogen	H	1	Thorium	Th	90
Indium	In	49	Thulium	Tm	69
Iodine	I	53	Tin	Sn	50
Iridium	Ir	77	Titanium	Ti	22
Iron	Fe	26	Tungsten	W	74
Krypton	Kr	36	Uranium	U	92
Lanthanum	La	57	Vanadium	V	23
Lead	Pb	82	Xenon	Xe	54
Lutetium	Lu	71	Ytterbium	Yb	70
Magnesium	Mg	12	Yttrium	Y	39
Manganese	Mn	25	Zinc	Zn	30
Mendelevium	Md	101	Zirconium	Zr	40

(Page left intentionally blank)

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC (μCi/ml)	COL. 1 Air (μCi/ml)	COL. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
1	H-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
	H-3	Gas (HT or T2) Submersion: Use above values as HT and T2 oxidize in air and in the body to HTO						
1	Be-7	W: all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
4	Be-7	Y: oxides, halides, and nitrates	0	2E+4	8E-6	3E-8	0	0
4	Be-10	W: see Be-7	1E+3 LLI wall (1E+3)	2E+2 0	6E-8 0	2E-10 0	0 2E-5	0 2E-4
4	Be-10	Y: see Be-7	0	1E+1	6E-9	2E-11	0	0
6	C-11 ²	Monoxide	0	1E+6	5E-4	2E-6	0	0
6	C-11 ²	Dioxide	0	6E+5	3E-4	9E-7	0	0
6	C-11 ²	Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	C-14	Monoxide	0	2E+6	7E-4	2E-6	0	0
6	C-14	Dioxide	0	2E+5	9E-5	3E-7	0	0
6	C-14	Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
9	F-18 ²	D: fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4 St. wall (5E+4)	7E+4 0	3E-5 0	1E-7 0	0 7E-4	0 7E-3
9	F-18 ²	W: fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	0	9E+4	4E-5	1E-7	0	0
9	F-18 ²	Y: lanthanum fluoride	0	8E+4	3E-5	1E-7	0	0
11	Na-22	D: all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Na-24	D: all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Mg-28	D: all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
12	Mg-28	W: oxides, hydroxides, carbides, halides, and nitrates	0	1E+3	5E-7	2E-9	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
13	Al-26	D: all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
13	Al-26	W: oxides, hydroxides, carbides, halides, and nitrates	0	9E+1	4E-8	1E-10	0	0
14	Si-31	D: all compounds except those given for W, Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
14	Si-31	W: oxides, carbides, hydroxides, and nitrates	0	3E+4	1E-5	5E-8	0	0
14	Si-31	Y: aluminosilicate glass	0	3E+4	1E-5	4E-8	0	0
14	Si-32	D: see Si-31	2E+3 LLI wall (3E+3)	2E+2 0	1E-7 0	3E-10 0	0 4E-5	0 4E-4
14	Si-32	W: see Si-31	0	1E+2	5E-8	2E-10	0	0
14	Si-32	Y: see Si-31	0	5E+0	2E-9	7E-12	0	0
15	P-32	D: all compounds except those given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
15	P-32	W: phosphates of Zn^{2+} , S^{3+} , Mg^{2+} , Fe^{3+} , Bi^{3+} , and lanthanides	0	4E+2	2E-7	5E-10	0	0
15	P-33	D: see P-32	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
15	P-33	W: see P-32	0	3E+3	1E-6	4E-9	0	0
16	S-35	Vapor		1E+4	6E-6	2E-8	0	0
16	S-35	D: sulfides and sulfates except those given for W	1E+4 LLI wall (8E+3)	2E+4 0	7E-6 0	2E-8 0	0 1E-4	0 1E-3
16	S-35	W: elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	0	2E+3	9E-7	3E-9	0	0
17	Cl-36	D: chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μ Ci)	COL. 2 Inhalation ALI (μ Ci)	COL. 3 Inhalation DAC (μ Ci/ml)	COL. 1 Air (μ Ci/ml)	COL. 2 Water (μ Ci/ml)	Monthly Average Concentration (μ Ci/ml)
17	Cl-36	W: chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	0	2E+2	1E-7	3E-10	0	0
17	Cl-38 ²	D: see Cl-36	2E+4 St. wall (3E+4)	4E+4 0	2E-5 0	6E-8 0	0 3E-4	0 3E-3
17	Cl-38 ²	W: see Cl-36	0	5E+4	2E-5	6E-8	0	0
17	Cl-39 ²	D: see Cl-36	2E+4 St. wall (4E+4)	5E+4 0	2E-5 0	7E-8 0	0 5E-4	0 5E-3
17	Cl-39 ²	W: see Cl-36	0	6E+4	2E-5	8E-8	0	0
18	Ar-37	Submersion ¹	0	0	1E+0	6E-3	0	0
18	Ar-39	Submersion ¹	0	0	2E-4	8E-7	0	0
18	Ar-41	Submersion ¹	0	0	3E-6	1E-8	0	0
19	K-40	D: all compounds	3E+2	4E+2	2E-7	6E-10	4E-6	4E-5
19	K-42	D: all compounds	5E+3	5E+3	2E-6	7E-9	6E-5	6E-4
19	K-43	D: all compounds	6E+3	9E+3	4E-6	1E-8	9E-5	9E-4
19	K-44 ²	D: all compounds	2E+4 St. wall (4E+4)	7E+4 0	3E-5 0	9E-8 0	0 5E-4	0 5E-3
19	K-45 ²	D: all compounds	3E+4 St. wall (5E+4)	1E+5 0	5E-5 0	2E-7 0	0 7E-4	0 7E-3
20	Ca-41	W: all compounds	3E+3 Bone Surf (4E+3)	4E+3 Bone Surf (4E+3)	2E-6 0	0 5E-9	0 6E-5	0 6E-4
20	Ca-45	W: all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20	Ca-47	W: all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
20	Sc-43	Y: all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
21	Sc-44m	Y: all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21	Sc-44	Y: all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21	Sc-46	Y: all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21	Sc-47	Y: all compounds	2E+3 LLI Wall (3E+3)	3E+3 0	1E-6 0	4E-9 0	0 4E-5	0 4E-4
21	Sc-48	Y: all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4
21	Sc-49 ²	Y: all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
22	Ti-44	D: all compounds except those given for W, Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
22	Ti-44	W: oxides, carbides, halides, nitrates, and hydroxides	0	3E+1	1E-8	4E-11	0	0
22	Ti-44	Y: SrTiO	0	6E+0	2E-9	8E-12	0	0
22	Ti-45	D: see Ti-44	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
22	Ti-45	W: see Ti-44	0	4E+4	1E-5	5E-8	0	0
22	Ti-45	Y: see Ti-44	0	3E+4	1E-5	4E-8	0	0
23	V-47 ²	D: all compounds except those given for W	3E+4 St. wall (3E+4)	8E+4 0	3E-5 0	1E-7 0	0 4E-4	4E-3
23	V-47	W: oxides, carbides, hydroxides, and halides	0	1E+5	4E-5	1E-7	0	0
23	V-48	D: see V-47	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
23	V-48	W: see V-47	0	6E+2	3E-7	9E-10	0	0
23	V-49	D: see V-47	7E+4 LLI wall (9E+4)	3E+4 Bone Surf (3E+4)	1E-5 0	0 5E-8	0 1E-3	1E-2
23	V-49	W: see V-47	0	2E+4	8E-6	2E-8	0	0
24	Cr-48	D: all compounds except those given for W, Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
24	Cr-48	W: halides and nitrates	0	7E+3	3E-6	1E-8	0	0
24	Cr-48	Y: oxides and hydroxides	0	7E+3	3E-6	1E-8	0	0
24	Cr-49 ²	D: see Cr-48	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
24	Cr-49 ²	W: see Cr-48	0	1E+5	4E-5	1E-7	0	0
24	Cr-49 ²	Y: see Cr-48	0	9E+4	4E-5	1E-7	0	0
24	Cr-51	D: see Cr-48	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
24	Cr-51	W: see Cr-48	0	2E+4	1E-5	3E-8	0	0
24	Cr-51	Y: see Cr-48	0	2E+4	8E-6	3E-8	0	0
25	Mn-51 ²	D: all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
25	Mn-51 ²	W: oxides, halides, hydroxides, and nitrates	0	6E+4	3E-5	8E-8	0	0
25	Mn-52m ²	D: see Mn-51	3E+4 St. wall (4E+4)	9E+4 0	4E-5 0	1E-7 0	0 5E-4	0 5E-3

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
25	Mn-52m ²	W: see Mn-51	0	1E+5	4E-5	1E-7	0	0
25	Mn-52	D: see Mn-51	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
25	Mn-52	W: see Mn-51	0	9E+2	4E-7	1E-9	0	0
25	Mn-53	D: see Mn-51	5E+4	1E+4	5E-6	0	7E-4	7E-3
			0	Bone Surf (2E+4)	0	3E-8	0	0
25	Mn-53	W: see Mn-51	0	1E+4	5E-6	2E-8	0	0
25	Mn-54	D: see Mn-51	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
25	Mn-54	W: see Mn-51	0	8E+2	3E-7	1E-9	0	0
25	Mn-56	D: see Mn-51	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
25	Mn-56	W: see Mn-51	0	2E+4	9E-6	3E-8	0	0
26	Fe-52	D: all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
26	Fe-52	W: oxides, halides, and hydroxides	0	2E+3	1E-6	3E-9	0	0
26	Fe-55	D: see Fe-52	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
26	Fe-55	W: see Fe-52	0	4E+3	2E-6	6E-9	0	0
26	Fe-59	D: see Fe-52	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
26	Fe-59	W: see Fe-52	0	5E+2	2E-7	7E-10	0	0
26	Fe-60	D: see Fe-52	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
26	Fe-60	W: see Fe-52	0	2E+1	8E-9	3E-11	0	0
27	Co-55	W: all compounds except those given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
27	Co-55	Y: oxides, halides, hydroxides, and nitrates	0	3E+3	1E-6	4E-9	0	0
27	Co-56	W: see Co-55	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
27	Co-56	Y: see Co-55	4E+2	2E+2	8E-8	3E-10	0	0
27	Co-57	W: see Co-55	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
27	Co-57	Y: see Co-55	4E+3	7E+2	3E-7	9E-10	0	0
27	Co-58m	W: see Co-55	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
27	Co-58m	Y: see Co-55	0	6E+4	3E-5	9E-8	0	0
27	Co-58	W: see Co-55	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
27	Co-58	Y: see Co-55	1E+3	7E+2	3E-7	1E-9	0	0
27	Co-60m ²	W: see Co-55	1E+6	4E+6	2E-3	6E-6	0	0
			St. wall (1E+6)	0	0	0	2E-2	2E-1
27	Co-60m ²	Y: see Co-55	0	3E+6	1E-3	4E-6	0	0
27	Co-60	W: see Co-55	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
27	Co-60	Y: see Co-55	2E+2	3E+1	1E-8	5E-11	0	0
27	Co-61 ²	W: see Co-55	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
27	Co-61 ²	Y: see Co-55	2E+4	6E+4	2E-5	8E-8	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
27	Co-62m ²	W: see Co-55	4E+4 St. wall (5E+4)	2E+5 0	7E-5 0	2E-7 0	0 7E-4	0 7E-3
27	Co-62m ²	Y: see Co-55	0	2E+5	6E-5	2E-7	0	0
28	Ni-56	D: all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
28	Ni-56	W: oxides, carbides, and hydroxides	0	1E+3	5E-7	2E-9	0	0
28	Ni-56	Vapor	0	1E+3	5E-7	2E-9	0	0
28	Ni-57	D: see Ni-56	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
28	Ni-57	W: see Ni-56	0	3E+3	1E-6	4E-9	0	0
28	Ni-57	Vapor	0	6E+3	3E-6	9E-9	0	0
28	Ni-59	D: see Ni-56	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
28	Ni-59	W: see Ni-56	0	7E+3	3E-6	1E-8	0	0
28	Ni-59	Vapor	0	2E+3	8E-7	3E-9	0	0
28	Ni-63	D: see Ni-56	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
28	Ni-63	W: see Ni-56	0	3E+3	1E-6	4E-9	0	0
28	Ni-63	Vapor	0	8E+2	3E-7	1E-9	0	0
28	Ni-65	D: see Ni-56	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
28	Ni-65	W: see Ni-56	0	3E+4	1E-5	4E-8	0	0
28	Ni-65	Vapor	0	2E+4	7E-6	2E-8	0	0
28	Ni-66	D: see Ni-56	4E+2 LLI wall (5E+2)	2E+3 0	7E-7 0	2E-9 0	0 6E-6	0 6E-5
28	Ni-66	W: see Ni-56	0	6E+2	3E-7	9E-10	0	0
28	Ni-66	Vapor	0	3E+3	1E-6	4E-9	0	0
29	Cu-60 ²	D: all compounds except those given for W, Y	3E+4 St. wall (3E+4)	9E+4 0	4E-5 0	1E-7 0	0 4E-4	0 4E-3
29	Cu-60 ²	W: sulfides, halides, and nitrates	0	1E+5	5E-5	2E-7	0	0
29	Cu-60 ²	Y: oxides and hydroxides	0	1E+5	4E-5	1E-7	0	0
29	Cu-61	D: see Cu-60	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
29	Cu-61	W: see Cu-60	0	4E+4	2E-5	6E-8	0	0
29	Cu-61	Y: see Cu-60	0	4E+4	1E-5	5E-8	0	0
29	Cu-64	D: see Cu-60	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
29	Cu-64	W: see Cu-60	0	2E+4	1E-5	3E-8	0	0
29	Cu-64	Y: see Cu-60	0	2E+4	9E-6	3E-8	0	0
29	Cu-67	D: see Cu-60	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
29	Cu-67	W: see Cu-60	0	5E+3	2E-6	7E-9	0	0
29	Cu-67	Y: see Cu-60	0	5E+3	2E-6	6E-9	0	0
30	Zn-62	Y: all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
30	Zn-63 ²	Y: all compounds	2E+4 St. wall (3E+4)	7E+4 0	3E-5 0	9E-8 0	0 3E-4	0 3E-3
30	Zn-65	Y: all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30	Zn-69m	Y: all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zn-69 ²	Y: all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30	Zn-71m	Y: all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zn-72	Y: all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31	Ga-65 ²	D: all compounds except those given for W	5E+4 St. wall (6E+4)	2E+5 0	7E-5 0	2E-7 0	0 9E-4	0 9E-3
31	Ga-65 ²	W: oxides, carbides, halides, nitrates, and hydroxides	0	2E+5	8E-5	3E-7	0	0
31	Ga-66	D: see Ga-65	1E+3	4E+3	1E-6	5E-9	1E-4	1E-3
31	Ga-66	W: see Ga-65	0	3E+3	1E-6	4E-9	0	0
31	Ga-67	D: see Ga-65	7E+3	1E+4	6E-6	2E-8	2E-4	2E-3
31	Ga-67	W: see Ga-65	0	1E+4	4E-6	1E-8	0	0
31	Ga-68 ²	D: see Ga-65	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
31	Ga-68 ²	W: see Ga-65	0	5E+4	2E-5	7E-8	0	0
31	Ga-70 ²	D: see Ga-65	5E+4 St. wall (7E+4)	2E+5 0	7E-5 0	2E-7 0	0 1E-3	0 1E-2
31	Ga-70 ²	W: see Ga-65	0	2E+5	8E-5	3E-7	0	0
31	Ga-72	D: see Ga-65	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
31	Ga-72	W: see Ga-65	0	3E+3	1E-6	4E-9	0	0
31	Ga-73	D: see Ga-65	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
31	Ga-73	W: see Ga-65	0	2E+4	6E-6	2E-8	0	0
32	Ge-66	D: all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
32	Ge-66	W: oxides, sulfides, and halides	0	2E+4	8E-6	3E-8	0	0
32	Ge-67 ²	D: see Ge-66	4E+4 St. wall (3E+4)	9E+4 0	4E-5 0	1E-7 0	0 6E-4	0 6E-3
32	Ge-67 ²	W: see Ge-66	0	1E+5	4E-5	1E-7	0	0
32	Ge-68	D: see Ge-66	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
32	Ge-68	W: see Ge-66	0	1E+2	4E-8	1E-10	0	0
32	Ge-69	D: see Ge-66	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
32	Ge-69	W: see Ge-66	0	8E+3	3E-6	1E-8	0	0
32	Ge-71	D: see Ge-66	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
32	Ge-71	W: see Ge-66	0	4E+4	2E-5	6E-8	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
32	Ge-75 ²	D: see Ge-66	4E+4 St. wall (7E+4)	8E+4 0	3E-5 0	1E-7 0	0 9E-4	0 9E-3
32	Ge-75 ²	W: see Ge-66	0	8E+4	4E-5	1E-7	0	0
32	Ge-77	D: see Ge-66	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
32	Ge-77	W: see Ge-66	0	6E+3	2E-6	8E-9	0	0
32	Ge-78 ²	D: see Ge-66	2E+4 St. Wall (2E+4)	2E+4 0	9E-6 0	3E-8 0	0 3E-4	0 3E-3
32	Ge-78 ²	W: see Ge-66	0	2E+4	9E-6	3E-8	0	0
33	As-69 ²	W: all compounds	3E+4 St. Wall (4E.04)	1E+5 0	5E-5 0	2E-7 0	0 6E-4	0 6E-3
33	As-70 ²	W: all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33	As-71	W: all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33	As-72	W: all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33	As-73	W: all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33	As-74	W: all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33	As-76	W: all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33	As-77	W: all compounds	4E+3 LLI wall (5E+3)	5E+3 0	2E-6 0	7E-9 0	0 6E-5	0 6E-4
33	As-78 ²	W: all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
34	Se-70 ²	D: all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
34	Se-70 ²	W: oxides, carbides, hydroxides, and elemental Se	1E+4	4E+4	2E-5	6E-8	0	0
34	Se-73m ²	D: see Se-70	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
34	Se-73m ²	W: see Se-70	3E+4	1E+5	6E-5	2E-7	0	0
34	Se-73	D: see Se-70	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
34	Se-73	W: see Se-70	0	2E+4	7E-6	2E-8	0	0
34	Se-75	D: see Se-70	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
34	Se-75	W: see Se-70	0	6E+2	3E-7	8E-10	0	0
34	Se-79	D: see Se-70	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
34	Se-79	W: see Se-70	0	6E+2	2E-7	8E-10	0	0
34	Se-81m ²	D: see Se-70	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
34	Se-81m ²	W: see Se-70	2E+4	7E+4	3E-5	1E-7	0	0
34	Se-81 ²	D: see Se-70	6E+4 St. wall (8E+4)	2E+5 0	9E-5 0	3E-7 0	0 1E-3	0 1E-2
34	Se-81 ²	W: see Se-70	0	2E+5	1E-4	3E-7	0	0
34	Se-83 ²	D: see Se-70	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
34	Se-83 ²	W: see Se-70	3E+4	1E+5	5E-5	2E-7	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
35	Br-74m ²	D: bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4 St. Wall (2E+4)	4E+4 0	2E-5 0	5E-8 0	0 3E-4	0 3E-3
35	Br-74m ²	W: bromides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	0	4E+4	2E-5	6E-8	0	0
35	Br-74 ²	D: see Br-74m	2E+4 St. wall (4E+4)	7E+4 0	3E-5 0	1E-7 0	0 5E-4	0 5E-3
35	Br-74 ²	W: see Br-74m	0	8E+4	4E-5	1E-7	0	0
35	Br-75 ²	D: see Br-74m	3E+4 St. wall (4E+4)	5E+4 0	2E-5 0	7E-8 0	0 5E-4	0 5E-3
35	Br-75 ²	W: see Br-74m	0	5E+4	2E-5	7E-8	0	0
35	Br-76	D: see Br-74m	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
35	Br-76	W: see Br-74m	0	4E+3	2E-6	6E-9	0	0
35	Br-77	D: see Br-74m	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
35	Br-77	W: see Br-74m	0	2E+4	8E-6	3E-8	0	0
35	Br-80m	D: see Br-74m	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
35	Br-80m	W: see Br-74m	0	1E+4	6E-6	2E-8	0	0
35	Br-80 ²	D: see Br-74m	5E+4 St. wall (9E+4)	2E+5 0	8E-5 0	3E-7 0	0 1E-3	0 1E-2
35	Br-80 ²	W: see Br-74m	0	2E+5	9E-5	3E-7	0	0
35	Br-82	D: see Br-74m	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
35	Br-82	W: see Br-74m	0	4E+3	2E-6	5E-9	0	0
35	Br-83	D: see Br-74m	5E+4 St. wall (7E+4)	6E+4 0	3E-5 0	9E-8 0	0 9E-4	0 9E-3
35	Br-83	W: see Br-74m	0	6E+4	3E-5	9E-8	0	0
35	Br-84 ²	D: see Br-74m	2E+4 St. wall (3E+4)	6E+4 0	2E-5 0	8E-8 0	0 4E-4	0 4E-3
35	Br-84 ²	W: see Br-74m	0	6E+4	3E-5	9E-8	0	0
36	Kr-74 ²	Submersion ¹	0	0	3E-6	1E-8	0	0
36	Kr-76	Submersion ¹	0	0	9E-6	4E-8	0	0
36	Kr-77 ²	Submersion ¹	0	0	4E-6	2E-8	0	0
36	Kr-79	Submersion ¹	0	0	2E-5	7E-8	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
	Kr-81	Submersion ¹	0	0	7E-4	3E-6	0	0
36	Kr-83m ²	Submersion ¹	0	0	1E-2	5E-5	0	0
36	Kr-85m	Submersion ¹	0	0	2E-5	1E-7	0	0
36	Kr-85	Submersion ¹	0	0	1E-4	7E-7	0	0
36	Kr-87	Submersion ¹	0	0	5E-6	2E-8	0	0
36	Kr-88	Submersion ¹	0	0	2E-6	9E-9	0	0
37	Rb-79 ²	D: all compounds	4E+4 St. wall (6E+4)	1E+5 0	5E-5 0	2E-7 0	0 8E-4	0 8E-3
37	Rb-81m ²	D: all compounds	2E+5 St. wall (3E+5)	3E+5 0	1E-4 0	5E-7 0	0 4E-3	0 4E-2
37	Rb-81	D: all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rb-82m	D: all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rb-83	D: all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37	Rb-84	D: all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rb-86	D: all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rb-87	D: all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37	Rb-88 ²	D: all compounds	2E+4 St. wall (3E+4)	6E+4 0	3E-5 0	9E-8 0	0 4E-4	0 4E-3
37	Rb-89 ²	D: all compounds	4E+4 St. wall (6E+4)	1E+5 0	6E-5 0	2E-7 0	0 9E-4	0 9E-3
38	Sr-80 ²	D: all soluble compounds except SrTiO	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
38	Sr-80 ²	Y: all insoluble compounds and SrTiO	0	1E+4	5E-6	2E-8	0	0
38	Sr-81 ²	D: see Sr-80	3E+4	8E+4	3E-5		3E-4	3E-3
38	Sr-81 ²	Y: see Sr-80	2E+4	8E+4	3E-5		0	0
38	Sr-82	D: see Sr-80	3E+2 LLI wall (2E+2)	4E+2 0	2E-7 0	6E-10 0	0 3E-6	0 3E-5
38	Sr-82	Y: see Sr-80	2E+2	9E+1	4E-8	1E-8	0	0
38	Sr-83	D: see Sr-80	3E+3	7E+3	3E-6	5E-9	3E-5	3E-4
38	Sr-83	Y: see Sr-80	2E+3	4E+3	1E-6	5E-9	0	0
38	Sr-85m ²	D: see Sr-80	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
38	Sr-85m ²	Y: see Sr-80	0	8E+5	4E-4	1E-6	0	0
38	Sr-85	D: see Sr-80	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
38	Sr-85	Y: see Sr-80	0	2E+3	6E-7	2E-9	0	0
38	Sr-87m	D: see Sr-80	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
38	Sr-87m	Y: see Sr-80	4E+4	2E+5	6E-5	2E-7	0	0
38	Sr-89	D: see Sr-80	6E+2 LLI wall	8E+2	4E-7	1E-9	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
			(6E+2)	0	0	0	8E-6	5E-5
38	Sr-89	Y: see Sr-80	5E+2	1E+2	6E-8	2E-10	0	0
38	Sr-90	D: see Sr-80	3E+1 Bone surf (4E+1)	2E+1 Bone Surf (2E+1)	8E-9 0	0 3E-11	0 5E-7	0 5E-6
38	Sr-90	Y: see Sr-80	0	4E+0	2E-9	6E-12	0	0
38	Sr-91	D: see Sr-80	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
38	Sr-91	Y: see Sr-80	0	4E+3	1E-6	5E-9	0	0
38	Sr-92	D: see Sr-80	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
38	Sr-92	Y: see Sr-80	0	7E+3	3E-6	9E-9	0	0
39	Y-86m ²	W: all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
39	Y-86m ²	Y: oxides and hydroxides	0	5E+4	2E-5	8E-8	0	0
39	Y-86	W: see Y-86m	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
39	Y-86	Y: see Y-86m	0	3E+3	1E-6	5E-9	0	0
39	Y-87	W: see Y-86m	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
39	Y-87	Y: see Y-86m	0	3E+3	1E-6	5E-9	0	0
39	Y-88	W: see Y-86m	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
39	Y-88	Y: see Y-86m	0	2E+2	1E-7	3E-10	0	0
39	Y-90m	W: see Y-86m	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
39	Y-90m	Y: see Y-86m	0	1E+4	5E-6	2E-8	0	0
39	Y-90	W: see Y-86m	4E+2 LLI wall (5E+2)	7E+2 0	3E-7 0	9E-10 0	0 7E-6	0 7E-5
39	Y-90	Y: see Y-86m	0	6E+2	3E-7	9E-10	0	0
39	Y-91m ²	W: see Y-86m	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
39	Y-91m ²	Y: see Y-86m	0	2E+5	7E-5	2E-7	0	0
39	Y-91	W: see Y-86m	5E+2 LLI wall (6E+2)	2E+2 0	7E-8 0	2E-10 0	0 8E-6	0 8E-5
39	Y-91	Y: see Y-86m	0	1E+2	5E-8	2E-10	0	0
39	Y-92	W: see Y-86m	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
39	Y-92	Y: see Y-86m	0	8E+3	3E-6	1E-8	0	0
39	Y-93	W: see Y-86m	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
39	Y-93	Y: see Y-86m	0	2E+3	1E-6	3E-9	0	0
39	Y-94 ²	W: see Y-86m	2E+4 St. wall (3E+4)	8E+4 0	3E-5 0	1E-7 0	0 4E-4	0 4E-3
39	Y-94 ²	Y: see Y-86m	0	8E+4	3E-5	1E-7	0	0
39	Y-95 ²	W: see Y-86m	4E+4 St. wall (5E+4)	2E+5 0	6E-6 0	2E-7 0	0 7E-4	0 7E-3
39	Y-95 ²	Y: see Y-86m	0	1E+5	6E-5	2E-7	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
40	Zr-86	D: all compounds except those given for W, Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
40	Zr-86	W: oxides, halides, nitrates, and hydroxides	0	3E+3	1E-6	4E-9	0	0
40	Zr-86	Y: carbide	0	2E+3	1E-6	3E-9	0	0
40	Zr-88	D: see Zr-86	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
40	Zr-88	W: see Zr-86	0	5E+2	2E-7	7E-10	0	0
40	Zr-88	Y: see Zr-86	0	3E+2	1E-7	4E-10	0	0
40	Zr-89	D: see Zr-86	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
40	Zr-89	W: see Zr-86	0	2E+3	1E-6	5E-9	0	0
40	Zr-89	Y: see Zr-86	0	2E+3	1E-6	3E-9	0	0
40	Zr-93	D: see Zr-86	1E+3 Bone surf (3E+3)	6E+0 Bone Surf (2E+1)	3E-9 0	0 2E-11	0 4E-5	0 4E-4
40	Zr-93	W: see Zr-86	0	2E+1 Bone Surf (6E+1)	1E-8 0	0 9E-11	0 0	0 0
40	Zr-93	Y: see Zr-86	0	6E+1 Bone Surf (7E+1)	2E-8 0	0 9E-11	0 0	0 0
40	Zr-95	D: see Zr-86	1E+3 0	1E+2 Bone Surf (3E+2)	5E-8 0	0 4E-10	2E-5 0	2E-4 0
40	Zr-95	W: see Zr-86	0	4E+2	2E-7	5E-10	0	0
40	Zr-95	Y: see Zr-86	0	3E+2	1E-7	4E-10	0	0
40	Zr-97	D: see Zr-86	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
40	Zr-97	W: see Zr-86	0	1E+3	6E-7	2E-9	0	0
40	Zr-97	Y: see Zr-86	0	1E+3	5E-7	2E-9	0	0
41	Nb-88 ²	W: all compounds except those given for Y	5E+4 St. wall (7E+4)	2E+5 0	9E-5 0	3E-7 0	0 1E-3	0 1E-2
41	Nb-88 ²	Y: oxides and hydroxides	0	2E+5	9E-5	3E-7	0	0
41	Nb-89 ² (66 m)	W: see Nb-88	1E+4	4E+4	2E-5	6E-8	1E-3	1E-2
41	Nb-89 ² (66 m)	Y: see Nb-88	0	4E+4	2E-5	5E-8	0	0
41	Nb-89 (122 m)	W: see Nb-88	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
41	Nb-89 (122 m)	Y: see Nb-88	0	2E+4	6E-6	2E-8	0	0
41	Nb-90	W: see Nb-88	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
41	Nb-90	Y: see Nb-88	0	2E+3	1E-6	3E-9	0	0
41	Nb-93m	W: see Nb-88	9E+3 LLI wall (1E+1)	2E+3 0	8E-7 0	3E-9 0	0 2E-4	0 2E-3
41	Nb-93m	Y: see Nb-88	0	2E+2	7E-8	2E-10	0	0
41	Nb-94	W: see Nb-88	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
41	Nb-94	Y: see Nb-88	0	2E+1	6E-9	2E-11	0	0
41	Nb-95m	W: see Nb-88	2E+3 LLI wall (2E+3)	3E+3 0	1E-6 0	4E-9 0	0 3E-5	0 3E-4
41	Nb-95m	Y: see Nb-88	0	2E+3	9E-7	3E-9	0	0
41	Nb-95	W: see Nb-88	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
41	Nb-95	Y: see Nb-88	0	1E+3	5E-7	2E-9	0	0
41	Nb-96	W: see Nb-88	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
41	Nb-96	Y: see Nb-88	0	2E+3	1E-6	3E-9	0	0
41	Nb-97 ²	W: see Nb-88	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
41	Nb-97 ²	Y: see Nb-88	0	7E+4	3E-5	1E-7	0	0
41	Nb-98 ²	W: see Nb-88	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
41	Nb-98 ²	Y: see Nb-88	0	5E+4	2E-5	7E-8	0	0
42	Mo-90	D: all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
42	Mo-90	Y: oxides, MoS, and hydroxides	2E+3	5E+3	2E-6	6E-9	0	0
42	Mo-93m	D: see Mo-90	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
42	Mo-93m	Y: see Mo-90	4E+3	1E+4	6E-6	2E-8	0	0
42	Mo-93	D: see Mo-90	4E+3	5E+3	2E-6	2E-9	5E-5	5E-4
424 2	Mo-93	Y: see Mo-90	2E+4	2E+2	8E-8	2E-10	0	0
42	Mo-99	D: see Mo-90	2E+3 LLI wall (1E+3)	3E+3 0	1E-6 0	4E-9 0	0 2E-5	0 2E-4
42	Mo-99	Y: see Mo-90	1E+3	1E+3	6E-7	2E-9	0	0
42	Mo-101 ²	D: see Mo-90	4E+4 St. wall (5E+4)	1E+5 0	6E-5 0	2E-7 0	0 7E-4	0 7E-3
42	Mo-101 ²	Y: see Mo-90	0	1E+5	6E-5	2E-7	0	0
43	Tc-93m ²	D: all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
43	Tc-93m ²	W: oxides, halides, hydroxides, and nitrates	0	3E+5	1E-4	4E-7	0	0
43	Tc-93	D: see Tc-93m	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
43	Tc-93	W: see Tc-93m	0	1E+5	4E-5	1E-7	0	0
43	Tc-94m ²	D: see Tc-93m	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
43	Tc-94m ²	W: see Tc-93m	0	6E+4	2E-5	8E-8	0	0
43	Tc-94	D: see Tc-93m	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
43	Tc-94	W: see Tc-93m	0	2E+4	1E-5	3E-8	0	0
43	Tc-95m	D: see Tc-93m	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
43	Tc-95m	W: see Tc-93m	0	2E+3	8E-7	3E-9	0	0
43	Tc-95	D: see Tc-93m	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
43	Tc-95	W: see Tc-93m	0	2E+4	8E-6	3E-8	0	0
43	Tc-96m ²	D: see Tc-93m	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
43	Tc-96m ²	W: see Tc-93m	0	2E+5	1E-4	3E-7	0	0
43	Tc-96	D: see Tc-93m	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
43	Tc-96	W: see Tc-93m	0	2E+3	9E-7	5E-9	0	0
43	Tc-97m	D: see Tc-93m	5E+3	7E+3 St wall (7E+3)	3E-6	0	6E-5	6E-4
			0		0	1E-8	0	0
43	Tc-97m	W: see Tc-93m	0	1E+3	5E-7	2E-9	0	0
43	Tc-97	D: see Tc-93m	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
43	Tc-97	W: see Tc-93m	0	6E+3	2E-6	8E-9	0	0
43	Tc-98	D: see Tc-93m	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
43	Tc-98	W: see Tc-93m	0	3E+2	1E-7	4E-10	0	0
43	Tc-99m	D: see Tc-93m	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
43	Tc-99m	W: see Tc-93m	0	2E+5	1E-4	3E-7	0	0
43	Tc-99	D: see Tc-93m	4E+3	5E+3 St wall (6E+3)	2E-6	0	6E-5	6E-4
			0		0	8E-9	0	0
43	Tc-99	W: see Tc-93m	0	7E+2	3E-7	9E-10	0	0
43	Tc-101 ²	D: see Tc-93m	9E+4 St. wall (1E+5)	3E+5	1E-4	5E-7	0	0
			0	0	0	0	2E-3	2E-2
43	Tc-101 ²	W: see Tc-93m	0	4E+5	2E-4	5E-7	0	0
43	Tc-104 ²	D: see Tc-93m	2E+4 St. wall (3E+4)	7E+4	3E-5	1E-7	0	0
			0	0	0	0	4E-4	4E-3
43	Tc-104 ²	W: see Tc-93m	0	9E+4	4E-5	1E-7	0	0
44	Ru-94 ²	D: all compounds except those given for W, Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
44	Ru-94 ²	W: halides	0	6E+4	3E-5	9E-8	0	0
44	Ru-94 ²	Y: oxides and hydroxides	0	6E+4	2E-5	8E-8	0	0
44	Ru-97	D: see Ru-94	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
44	Ru-97	W: see Ru-94	0	1E+4	5E-6	2E-8	0	0
44	Ru-97	Y: see Ru-94	0	1E+4	5E-6	2E-8	0	0
44	Ru-103	D: see Ru-94	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
44	Ru-103	W: see Ru-94	0	1E+3	4E-7	1E-9	0	0
44	Ru-103	Y: see Ru-94	0	6E+2	3E-7	9E-10	0	0
44	Ru-105	D: see Ru-94	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
44	Ru-105	W: see Ru-94	0	1E+4	6E-6	2E-8	0	0
44	Ru-105	Y: see Ru-94	0	1E+4	5E-6	2E-8	0	0
44	Ru-106	D: see Ru-94	2E+2 LLI wall (2E+2)	9E+1	4E-8	1E-10	0	0
			0	0	0	0	3E-6	3E-5
44	Ru-106	W: see Ru-94	0	5E+1	2E-8	8E-11	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
44	Ru-106	Y: see Ru-94	0	1E+1	5E-9	2E-11	0	0
44	Rh-99m	D: all compounds except those given for W, Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
45	Rh-99m	W: halides	0	8E+4	3E-5	1E-7	0	0
	Rh-99m	Y: oxides and hydroxides	0	7E+4	3E-5	9E-8	0	0
45	Rh-99	D: see Rh-99m	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
45	Rh-99	W: see Rh-99m	0	2E+3	9E-7	3E-9	0	0
45	Rh-99	Y: see Rh-99m	0	2E+3	8E-7	3E-9	0	0
45	Rh-100	D: see Rh-99m	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
45	Rh-100	W: see Rh-99m	0	4E+3	2E-6	6E-9	0	0
45	Rh-100	Y: see Rh-99m	0	4E+3	2E-6	5E-9	0	0
45	Rh-101m	D: see Rh-99m	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
45	Rh-101m	W: see Rh-99m	0	8E+3	4E-6	1E-8	0	0
45	Rh-101m	Y: see Rh-99m	0	8E+3	3E-6	1E-8	0	0
45	Rh-101	D: see Rh-99m	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
45	Rh-101	W: see Rh-99m	0	8E+2	3E-7	1E-9	0	0
45	Rh-101	Y: see Rh-99m	0	2E+2	6E-8	2E-10	0	0
45	Rh-102m	D: see Rh-99m	1E+3 LLI wall (1E+3)	5E+2 0	2E-7 0	7E-10 0	0 2E-5	0 2E-4
45	Rh-102m	W: see Rh-99m	0	4E+2	2E-7	5E-10	0	0
45	Rh-102m	Y: see Rh-99m	0	1E+2	5E-8	5E-10	0	0
45	Rh-102	D: see Rh-99m	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
45	Rh-102	W: see Rh-99m	0	2E+2	7E-8	2E-10	0	0
45	Rh-102	Y: see Rh-99m	0	6E+1	2E-8	8E-11	0	0
45	Rh-103m ²	D: see Rh-99m	4E+5	1E+6	5E-4	2E-6	6E-6	6E-5
45	Rh-103m ²	W: see Rh-99m	0	1E+6	5E-4	2E-6	0	0
45	Rh-103m ²	Y: see Rh-99m	0	1E+6	5E-4	2E-6	0	0
45	Rh-105	D: see Rh-99m	4E+3 LLI wall (4E+3)	1E+4 0	5E-6 0	2E-8 0	0 5E-5	0 5E-4
45	Rh-105	W: see Rh-99m	0	6E+3	3E-6	9E-9	0	0
45	Rh-105	Y: see Rh-99m	0	6E+3	2E-6	8E-9	0	0
45	Rh-106m	D: see Rh-99m	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
45	Rh-106m	W: see Rh-99m	0	4E+4	2E-5	5E-8	0	0
45	Rh-106m	Y: see Rh-99m	0	4E+4	1E-5	5E-8	0	0
45	Rh-107 ²	D: see Rh-99m	7E+4 St. wall (9E+4)	2E+5 0	1E-4 0	3E-7 0	0 1E-3	0 1E-2
45	Rh-107 ²	W: see Rh-99m	0	3E+5	1E-4	4E-7	0	0
45	Rh-107 ²	Y: see Rh-99m	0	3E+5	1E-4	3E-7	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
46	Pd-100	D: all compounds except those given for W, Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
	Pd-100	W: nitrates	0	1E+3	5E-7	2E-9	0	0
46	Pd-100	Y: oxides and hydroxides	0	1E+3	6E-7	2E-9	0	0
46	Pd-101	D: see Pd-100	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
46	Pd-101	W: see Pd-100	0	3E+4	1E-5	5E-8	0	0
46	Pd-101	Y: see Pd-100	0	3E+4	1E-5	4E-8	0	0
46	Pd-103	D: see Pd-100	6E+3 LLI wall (7E+3)	6E+3 0	3E-6 0	9E-9 0	0 1E-4	0 1E-3
46	Pd-103	W: see Pd-100	0	4E+3	2E-6	6E-9	0	0
46	Pd-103	Y: see Pd-100	0	4E+3	1E-6	5E-9	0	0
46	Pd-107	D: see Pd-100	3E+4 LLI wall (4E+4)	2E+4 Kidneys (2E+4)	9E-6 0	0 3E-8	0 5E-4	0 5E-3
46	Pd-107	W: see Pd-100	0	7E+3	3E-6	1E-8	0	0
46	Pd-107	Y: see Pd-100	0	4E+2	2E-7	6E-10	0	0
46	Pd-109	D: see Pd-100	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
46	Pd-109	W: see Pd-100	0	5E+3	2E-6	8E-9	0	0
46	Pd-109	Y: see Pd-100	0	5E+3	2E-6	6E-9	0	0
47	Ag-102 ²	D: all compounds except those given for W, Y	5E+4 St. wall (6E+4)	2E+5 0	8E-5 0	2E-7 0	0 9E-4	0 9E-3
	Ag-102 ²²²	W: nitrates and sulfides	0	2E+5	9E-5	3E-7	0	0
47	Ag-102 ²	Y: oxides and hydroxides	0	2E+5	8E-5	3E-7	0	0
47	Ag-103 ²	D: see Ag-102	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
47	Ag-103 ²	W: see Ag-102	0	1E+5	5E-5	2E-7	0	0
47	Ag-103 ²	Y: see Ag-102	0	1E+5	5E-5	2E-7	0	0
47	Ag-104m ²	D: see Ag-102	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
47	Ag-104m ²	W: see Ag-102	0	1E+5	5E-5	2E-7	0	0
47	Ag-104m ²	Y: see Ag-102	0	1E+5	5E-5	2E-7	0	0
47	Ag-104 ²	D: see Ag-102	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
47	Ag-104 ²	W: see Ag-102	0	1E+5	6E-5	2E-7	0	0
47	Ag-104 ²	Y: see Ag-102	0	1E+5	6E-5	2E-7	0	0
47	Ag-105	D: see Ag-102	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
47	Ag-105	W: see Ag-102	0	2E+3	7E-7	2E-9	0	0
47	Ag-105	Y: see Ag-102	0	2E+3	7E-7	2E-9	0	0
47	Ag-106m	D: see Ag-102	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
47	Ag-106m	W: see Ag-102	0	9E+2	4E-7	1E-9	0	0
47	Ag-106m	Y: see Ag-102	0	9E+2	4E-7	1E-9	0	0
47	Ag-106 ²	D: see Ag-102	6E+4	2E+5	8E-5	3E-7	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
			St. wall (6E+4)	0	0	0	9E-4	9E-3
47	Ag-106 ²	W: see Ag-102	0	2E+5	9E-5	3E-7	0	0
47	Ag-106 ²	Y: see Ag-102	0	2E+5	8E-5	3E-7	0	0
47	Ag-108m	D: see Ag-102	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
47	Ag-108m	W: see Ag-102	0	3E+2	1E-7	4E-10	0	0
47	Ag-108m	Y: see Ag-102	0	2E+1	1E-8	3E-11	0	0
47	Ag-110m	D: see Ag-102	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
47	Ag-110m	W: see Ag-102	0	2E+2	8E-8	3E-10	0	0
47	Ag-110m	Y: see Ag-102	0	9E+1	4E-8	1E-10	0	0
47	Ag-111	D: see Ag-102	9E+2 LLI wall (1E+3)	2E+3 Liver (2E+3)	6E-7	0	0	0
47	Ag-111	W: see Ag-102	0	9E+2	4E-7	1E-9	0	0
47	Ag-111	Y: see Ag-102	0	9E+2	4E-7	1E-9	0	0
47	Ag-112	D: see Ag-102	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
47	Ag-112	W: see Ag-102	0	1E+4	4E-6	1E-8	0	0
47	Ag-112	Y: see Ag-102	0	9E+3	4E-6	1E-8	0	0
47	Ag-115 ²	D: see Ag-102	3E+4 St. wall (3E+4)	9E+4	4E-5	1E-7	0	0
47	Ag-115 ²	W: see Ag-102	0	9E+4	43E-5	1E-7	0	0
47	Ag-115 ²	Y: see Ag-102	0	8E+4	3E-5	1E-7	0	0
48	Cd-104 ²	D: all compounds except those given for W, Y	2E+4	7E+4	5E-5	9E-8	3E-4	3E-3
48	Cd-104 ²	W: sulfides, halides, and nitrates	0	1E+5	5E-5	2E-7	0	0
48	Cd-104 ²	Y: oxides and hydroxides	0	1E+5	5E-5	2E-7	0	0
48	Cd-107	D: see Cd-104	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
48	Cd-107	W: see Cd-104	0	6E+4	2E-5	8E-8	0	0
48	Cd-107	Y: see Cd-104	0	5E+4	2E-5	7E-8	0	0
48	Cd-109	D: see Cd-104	2E+2 Kidneys (4E+2)	5E+1 Kidney (5E+1)	1E-8	0	0	0
48	Cd-109	W: see Cd-104	0	1E+2 Kidney (1E+2)	5E-8	0	0	0
48	Cd-109	Y: see Cd-104	0	1E+2	5E-8	2E-10	0	0
48	Cd-113m	D: see Cd-104	2E+1 Kidneys (4E+1)	2E+0 Kidney (4E+0)	1E-9	0	0	0
48	Cd-113m	W: see Cd-104	0	8E+0 Kidney (1E+0)	4E-9	0	0	0
			0		0	2E-11	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
48	Cd-113m	Y: see Cd-104	0	1E+1	5E-9	2E-11	0	0
48	Cd-113	D: see Cd-104	2E+1 Kidneys (3E+1)	2E+0 Kidney (3E+0)	9E-10	0	0	0
48	Cd-113	W: see Cd-104	0	8E+0 Kidney (8E+0)	3E-9	0	0	0
48	Cd-113	Y: see Cd-104	0	1E+1	6E-9	2E-11	0	0
48	Cd-115m	D: see Cd-104	3E+2	5E+1 Kidney (8E+1)	2E-8	0	4E-6	4E-5
48	Cd-115m	W: see Cd-104	0	1E+2	5E-8	2E-10	0	0
48	Cd-115m	Y: see Cd-104	0	1E+2	6E-8	2E-10	0	0
48	Cd-115	D: see Cd-104	9E+2 LLI Wall (1E+3)	1E+3	6E-7	2E-9	0	0
48	Cd-115	W: see Cd-104	0	1E+3	5E-7	2E-9	0	0
48	Cd-115	Y: see Cd-104	0	1E+3	6E-7	2E-9	0	0
48	Cd-117m	D: see Cd-104	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
48	Cd-117m	W: see Cd-104	0	2E+4	7E-6	2E-8	0	0
48	Cd-117m	Y: see Cd-104	0	1E+4	6E-6	2E-8	0	0
48	Cd-117	D: see Cd-104	5E+3	1E+4	5E-6	2E-8	3E-4	3E-3
48	Cd-117	W: see Cd-104	0	2E+4	7E-6	2E-8	0	0
48	Cd-117	Y: see Cd-104	0	1E+4	6E-6	2E-8	0	0
49	In-109	D: all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
49	In-109	W: oxides, halides, hydroxides, and nitrates	0	6E+4	3E-5	9E-8	0	0
49	In-110 ² (69.1 m)	D: see In-109	2E+4	4E+4	2E-5	6E-8	0	0
49	In-110 ² (69.1 m)	W: see In-109	0	6E+4	2E-5	8E-8	7E-3	7E-4
49	In-110 (4.9 h)	D: see In-109	5E+3	2E+4	7E-6	2E-8	0	0
49	In-110 (4.9 h)	W: see In-109	0	2E+4	8E-6	3E-8	0	0
49	In-111	D: see In-109	4E+3	6E+3	3E-6	9E-9	6E-3	6E-4
49	In-111	W: see In-109	0	6E+3	3E-6	9E-7	0	0
49	In-112 ²	D: see In-109	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
49	In-112 ²	W: see In-109	0	7E+5	3E-4	1E-6	0	0
49	In-113m ²	D: see In-109	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
49	In-113m ²	W: see In-109	0	2E+5	8E-5	3E-7	0	0
49	In-114m	D: see In-109	3E+2 LLI Wall (4E+2)	6E+1	3E-8	9E-11	0	0
49	In-114m	W: see In-109	0	1E+2	4E-8	1E-10	0	0
49	In-115m	D: see In-109	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
49	In-115m	W: see In-109	0	5E+4	2E-5	7E-8	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
49	In-115	D: see In-109	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
49	In-115	W: see In-109	0	5E+0	2E-9	8E-12	0	0
49	In-116m ²	D: see In-109	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
49	In-116m ²	W: see In-109	0	1E+5	3E-5	2E-7	0	0
49	In-117m ²	D: see In-109	1E+4	3E+4	1E-5	5E-8	2E-4	3E-3
49	In-117m ²	W: see In-109	0	4E+4	2E-5	6E-8	0	0
49	In-117 ²	D: see In-109	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
49	In-117m ²	W: see In-109	0	2E+5	9E-5	3E-7	0	0
494 9	In-119m ²	D: see In-109	4E+4 St Wall (5E+4)	1E+5 0	5E-5 0	2E-7 0	0 7E-4	0 7E-3
49	In-119m ²	W: see In-109	0	1E+5	6E-5	2E-7	0	0
50	Sn-110	D: all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
	Sn-110	W: sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	0	1E+4	5E-6	2E-8	0	0
50	Sn-111 ²	D: see Sn-110	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
50	Sn-111 ²	W: see Sn-110	0	3E+5	1E-4	4E-7	0	0
50	Sn-113	D: see Sn-110	2E+3 LLI Wall (2E+3)	1E+3 0	5E-7 0	2E-9 0	0 3E-5	0 3E-4
50	Sn-113	W: see Sn-110	0	5E+2	2E-7	8E-10	0	0
50	Sn-117m	D: see Sn-110	2E+3 LLI Wall (2E+)	1E+3 Bone surf (2E+3)	5E-7 0	0 3E-9	0 3E-5	0 3E-4
50	Sn-117m	W: see Sn-110	0	1E+3	6E-7	2E-9	0	0
50	Sn-119m	D: see Sn-110	3E+3 LLI Wall (4E+3)	2E+3 0	1E-6 0	3E-9 0	0 6E-5	0 6E-4
50	Sn-119m	W: see Sn-110	0	1E+3	4E-7	1E-9	0	0
50	Sn-121m	D: see Sn-110	3E+3 LLI Wall (4E+3)	9E+2 0	4E-7 0	1E-9 0	0 5E-5	0 5E-4
50	Sn-121m	W: see Sn-110	0	5E+2	2E-7	8E-10	0	0
50	Sn-121	D: see Sn-110	6E+3 LLI Wall (6E+3)	2E+4 0	6E-6 0	2E-8 0	0 8E-5	0 8E-4
50	Sn-121	W: see Sn-110	0	1E+4	5E-6	2E-8	0	0
50	Sn-123m ²	D: see Sn-110	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
50	Sn-123m ²	W: see Sn-110	0	1E+5	6E-5	2E-7	0	0
50	Sn-123	D: see Sn-110	5E+2 LLI Wall (6E+2)	6E+2 0	3E-7 0	9E-10 0	0 9E-6	0 9E-5

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μ Ci)	COL. 2 Inhalation ALI (μ Ci)	COL. 3 Inhalation DAC (μ Ci/ml)	COL. 1 Air (μ Ci/ml)	COL. 2 Water (μ Ci/ml)	Monthly Average Concentration (μ Ci/ml)
50	Sn-123	W: see Sn-110	0	2E+2	7E-8	2E-10	0	0
50	Sn-125	D: see Sn-110	4E+2 LLI Wall (5E+2)	9E+2 0	4E-7 0	1E-9 0	0 6E-6	0 6E-5
50	Sn-125	W: see Sn-110	0	4E+2	1E-7	5E-10	0	0
50	Sn-126	D: see Sn-110	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
50	Sn-126	W: see Sn-110	0	7E+1	3E-8	9E-11	0	0
50	Sn-127	D: see Sn-110	7E+3	2E+4	8E-6	3E-8	9E-4	9E-4
50	Sn-127	W: see Sn-110	0	2E+4	8E-6	3E-8	0	0
50	Sn-128 ²	D: see Sn-110	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
50	Sn-128 ²	W: see Sn-110	0	4E+4	1E-5	5E-8	0	0
51	Sb-115 ²	D: all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
51	Sb-115 ²	W: oxides, halides, sulfides, sulfates, nitrates, and hydroxides,	0	3E+5	1E-4	4E-7	0	0
51	Sb-116m ²	D: see Sb-115	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
51	Sb-116m ²	W: see Sb-115	0	1E+5	6E-5	2E-7	0	0
51	Sb-116 ²	D: see Sb-115	7E+4 St Wall (9E+4)	3E+5 0	1E-4 0	4E-7 0	0 3E-4	0 3E-3
51	Sb-116 ²	W: see Sb-115	0	3E+5	1E-4	5E-7	0	0
51	Sb-117	D: see Sb-115	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
51	Sb-117	W: see Sb-115	0	3E+5	1E-4	4E-7	0	0
51	Sb-118m ²	D: see Sb-115	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
51	Sb-118m ²	W: see Sb-115	5E+3	2E+4	9E-6	3E-8	0	0
51	Sb-119	D: see Sb-115	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
51	Sb-119	W: see Sb-115	2E+4	3E+4	1E-5	4E-8	0	0
51	Sb-120 ² (16 m)	D: see Sb-115	1E+5 St Wall (2E+5)	4E+5 0	2E-4 0	6E-7 0	0 2E-3	0 2E-2
51	Sb-120 ² (16 m)	W: see Sb-115	0	5E+5	2E-4	7E-7	0	0
51	Sb-120 (5.76 d)	D: see Sb-115	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
51	Sb-120 (5.76 d)	W: see Sb-115	9E+2	1E+3	5E-7	2E-9	0	0
51	Sb-122	D: see Sb-115	8E+2 LLI Wall (8E+2)	2E+3 0	1E-6 0	3E-9 0	0 1E-5	0 1E-4
51	Sb-122	W: see Sb-115	7E+2	1E+3	4E-7	2E-9	0	0
51	Sb-124m ²	D: see Sb-115	3E+5	8E+5	2E-4	1E-6	3E-3	2E-2
51	Sb-124m ²	W: see Sb-115	2E+5	6E+5	4E-4	8E-7	0	0
51	Sb-124	D: see Sb-115	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
51	Sb-124	W: see Sb-115	5E+2	2E+2	1E-7	3E-10	0	0
51	Sb-125	D: see Sb-115	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
51	Sb-125	W: see Sb-115	0	5E+2	2E-7	7E-10	0	0
51	Sb-126m ²	D: see Sb-115	5E+4 St Wall (7E+4)	2E+5 0	8E-5 0	3E-7 0	0 9E-4	0 9E-3
51	Sb-126m ²	W: see Sb-115	0	2E+5	8E-5	3E-7	0	0
51	Sb-126	D: see Sb-115	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
51	Sb-126	W: see Sb-115	5E+2	5E+2	2E-7	7E-10	0	0
51	Sb-127	D: see Sb-115	8E+2 LLI Wall (8E+2)	2E+3 0	9E-7 0	3E-9 0	0 1E-5	0 1E-4
51	Sb-127	W: see Sb-115	7E+2	9E+2	4E-7	1E-9	0	0
51	Sb-128 ² (10.4 m)	D: see Sb-115	8E+4 St Wall (1E+5)	4E+5 0	2E-4 0	5E-7 0	0 1E-3	0 1E-2
51	Sb-128 ² (10.4 m)	W: see Sb-115	0	4E+5	2E-4	6E-7	0	0
51	Sb-128 (9.01 h)	D: see Sb-115	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
51	Sb-128 (9.01 h)	W: see Sb-115	0	3E+3	1E-6	5E-9	0	0
51	Sb-129	D: see Sb-115	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
51	Sb-129	W: see Sb-115	0	9E+3	4E-6	1E-8	0	0
51	Sb-130 ²	D: see Sb-115	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
51	Sb-130 ²	W: see Sb-115	0	8E+4	3E-5	1E-7	0	0
51	Sb-131 ²	D: see Sb-115	1E+4 Thyroid (2E+4)	2E+4 Thyroid (4E+4)	1E-5	0 6E-8	0 2E-4	0 2E-3
51	Sb-131 ²	W: see Sb-115	0 0	2E+4 Thyroid (4E+4)	1E-5 0	0 6E-8	0 0	0 0
52	Te-116	D: all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
52	Te-116	W: oxides, nitrates, and hydroxides	0	3E+4	1E-5	4E-8	0	0
52	Te-121m	D: see Te-116	5E+2 Bone Surf (7E+2)	2E+2 Bone surf (4E+2)	8E-8 0	0 5E-10	0 1E-5	0 1E-4
52	Te-121m	W: see Te-116	0	4E+2	2E-7	6E-10	0	0
52	Te-121	D: see Te-116	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
52	Te-121	W: see Te-116	0	3E+3	1E-6	4E-9	0	0
52	Te-123m	D: see Te-116	6E+2 Bone Surf (1E+3)	2E+2 Bone surf (5E+2)	9E-8 0	0 8E-10	0 1E-5	0 1E-4
52	Te-123m	W: see Te-116	0	2E+2	2E-7	8E-10	0	0
52	Te-123	D: see Te-116	5E+2 Bone Surf (1E+3)	2E+2 Bone surf (5E+2)	8E-8	0 7E-10	0 2E-5	0 2E-4
52	Te-123	W: see Te-116	0	4E+2	2E-7	0	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
			0	Bone surf (1E+3)	0	2E-9	0	0
52	Te-125m	D: see Te-116	1E+3 Bone Surf (1E+3)	4E+2 Bone surf (1E+3)	2E-7 0	0 1E-9	2E-5 0	2E-4 0
52	Te-125m	W: see Te-116	0	7E+2	3E-7	1E-9	0	0
52	Te-127m	D: see Te-116	6E+2 0	3E+2 Bone surf (4E+2)	1E-7 0	0 6E-10	9E-6 0	9E-5 0
52	Te-127m	W: see Te-116	0	3E+2	1E-7	4E-10	0	0
52	Te-127	D: see Te-116	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
52	Te-127	W: see Te-116	0	2E+4	7E-6	2E-8	0	0
52	Te-129m	D: see Te-116	5E+2	6E+2	3E-7	9E-10	7E-6	7E-6
52	Te-129m	W: see Te-116	0	2E+2	1E-7	3E-10	0	0
52	Te-129 ²	D: see Te-116	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
52	Te-129 ²	W: see Te-116	0	7E+4	3E-5	1E-7	0	0
52	Te-131m	D: see Te-116	3E+2 Thyroid (6E+2)	4E+2 Thyroid (1E+3)	2E-7 0	0 2E-9	0 8E-6	0 8E-5
52	Te-131m	W: see Te-116	0 0	4E+2 Thyroid (9E+2)	2E-7 0	0 1E-9	0 0	0 0
52	Te-131 ²	D: see Te-116	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 0	0 2E-8	0 8E-5	0 8E-4
52	Te-131 ²	W: see Te-116	0 0	5E+3 Thyroid (1E+4)	2E-6 0	0 2E-8	0 0	0 0
52	Te-132	D: see Te-116	2E+2 Thyroid (7E+2)	2E+2 Thyroid (2E+2)	9E-8 0	0 1E-9	0 9E-6	0 9E-5
52	Te-132	W: see Te-116	0 0	2E+2 Thyroid (6E+2)	9E-8 0	0 9E-10	0 0	0 0
52	Te-133m ²	D: see Te-116	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 0	0 2E-8	0 9E-3	0 9E-4
52	Te-133m ²	W: see Te-116	0 0	5E+3 Thyroid (1E+4)	2E-6 0	0 2E-8	0 0	0 0
52	Te-133 ²	D: see Te-116	1E+4 Thyroid (3E+4)	2E+4 Thyroid (6E+4)	9E-6	0 8E-8	0 4E-4	0 4E-3
52	Te-133 ²	W: see Te-116	0 0	2E+4 Thyroid (6E+4)	9E-6 0	0 8E-8	0 0	0 0
52	Te-134 ²	D: see Te-116	2E+4 Thyroid	2E+4 Thyroid	1E-5	0	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
			(2E+4)	(5E+4)		7E-8	3E-4	3E-3
52	Te-134 ²	W: see Te-116	0	2E+4	1E-5	0	0	0
			0	Thyroid (5E+4)	0	7E-8	0	0
53	I-120m ²	D: all compounds	1E+4	2E+4	9E-6	3E-8	0	0
			Thyroid (1E+4)	0	0	0	2E-4	2E-3
53	I-120 ²	D: all compounds	4E+3	9E+3	4E-6	0	0	0
			Thyroid (8E+3)	Thyroid (1E+4)	0	2E-8	1E-4	1E-3
53	I-121	D: all compounds	1E+4	2E+4	8E-6	0	0	0
			Thyroid (3E+4)	Thyroid (5E+4)	0	7E-8	4E-4	4E-3
53	I-123	D: all compounds	3E+3	6E+3	3E-6	0	0	0
			Thyroid (1E+4)	Thyroid (2E+4)	0	2E-8	1E-4	1E-3
53	I-124	D: all compounds	5E+1	8E+1	3E-8	0	0	0
			Thyroid (2E+2)	Thyroid (3E+2)	0	4E-10	2E-6	2E-5
53	I-125	D: all compounds	4E+1	6E+1	3E-8	0	0	0
			Thyroid (1E+2)	Thyroid (2E+2)	0	3E-10	2E-6	2E-5
53	I-126	D: all compounds	2E+1	4E+1	1E-8	0	0	0
			Thyroid (7E+1)	Thyroid (1E+2)	0	2E-10	1E-6	1E-5
53	I-128 ²	D: all compounds	4E+4	1E+5	5E-5	2E-7	0	0
			St Wall (6E+4)	0	0	0	8E-4	8E-3
53	I-129	D: all compounds	5E+0	9E+0	4E-9	0	0	0
			Thyroid (2E+1)	Thyroid (3E+1)	0	4E-11	2E-7	2E-6
53	I-130	D: all compounds	4E+2	7E+2	3E-7	0	0	0
			Thyroid (1E+3)	Thyroid (7E+2)	0	3E-9	2E-5	2E-4
53	I-131	D: all compounds	3E+1	5E+1	2E-8	0	0	0
			Thyroid (9E+1)	Thyroid (2E+2)	0	2E-9	1E-6	1E-5
53	I-132m ²	D: all compounds	4E+3	8E+3	4E-6	0	0	0
			Thyroid (1E+4)	Thyroid (2E+4)	0	3E-8	1E-4	1E-3
53	I-132	D: all compounds	4E+3	8E+3	3E-6	0	0	0
			Thyroid (9E+3)	Thyroid (1E+4)	0	2E-8	1E-4	1E-3
53	I-133	D: all compounds	1E+2	3E+2	1E-7	0	0	0
			Thyroid (5E+2)	Thyroid (9E+2)	0	1E-9	7E-6	7E-5
53	I-134 ²	D: all compounds	2E+4	5E+4	2E-5	6E-8	0	0
			Thyroid					

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci/ml}$)	COL. 1 Air ($\mu\text{Ci/ml}$)	COL. 2 Water ($\mu\text{Ci/ml}$)	Monthly Average Concentration ($\mu\text{Ci/ml}$)
			(3E+4)	0		0	4E-4	4E-3
53	I-135	D: all compounds	8E+2 Thyroid (3E+3)	2E+3 Thyroid (4E+3)	7E-7 0	0 6E-9	0 3E-5	0 3E-4
54	Xe-120 ²	Submersion1	0	0	1E-5	4E-8	0	0
54	Xe-121 ²	Submersion1	0	0	2E-6	1E-8	0	0
54	Xe-122	Submersion1	0	0	7E-5	3E-7	0	0
54	Xe-123	Submersion1	0	0	6E-6	3E-8	0	0
54	Xe-125	Submersion1	0	0	2E-5	7E-8	0	0
54	Xe-127	Submersion1	0	0	1E-5	6E-8	0	0
54	Xe-129m	Submersion1	0	0	2E-4	9E-7	0	0
54	Xe-131m	Submersion1	0	0	4E-4	2E-6	0	0
54	Xe-133m	Submersion1	0	0	1E-4	6E-7	0	0
54	Xe-133	Submersion1	0	0	1E-4	5E-7	0	0
54	Xe-135m ²	Submersion1	0	0	9E-6	4E-8	0	0
54	Xe-135	Submersion1	0	0	1E-5	7E-8	0	0
54	Xe-138 ²	Submersion1	0	0	4E-6	2E-8	0	0
55	Cs-125 ²	D: all compounds	5E+4 St Wall (9E+4)	1E+5	6E-5	2E-7 0	0 1E-3	0 1E-2
55	Cs-127	D: all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55	Cs-129	D: all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55	Cs-130 ²	D: all compounds	6E+4 St Wall (1E+5)	2E+5 0	8E-5 0	3E-7 0	0 1E-3	0 1E-2
55	Cs-131	D: all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55	Cs-132	D: all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55	Cs-134m	D: all compounds	1E+5 St Wall (1E+5)	1E+5 0	6E-5 0	2E-7 0	0 2E-3	0 2E-2
55	Cs-134	D: all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55	Cs-135m ²	D: all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55	Cs-135	D: all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55	Cs-136	D: all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5
55	Cs-137	D: all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55	Cs-138 ²	D: all compounds	2E+4 St Wall (3E+4)	6E+4 0	2E-5 0	8E-8 0	0 4E-4	0 4E-3
56	Ba-126 ²	D: all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56	Ba-128	D: all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56	Ba-131m ²	D: all compounds	4E+5 St Wall (5E+5)	1E+6 0	6E-4 0	2E-6 0	0 7E-3	0 7E-2
56	Ba-131	D: all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
56	Ba-133m	D: all compounds	2E+3 LLI Wall (3E+3)	9E+3 0	4E-6 0	1E-8 0	0 4E-5	0 4E-4
56	Ba-133	D: all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56	Ba-135m	D: all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56	Ba-139 ²	D: all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56	Ba-140	D: all compounds	5E+2 LLI Wall (6E+2)	1E+3 0	6E-7 0	2E-9 0	0 8E-6	0 8E-5
56	Ba-141 ²	D: all compounds	2E+4	7E+4	3E-5	1E-7	4E-4	4E-3
56	Ba-142 ²	D: all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57	La-131 ²	D: all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
	La-131 ²	W: oxides and hydroxides	0	2E+5	7E-5	2E-7	0	0
57	La-132	D: see La-131	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
57	La-132	W: see La-131	0	1E+4	5E-6	2E-8	0	0
57	La-135	D: see La-131	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
57	La-135	W: see La-131	0	9E+4	4E-5	1E-7	0	0
57	La-137	D: see La-131	1E+4 0	6E+1 Liver (7E+1)	3E-8 0	0 1E-10	2E-4 0	2E-3 0
57	La-137	W: see La-131	0	3E+2 Liver (3E+2)	1E-7 0	0 4E-10	0 0	0 0
57	La-138	D: see La-131	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
57	La-138	W: see La-131	0	1E+1	6E-9	2E-11	0	0
57	La-140	D: see La-131	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
57	La-140	W: see La-131	0	1E+3	5E-7	2E-9	0	0
57	La-141	D: see La-131	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
57	La-141	W: see La-131	0	1E+4	5E-6	2E-8	0	0
57	La-142 ²	D: see La-131	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
57	La-142 ²	W: see La-131	0	3E+4	1E-5	5E-8	0	0
57	La-143 ²	D: see La-131	4E+4 St Wall (4E+4)	1E+5 0	4E-5 0	1E-7 0	0 5E-4	0 5E-3
57	La-143 ²	W: see La-131	0	9E+4	4E-5	1E-7	0	0
58	Ce-134	W: all compounds except those given for Y	5E+2 LLI Wall (6E+2)	7E+2 0	3E-7 0	1E-9 0	0 5E-4	0 5E-3
58	Ce-134	Y: fluorides, oxides, and hydroxides	0	7E+2	3E-7	9E-10	0	0
58	Ce-135	W: see Ce-134	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
58	Ce-135	Y: see Ce-134	0	4E+3	1E-6	5E-9	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
58	Ce-137m	W: see Ce-134	2E+3 LLI Wall (2E+3)	4E+3 0	2E-6 0	6E-9 0	0 3E-5	0 3E-4
58	Ce-137m	Y: see Ce-134	0	4E+3	2E-6	5E-9	0	0
58	Ce-137	W: see Ce-134	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
58	Ce-137	Y: see Ce-134	0	1E+5	5E-5	2E-7	0	0
58	Ce-139	W: see Ce-134	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
58	Ce-139	Y: see Ce-134	0	7E+2	3E-7	9E-10	0	0
58	Ce-141	W: see Ce-134	2E+3 LLI Wall (2E+3)	7E+2 0	3E-7 0	1E-9 0	0 3E-5	0 3E-4
58	Ce-141	Y: see Ce-134	0	6E+2	2E-7	8E-10	0	0
58	Ce-143	W: see Ce-134	1E+3 LLI Wall (1E+3)	2E+3 0	8E-7 0	3E-9 0	0 2E-5	0 2E-4
58	Ce-143	Y: see Ce-134	0	2E+3	7E-7	2E-9	0	0
58	Ce-144	W: see Ce-134	2E+2 LLI Wall (3E+2)	3E+1 0	1E-8 0	4E-11 0	0 3E-6	0 3E-5
58	Ce-144	Y: see Ce-134	0	1E+1	6E-9	2E-11	0	0
59	Pr-136 ²	W: all compounds except those given for Y	5E+4 St Wall (7E+4)	2E+5 0	1E-4 0	3E-7 0	0 1E-3	0 1E-2
59	Pr-136 ²	Y: carbides, oxides, hydroxides, and fluorides	0	2E+5	9E-5	3E-7	0	0
59	Pr-137 ²	W: see Pr-136	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
59	Pr-137 ²	Y: see Pr-136	0	1E+5	6E-5	2E-7	0	0
59	Pr-138m	W: see Pr-136	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
59	Pr-138m	Y: see Pr-136	0	4E+4	2E-5	6E-8	0	0
59	Pr-139	W: see Pr-136	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
59	Pr-139	Y: see Pr-136	0	1E+5	5E-5	2E-7	0	0
59	Pr-142m ²	W: see Pr-136	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
59	Pr-142m ²	Y: see Pr-136	0	1E+5	5E-5	2E-7	0	0
59	Pr-142	W: see Pr-136	1E+3	2E+3	9E-7	3E-9	1E-5	1E-5
59	Pr-142	Y: see Pr-136	0	2E+3	8E-7	3E-9	0	0
59	Pr-143	W: see Pr-136	9E+2 LLI Wall (1E+3)	8E+2 0	3E-7 0	1E-9 0	0 2E-5	0 2E-4
59	Pr-143	Y: see Pr-136	0	7E+2	3E-7	9E-10	0	0
59	Pr-144	W: see Pr-136	3E+4 St Wall (4E+4)	1E+5 0	5E-5 0	2E-7 0	0 6E-4	0 6E-3
59	Pr-144	Y: see Pr-136	0	1E+5	5E-5	2E-7	0	0
59	Pr-145	W: see Pr-136	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
59	Pr-145	Y: see Pr-136	0	8E+3	3E-6	1E-8	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
59	Pr-147 ²	W: see Pr-136	5E+4 St Wall (8E+4)	2E+5 0	8E-5 0	3E-7 0	0 1E-3	0 1E-2
59	Pr-147 ²	Y: see Pr-136	0	2E+5	8E-5	3E-7	0	0
60	Nd-136 ²	W: all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
60	Nd-136 ²	Y: oxides, carbides, hydroxides, and fluorides	0	5E+4	2E-5	8E-8	0	0
60	Nd-138	W: see Nd-136	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
60	Nd-138	Y: see Nd-136	0	5E+3	2E-6	7E-9	0	0
60	Nd-139m ²	W: see Nd-136	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
60	Nd-139m ²	Y: see Nd-136	0	1E+4	6E-6	2E-8	0	0
60	Nd-139	W: see Nd-136	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
60	Nd-139	Y: see Nd-136	0	3E+5	1E-4	4E-7	0	0
60	Nd-141	W: see Nd-136	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
60	Nd-141	Y: see Nd-136	0	6E+5	3E-4	9E-7	0	0
60	Nd-147	W: see Nd-136	1E+3 LLI Wall (1E+3)	9E+2 0	4E-7 0	1E-9 0	0 2E-5	0 2E-4
60	Nd-147	Y: see Nd-136	0	8E+2	4E-7	1E-9	0	0
60	Nd-149 ²	W: see Nd-136	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
60	Nd-149 ²	Y: see Nd-136	0	2E+4	1E-5	3E-8	0	0
60	Nd-151 ²	W: see Nd-136	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
60	Nd-151 ²	Y: see Nd-136	0	2E+5	8E-5	3E-7	0	0
61	Pm-141 ²	W: all compounds except those given for Y	5E+4 St Wall (6E+4)	2E+5 0	8E-5 0	3E-7 0	0 8E-4	0 8E-3
61	Pm-141 ²	Y: carbides, oxides, fluorides, and hydroxides,	0	2E+5	7E-5	2E-7	0	0
61	Pm-143	W: see Pm-141	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
61	Pm-143	Y: see Pm-141	0	7E+2	3E-7	1E-9	0	0
61	Pm-144	W: see Pm-141	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
61	Pm-144	Y: see Pm-141	0	1E+2	5E-8	2E-10	0	0
61	Pm-145	W: see Pm-141	1E+4 0	2E+2 Bone surf (2E+2)	7E-8 0	0 3E-10	1E-4 0	1E-3 0
61	Pm-145	Y: see Pm-141	0	2E+2	8E-8	3E-10	0	0
61	Pm-146	W: see Pm-141	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
61	Pm-146	Y: see Pm-141	0	4E+1	2E-8	6E-11	0	0
61	Pm-147	W: see Pm-141	4E+3 LLI Wall (5E+3)	1E+2 Bone surf (2E+2)	5E-8 0	0 3E-10	0 7E-5	0 7E-4
61	Pm-147	Y: see Pm-141	0	1E+2	6E-8	2E-10	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
61	Pm-148m	W: see Pm-141	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
61	Pm-148m	Y: see Pm-141	0	3E+2	1E-7	5E-10	0	0
61	Pm-148	W: see Pm-141	4E+2 LLI Wall (5E+2)	5E+2 0	2E-7 0	8E-10 0	0 7E-6	0 7E-5
61	Pm-148	Y: see Pm-141	0	5E+2	2E-7	7E-10	0	0
61	Pm-149	W: see Pm-141	1E+3 LLI Wall (1E+3)	2E+3 0	8E-7 0	3E-9 0	0 2E-5	0 2E-4
61	Pm-149	Y: see Pm-141	0	2E+3	8E-7	2E-9	0	0
61	Pm-150	W: see Pm-141	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
61	Pm-150	Y: see Pm-141	0	2E+4	7E-6	2E-8	0	0
61	Pm-151	W: see Pm-141	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
61	Pm-151	Y: see Pm-141	0	3E+3	1E-6	4E-9	0	0
62	Sm-141m ²	W: all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Sm-141 ²	W: all compounds	5E+4 St Wall (6E+4)	2E+5 0	8E-5 0	2E-7 0	0 8E-4	0 8E-3
62	Sm-142 ²	W: all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Sm-145	W: all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Sm-146	W: all compounds	1E+1 Bone Surf (3E+1)	4E+2 Bone surf (6E-2)	1E-11 0	0 9E-14	0 3E-7	0 3E-6
62	Sm-147	W: all compounds	2E+1 Bone Surf (3E+1)	4E+2 Bone surf (7E-2)	2E-11 0	0 1E-13	0 4E-7	0 4E-6
62	Sm-151	W: all compounds	1E+4 LLI Wall (1E+4)	1E+2 Bone surf (7E+2)	4E-8 0	0 2E-10	0 2E-4	0 2E-3
62	Sm-153	W: all compounds	2E+3 LLI Wall (2E+3)	3E+3 0	1E-6 0	4E-9 0	0 3E-5	0 3E-4
62	Sm-155 ²	W: all compounds	6E+4 St Wall (8E+4)	2E+5	9E-5	3E-7 0	0 1E-3	0 1E-2
62	Sm-156	W: all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63	Eu-145	W: all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63	Eu-146	W: all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63	Eu-147	W: all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63	Eu-148	W: all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63	Eu-149	W: all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Eu-150 (12.62 h)	W: all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Eu-150 (34.2 y)	W: all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Eu-152m	W: all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Eu-152	W: all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Eu-154	W: all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
63	Eu-155	W: all compounds	4E+3 0	9E+1 Bone surf (1E+2)	4E-8 0	0 2E-10	5E-5 0	5E-4 0
63	Eu-156	W: all compounds	6E+2	5E+2	2E-7	6E-10	0	0
63	Eu-157	W: all compounds	2E+3	5E+3	2E-6	7E-9	8E-6	8E-5
63	Eu-158 ²	W: all compounds	2E+4	6E+4	2E-5	8E-8	3E-5	3E-4
64	Gd-145	D: all compounds except those given for W	5E+4 St Wall (5E+4)	2E+5 0	6E-5 0	2E-7 0	3E-4 0	3E-3 0
64	Gd-145	W: fluorides, oxides, and hydroxides	0	2E+5	7E-5	2E-7	0	0
64	Gd-146	D: see Gd-145	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
64	Gd-146	W: see Gd-145	0	3E+2	1E-7	4E-10	0	0
64	Gd-147	D: see Gd-145	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
64	Gd-147	W: see Gd-145	0	4E+3	1E-6	5E-9	0	0
64	Gd-148	D: see Gd-145	1E+1 Bone Surf (2E+1)	8E+3 Bone surf (2E-2)	3E-12 0	0 2E-14	0 3E-7	0 3E-6
64	Gd-148	W: see Gd-145	0	3E-2 Bone surf (6E-2)	1E-11 0	0 8E-14	0 0	0 0
64	Gd-149	D: see Gd-145	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
64	Gd-149	W: see Gd-145	0	2E+3	1E-6	3E-9	0	0
64	Gd-151	D: see Gd-145	6E+3	4E+2 Bone surf (6E+2)	2E-7 0	0 9E-10	9E-5 0	9E-4 0
64	Gd-151	W: see Gd-145	0	1E+3	5E-7	2E-9	0	0
64	Gd-152	D: see Gd-145	2E+1 Bone Surf (3E+1)	1E-2 Bone surf (2E-2)	4E-12	0 3E-14	0 4E-7	0 4E-6
64	Gd-152	W: see Gd-145	0	4E-2 Bone surf (1E+2)	2E-11 0	0 1E-13	0 0	0 0
64	Gd-153	D: see Gd-145	5E+3 Bone Surf (2E+2)	1E+2 0	6E-8 0	0 3E-10	6E-5 0	6E-4 0
64	Gd-153	W: see Gd-145	0	6E+2	2E-7	8E-10	0	0
64	Gd-159	D: see Gd-145	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
64	Gd-159	W: see Gd-145	0	6E+3	2E-6	8E-9	0	0
65	Tb-147 ²	W: all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
64	Tb-149	W: all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65	Tb-150	W: all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65	Tb-151	W: all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65	Tb-153	W: all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65	Tb-154	W: all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
65	Tb-155	W: all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4
65	Tb-156m (5.0 h)	W: all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3
65	Tb-156m (24.4 h)	W: all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3
65	Tb-156	W: all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
65	Tb-157	W: all compounds	5E+4 LLI Wall (5E+4)	3E+2 Bone surf (6E+2)	1E-7 0	0 8E-10	0 7E-4	0 7E-3
65	Tb-158	W: all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Tb-160	W: all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Tb-161	W: all compounds	2E+3 LLI Wall (2E+3)	2E+3 0	7E-7 0	2E-9 0	0 3E-5	0 3E-4
66	Dy-155	W: all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66	Dy-157	W: all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66	Dy-159	W: all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66	Dy-165	W: all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66	Dy-166	W: all compounds	6E+2 LLI Wall (8E+2)	7E+2 0	3E-7 0	1E-9 0	0 1E-5	0 1E-4
67	Ho-155 ²	W: all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67	Ho-157 ²	W: all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67	Ho-159 ²	W: all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Ho-161	W: all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Ho-162m ²	W: all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Ho-162 ²	W: all compounds	5E+5 St Wall (1E+5)	2E+6 0	1E-3 0	3E-6 0	0 1E-2	0 1E-1
67	Ho-164m ²	W: all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Ho-164 ²	W: all compounds	2E+5 St Wall (2E+5)	6E+5 0	3E-4 0	9E-7 0	0 3E-3	0 3E-2
67	Ho-166m	W: all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Ho-166	W: all compounds	9E+2 LLI Wall (9E+2)	2E+3 0	7E-7 0	2E-9 0	0 1E-5	0 1E-4
67	Ho-167	W: all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Er-161	W: all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Er-165	W: all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Er-169	W: all compounds	3E+3 LLI Wall (4E+3)	3E+3 0	1E-6 0	4E-9 0	0 5E-5	0 5E-4
68	Er-171	W: all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Er-172	W: all compounds	1E+3 LLI Wall (1E+3)	1E+3 0	6E-7 0	2E-9 0	0 2E-5	0 2E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci/ml}$)	COL. 1 Air ($\mu\text{Ci/ml}$)	COL. 2 Water ($\mu\text{Ci/ml}$)	Monthly Average Concentration ($\mu\text{Ci/ml}$)
69	Tm-162 ²	W: all compounds	7E+4 St Wall (7E+4)	3E+5 0	1E-4 0	4E-7 0	0 1E-3	0 1E-2
69	Tm-166	W: all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Tm-167	W: all compounds	2E+3 LLI Wall (2E+3)	2E+3 0	8E-7 0	3E-9 0	0 3E-5	0 3E-4
69	Tm-170	W: all compounds	8E+2 LLI Wall (1E+3)	2E+2 0	9E-8 0	3E-10 0	0 1E-5	0 1E-4
69	Tm-171	W: all compounds	1E+4 LLI Wall (1E+4)	3E+2 Bone surf (6E+2)	1E-7 0	0 8E-10	0 2E-4	0 2E-3
69	Tm-172	W: all compounds	7E+2 LLI Wall (8E+2)	1E+3 0	5E-7 0	2E-9 0	0 1E-5	0 1E-4
69	Tm-173	W: all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69	Tm-175 ²	W: all compounds	7E+4 St Wall (9E+4)	3E+5 0	1E-4 0	4E-7 0	0 1E-3	0 1E-2
70	Yb-162 ²	W: all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
70	Yb-162 ²	Y: fluorides, oxides, and hydroxides	0	3E+5	1E-4	4E-7	0	0
70	Yb-166	W: see Yb-162	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
70	Yb-166	Y: see Yb-162	0	2E+3	8E-7	3E-9	0	0
70	Yb-167 ²	W: see Yb-162	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
70	Yb-167 ²	Y: see Yb-162	0	7E+5	3E-4	1E-6	0	0
70	Yb-169	W: see Yb-162	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
70	Yb-169	Y: see Yb-162	0	7E+2	3E-7	1E-9	0	0
70	Yb-175	W: see Yb-162	3E+3 LLI Wall (3E+3)	4E+3 0	1E-6 0	5E-9 0	0 4E-5	0 4E-4
70	Yb-175	Y: see Yb-162	0	3E+3	1E-6	5E-9	0	0
70	Yb-177 ²	W: see Yb-162	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
70	Yb-177 ²	Y: see Yb-162	0	5E+4	2E-5	6E-8	0	0
70	Yb-178 ²	W: see Yb-162	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
70	Yb-178 ²	Y: see Yb-162	0	4E+4	2E-5	5E-8	0	0
71	Lu-169	W: all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
71	Lu-169	Y: fluorides, oxides, and hydroxides	0	4E+3	2E-6	6E-9	0	0
71	Lu-170	W: see Lu-169	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
71	Lu-170	Y: see Lu-169	0	2E+3	8E-7	3E-9	0	0
71	Lu-171	W: see Lu-169	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
71	Lu-171	Y: see Lu-169	0	2E+3	8E-7	3E-9	0	0
71	Lu-172	W: see Lu-169	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
71	Lu-172	Y: see Lu-169	0	1E+3	5E-7	2E-9	0	0
71	Lu-173	W: see Lu-169	5E+3	3E+2 Bone surf (5E+2)	1E-7	0	7E-5	7E-4
71	Lu-173	Y: see Lu-169	0	3E+2	1E-7	6E-10	0	0
71	Lu-174m	W: see Lu-169	2E+3 LLI Wall (3E+3)	2E+2 Bone surf (3E+2)	1E-7	0	0	0
71	Lu-174m	Y: see Lu-169	0	2E+2	9E-8	3E-10	0	0
71	Lu-174	W: see Lu-169	5E+3	1E+2 Bone surf (2E+2)	5E-8	0	7E-5	7E-4
71	Lu-174	Y: see Lu-169	0	2E+2	6E-8	3E-10	0	0
71	Lu-176m	W: see Lu-169	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
71	Lu-176m	Y: see Lu-169	0	2E+4	9E-6	3E-8	0	0
71	Lu-176	W: see Lu-169	7E+2	5E+0 Bone surf (1E+1)	2E-9	0	1E-5	1E-4
71	Lu-176	Y: see Lu-169	0	8E+0	3E-9	2E-11	0	0
71	Lu-177m	W: see Lu-169	7E+2	1E+2 Bone surf (1E+2)	5E-8	0	1E-5	1E-4
71	Lu-177m	Y: see Lu-169	0	8E+1	3E-8	2E-10	0	0
71	Lu-177	W: see Lu-169	2E+3 LLI Wall (3E+3)	2E+3	9E-7	0	4E-5	4E-4
71	Lu-177	Y: see Lu-169	0	2E+3	9E-7	3E-9	0	0
71	Lu-178m ²	W: see Lu-169	5E+4 St Wall (6E+4)	2E+5	8E-5	0	8E-4	8E-3
71	Lu-178m ²	Y: see Lu-169	0	2E+5	7E-5	2E-7	0	0
71	Lu-178 ²	W: see Lu-169	4E+4 St Wall (4E+4)	1E+5	5E-5	0	0	0
71	Lu-178 ²	Y: see Lu-169	0	1E+5	5E-5	2E-7	6E-4	6E-3
71	Lu-179	W: see Lu-169	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
71	Lu-179	Y: see Lu-169	0	2E+4	6E-6	3E-8	0	0
72	Hf-170	D: all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
72	Hf-170	W: nitrates, oxides, hydroxides, and carbides	0	5E+3	2E-6	6E-9	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC (μCi/ml)	COL. 1 Air (μCi/ml)	COL. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
72	Hf-172	D: see Hf-170	1E+3	9E+0 Bone surf (2E+1)	4E-9 0	0 3E-11	2E-5 0	2E-4 0
72	Hf-172	W: see Hf-170	0 0	4E+1 Bone surf (6E+1)	2E-8 0	0 8E-11	0 0	0 0
72	Hf-173	D: see Hf-170	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
72	Hf-173	W: see Hf-170	0	1E+4	5E-6	2E-8	0	0
72	Hf-175	D: see Hf-170	3E+3 0	9E+2 Bone surf (1E+3)	4E-7 0	0 1E-9	4E-5 0	4E-4 0
72	Hf-175	W: see Hf-170	0	1E+3	5E-7	2E-9	0	0
72	Hf-177m ²	D: see Hf-170	2E+4	6E+4	2E-5	8E-8	3E-4	3E-4
72	Hf-177m ²	W: see Hf-170	0	9E+4	4E-5	1E-7	0	0
72	Hf-178m	D: see Hf-170	3E+2 0	1E+0 Bone surf (2E+0)	5E-10 0	0 3E-12	3E-6 0	3E-5 0
72	Hf-178m	W: see Hf-170	0 0	5E+0 Bone surf (9E+0)	2E-9 0	0 1E-11	0 0	0 0
72	Hf-179m	D: see Hf-170	1E+3	3E+2 Bone surf (6E+2)	1E-7 0	0 8E-10	1E-5 0	1E-4 0
72	Hf-179m	W: see Hf-170	0	6E+2	3E-7	8E-10	0	0
72	Hf-180m	D: see Hf-170	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
72	Hf-180m	W: see Hf-170	0	3E+4	1E-5	4E-8	0	0
72	Hf-181	D: see Hf-170	1E+3 0	2E+2 Bone surf (4E+2)	7E-8 0	0 6E-10	2E-5 0	2E-4 0
72	Hf-181	W: see Hf-170	0	4E+2	2E-7	6E-10	0	0
72	Hf-182m ²	D: see Hf-170	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
72	Hf-182m ²	W: see Hf-170	0	1E+5	6E-5	2E-7	0	0
72	Hf-182	D: see Hf-170	2E+2 Bone Surf (4E+2)	8E-1 Bone surf (2E+0)	3E-10 0	0 2E-12	0 5E-6	0 5E-5
72	Hf-182	W: see Hf-170	0 0	3E+0 Bone surf (7E+0)	1E-9 0	0 1E-11	0 0	0 0
72	Hf-183 ²	D: see Hf-170	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
72	Hf-183 ²	W: see Hf-170	0	6E+4	2E-5	8E-8	0	0
72	Hf-184	D: see Hf-170	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
72	Hf-184	W: see Hf-170	0	6E+3	3E-6	9E-9	0	0
73	Ta-172 ²	W: all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
73	Ta-172 ²	Y: elemental Ta, halides, oxides, hydroxides, carbides, nitrates, and nitrides	0	1E+5	4E-5	1E-7	0	0
73	Ta-173	W: see Ta-172	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
73	Ta-173	Y: see Ta-172	0	2E+4	7E-6	2E-8	0	0
73	Ta-174 ²	W: see Ta-172	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
73	Ta-174 ²	Y: see Ta-172	0	9E+4	4E-5	1E-7	0	0
73	Ta-175	W: see Ta-172	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
73	Ta-175	Y: see Ta-172	0	1E+4	6E-6	2E-8	0	0
73	Ta-176	W: see Ta-172	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
73	Ta-176	Y: see Ta-172	0	1E+4	5E-6	2E-8	0	0
73	Ta-177	W: see Ta-172	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
73	Ta-177	Y: see Ta-172	0	2E+4	7E-6	2E-8	0	0
73	Ta-178	W: see Ta-172	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
73	Ta-178	Y: see Ta-172	0	7E+4	3E-5	1E-7	0	0
73	Ta-179	W: see Ta-172	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
73	Ta-179	Y: see Ta-172	0	9E+2	4E-7	1E-9	0	0
73	Ta-180m	W: see Ta-172	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
73	Ta-180m	Y: see Ta-172	0	6E+4	2E-5	8E-8	0	0
73	Ta-180	W: see Ta-172	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
73	Ta-180	Y: see Ta-172	0	2E+1	1E-8	3E-11	0	0
73	Ta-182m ²	W: see Ta-172	2E+5 St Wall (2E+5)	5E+5 0	2E-4 0	8E-7 0	0 3E-3	0 3E-2
73	Ta-182m ²	Y: see Ta-172	0	4E+5	2E-4	6E-7	0	0
73	Ta-182	W: see Ta-172	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
73	Ta-182	Y: see Ta-172	0	1E+2	6E-8	2E-10	0	0
73	Ta-183	W: see Ta-172	9E+2 LLI Wall (1E+3)	1E+3 0	5E-7 0	2E-9 0	0 2E-5	0 2E-4
73	Ta-183	Y: see Ta-172	0	1E+3	4E-7	1E-9	0	0
73	Ta-184	W: see Ta-172	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
73	Ta-184	Y: see Ta-172	0	5E+3	2E-6	7E-9	0	0
73	Ta-185 ²	W: see Ta-172	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
73	Ta-185 ²	Y: see Ta-172	0	6E+4	3E-5	9E-8	0	0
73	Ta-186 ²	W: see Ta-172	5E+4 (St Wall (7E+4)	2E+5 0	1E-4 0	3E-7 0	0 1E-3	0 1E-2
73	Ta-186 ²	Y: see Ta-172	0	2E+5	9E-5	3E-7	0	0
74	W-176	D: all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74	W-177	D: all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74	W-178	D: all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
74	W-179 ²	D: all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74	W-181	D: all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74	W-185	D: all compounds	2E+3 LLI Wall (3E+3)	7E+3 0	3E-6 0	9E-9 0	0 4E-5	0 4E-4
74	W-187	D: all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74	W-188	D: all compounds	4E+2 LLI Wall (5E+2)	1E+3 0	5E-7 0	2E-9 0	0 6E-6	0 6E-5
75	Re-177 ²	D: all compounds except those given for W	9E+4 St Wall (1E+5)	3E+5 0	1E-4 0	4E-7 0	0 2E-3	0 2E-2
75	Re-177 ²	W: nitrates, oxides, and hydroxides	0	4E+5	1E-4	5E-7	0	0
75	Re-178 ²	D: see Re-177	7E+4 St Wall (1E+5)	3E+5 0	1E-4 0	4E-7 0	0 1E-3	0 1E-2
75	Re-178 ²	W: see Re-177	0	3E+5	1E-4	4E-7	0	0
75	Re-181	D: see Re-177	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
75	Re-181	W: see Re-177	0	9E+3	4E-6	1E-8	0	0
75	Re-182 (12.7 h)	D: see Re-177	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
75	Re-182 (12.7 h)	W: see Re-177	0	2E+4	6E-6	2E-8	0	0
75	Re-182 (64.0 h)	D: see Re-177	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
75	Re-182 (64.0 h)	W: see Re-177	0	2E+3	9E-7	3E-9	0	0
75	Re-184m	D: see Re-177	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
75	Re-184m	W: see Re-177	0	4E+2	2E-7	6E-10	0	0
75	Re-184	D: see Re-177	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
75	Re-184	W: see Re-177	0	1E+3	6E-7	2E-9	0	0
75	Re-186m	D: see Re-177	1E+3 St Wall (2E+3)	2E+3 St wall (2E+3)	7E-7 0	0 3E-9	0 2E-5	0 2E-4
75	Re-186m	W: see Re-177	0	2E+2	6E-8	2E-10	0	0
75	Re-186	D: see Re-177	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
75	Re-186	W: see Re-177	0	2E+3	7E-7	2E-9	0	0
75	Re-187	D: see Re-177	6E+5 0	8E+5 St wall (9E+5)	4E-4 0	0 1E-6	8E-3 0	8E-2 0
75	Re-187	W: see Re-177	0	1E+5	4E-5	1E-7	0	0
75	Re-188m ²	D: see Re-177	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
75	Re-188m ²	W: see Re-177	0	1E+5	6E-5	2E-7	0	0
75	Re-188	D: see Re-177	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
75	Re-188	W: see Re-177	0	3E+3	1E-6	4E-9	0	0
75	Re-189	D: see Re-177	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
75	Re-189	W: see Re-177	0	4E+3	2E-6	6E-9	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
76	Os-180 ²	D: all compounds except those given for W, Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
76	Os-180 ²	W: halides and nitrates	0	5E+5	2E-4	7E-7	0	0
76	Os-180 ²	Y: oxides and hydroxides	0	5E+5	2E-4	6E-7	0	0
76	Os-181 ²	D: see Os-180	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
76	Os-181 ²	W: see Os-180	0	5E+4	2E-5	6E-8	0	0
76	Os-181 ²	Y: see Os-180	0	4E+4	2E-5	6E-8	0	0
76	Os-182	D: see Os-180	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
76	Os-182	W: see Os-180	0	4E+3	2E-6	6E-9	0	0
76	Os-182	Y: see Os-180	0	4E+3	2E-6	6E-9	0	0
76	Os-185	D: see Os-180	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
76	Os-185	W: see Os-180	0	8E+2	3E-7	1E-9	0	0
76	Os-185	Y: see Os-180	0	8E+2	3E-7	1E-9	0	0
76	Os-189m	D: see Os-180	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
76	Os-189m	W: see Os-180	0	2E+5	9E-5	3E-7	0	0
76	Os-189m	Y: see Os-180	0	2E+5	7E-5	2E-7	0	0
76	Os-191m	D: see Os-180	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
76	Os-191m	W: see Os-180	0	2E+4	8E-6	3E-8	0	0
76	Os-191m	Y: see Os-180	0	2E+4	7E-6	2E-8	0	0
76	Os-191	D: see Os-180	2E+3 LLI Wall (3E+3)	2E+3 0	9E-7 0	3E-9 0	0 3E-5	0 3E-4
76	Os-191	W: see Os-180	0	2E+3	7E-7	2E-9	0	0
76	Os-191	Y: see Os-180	0	1E+3	6E-7	2E-9	0	0
76	Os-193	D: see Os-180	2E+3 LLI Wall (2E+3)	5E+3 0	2E-6 0	6E-9 0	0 2E-5	0 2E-4
76	Os-193	W: see Os-180	0	3E+3	1E-6	4E-9	0	0
76	Os-193	Y: see Os-180	0	3E+3	1E-6	4E-9	0	0
76	Os-194	D: see Os-180	4E+2 LLI Wall (6E+2)	4E+1 0	2E-8 0	6E-11 0	0 8E-6	0 8E-5
76	Os-194	W: see Os-180	0	6E+1	2E-8	6E-11	0	0
76	Os-194	Y: see Os-180	0	8E+0	3E-9	1E-11	0	0
77	Ir-182 ²	D: all compounds except those given for W, Y	4E+4 St Wall (4E+4)	1E+5 0	6E-5 0	2E-7 0	0 6E-4	0 6E-3
77	Ir-182 ²	W: halides, nitrates, and metallic Ir	0	2E+5	6E-5	2E-7	0	0
77	Ir-182 ²	Y: oxides and hydroxides	0	1E+5	5E-5	2E-7	0	0
77	Ir-184	D: see Ir-182	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
77	Ir-184	W: see Ir-182	0	3E+4	1E-5	5E-8	0	0
77	Ir-184	Y: see Ir-182	0	3E+4	1E-5	4E-8	0	0
77	Ir-185	D: see Ir-182	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
77	Ir-185	W: see Ir-182	0	1E+4	5E-6	2E-8	0	0
77	Ir-185	Y: see Ir-182	0	1E+4	4E-6	1E-8	0	0
77	Ir-186	D: see Ir-182	2E+3	8E+3	3E-6	1E-8	3E-5	3E-5
77	Ir-186	W: see Ir-182	0	6E+3	3E-6	9E-9	0	0
77	Ir-186	Y: see Ir-182	0	6E+3	2E-6	8E-9	0	0
77	Ir-187	D: see Ir-182	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
77	Ir-187	W: see Ir-182	0	3E+4	1E-5	4E-8	0	0
77	Ir-187	Y: see Ir-182	0	3E+4	1E-5	4E-8	0	0
77	Ir-188	D: see Ir-182	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
77	Ir-188	W: see Ir-182	0	4E+3	1E-6	5E-9	0	0
77	Ir-188	Y: see Ir-182	0	3E+3	1E-6	5E-9	0	0
77	Ir-189	D: see Ir-182	5E+3 LLI Wall (5E+3)	5E+3 0	2E-6 0	7E-9 0	0 7E-5	0 7E-4
77	Ir-189	W: see Ir-182	0	4E+3	2E-6	5E-9	0	0
77	Ir-189	Y: see Ir-182	0	4E+3	1E-6	5E-9	0	0
77	Ir-190m ²	D: see Ir-182	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
77	Ir-190m ²	W: see Ir-182	0	2E+5	9E-5	3E-7	0	0
77	Ir-190m ²	Y: see Ir-182	0	2E+5	8E-5	3E-7	0	0
77	Ir-190	D: see Ir-182	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
77	Ir-190	W: see Ir-182	0	1E+3	4E-7	1E-9	0	0
77	Ir-190	Y: see Ir-182	0	9E+2	4E-7	1E-9	0	0
77	Ir-192m	D: see Ir-182	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
77	Ir-192m	W: see Ir-182	0	2E+2	9E-8	3E-10	0	0
77	Ir-192m	Y: see Ir-182	0	2E+1	6E-9	2E-11	0	0
77	Ir-192	D: see Ir-182	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
77	Ir-192	W: see Ir-182	0	4E+2	2E-7	6E-10	0	0
77	Ir-192	Y: see Ir-182	0	2E+2	9E-8	3E-10	0	0
77	Ir-194m	D: see Ir-182	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
77	Ir-194m	W: see Ir-182	0	2E+2	7E-8	2E-10	0	0
77	Ir-194m	Y: see Ir-182	0	1E+2	4E-8	1E-10	0	0
77	Ir-194	D: see Ir-182	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
77	Ir-194	W: see Ir-182	0	2E+3	9E-7	3E-9	0	0
77	Ir-194	Y: see Ir-182	0	2E+3	8E-7	3E-9	0	0
77	Ir-195m	D: see Ir-182	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
77	Ir-195m	W: see Ir-182	0	3E+4	1E-5	4E-8	0	0
77	Ir-195m	Y: see Ir-182	0	2E+4	9E-6	3E-8	0	0
77	Ir-195	D: see Ir-182	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
77	Ir-195	W: see Ir-182	0	5E+4	2E-5	7E-8	0	0
77	Ir-195	Y: see Ir-182	0	4E+4	2E-5	6E-8	0	0
78	Pt-186	D: all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
78	Pt-188	D: all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	0
78	Pt-189	D: all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	0
78	Pt-191	D: all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78	Pt-193m	D: all compounds	3E+3 LLI Wall (3E+4)	6E+3 0	3E-6 0	8E-9 0	0 4E-5	0 4E-4
78	Pt-193	D: all compounds	4E+4 LLI Wall (5E+4)	2E+4 0	1E-5 0	3E-8 0	0 6E-4	0 6E-3
78	Pt-195m	D: all compounds	2E+3 LLI Wall (2E+3)	4E+3 0	2E-6 0	6E-9 0	0 3E-5	0 3E-4
78	Pt-197m ²	D: all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78	Pt-197	D: all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78	Pt-199 ²	D: all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78	Pt-200	D: all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
79	Au-193	D: all compounds except those given for W, Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
79	Au-193	W: halides and nitrates	0	2E+4	9E-6	3E-8	0	0
79	Au-193	Y: oxides and hydroxides	0	2E+4	8E-6	3E-8	0	0
79	Au-194	D: see Au-193	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
79	Au-194	W: see Au-193	0	5E+3	2E-6	8E-9	0	0
79	Au-194	Y: see Au-193	0	5E+3	2E-6	7E-9	0	0
79	Au-195	D: see Au-193	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
79	Au-195	W: see Au-193	0	1E+3	6E-7	2E-9	0	0
79	Au-195	Y: see Au-193	0	4E+2	2E-7	6E-10	0	0
79	Au-198m	D: see Au-193	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
79	Au-198m	W: see Au-193	0	1E+3	5E-7	2E-9	0	0
79	Au-198m	Y: see Au-193	0	1E+3	5E-7	2E-9	0	0
79	Au-198	D: see Au-193	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
79	Au-198	W: see Au-193	0	2E+3	8E-7	3E-9	0	0
79	Au-198	Y: see Au-193	0	2E+3	7E-7	2E-9	0	0
79	Au-199	D: see Au-193	3E+3 LLI Wall (3E+3)	9E+3 0	4E-6 0	1E-8 0	0 4E-5	0 4E-4
79	Au-199	W: see Au-193	0	4E+3	2E-6	6E-9	0	0
79	Au-199	Y: see Au-193	0	4E+3	2E-6	5E-9	0	0
79	Au-200m	D: see Au-193	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
79	Au-200m	W: see Au-193	0	3E+3	1E-6	4E-9	0	0
79	Au-200m	Y: see Au-193	0	2E+4	1E-6	3E-9	0	0
79	Au-200 ²	D: see Au-193	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
79	Au-200 ²	W: see Au-193	0	8E+4	3E-5	1E-7	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
79	Au-200 ²	Y: see Au-193	0	7E+4	3E-5	1E-7	0	0
79	Au-201 ²	D: see Au-193	7E+4 St Wall (9E+4)	2E+5 0	9E-5 0	3E-7 0	0 1E-3	0 1E-2
79	Au-201 ²	W: see Au-193	0	2E+5	1E-4	3E-7	0	0
79	Au-201 ²	Y: see Au-193	0	2E+5	9E-5	3E-7	0	0
80	Hg-193m	Vapor	0	8E+3	4E-6	1E-8	0	0
80	Hg-193m	Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
80	Hg-193m	D: sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
80	Hg-193m	W: halides, nitrates, sulfides, oxides, and hydroxides	0	8E+3	3E-6	1E-8	0	0
80	Hg-193	Vapor	0	3E+4	1E-5	4E-8	0	0
80	Hg-193	Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
80	Hg-193	D: see Hg-193m	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
80	Hg-193	W: see Hg-193m	0	4E+4	2E-5	6E-8	0	0
80	Hg-194	Vapor	0	3E+1	1E-8	4E-11	0	0
80	Hg-194	Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
80	Hg-194	D: see Hg-193m	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
80	Hg-194	W: see Hg-193m	0	1E+2	5E-8	2E-10	0	0
80	Hg-195m	Vapor	0	4E+3	2E-6	6E-9	0	0
80	Hg-195m	Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
80	Hg-195m	D: see Hg-193m	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
80	Hg-195m	W: see Hg-193m	0	4E+3	2E-6	5E-9	0	0
80	Hg-195	Vapor	0	3E+4	1E-5	4E-8	0	0
80	Hg-195	Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
80	Hg-195	D: see Hg-193m	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
80	Hg-195	W: see Hg-193m	0	3E+4	1E-5	5E-8	0	0
80	Hg-197m	Vapor	0	5E+3	2E-6	7E-9	0	0
80	Hg-197m	Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
80	Hg-197m	D: see Hg-193m	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
80	Hg-197m	W: see Hg-193m	0	5E+3	2E-6	7E-9	0	0
80	Hg-197	Vapor	0	8E+3	4E-6	1E-8	0	0
80	Hg-197	Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
80	Hg-197	D: see Hg-193m	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
80	Hg-197	W: see Hg-193m	0	9E+3	4E-6	1E-8	0	0
80	Hg-199m ²	Vapor	0	8E+4	3E-5	1E-7	0	0
80	Hg-199m ²	Organic D	6E+4 St Wall (1E+5)	2E+5 0	7E-5 0	1E-7 0	0 1E-3	0 1E-2
80	Hg-199m ²	D: see Hg-193m	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
80	Hg-199m ²	W: see Hg-193m	0	2E+5	7E-5	2E-7	0	0
80	Hg-203	Vapor	0	8E+2	4E-7	1E-9	0	0
80	Hg-203	Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
80	Hg-203	D: see Hg-193m	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
80	Hg-203	W: see Hg-193m	0	1E+3	5E-7	2E-9	0	0
81	Tl-194m ²	D: all compounds	5E+4 St Wall (7E+4)	2E+5 0	6E-5 0	2E-7 0	0 1E-3	0 1E-2
81	Tl-194 ²	D: all compounds	3E+5 St Wall (3E+5)	6E+5 0	2E-4 0	8E-7 0	0 4E-2	0 4E-1
81	Tl-195 ²	D: all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81	Tl-197	D: all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81	Tl-198m ²	D: all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81	Tl-198	D: all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81	Tl-199	D: all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81	Tl-200	D: all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81	Tl-201	D: all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81	Tl-202	D: all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
81	Tl-204	D: all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82	Pb-195m ²	D: all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82	Pb-198	D: all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82	Pb-199 ²	D: all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82	Pb-200	D: all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82	Pb-201	D: all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82	Pb-202m	D: all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82	Pb-202	D: all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82	Pb-203	D: all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82	Pb-205	D: all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82	Pb-209	D: all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Pb-210	D: all compounds	6E-1 Bone Surf (1E+0)	2E+1 Bone surf (4E-1)	1E-10 0	0 6E-13	0 1E-8	0 1E-7
82	Pb-211 ²	D: all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82	Pb-212	D: all compounds	8E+1 Bone Surf (1E+2)	3E+1 0	1E-8 0	5E-11 0	0 2E-6	0 2E-5
82	Pb-214 ²	D: all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83	Bi-200 ²	D: nitrates	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
83	Bi-200 ²	W: all other compounds	0	1E+5	4E-5	1E-7	0	0
83	Bi-201 ²	D: see Bi-200	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
83	Bi-201 ²	W: see Bi-200	0	4E+4	2E-5	5E-8	0	0
83	Bi-202 ²	D: see Bi-200	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
83	Bi-202 ²	W: see Bi-200	0	8E+4	3E-5	1E-7	0	0
83	Bi-203	D: see Bi-200	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
83	Bi-203	W: see Bi-200	0	6E+3	3E-6	9E-9	0	0
83	Bi-205	D: see Bi-200	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
83	Bi-205	W: see Bi-200	0	1E+3	5E-7	2E-9	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
83	Bi-206	D: see Bi-200	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
83	Bi-206	W: see Bi-200	0	9E+2	4E-7	1E-9	0	0
83	Bi-207	D: see Bi-200	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
83	Bi-207	W: see Bi-200	0	4E+2	1E-7	5E-10	0	0
83	Bi-210m	D: see Bi-200	4E+1 Kidneys (6E+1)	5E+0 Kidney (6E+0)	2E-9 0	0 9E-12	0 8E-7	0 8E-6
83	Bi-210m	W: see Bi-200	0	7E-1	3E-10	9E-13	0	0
83	Bi-210	D: see Bi-200	8E+2	2E+2 Kidney (4E+2)	1E-7 0	0 5E-10	1E-5 0	1E-4 0
83	Bi-210	W: see Bi-200	0	3E+1	1E-8	4E-11	0	0
83	Bi-212 ²	D: see Bi-200	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
83	Bi-212 ²	W: see Bi-200	0	3E+2	1E-7	4E-10	0	0
83	Bi-213 ²	D: see Bi-200	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
83	Bi-213 ²	W: see Bi-200	0	4E+2	1E-7	5E-10	0	0
83	Bi-214 ²	D: see Bi-200	2E+4 St Wall (2E+4)	8E+2 0	3E-7 0	1E-9 0	0 3E-4	0 3E-3
83	Bi-214 ²	W: see Bi-200	0	9E-2	4E-7	1E-9	0	0
84	Po-203 ²	D: all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
84	Po-203 ²	W: nitrates, oxides, and hydroxides	0	9E+4	4E-5	1E-7	0	0
84	Po-205 ²	D: see Po-203	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
84	Po-205 ²	W: see Po-203	0	7E+4	3E-5	1E-7	0	0
84	Po-207	D: see Po-203	8E+3	3E+4	1E-5	3E-8	1E-4	1E-4
84	Po-207	W: see Po-203	0	3E+4	1E-5	4E-8	0	0
84	Po-210	D: see Po-203	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
84	Po-210	W: see Po-203	0	6E-1	3E-10	9E-13	0	0
85	At-207 ²	D: halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
85	At-207 ²	W: all compounds except those given in D	0	2E+3	9E-7	3E-9	0	0
85	At-211	D: halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
85	At-211	W: all compounds except those given in D	0	5E+1	2E-8	8E-11	0	0
86	Rn-220	With daughters removed	0	2E+4	7E-6	2E-8	0	0
86	Rn-220	With daughters present	0	2E+1 (or 12 working level months)	9E-9	3E-11 (or 1.0 working level)	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
86	Rn-222	With daughters removed	0	1E+4	4E-6	1E-8	0	0
86	Rn-222	With daughters present	0	1E+2 (or 12 working level months)	3E-8	1E-10 (or 0.33 working level)	0	0
87	Fr-222 ²	D: all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87	Fr-232 ²	D: all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Ra-223	W: all compounds	5E+0 Bone Surf (9E+0)	7E-1 0	3E-10 0	9E-13 0	0 1E-7	0 1E-6
88	Ra-224	W: all compounds	8E+0 Bone Surf (2E+1)	2E+0 0	7E-10 0	2E-12 0	0 2E-7	0 2E-6
88	Ra-225	W: all compounds	8E+0 Bone Surf (2E+1)	7E-1 0	3E-10 0	9E-13 0	0 2E-7	0 2E-6
88	Ra-226	W: all compounds	2E+0 Bone Surf (5E+0)	6E-1	3E-10	9E-13	0 6E-8	0 6E-7
88	Ra-227 ²	W: all compounds	2E+4 Bone Surf (2E+4)	1E+4 Bone surf (2E+4)	6E-6 0	0 3E-8	0 3E-4	0 3E-3
88	Ra-228	W: all compounds	2E+0 Bone Surf (4E+0)	1E+0 0	5E-10 0	2E-12 0	0 6E-8	0 6E-7
89	Ac-224	D: all compounds except those given for W, Y	2E+3 LLI Wall 2E+3	3E+1 Bone surf (4E+1)	1E-8 0	0 5E-11	0 3E-5	0 3E-4
89	Ac-224	W: halides and nitrates	0	5E+1	2E-8	7E-11	0	0
89	Ac-224	Y: oxides and hydroxides	0	5E+1	2E-8	6E-11	0	0
89	Ac-225	D: see Ac-224	5E+1 LLI Wall (5E+)	3E-1 Bone surf (5E-1)	1E-10 0	0 7E-13	0 7E-7	0 7E-6
89	Ac-225	W: see Ac-224	0	6E-1	3E-10	9E-13	0	0
89	Ac-225	Y: see Ac-224	0	6E-1	3E-10	9E-13	0	0
89	Ac-225	D: see Ac-224	1E+2 LLI Wall (1E+2)	3E+0 Bone surf (4E+0)	1E-9 0	0 5E-12	0 2E-6	0 2E-5
89	Ac-225	W: see Ac-224	0	5E+0	2E-9	7E-12	0	0
89	Ac-225	Y: see Ac-224	0	5E+0	2E-9	6E-12	0	0
89	Ac-227	D: see Ac-224	2E-1 Bone Surf (4E-1)	4E-4 Bone surf (8E-4)	2E-13 0	0 1E-15	0 5E-9	0 5E-8
89	Ac-227	W: see Ac-224	0	2E-3	7E-13	0	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
			0	Bone surf (3E-3)	0	4E-15	0	0
89	Ac-227	Y: see Ac-224	0	4E-3	2E-12	6E-15	0	0
89	Ac-228	D: see Ac-224	2E+3	9E+0	4E-9	0	3E-5	3E-4
			0	Bone surf (4E+1)	0	2E-11	0	0
89	Ac-228	W: see Ac-224	0	4E+1	2E-8	0	0	0
			0	Bone surf (6E+1)	0	8E-11	0	0
89	Ac-228	Y: see Ac-224	0	4E+1	2E-8	6E-11	0	0
90	Th-226	W: all compounds except those given for Y	5E+3	2E+2	6E-8	2E-10	0	0
			St Wall (5E+3)	0	0	0	7E-5	7E-4
90	Th-226 ²	Y: oxides and hydroxides	0	1E+2	6E-8	2E-10	0	0
90	Th-227	W: see Th-226	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
90	Th-227	Y: see Th-226	0	3E-1	1E-10	5E-13	0	0
90	Th-228	W: see Th-226	6E+0	1E-2	4E-12	0	0	0
			Bone Surf (1E+1)	Bone surf (2E-2)	0	3E-14	2E-7	2E-6
90	Th-228	Y: see Th-226	0	2E-2	7E-12	2E-14	0	0
90	Th-229	W: see Th-226	6E-1	9E-4	4E-13	0	0	0
			Bone Surf (1E+0)	Bone surf (2E-3)	0	3E-15	2E-8	2E-7
90	Th-229	Y: see Th-226	0	2E-3	1E-12	0	0	0
			0	Bone surf (3E-3)	0	4E-15	0	0
90	Th-230	W: see Th-226	4E+0	6E-3	3E-12	0	0	0
			Bone Surf (9E+0)	Bone surf (2E-2)	0	2E-14	1E-7	1E-6
90	Th-230	Y: see Th-226	0	2E-2	6E-12	0	0	0
			0	Bone surf (2E-2)		3E-14	0	0
90	Th-231	W: see Th-226	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
90	Th-231	Y: see Th-226	0	6E+3	3E-6	9E-9	0	0
90	Th-232	W: see Th-226	7E-1	1E-3	5E-13	0	0	0
			Bone Surf (2E+0)	Bone surf (3E-3)	0	4E-15	3E-8	3E-7
90	Th-232	Y: see Th-226	0	3E-3	1E-12	0	0	0
			0	Bone surf (4E-3)		6E-15	0	0
90	Th-234	W: see Th-226	3E+2	2E+2	8E-8	3E-10	0	0
			LLI Wall (4E+2)	0	0	0	5E-6	5E-5
90	Th-234	Y: see Th-226	0	2E+2	6E-8	2E-10	0	0
91	Pa-227 ²	W: all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
91	Pa-227 ²	Y: oxides and hydroxides	0	1E+2	4E-8	1E-10	0	0
91	Pa-228	W: see Pa-227	1E+3	1E+1	5E-9	0	2E-5	2E-4
			0	Bone surf (2E+1)	0	3E-11	0	0
91	Pa-228	Y: see Pa-227	0	1E+1	5E-9	2E-11	0	0
91	Pa-230	W: see Pa-227	6E+2	5E+0	2E-9	7E-12	0	0
			Bone Surf (9E+2)	0	0	0	1E-5	1E-4
91	Pa-230	Y: see Pa-227	0	4E+0	1E-9	5E-12	0	0
91	Pa-231	W: see Pa-227	2E-1	3E-3	6E-13	0	0	0
			Bone Surf (5E-1)	Bone surf (4E-3)	0	6E-15	6E-9	6E-8
91	Pa-231	Y: see Pa-227	0	4E-3	2E-12	0	0	0
			0	Bone surf (6E-3)	0	8E-15	0	0
91	Pa-232	W: see Pa-227	1E+3	2E+1	9E-9	0	2E-5	2E-4
			0	Bone surf (6E+1)	0	8E-11	0	0
91	Pa-232	Y: see Pa-227	0	6E+1	2E-8	0	0	0
			0	Bone surf (7E+0)	0	1E-10	0	0
91	Pa-233	W: see Pa-227	1E+3	7E+2	2E-7	1E-9	0	0
			LLI Wall (2E+3)	0	0	0	2E-5	2E-4
91	Pa-233	Y: see Pa-227	0	6E+2	3E-7	8E-10	0	0
91	Pa-234	W: see Pa-227	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
91	Pa-234	Y: see Pa-227	0	7E+3	3E-6	9E-9	0	0
92	U-230	D: UF ₆ , UO ₂ F ₂ , UO ₂ (NO ₃) ₂	4E+0	4E-1	2E-10	0	0	0
			Bone Surf (6E+0)	Bone surf (6E-1)	0	8E-13	8E-8	8E-7
92	U-230	W: UO ₃ , UF ₄ , UCl ₄	0	4E-1	1E-10	5E-13	0	0
92	U-230	Y: UO ₂ , U ₃ O ₈	0	3E-1	1E-10	4E-13	0	0
92	U-231	D: see U-230	5E+3	8E+3	3E-6	1E-8	0	0
			LLI Wall (4E+3)	0	0	0	6E-5	6E-4
92	U-231	W: see U-230	0	6E+3	2E-6	8E-9	0	0
92	U-231	Y: see U-230	0	5E+3	2E-6	6E-9	0	0
92	U-232	D: see U-230	2E+0	2E-1	9E-11	0	0	0
			Bone Surf (4E+0)	Bone surf (4E-1)	0	6E-13	6E-8	6E-7
92	U-232	W: see U-230	0	4E-1	2E-10	5E-13	0	0
92	U-232	Y: see U-230	0	8E-3	3E-12	1E-14	0	0
92	U-233	D: see U-230	1E+1	1E+0	5E-10	0	0	0
			Bone Surf (2E+1)	Bone surf (2E+0)	0	3E-12	3E-7	3E-6
92	U-233	W: see U-230	0	7E-1	3E-10	1E-12	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
92	U-233	Y: see U-230	0	4E-2	2E-11	5E-14	0	0
92	U-234 ³	D: see U-230	1E+1 Bone Surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 0	0 3E-12	0 3E-7	0 3E-6
92	U-234 ³	W: see U-230	0	7E-1	3E-10	1E-12	0	0
92	U-234 ³	Y: see U-230	0	4E-2	2E-11	5E-14	0	0
92	U-235 ³	D: see U-230	1E+1 Bone Surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 0	0 3E-12	0 3E-7	0 3E-7
92	U-235 ³	W: see U-230	0	8E-1	3E-10	1E-12	0	0
92	U-235 ³	Y: see U-230	0	4E-2	2E-11	6E-14	0	0
92	U-236	D: see U-230	1E+1 Bone Surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 0	0 3E-12	0 3E-7	0 3E-6
92	U-236	W: see U-230	0	8E-1	3E-10	1E-12	0	0
92	U-236	Y: see U-230	0	4E-2	2E-11	6E-14	0	0
92	U-237	D: see U-230	2E+3 LLI Wall (2E+3)	3E+3 0	1E-6 0	4E-9 0	0 3E-5	0 3E-4
92	U-237	W: see U-230	0	2E+3	7E-7	2E-9	0	0
92	U-237	Y: see U-230	0	2E+3	6E-7	2E-9	0	0
92	U-238 ³	D: see U-230	1E+1 Bone Surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 0	0 3E-12	0 3E-7	0 3E-6
92	U-237	W: see U-230	0	8E-1	3E-10	1E-12	0	0
92	U-237	Y: see U-230	0	4E-2	2E-11	6E-14	0	0
92	U-239 ²	D: see U-230	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
92	U-239 ²	W: see U-230	0	2E+5	7E-5	2E-7	0	0
92	U-239 ²	Y: see U-230	0	2E+5	6E-5	2E-7	0	0
92	U-240	D: see U-230	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
92	U-240	W: see U-230	0	3E+3	1E-6	4E-9	0	0
92	U-240	Y: see U-230	0	2E+3	1E-6	3E-9	0	0
92	U-Nat ³	D: see U-230	1E+1 Bone Surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 0	0 3E-12	0 3E-7	0 3E-6
92	U-Nat ³	W: see U-230	0	8E-1	3E-10	9E-13	0	0
92	U-Nat ³	Y: see U-230	0	5E-2	2E-11	9E-14	0	0
93	Np-232 ²	W: all compounds	1E+5 0	2E+3 Bone surf (5E+2)	7E-7 0	0 6E-9	2E-3 0	2E-2 0
93	Np-233 ²	W: all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93	Np-234	W: all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93	Np-235	W: all compounds	2E+4 LLI Wall 2E+4	8E+2 Bone surf (1E+3)	3E-7 0	0 2E-9	0 3E-4	0 3E-3

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
93	Np-236 (1E+5 y)	W: all compounds	3E+0 Bone Surf (6E+0)	2E-2 Bone surf (5E-2)	9E-12 0	0 8E-14	0 9E-8	0 9E-7
93	Np-236: (22.5 h)	W: all compounds	3E+3 Bone Surf (4E+3)	3E+1 Bone surf (7E+1)	1E-8 0	0 1E-10	0 5E-5	0 5E-4
93	Np-237	W: all compounds	5E-1 Bone Surf (1E+0)	4E-3 Bone surf (1E-2)	2E-12 0	0 1E-14	0 2E-8	0 2E-7
93	Np-238	W: all compounds	1E+3	6E+1 Bone surf (2E+2)	3E-8 0	0 2E-10	2E-5 0	2E-4 0
93	Np-239	W: all compounds	2E+3 LLI Wall (2E+3)	2E+3 0	9E-7 0	3E-9 0	0 2E-5	0 2E-4
93	Np-240 ²	W: all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94	Pu-234	W: all compounds except PuO ₂	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
94	Pu-234	Y: PuO ₂	0	2E+2	8E-8	3E-10	0	0
94	Pu-235 ²	W: see Pu-234	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
94	Pu-235	Y: see Pu-234	0	3E+6	1E-3	3E-6	0	0
94	Pu-236	W: see Pu-234	2E+0 Bone Surf (4E+0)	2E-2 Bone surf (4E-2)	8E-12	0 5E-14	0 6E-8	0 6E-7
94	Pu-236	Y: see Pu-234	0	4E-2	2E-11	6E-14	0	0
94	Pu-237	W: see Pu-234	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
94	Pu-237	Y: see Pu-234	0	3E+3	1E-6	4E-9	0	0
94	Pu-238	W: see Pu-234	9E-1 Bone Surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 0	0 2E-14	0 2E-8	0 2E-7
94	Pu-238	Y: see Pu-234	0	2E-2	8E-12	2E-14	0	0
94	Pu-239	W: see Pu-234	8E-1 Bone Surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 0	0 2E-14	0 2E-8	0 2E-7
94	Pu-239	Y: see Pu-234	0	2E-2 Bone surf (2E-2)	7E-12 0	0 2E-14	0 0	0 0
94	Pu-240	W: see Pu-234	8E-1 Bone Surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12	0 2E-14	0 2E-8	0 2E-7
94	Pu-240	Y: see Pu-234	0	2E-2 Bone surf (2E-2)	7E-12 0	0 2E-14	0 0	0 0
94	Pu-241	W: see Pu-234	4E+1 Bone Surf (7E+1)	3E-1 Bone surf (6E-1)	1E-10 0	0 8E-13	0 2E-6	0 2E-5
94	Pu-241	Y: see Pu-234	0	8E-1 Bone surf	3E-10	0	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
			0	(1E+0)	0	1E-12	0	0
94	Pu-242	W: see Pu-234	8E-1 Bone Surf (1E+0)	7E-3 Bone surf (1E-2)	3E-12 0	0 2E-14	0 2E-8	0 2E-7
94	Pu-242	Y: see Pu-234	0 0	2E-2 Bone surf (2E-2)	7E-12 0	0 2E-14	0 0	0 0
94	Pu-243	W: see Pu-234	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
94	Pu-243	Y: see Pu-234	0	4E+4	2E-5	5E-8	0	0
94	Pu-244	W: see Pu-234	8E-1 Bone Surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 0	0 2E-14	0 2E-8	0 2E-7
94	Pu-244	Y: see Pu-234	0	2E-2 Bone surf (2E-2)	7E-12 0	0 2E-14	0 0	0 0
94	Pu-245	W: see Pu-234	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
94	Pu-245	Y: see Pu-234	0	4E+3	2E-6	6E-9	0	0
94	Pu-246	W: see Pu-234	4E+2 LLI Wall (4E+2)	3E+2 0	1E-7 0	4E-10 0	0 6E-6	0 6E-5
94	Pu-246	Y: see Pu-234	0	3E+2	1E-7	4E-10	0	0
95	Am-237 ²	W: all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95	Am-238 ²	W: all compounds	4E+4	3E+3 Bone surf (6E+3)	1E-6 0	0 9E-9	5E-4 0	5E-3 0
95	Am-239	W: all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Am-240	W: all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95	Am-241	W: all compounds	8E-1 Bone Surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 0	0 2E-14	0 2E-8	0 2E-7
95	Am-242m	W: all compounds	8E-1 Bone Surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 0	0 2E-14	0 2E-8	0 2E-7
95	Am-242	W: all compounds	4E+3	8E+1 Bone surf (9E+1)	4E-8 0	0 1E-10	5E-5 0	5E-4 0
95	Am-243	W: all compounds	8E-1 Bone Surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 0	0 2E-14	0 2E-8	0 2E-7
95	Am-244m ²	W: all compounds	6E+4 St Wall (8E+4)	4E+3 Bone surf (7E+3)	2E-6 0	0 1E-8	0 1E-3	0 1E-2
95	Am-244	W: all compounds	3E+3 0	2E+2 Bone surf (3E+2)	8E-8 0	0 4E-10	4E-5 0	4E-4 0
95	Am-245	W: all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Am-246m ²	W: all compounds	5E+4 St Wall	2E+5	8E-5	3E-7	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci/ml}$)	COL. 1 Air ($\mu\text{Ci/ml}$)	COL. 2 Water ($\mu\text{Ci/ml}$)	Monthly Average Concentration ($\mu\text{Ci/ml}$)
			(6E+4)	0	0	0	8E-4	8E-3
95	Am-246 ²	W: all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Cm-238	W: all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Cm-240	W: all compounds	6E+1 Bone Surf (8E+1)	6E- Bone surf (6E-1)	2E-10 0	0 9E-13	0 1E-6	0 1E-5
96	Cm-241	W: all compounds	1E+3 0	3E+1 Bone surf (4E+1)	1E-8 0	0 5E-11	2E-5 0	2E-4 0
96	Cm-242	W: all compounds	3E+1 Bone Surf (5E+1)	3E-1 Bone surf (3E-1)	1E-10 0	0 4E-13	0 7E-7	0 7E-6
96	Cm-243	W: all compounds	1E+0 Bone Surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12 0	0 2E-14	0 3E-8	0 3E-7
96	Cm-244	W: all compounds	1E+0 Bone Surf (2E+0)	1E-2 Bone surf (2E-2)	5E-12 0	0 3E-14	0 3E-8	0 3E-7
96	Cm-245	W: all compounds	7E-1 Bone Surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 0	0 2E-14	0 2E-8	0 2E-7
96	Cm-246	W: all compounds	7E-1 Bone Surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12	0 2E-14	0 2E-8	0 2E-7
96	Cm-247	W: all compounds	8E-1 Bone Surf (1E+0)	6E-3 Bone surf (1E-2)	3E-10 0	0 2E-14	0 2E-8	0 2E-7
96	Cm-248	W: all compounds	2E-1 Bone Surf (4E-1)	2E-3 Bone surf (3E-3)	7E-13 0	0 4E-15	0 5E-9	0 5E-8
96	Cm-249 ²	W: all compounds	5E+4 0	2E+4 Bone surf (3E+4)	7E-6 0	0 4E-8	7E-4 0	7E-3 0
96	Cm-250	W: all compounds	4E-2 Bone Surf (6E-2)	3E-4 Bone surf (5E-4)	1E-13	0 8E-16	0 9E-10	0 9E-9
97	Bk-245	W: all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97	Bk-246	W: all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97	Bk-247	W: all compounds	5E-1 Bone Surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12 0	0 1E-14	0 2E-8	0 2E-7
97	Bk-249	W: all compounds	2E+2 Bone Surf (5E+2)	2E+0 Bone surf (4E+0)	7E-10 0	0 5E-12	0 6E-6	0 6E-5
97	Bk-250	W: all compounds	9E+3 0	3E+2 Bone surf (7E+2)	1E-7 0	0 1E-9	1E-4 0	1E-3 0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μ Ci)	COL. 2 Inhalation ALI (μ Ci)	COL. 3 Inhalation DAC (μ Ci/ml)	COL. 1 Air (μ Ci/ml)	COL. 2 Water (μ Ci/ml)	Monthly Average Concentration (μ Ci/ml)
98	Cf-244 ²	W: all compounds except those given for Y	3E+4 St Wall (3E+4)	6E+2 0	2E-7 0	8E-10	0 4E-4	0 4E-3
98	Cf-244 ²	Y: oxides and hydroxides	0	6E+2	2E-7	8E-10	0	0
98	Cf-246	W: see Cf-244	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
98	Cf-246	Y: see Cf-244	0	9E+0	4E-9	1E-11	0	0
98	Cf-248	W: see Cf-244	8E+0 Bone Surf (2E+1)	6E-2 Bone surf (1E-1)	3E-11 0	0 2E-13	0 2E-7	0 2E-6
98	Cf-248	Y: see Cf-244	0	1E-1	4E-11	1E-13	0	0
98	Cf-249	W: see Cf-244	5E-1 Bone Surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12 0	0 1E-14	0 2E-8	0 2E-7
98	Cf-249	Y: see Cf-244	0 0	1E-2 Bone surf (1E-2)	4E-12 0	0 2E-14	0 0	0 0
98	Cf-250	W: see Cf-244	1E+0 Bone Surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12 0	0 3E-14	0 3E-8	0 3E-8
98	Cf-250	Y: see Cf-244	0	3E-2	1E-11	4E-14	0	0
98	Cf-251	W: see Cf-244	5E-1 Bone Surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12	0 1E-14	0 2E-8	0 2E-7
98	Cf-251	Y: see Cf-244	0 0	1E-2 Bone surf (1E-2)	4E-12 0	0 2E-14	0 0	0 0
98	Cf-252	W: see Cf-244	2E+0 Bone Surf (5E+0)	2E-2 Bone surf (4E-2)	8E-12 0	0 5E-14	0 7E-8	0 7E-7
98	Cf-252	Y: see Cf-244	0	3E-2	1E-11	5E-14	0	0
98	Cf-253	W: see Cf-244	2E+2 Bone Surf (4E+2)	2E+0 0	8E-10 0	2E-12 0	0 5E-6	0 5E-4
98	Cf-253	Y: see Cf-244	0	2E+0	7E-10	2E-12	0	0
98	Cf-254	W: see Cf-244	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
98	Cf-254	Y: see Cf-244	0	2E-2	7E-12	2E-14	0	0
99	Es-250	W: all compounds	4E+4 0	5E+2 Bone surf (12E+3)	2E-7 0	0 2E-9	0 0	0 0
99	Es-251	W: all compounds	7E+3 0	9E+2 Bone surf (1E+3)	4E-7 0	0 2E-9	1E-4 0	1E-3 0
99	Es-253	W: all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99	Es-254m	W: all compounds	3E+2 LLI Wall (3E+2)	1E+1 0	4E-9 0	1E-11 0	0 4E-6	0 4E-5

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC (μCi/ml)	COL. 1 Air (μCi/ml)	COL. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
99	Es-254	W: all compounds	8E+0 Bone Surf (2E+1)	7E-2 Bone surf (1E-1)	3E-11 0	0 2E-13	0 2E-7	0 2E-6
100	Fm-252	W: all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100	Fm-253	W: all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fm-254	W: all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fm-255	W: all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fm-257	W: all compounds	2E+1 Bone Surf (4E+1)	2E-1 Bone surf (2E-1)	7E-11 0	0 3E-13	0 5E-7	0 5E-6
101	Md-257	W: all compounds	7E+3 0	8E+1 Bone surf (9E+1)	4E-8 0	0 1E-10	1E-4 0	1E-3 0
101	Md-258	W: all compounds	3E+1 Bone Surf (5E+1)	2E-1 Bone surf (3E-1)	1E-10 0	0 5E-13	0 6E-7	0 6E-6
---	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours	SUBMERSION ¹	0	2E+2	1E-7	1E-9	0	0
---	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours		0	2E-1	1E-10	1E-12	1E-8	1E-7

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC (μCi/ml)	COL. 1 Air (μCi/ml)	COL. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
---	Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known		0	4E-4	2E-13	1E-15	2E-9	2E-8
	If it is known that Ac-227-D and Cm-250-W are not present		0	7E-4	3E-13	0	0	0
	If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present		0	7E-3	3E-12	0	0	0
	If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228,-W,Y, Th-230-Y, U-233-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W,		0	7E-2	3E-11	0	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC ($\mu\text{Ci}/\text{ml}$)	COL. 1 Air ($\mu\text{Ci}/\text{ml}$)	COL. 2 Water ($\mu\text{Ci}/\text{ml}$)	Monthly Average Concentration ($\mu\text{Ci}/\text{ml}$)
	Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-252-W,Y, are not present							
	If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W Ra-223-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, C-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present		0	7E-1	3E-10	0	0	0
	If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, u-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present		0	7E+0	3E-9	0	0	0
	If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-248-W, and Cm-250-W		0	0	0	1E-14	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC (μCi/ml)	COL. 1 Air (μCi/ml)	COL. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
	are not present							
	If, in addition, it is known that Sm-146-W, Gd-148-D, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-2333-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-2, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present		0	0	0	1E-13	0	0
	If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D-W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W,Y, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present		0	0	0	1E-12	0	0

At. No.	Radionuclide	Class	TABLE I Occupational Values			TABLE II Effluent Concentrations		TABLE III Release to Sewers
			COL. 1 Oral Ingestion ALI (μCi)	COL. 2 Inhalation ALI (μCi)	COL. 3 Inhalation DAC (μCi/ml)	COL. 1 Air (μCi/ml)	COL. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
	If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Ex-254, Fm-257, and Md-258 are not present		0	0	0	0	1E-6	1E-5

FOOTNOTES:

- 1 "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.
- 2 These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other measuring instruments that measure external exposure to demonstrate compliance with the limits.
- 3 For soluble mixtures, of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor. If the percent by weight (enrichment) or U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. for any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

$$SA = 3.6E-7 \text{ curies/gram U} \quad \text{U-depleted}$$

$$SA = [0.4 + 0.38(\text{enrichment}^2)] E-6, \quad \text{enrichment} \geq 0.72$$

Where enrichment is the percentage by weight of U-235, expressed as percent

NOTE:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be present from the mixture; or
3. If the mixture of radionuclides consists of uranium and its daughters in ore dust (10 µm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 µCi of gross alpha activity from uranium 238, uranium 234, thorium 230, and radium 226 per milliliter of air; 3E-11 µCi of natural uranium of air; or 45 micrograms of natural uranium per cubic meter of air.
4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993 for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., unity)

Example: If radionuclides "A", "B", and "C" are present in concentrations C_A , C_B , and C_C , and if the applicable DACs are DAC_A , DAC_B , and DAC_C , respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
PROTECTION FACTORS FOR RESPIRATORS

July 1993

ATTACHMENT 2

PROTECTION FACTORS FOR RESPIRATORS*

Description ^b	Protection Factors ^d		Tested & Certified Equipment	
	Modes ^c	Particulates only	Particulates, gases, vapors ^c	National Institute for Occupational Safety and Health & Mike Safety And Health Administration tests for permissibility
I. AIR -PURIFYING RESPIRATORS ^f				
Facepiece, half-mask ^g Facepiece, full Facepiece, half-mask full, or hood	NP NP PP	10 50 1000		30 CFR 11, Subpart K.
II. ATMOSPHERE-SUPPLYING RESPIRATORS				
1. Air-line respirator Facepiece, half-mask Facepiece, half-mask Facepiece, full Facepiece, full Facepiece, full Hood Suit	CF D CF D PD CF CF		1000 5 2000 5 2000 h i	30 CFR 11, Subpart J. j
2. Self-contained breathing apparatus (SCBA) Facepiece, full Facepiece, full Facepiece, full Facepiece, full	D PD RD RP		50 10000 ^k 50 5000 ^l	30 CFR, Subpart H
III. COMBINATION RESPIRATORS				
Any combination of air-purifying and atmosphere-supplying respirators	Protection factor for type and mode or operation as listed above			30 CFR 11 11.63(b)

FOOTNOTES

- (a) For use in the selection of respiratory protection equipment to be used only where the contaminants have been identified and the concentrations, or possible concentrations, are known
- (b) Only for shaven faces and where nothing interferes with the seal of tight-fitting facepieces against the skin. Hoods and suits are excepted
- (c) The mode symbols are defined as follows:

CF = continuous flow

D = demand

NP = negative pressure, that is, always negative phase during inhalation

PD = pressure demand, that is, always positive pressure

PR = positive pressure

RD = demand, recirculating or closed circuit

RP = pressure demand, recirculating or closed circuit

- (d) (1) The protection factor is a measure of the degree of protection afforded by a respirator, defined as the ration of the concentration of airborne radioactive material outside the respiratory protective equipment to that inside the equipment, usually inside the facepiece, under conditions of use. It is applied to the ambient airborne concentration to estimate the concentrations inhaled by the wearer according to the following formula

$$\text{Concentration inhaled} = \frac{\text{Ambient airborne Concentration}}{\text{Protection factor}}$$

- (2) The protection factors apply:

- (i) Only for individuals trained in using respirators and wearing properly fitted respirators that are used and maintained under supervision on a well planned respiratory protective program.
- (ii) For air-purifying respirators only when high efficiency particulate filters, above 99.97 percent removal efficiency by thermally generated 0.3 micrometer dioctyl phthalate (DOP) test of equivalent, are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards.
- (iii) No adjustment is to be made for the use of sorbents against radioactive material in the form of gases or vapors.

- (iv) For atmosphere-supplying respirators only when supplied with adequate respirable air. Respirable air shall be provided of the quality and quantity required in accordance with the National Institute for Occupational Safety and Health and the Mine Safety Administration certification described in 30 CFR 11. Oxygen and air shall not be used in the same apparatus.
- (e) Excluding radioactive contaminants that present an absorption or submersion hazard. For tritium oxide, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of less than 2 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. If the protection factor of respiratory protective equipment is 5,, the effective protection factor for tritium is about 1.4; with protection factors of 10, the effective factor of tritium oxide is 1.7; and with protection factors of 100 or more, the effective factor for tritium oxide is about 1.9. Air-purifying respirators are not suitable for protection against tritium oxide. See also footnote I concerning supplied-air suits.
- (f) Canisters and cartridges shall not be used beyond service-life limitation.
- (g) Under-chin type only. This type of respirator is not satisfactory for use where it might be possible, such as, if an accident or emergency were to occur, for the ambient airborne concentration to reach instantaneous values greater than 10 time the pertinent values in the State of Florida Bureau of Radiation Control ALLs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3. This type of respirator is not suitable for protection against plutonium or other high-toxicity materials. The mask is to be tested for fit prior to use, each time it is donned.
- (h)
 - (1) Equipment shall be operated in a manner that ensures that proper air flow-rates are maintained. A protection factor of no more than 1000 may be utilized for tested-and-certified supplied-air hoods when a minimum air flow of 6 ft³/min. (0.17 m³/min.) is maintained and calibrated air line pressure gauges or flow measuring device are used. A protection factor of up to 2000 may be used for tested-and-certified hoods only when the air flow is maintained at the manufacturer's recommended maximum rate for the equipment, this rate is greater than 6 ft³/min. (0.17 m³/min.) and calibrated air line pressure gauges or flow measuring devices are used.
 - (2) The design of the supplied-air hood or helmet, with a minimum flow of 6 ft³/min. (0.17 m³/min.) of air, may determine its overall efficiency and the protection it provides. For example, some hoods aspirate contaminated air into the breathing zone when the wearer works with hands-over-head. This aspiration may be overcome if a short cape-like extension to the hood is worn under a coat or overalls. Other limitations specified by the approval agency shall be considered before using a hood in certain types of atmospheres. See footnote i.

- (l) Appropriate protection factors shall be determined, taking into account the design of the suit and its permeability to the contaminant under conditions of use. There shall be a standby rescue person equipped with a respirator or other apparatus appropriate for the potential hazards and communications equipment whenever supplied-air suits are used
- (j) No approval schedules are currently available for this equipment. Equipment is to be evaluated by testing or on the basis of reliable test information
- (k) This type of respirator may provide greater protection and be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure, such as skin absorption must be taken into account in such circumstances.
- (l) Quantitative fit testing shall be performed on each individual, and no more than 0.02 percent leakage is allowed with this type of apparatus. Perceptible outward leakage of gas from this or any positive pressure self-contained breathing apparatus is unacceptable because service life will be reduced substantially. Special training in the use of this type of apparatus shall be provided to the wearer.

Note 1: Protection factors for respirators approved by the U.S. Bureau of Mines and the National Institute for Occupational Safety and Health, according the applicable approvals for respirator for type and mode of use to protect against airborne radionuclides, may be used to the extent that they do not exceed the protection factors listed in this table. The protection factors listed in this table may not be appropriate to circumstances where chemical or other respiratory hazards exist in addition to radioactive hazards. The selection and use of respirators for such circumstances should take into account applicable approvals of the U.S. Bureau of Mines and the National Institute for Occupational Safety and Health.

Note 2: Radioactive contaminants, for which the concentration values in State of Florida Bureau of Radiation Control. ALIs, DACs, and Effluent Concentrations, July 1003. Table I, Column 3 are based on internal dose due to inhalation, may present external exposure hazards at higher concentrations. Under these circumstances, limitations of occupancy may have to be governed by external dose limits.

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
PROTECTION FACTORS FOR RESPIRATORS

May 2006

PROTECTION FACTORS FOR RESPIRATORS^(a)

The following definitions apply:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
**RADIOACTIVE MATERIAL
REQUIRING LABELING**

May 2000

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Actinium-224	1	Antimony-125	100
Actinium-225	0.01	Antimony-126	100
Actinium-226	0.1	Antimony-126m	1000
Actinium-227	0.001	Antimony-127	100
Actinium-228	1	Antimony-128 (10.4m)	1000
Aluminum-26	10	Antimony-128 (9.01h)	100
Americium-237	1000	Antimony-129	100
Americium-238	100	Antimony-130	1000
Americium-239	1000	Antimony-131	1000
Americium-240	100	Argon-41	1000
Americium-241	0.001	Arsenic-72	100
Americium-242	10	Arsenic-73	100
Americium-242m	0.001	Arsenic-74	100
Americium-243	0.001	Arsenic-76	100
Americium-244	10	Astatine-207	100
Americium-244m	100	Astatine-211	10
Americium-245	1000	Barium-126	1000
Americium-246	1000	Barium-128	100
Americium-246m	1000	Barium-131	100
Antimony-115	1000	Barium-131m	1000
Antimony-116	1000	Barium-133	100
Antimony-116m	1000	Barium-133m	100
Antimony-117	1000	Barium-135m	100
Antimony-118m	1000	Barium-139	1000
Antimony-119	1000	Barium-140	100
Antimony-120 (16m)	1000	Barium-141	1000
Antimony-120 (5.76d)	100	Barium-142	1000
Antimony-122	100	Berkelium-245	100
Antimony-124	10	Berkelium-246	100
Antimony-124m	1000	Berkelium-247	0.001

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Berkelium-249	0.1	Cadmium-117	1000
Berkelium-250	10	Cadmium-117m	1000
Beryllium-10	1	Calcium-41	100
Beryllium-7	1000	Calcium-45	100
Bismuth-200	1000	Calcium-47	100
Bismuth-201	1000	Californium-244	100
Bismuth-202	1000	Californium-246	1
Bismuth-203	100	Californium-248	0.01
Bismuth-205	100	Californium-249	0.001
Bismuth-206	100	Californium-250	0.001
Bismuth-207	10	Californium-251	0.001
Bismuth-210	1	Californium-252	0.001
Bismuth-210m	0.1	Californium-253	0.1
Bismuth-212	10	Californium-254	0.001
Bismuth-213	10	Carbon-11	1000
Bismuth-214	100	Carbon-14	100
Bromine-74	1000	Cerium-134	100
Bromine-74m	1000	Cerium-135	100
Bromine-75	1000	Cerium-137	1000
Bromine-76	100	Cerium-137m	100
Bromine-77	1000	Cerium-139	100
Bromine-80	1000	Cerium-141	100
Bromine-80m	1000	Cerium-143	100
Bromine-82	100	Cerium-144	1
Bromine-83	1000	Cesium-125	1000
Bromine-84	1000	Cesium-127	1000
Cadmium-104	1000	Cesium-129	1000
Cadmium-107	1000	Cesium-130	1000
Cadmium-109	1	Cesium-131	1000
Cadmium-113	100	Cesium-132	100
Cadmium-113m	0.1	Cesium-134	10
Cadmium-115	100	Cesium-134m	1000
Cadmium-115m	10	Cesium-135	100

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Cesium-135m	1000	Dysprosium-166	100
Cesium-136	10	Einsteinium-250	100
Cesium-137	10	Einsteinium-251	100
Cesium-138	1000	Einsteinium-253	0.1
Chlorine-36	10	Einsteinium-254	0.01
Chromium-48	1000	Einsteinium-254m	1
Chromium-49	1000	Erbium-161	1000
Chromium-51	1000	Erbium-165	1000
Cobalt-55	100	Erbium-169	100
Cobalt-56	10	Erbium-171	100
Cobalt-57	1000	Erbium-172	100
Cobalt-60	1	Europium-145	100
Cobalt-61	1000	Europium-146	100
Cobalt-62m	1000	Europium-147	100
Copper-60	1000	Europium-148	10
Copper-61	1000	Europium-149	100
Copper-64	1000	Europium-150 (12.62h)	100
Copper-67	1000	Europium-150 (34.2y)	1
Curium-238	100	Europium-152	1
Curium-240	0.1	Europium-152m	100
Curium-241	1	Europium-154	1
Curium-242	0.01	Europium-155	10
Curium-243	0.001	Europium-156	100
Curium-244	0.001	Europium-157	100
Curium-245	0.001	Europium-158	1000
Curium-246	0.001	Fermium-252	1
Curium-247	0.001	Fermium-253	1
Curium-248	0.001	Fermium-254	10
Curium-249	1000	Fermium-255	1
Dysprosium-155	1000	Fermium-257	0.01
Dysprosium-157	1000	Fluorine-18	1000
Dysprosium-159	100	Francium-222	100
Dysprosium-165	1000		

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Francium-223	100	Hafnium-170	100
Gadolinium-145	1000	Hafnium-172	1
Gadolinium-146	10	Hafnium-173	1000
Gadolinium-147	100	Hafnium-175	100
Gadolinium-148	0.001	Hafnium-177m	1000
Gadolinium-149	100	Hafnium-178m	0.1
Gadolinium-151	10	Hafnium-179m	10
Gadolinium-152	100	Hafnium-180m	1000
Gadolinium-153	10	Hafnium-181	10
Gadolinium-159	100	Hafnium-182	0.1
Gallium-65	1000	Hafnium-182m	1000
Gallium-66	100	Hafnium-183	1000
Gallium-67	1000	Hafnium-184	100
Gallium-68	1000	Holmium-155	1000
Gallium-70	1000	Holmium-157	1000
Gallium-72	100	Holmium-159	1000
Gallium-73	1000	Holmium-161	1000
Germanium-66	1000	Holmium-162	1000
Germanium-67	1000	Holmium-162m	1000
Germanium-68	10	Holmium-164	1000
Germanium-69	1000	Holmium-164m	1000
Germanium-71	1000	Holmium-166	100
Germanium-75	1000	Holmium-166m	1
Germanium-77	1000	Holmium-167	1000
Gold-193	1000	Hydrogen-3	1000
Gold-194	100	Indium-109	1000
Gold-195	10	Indium-110m (69.1m)	1000
Gold-198	100	Indium-111	100
Gold-198m	100	Indium-112	1000
Gold-199	100	Indium-113m	1000
Gold-200	1000	Indium-114m	10
Gold-200m	100	Indium-115	100
Gold-201	1000	Indium-115m	1000

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Indium-116m	1000	Iridium-194	100
Indium-117	1000	Iridium-194m	10
Indium-117m	1000	Iridium-195	1000
Indium-119m	1000	Iridium-195m	1000
Indium-110 (4.9h)	1000	Iron-52	100
Iodine-120	100	Iron-55	100
Iodine-120m	1000	Iron-59	10
Iodine-121	1000	Iron-60	1
Iodine-123	100	Krypton-74	1000
Iodine-124	10	Krypton-76	1000
Iodine-125	1	Krypton-77	1000
Iodine-126	1	Krypton-79	1000
Iodine-128	1000	Krypton-81	1000
Iodine-129	1	Krypton-83m	1000
Iodine-130	10	Krypton-85	1000
Iodine-131	1	Krypton-85m	1000
Iodine-132	100	Krypton-87	1000
Iodine-132m	100	Krypton-88	1000
Iodine-133	10	Lanthanum-131	1000
Iodine-134	1000	Lanthanum-132	100
Iodine-135	100	Lanthanum-135	1000
Iridium-182	1000	Lanthanum-137	10
Iridium-184	1000	Lanthanum-138	100
Iridium-185	1000	Lanthanum-140	100
Iridium-186	100	Lanthanum-141	100
Iridium-187	1000	Lanthanum-142	1000
Iridium-188	100	Lanthanum-143	1000
Iridium-189	100	Lead-195m	1000
Iridium-190	100	Lead-198	1000
Iridium-190m	1000	Lead-199	1000
Iridium-192 (73.8d)	1	Lead-200	100
Iridium-192m (1.4m)	10	Lead-201	1000
		Lead-202	10

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Lead-202m	1000	Mercury-194	1
Lead-203	1000	Mercury-195	1000
Lead-205	100	Mercury-195m	100
Lead-209	1000	Mercury-197	1000
Lead-210	0.01	Mercury-197m	100
Lead-211	100	Mercury-199m	1000
Lead-212	1	Mercury-203	100
Lead-214	100	Molybdenum-101	1000
Lutetium-169	100	Molybdenum-90	100
Lutetium-170	100	Molybdenum-93	10
Lutetium-171	100	Molybdenum-93m	100
Lutetium-172	100	Molybdenum-99	100
Lutetium-173	10	Neodymium-136	1000
Lutetium-174	10	Neodymium-138	100
Lutetium-174m	10	Neodymium-139	1000
Lutetium-176	100	Neodymium-139m	1000
Lutetium-176m	1000	Neodymium-141	1000
Lutetium-177	100	Neodymium-147	100
Lutetium-177m	10	Neodymium-149	1000
Lutetium-178	1000	Neodymium-151	1000
Lutetium-178m	1000	Neptunium-232	100
Lutetium-179	1000	Neptunium-233	1000
Magnesium-28	100	Neptunium-234	100
Manganese-51	1000	Neptunium-235	100
Manganese-52	100	Neptunium-236 (1.15E+5y)	0.001
Manganese-52m	1000	Neptunium-236 (22.5h)	1
Manganese-53	1000	Neptunium-237	0.001
Manganese-54	100	Neptunium-238	10
Manganese-56	1000	Neptunium-239	100
Mendelevium-257	10	Neptunium-240	1000
Mendelevium-258	0.01	Nickel-56	100
Mercury-193	1000	Nickel-57	100
Mercury-193m	100		

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Nickel-59	100	Platinum-188	100
Nickel-63	100	Platinum-189	1000
Nickel-65	1000	Platinum-191	100
Nickel-66	10	Platinum-193	1000
Niobium-88	1000	Platinum-193m	100
Niobium-89 (122m)	1000	Platinum-195m	100
Niobium-89m (66m)	1000	Platinum-197	100
Niobium-90	100	Platinum-197m	1000
Niobium-93m	10	Platinum-199	1000
Niobium-94	1	Platinum-200	100
Niobium-95	100	Plutonium-234	10
Niobium-95m	100	Plutonium-235	1000
Niobium-96	100	Plutonium-236	0.001
Niobium-97	1000	Plutonium-237	100
Niobium-98	1000	Plutonium-238	0.001
Osmium-180	1000	Plutonium-239	0.001
Osmium-181	1000	Plutonium-240	0.001
Osmium-182	100	Plutonium-241	0.01
Osmium-185	100	Plutonium-242	0.001
Osmium-189m	1000	Plutonium-243	1000
Osmium-191	100	Plutonium-244	0.001
Osmium-191m	1000	Plutonium-245	100
Osmium-193	100	Polonium-203	1000
Osmium-194	1	Polonium-205	1000
Palladium-100	100	Polonium-207	1000
Palladium-101	1000	Polonium-210	0.1
Palladium-103	100	Potassium-40	100
Palladium-107	10	Potassium-42	1000
Palladium-109	100	Potassium-43	1000
Phosphorus-32	10	Potassium-44	1000
Phosphorus-33		Potassium-45	1000
Platinum-186	1000	Praseodymium-136	1000
		Praseodymium-137	1000

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Praseodymium-138m	1000	Radon-222	1
Praseodymium-139	1000	Rhenium-177	1000
Praseodymium-142	100	Rhenium-178	1000
Praseodymium-142m	1000	Rhenium-181	1000
Praseodymium-143	100	Rhenium-182 (12.7)	1000
Praseodymium-144	1000	Rhenium-182 (64.0h)	100
Praseodymium-145	100	Rhenium-184	100
Praseodymium-147	1000	Rhenium-184m	10
Promethium-141	1000	Rhenium-186	100
Promethium-143	100	Rhenium-186m	10
Promethium-144	10	Rhenium-187	1000
Promethium-145	10	Rhenium-188	100
Promethium-146	1	Rhenium-188m	1000
Promethium-147	10	Rhenium-189	100
Promethium-148	10	Rhodium-100	100
Promethium-148m	10	Rhodium-101	10
Promethium-149	100	Rhodium-101m	1000
Promethium-150	1000	Rhodium-102	10
Promethium-151	100	Rhodium-102m	10
Protactinium-227	10	Rhodium-103m	1000
Protactinium-228	1	Rhodium-105	100
Protactinium-230	0.1	Rhodium-106m	1000
Protactinium-231	0.001	Rhodium-107	1000
Protactinium-232	1	Rhodium-99	100
Protactinium-233	100	Rhodium-99m	1000
Protactinium-234	100	Rubidium-79	1000
Radium-223	0.1	Rubidium-81	1000
Radium-224	0.1	Rubidium-81m	1000
Radium-225	0.1	Rubidium-82m	1000
Radium-226	0.1	Rubidium-83	100
Radium-227	1000	Rubidium-84	100
Radium-228	0.1	Rubidium-86	100
Radon-220	1		

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Ruthenium-103	100	Silver-103	1000
Ruthenium-105	1000	Silver-104	1000
Ruthenium-106	1	Silver-104m	1000
Ruthenium-94	1000	Silver-105	100
Ruthenium-97	1000	Silver-106	1000
Samarium-141	1000	Silver-106m	100
Samarium-141m	1000	Silver-108m	1
Samarium-142	1000	Silver-111	100
Samarium-145	100	Silver-112	100
Samarium-146	1	Silver-115	1000
Samarium-147	100	Silver-110m	10
Samarium-151	10	Sodium-22	10
Samarium-153	100	Sodium-24	100
Samarium-155	1000	Strontium-81	1000
Samarium-156	1000	Strontium-83	100
Scandium-43	1000	Strontium-85	10
Scandium-44	100	Strontium-85m	1000
Scandium-44m	100	Strontium-90	0.1
Scandium-46	10	Strontium-91	100
Scandium-47	100	Strontium-92	100
Scandium-48	100	Sulfur-35	100
Scandium-49	1000	Tantalum-172	1000
Selenium-70	1000	Tantalum-173	1000
Selenium-73	100	Tantalum-174	1000
Selenium-73m	1000	Tantalum-175	1000
Selenium-75	100	Tantalum-176	100
Selenium-79	100	Tantalum-177	1000
Selenium-81	1000	Tantalum-178	1000
Selenium-81m	1000	Tantalum-179	100
Selenium-83	1000	Tantalum-180	100
Silicon-31	1000	Tantalum-180m	1000
Silicon-32	1	Tantalum-182	10
Silver-102	1000	Tantalum-182m	1000

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Tantalum-183	100	Terbium-147	1000
Tantalum-184	100	Terbium-149	100
Tantalum-185	1000	Terbium-150	1000
Tantalum-186	1000	Terbium-151	100
Technetium-101	1000	Terbium-153	1000
Technetium-104	1000	Terbium-154	100
Technetium-93	1000	Terbium-155	1000
Technetium-93m	1000	Terbium-156	100
Technetium-94	1000	Terbium-156m (24.4h)	1000
Technetium-94m	1000	Terbium-156m (5.0h)	1000
Technetium-96	100	Terbium-157	10
Technetium-96m	1000	Terbium-158	1
Technetium-97	1000	Terbium-160	10
Technetium-97m	100	Terbium-161	100
Technetium-98	10	Thallium-194	1000
Technetium-99	100	Thallium-194m	1000
Technetium-99m	1000	Thallium-195	1000
Tellurium-116	1000	Thallium-197	1000
Tellurium-121	100	Thallium-198	1000
Tellurium-121m	10	Thallium-198m	1000
Tellurium-123	100	Thallium-199	1000
Tellurium-123m	10	Thallium-200	1000
Tellurium-125m	10	Thallium-201	1000
Tellurium-127	1000	Thallium-202	100
Tellurium-127m	10	Thallium-204	100
Tellurium-129	1000	Thorium-226	10
Tellurium-129m	10	Thorium-227	0.01
Tellurium-131	100	Thorium-228	0.001
Tellurium-131m	10	Thorium-229	0.001
Tellurium-132	10	Thorium-230	0.001
Tellurium-133	1000	Thorium-231	100
Tellurium-133m	100	Thorium-232	100
Tellurium-134	1000		

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Thorium-234	10	Uranium-230	0.01
Thorium-natural	100	Uranium-231	100
Thulium-162	1000	Uranium-232	0.001
Thulium-166	100	Uranium-233	0.001
Thulium-167	100	Uranium-234	0.001
Thulium-170	10	Uranium-235	0.001
Thulium-171	10	Uranium-236	0.001
Thulium-172	100	Uranium-237	100
Thulium-173	100	Uranium-238	100
Thulium-175	1000	Uranium-239	1000
Tin-110	100	Uranium-240	100
Tin-111	1000	Uranium-natural	100
Tin-113	100	Vanadium-47	1000
Tin-117m	100	Vanadium-48	100
Tin-119m	100	Vanadium-49	1000
Tin-121	1000	Xenon-120	1000
Tin-121m	100	Xenon-121	1000
Tin-123	10	Xenon-122	1000
Tin-123m	1000	Xenon-123	1000
Tin-125	10	Xenon-125	1000
Tin-126	10	Xenon-127	1000
Tin-127	1000	Xenon-129m	1000
Tin-128	1000	Xenon-131m	1000
Titanium-44	1	Xenon-133	1000
Titanium-45	1000	Xenon-133m	1000
Tungsten-176	1000	Xenon-135	1000
Tungsten-177	1000	Xenon-135m	1000
Tungsten-178	1000	Xenon-138	1000
Tungsten-179	1000	Ytterbium-162	1000
Tungsten-181	1000	Ytterbium-166	100
Tungsten-185	100	Ytterbium-167	1000
Tungsten-187	100	Ytterbium-169	100
Tungsten-188	10	Ytterbium-175	100

64E-5 Florida Administrative Code ATT 3 -- Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Ytterbium-177	1000	Zinc-69m	100
Ytterbium-178	1000	Zinc-71m	1000
Yttrium-86	100	Zinc-72	100
Yttrium-86m	1000	Zirconium-86	100
Yttrium-87	100	Zirconium-88	10
Yttrium-88	10	Zirconium-89	100
Yttrium-90	10	Zirconium-93	1
Yttrium-90m	1000	Zirconium-95	10
Yttrium-91	10	Zirconium-97	100
Yttrium-91m	1000	Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001
Yttrium-92	100	Any radionuclide other than emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01
Yttrium-93	100		
Yttrium-94	1000		
Yttrium-95	1000		
Zinc-62	100		
Zinc-63	1000		
Zinc-65	10		
Zinc-69	1000		

To convert μCi to kBq, multiple μCi value by 37.

Federal Policy as described in 45 CFR Part 46 dated 11/09/2009 which is herein incorporated by reference in 64E-5.601(5)(b), F.A.C

Electronic Code of Federal Regulations
e-CFR
TM

e-CFR Data is current as of November 9, 2009

Title 45: Public Welfare

[Browse Previous](#) | [Browse Next](#)

PART 46—PROTECTION OF HUMAN SUBJECTS

Section Contents

[Subpart A—Basic HHS Policy for Protection of Human Research Subjects](#)

[§ 46.101 To what does this policy apply?](#)

[§ 46.102 Definitions.](#)

[§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.](#)

[§§ 46.104-46.106 \[Reserved\]](#)

[§ 46.107 IRB membership.](#)

[§ 46.108 IRB functions and operations.](#)

[§ 46.109 IRB review of research.](#)

[§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.](#)

[§ 46.111 Criteria for IRB approval of research.](#)

[§ 46.112 Review by institution.](#)

[§ 46.113 Suspension or termination of IRB approval of research.](#)

[§ 46.114 Cooperative research.](#)

[§ 46.115 IRB records.](#)

[§ 46.116 General requirements for informed consent.](#)

[§ 46.117 Documentation of informed consent.](#)

[§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.](#)

[§ 46.119 Research undertaken without the intention of involving human subjects.](#)

[§ 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.](#)

[§ 46.121 \[Reserved\]](#)

[§ 46.122 Use of Federal funds.](#)

[§ 46.123 Early termination of research support: Evaluation of applications and proposals.](#)

[§ 46.124 Conditions.](#)

[Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research](#)

[§ 46.201 To what do these regulations apply?](#)

[§ 46.202 Definitions.](#)

[§ 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.](#)

[§ 46.204 Research involving pregnant women or fetuses.](#)

[§ 46.205 Research involving neonates.](#)

[§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.](#)

[§ 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.](#)

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

- [§ 46.301 Applicability.](#)
- [§ 46.302 Purpose.](#)
- [§ 46.303 Definitions.](#)
- [§ 46.304 Composition of Institutional Review Boards where prisoners are involved.](#)
- [§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.](#)
- [§ 46.306 Permitted research involving prisoners.](#)

Subpart D—Additional Protections for Children Involved as Subjects in Research

- [§ 46.401 To what do these regulations apply?](#)
- [§ 46.402 Definitions.](#)
- [§ 46.403 IRB duties.](#)
- [§ 46.404 Research not involving greater than minimal risk.](#)
- [§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.](#)
- [§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.](#)
- [§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.](#)
- [§ 46.408 Requirements for permission by parents or guardians and for assent by children.](#)
- [§ 46.409 Wards.](#)

Subpart E—Registration of Institutional Review Boards

- [§ 46.501 What IRBs must be registered?](#)
- [§ 46.502 What information must be provided when registering an IRB?](#)
- [§ 46.503 When must an IRB be registered?](#)
- [§ 46.504 How must an IRB be registered?](#)
- [§ 46.505 When must IRB registration information be renewed or updated?](#)

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).

Editorial Note: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

Subpart A—Basic HHS Policy for Protection of Human Research Subjects



[top](#)

Authority: 5 U.S.C. 301; 42 U.S.C. 289, 42 U.S.C. 300v–1(b).

Source: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§ 46.101 To what does this policy apply?



[top](#)

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the Federal Register in such other manner as provided in department or agency procedures.¹

¹ Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A–D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.102 Definitions.



[top](#)

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.



[top](#)

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§§ 46.104-46.106 [Reserved]



[top](#)

§ 46.107 IRB membership.



[top](#)

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall

be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.



[top](#)

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in §46.103(b)(4) and, to the extent required by, §46.103(b)(5).

(b) Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 46.109 IRB review of research.



[top](#)

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under Control Number 0990–0260)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.[top](#)

(a) The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.111 Criteria for IRB approval of research.[top](#)

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.



[_top](#)

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.



[_top](#)

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.114 Cooperative research.



[_top](#)

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ 46.115 IRB records.



[_top](#)

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

- (4) Copies of all correspondence between the IRB and the investigators.
- (5) A list of IRB members in the same detail as described in §46.103(b)(3).
- (6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).
- (7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.116 General requirements for informed consent.



[top](#)

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.117 Documentation of informed consent.



[top](#)

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116.

This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.



[top](#)

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 46.119 Research undertaken without the intention of involving human subjects.



[top](#)

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.



[top](#)

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department

or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 [Reserved]



[top](#)

§ 46.122 Use of Federal funds.



[top](#)

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 46.123 Early termination of research support: Evaluation of applications and proposals.



[top](#)

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 46.124 Conditions.



[top](#)

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research



[top](#)

Source: 66 FR 56778, Nov. 13, 2001, unless otherwise noted.

§ 46.201 To what do these regulations apply?



[top](#)

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS

employees.

(b) The exemptions at §46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of §46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in §46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Definitions.



[top](#)

The definitions in §46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

§ 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.



[top](#)

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§ 46.204 Research involving pregnant women or fetuses.



[top](#)

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

§ 46.205 Research involving neonates.



[top](#)

(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

(3) Individuals engaged in the research will have no part in determining the viability of a neonate.

(4) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if

the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

- (1) Vital functions of the neonate will not be artificially maintained;
- (2) The research will not terminate the heartbeat or respiration of the neonate;
- (3) There will be no added risk to the neonate resulting from the research;
- (4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- (5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.



[top](#)

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§ 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.



[top](#)

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of §§46.204 or 46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

(1) That the research in fact satisfies the conditions of §46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or

alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects



[top](#)

Source: 43 FR 53655, Nov. 16, 1978, unless otherwise noted.

§ 46.301 Applicability.



[top](#)

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.



[top](#)

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.



[top](#)

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) *DHHS* means the Department of Health and Human Services.

(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

[top](#)

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8386, Jan. 26, 1981]

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

[top](#)

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under §46.306 (a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

[top](#)

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research



[top](#)

Source: 48 FR 9818, Mar. 8, 1983, unless otherwise noted.

§ 46.401 To what do these regulations apply?



[top](#)

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of §46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of Subpart A are applicable to this subpart.

[48 FR 9818, Mar. 8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991]

§ 46.402 Definitions.

[top](#)

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

- (a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
- (b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- (c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.
- (d) *Parent* means a child's biological or adoptive parent.
- (e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

[top](#)

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

[top](#)

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

[top](#)

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

- (a) The risk is justified by the anticipated benefit to the subjects;
- (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- (c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

[top](#)

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- (a) The risk represents a minor increase over minimal risk;
- (b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- (c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- (d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.



[top](#)

HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

- (a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- (b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
 - (1) That the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or
 - (2) The following:
 - (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - (ii) The research will be conducted in accordance with sound ethical principles;
 - (iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.



[top](#)

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.



[top](#)

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Subpart E—Registration of Institutional Review Boards



[top](#)

Source: 74 FR 2405, Jan. 15, 2009, unless otherwise noted.

§ 46.501 What IRBs must be registered?



[top](#)

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under §46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§ 46.502 What information must be provided when registering an IRB?

[top](#)

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§ 46.503 When must an IRB be registered?

[top](#)

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under §46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

§ 46.504 How must an IRB be registered?

[top](#)

Each IRB must be registered electronically through <http://ohrp.cit.nih.gov/efile> unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

§ 46.505 When must IRB registration information be renewed or updated?

[top](#)

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with §46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must

be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

[Browse Previous](#) | [Browse Next](#)

For questions or comments regarding e-CFR editorial content, features, or design, email ecfr@nara.gov.

For questions concerning e-CFR programming and delivery issues, email webteam@gpo.gov.

[Section 508 / Accessibility](#)

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
DH FORM 1622
OCCUPATIONAL EXPOSURE
RECORD FOR A MONITORING
PERIOD
July 1993



OCCUPATIONAL EXPOSURE RECORD FOR A MONITORING PERIOD

1. NAME (LAST, FIRST MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE	5. DATE OF BIRTH
--------------------------------------	--------------------------	------------	---	------------------

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER(S)	9A. <input type="checkbox"/> RECORD <input type="checkbox"/> ESTIMATE	9B. <input type="checkbox"/> ROUTINE <input type="checkbox"/> PSE
----------------------	--------------------------------	--------------------------------------	---	---

INTAKES				DOSES (in rem)	
10A. RADIONUCLIDE	10B. CLASS	10C. MODE	10D. INTAKE IN μ Ci		
				DEEP DOSE EQUIVALENT (DDE)	11.
				EYE DOSE EQUIVALENT TO THE LENS OF THE EYE (LDE)	12.
				SHALLOW DOSE EQUIVALENT, WHOLE BODY (SDE,WB)	13.
				COMMITTED DOSE EQUIVALENT, MAX EXTREMITY (SDE,ME)	14.
				COMMITTED DOSE EQUIVALENT (CEDE)	15.
				COMMITTED DOSE EQUIVALENT MAXIMALLY EXPOSED ORGAN (CDE)	16.
				TOTAL EFFECTIVE DOSE EQUIVALENT (BLOCKS 11+15) (TEDE)	17.
				TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN (BLOCKS 11+16) (TODE)	18.
				19. COMMENTS	

20. SIGNATURE -- LICENSEE OR REGISTRANT	21. DATE PREPARED
---	-------------------

1. Type or print the full name of the monitored individual in the order of last name (include "jr.", "Sr.", III", etc.), first name, middle name, middle initial (If applicable).
2. Enter the individual's identification number, including punctuation. this number should be the 9-digit social security number if at all possible, If the individual has no social security number, enter the number from another official identification such as a passport or work permit.
3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other
4. Check the box that denotes the sex of the individual being monitored.
5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.
6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.
7. Enter the name of the licensee or registrant.
8. Enter the Agency license or registration number or numbers.

- 9A. Place an "X" in Record or Estimate. Choose "record" if the dose data listed represents a final determination of the dose received to the best of the licensee's or registrants knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of the TLD results that are yet available.
- 9B. Place an "X" in either Routine or PSE. Choose "Routine" if the data represents the results of monitoring for routine exposures. Choose "PSE" if the dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSEs.
- 10A. Enter the symbol for each radionuclide that resulted in an inter exposure recorded for the individual in the format "Xx-###x," for instance Cs-139 or Tc-99m.
- 10B. Enter the lung clearance class as listed in Appendix B to Part D (D, W, Y, V, or O for other) for all intakes by inhalation.
- 10C. Enter the mode of intake. For inhalation, enter "H." For absorption through the skin, enter "B." For oral ingestion, enter "G." for injection, enter "J."
- 10D. Enter the intake of each radionuclide in μCi .
11. Enter the deep dose equivalent (DDE) to the whole body.
12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.
13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE, WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE, ME).
15. Enter the committed effective dose equivalent (CEDE) or "NR" for "Not Required" or "NC" for "Not Calculated".
16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for "Not Required" or "NC" for "Not Calculated".
17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.
18. Enter the total organ dose equivalent (TODE) for maximally exposed organ. The TODE is the sum of items 11 and 16.
19. Signature of the person designated to represent the licensee or registrant.
20. Enter the date this form was prepared.
21. COMMENTS.
In the space provided, enter additional information that might be needed to determine compliance with limits. An example might be to enter the note that the SDE,ME was the result of exposure from a discrete hot particle. Another possibility would be to indicate that an overexposed report has been sent to the Agency in reference to the exposure report.

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
DH FORM 1623
CUMULATIVE OCCUPATIONAL
EXPOSURE HISTORY
July 1993



CUMULATIVE OCCUPATIONAL EXPOSURE HISTORY

1. NAME (LAST, FIRST, MIDDLE INITIAL)				2. IDENTIFICATION NUMBER		3. ID TYPE	4. SEX MALE <input type="checkbox"/> FEMALE <input type="checkbox"/>		5. DATE OF BIRTH
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD <input type="checkbox"/> ESTIMATE <input type="checkbox"/> NO RECORD <input type="checkbox"/>		10. ROUTINE <input type="checkbox"/> PSE <input type="checkbox"/>	
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODD	
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD <input type="checkbox"/> ESTIMATE <input type="checkbox"/> NO RECORD <input type="checkbox"/>		10. ROUTINE <input type="checkbox"/> PSE <input type="checkbox"/>	
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODD	
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD <input type="checkbox"/> ESTIMATE <input type="checkbox"/> NO RECORD <input type="checkbox"/>		10. ROUTINE <input type="checkbox"/> PSE <input type="checkbox"/>	
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODD	
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD <input type="checkbox"/> ESTIMATE <input type="checkbox"/> NO RECORD <input type="checkbox"/>		10. ROUTINE <input type="checkbox"/> PSE <input type="checkbox"/>	
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODD	
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD <input type="checkbox"/> ESTIMATE <input type="checkbox"/> NO RECORD <input type="checkbox"/>		10. ROUTINE <input type="checkbox"/> PSE <input type="checkbox"/>	
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODD	
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD <input type="checkbox"/> ESTIMATE <input type="checkbox"/> NO RECORD <input type="checkbox"/>		10. ROUTINE <input type="checkbox"/> PSE <input type="checkbox"/>	
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODD	
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD <input type="checkbox"/> ESTIMATE <input type="checkbox"/> NO RECORD <input type="checkbox"/>		10. ROUTINE <input type="checkbox"/> PSE <input type="checkbox"/>	
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODD	
19. SIGNATURE OF MONITORED INDIVIDUAL		20. DATE SIGNED	21. CERTIFYING ORGANIZATION			22. SIGNATURE OF DESIGNEE			23. DATE SIGNED

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF DH FORM 1623 JULY 93
(All doses should be stated in rems)

PAGE _____ OF _____

1. Type or print the full name of the monitored individual in the order of last name (include "jr.", "Sr.", III", etc.), first name, middle name, middle initial (If applicable).
2. Enter the individual's identification number, including punctuation. this number should be the 9-digit social security number if at all possible, If the individual has no social security number, enter the number from another official identification such as a passport or work permit.
3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other
4. Check the box that denotes the sex of the individual being monitored.
5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.
6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.
7. Enter the name of the licensee or registrant.
8. Enter the Agency license or registration number or numbers.

9. Place an "X" in Record or Estimate. Choose "record" if the dose data listed represents a final determination of the dose received to the best of the licensee's or registrants knowledge. Choose "Estimate " only if the listed dose data are preliminary and will be superseded by a final determination resulting in subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of the TLD results that are yet available.
10. Place an "X" in either Routine or PSE. Choose "Routine" if the data represents the results of monitoring for routine exposures. Choose "PSE" if the dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSEs.
11. Enter the deep dose equivalent (DDE) to the whole body.
12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.
13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE, WB).
14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE, ME).
15. Enter the committed effective dose equivalent (CEDE) or "NR" for "Not Required" or "NC" for "Not Calculated".
16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for Required" or "NC" for "Not Calculated".

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.
18. Enter the total organ dose equivalent (TODE) for maximally exposed organ. The TODE is the sum of items 11 and 16.
19. Signature of the monitored individual. The signature of the monitored individual on this form indicates that the information contained on the form is complete and correct to the best of his or her knowledge.
20. Enter the date this form was signed by the monitored individual.
21. [OPTIONAL]S. Enter the name of the licensee, registrant or facility not licensed by the Agency, providing monitoring for exposure to radiation (such as a DOE facility) or the employer if the individual is no employed by the licensee or registrant and the employer chooses to maintain exposure records for its employees.
22. [OPTIONAL] Signature of the person designated to represent the licensee, registrant or employer entered in item 21. The licensee registrant or employer who chooses to countersign the form should have on file documentation of all the information on the Agency Form Y being signed.
23. {OPTIONAL] Enter the date this form was signed by the designated representative.

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
DH FORM 1059
**CERTIFICATE - DISPOSITION OF RADIOACTIVE
MATERIALS**



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL**

Bin #C21 ? 4052 Bald Cypress Way ? TALLAHASSEE, FLORIDA 32399-1741

CERTIFICATE - DISPOSITION OF RADIOACTIVE MATERIALS

(All items MUST be completed, please print)

LICENSEE NAME AND ADDRESS	LICENSE NUMBER
	LICENSE EXPIRATION DATE

THE LICENSEE OR ANY INDIVIDUAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE LICENSEE CERTIFIES THAT:
(Check and complete the appropriate item(s) below.)

A. MATERIALS DATA (Check one and complete, as necessary)

1. NO MATERIALS HAVE EVER BEEN PROCESSED OR PROCURED BY THE LICENSEE UNDER THIS LICENSE

OR

2. ALL MATERIALS PROCURED OR PROCESSED BY THE LICENSEE UNDER THE LICENSE NUMBER CITED ABOVE HAVE BEEN TRANSFERRED ON

DATE:	TO:		
		LICENSE NUMBER:	

OR

3. ALL MATERIALS PROCURED OR PROCESSED BY THE LICENSEE UNDER THE LICENSE NUMBER CITED ABOVE HAVE BEEN TRANSFERRED ON

DATE:	TO:		
		WHICH HAS LICENSE NUMBER	ISSUED BY THE STATE OF

OR

4. MATERIALS HAVE BEEN DISPOSED OF IN THE FOLLOWING MANNER. (Describe specific disposal procedures - if additional space is needed, use the reverse of this form, or provide attachments)

B. OTHER DATA

1. OUR LICENSE HAS NOT YET EXPIRED, PLEASE TERMINATE IT.

2. WAS A RADIATION SURVEY CONDUCTED TO CONFIRM THE ABSENCE OF LICENSED RADIOACTIVE MATERIALS AND TO DETERMINE WHETHER ANY CONTAMINATION REMAINS ON THE PREMISES COVERED BY THE LICENSE? (Check one)

NO

YES, THE RESULTS (Check one)

ARE ATTACHED, OR

WERE FORWARDED TO DEPARTMENT OF HEALTH ON (Date)

3. THE PERSON TO BE CONTACTED REGARDING THIS INFORMATION PROVIDED ON THIS FORM

NAME	TELEPHONE NUMBER
------	------------------

4. MAIL ALL FUTURE CORRESPONDENCE REGARDING LICENSE TO

RETURN TO: BUREAU OF RADIATION CONTROL BIN #C21 4052 BALD CYPRESS WAY TALLAHASSEE, FL 32399-1741	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th align="center" colspan="2">CERTIFYING OFFICIAL</th> </tr> <tr> <td style="width:70%; padding: 5px;">SIGNATURE</td> <td style="width:30%; padding: 5px;">DATE</td> </tr> <tr> <td style="padding: 5px;">PRINTED NAME AND TITLE</td> <td></td> </tr> </table>	CERTIFYING OFFICIAL		SIGNATURE	DATE	PRINTED NAME AND TITLE	
CERTIFYING OFFICIAL							
SIGNATURE	DATE						
PRINTED NAME AND TITLE							

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
DH FORM 1054
RADIOACTIVE MATERIALS LICENSE
APPLICATION -- Non-Human Use

**RADIOACTIVE MATERIALS PROGRAM
APPLICATION FOR RADIOACTIVE MATERIALS LICENSE
NON-HUMAN USE**

INSTRUCTIONS - Complete Items 1 – 15 as applicable. Item 15 must be completed on all applications. Use supplemental sheets where necessary. **Mail the original and one copy to:** Department of Health, Bureau of Radiation Control, Radioactive Materials Program, 4052 Bald Cypress Way, Bin #C21, Tallahassee, FL 32399-1741. *Regulatory Guidance Documents are available from the Bureau of Radiation Control to assist in completing this application.*

1.a. LEGAL NAME, MAILING ADDRESS

(Include ZIP code), FEI #, Phone & Fax Numbers:

FEI # _____

Telephone # _____

Fax # _____

1.b. STREET ADDRESS WHERE RADIOACTIVE MATERIALS WILL BE USED OR STORED (Include ZIP Code)

Same as 1.a.

2.a. LICENSE APPLICATION FEE CATEGORY

(See 64E-5.204, F.A.C., for license descriptions)

b. LICENSE FEE ENCLOSED: \$ _____

3. THIS IS AN APPLICATION FOR:

- a. New License**
- b. Amendment To License Number:** _____
- c. Renewal Of License Number:** _____

4. INDIVIDUAL USERS & REQUESTED USES

(Name all individuals who may receive, possess, prepare, use or transfer radioactive materials or directly supervise others in these activities.)

SEE ATTACHED LIST

5.a. RADIATION SAFETY OFFICER (RSO):
(Name and Contact Information)

Name: _____

RSO Phone #: _____

RSO E-Mail: _____

5.b. ALTERNATE EMERGENCY CONTACT:

Name: _____

Contact Phone #: _____

Contact E-Mail: _____

Florida Bureau of Radiation Control - Application For Radioactive Materials License
NON-HUMAN USE

6. TRAINING AND EXPERIENCE IN RADIATION SAFETY

a. FORMAL TRAINING IN RADIATION SAFETY: Describe the formal training for each individual named in Items 4 and 5, including principles and practices of radiation protection, radioactivity measurement, monitoring techniques and the use of instruments, mathematics and calculations basic to the use and measurement of radioactivity, and biological effects of radiation. Include the name of the person or institution providing the training, duration of training and when training was received. Attach a copy of any training certificate received if applicable.

SEE ATTACHED LIST

b. EXPERIENCE: Describe the radiation work experience for each individual named in Items 4 and 5, including where the experience was obtained or attach a copy of a radioactive materials license that identifies them by name as an authorized user. Include a list of radioisotopes and the maximum activity of each use. Work experience or on-the-job training should be commensurate with the proposed use.

SEE ATTACHED LIST

7. RADIOACTIVE MATERIAL

a. Isotope	b. Chemical or Physical Form (If sealed sources, include manufacturer name and model numbers)	c. Maximum Amount Or Activity Possessed At Any One Time. (If sealed source, state the number of sources, maximum activity per source and total activity)
Ex. Co-60	Sealed source XYZ Corp. Model XYZ for use in XYZ Corp Model AAA therapy device or liquid/gas/powder.	30 sources, 2 curies each for a total of 60 curies.

SEE ATTACHED LIST

**Florida Bureau of Radiation Control - Application For Radioactive Materials License
NON-HUMAN USE**

8. DESCRIBE THE PURPOSE FOR WHICH EACH RADIOACTIVE MATERIAL LISTED IN ITEM 7, ABOVE WILL BE USED.

(For each sealed source, include the manufacturer's name and model number of the device, gauge or storage container where the source will be used or stored. List a line item for each different type of use for the same or different isotopes.

Ex. Co-60 to be used in a xyz corporation model AAA device in a BBB source holder for the measuring of density of materials in a process vessel.

SEE ATTACHED LIST

9. LIST EACH TYPE OF RADIATION DETECTION INSTRUMENT (i.e., survey meters, counters, etc.)

TYPE OF INSTRUMENTS (include manufacturer and model number of each)	USE (e.g., monitoring, surveying, measuring)	RADIATION DETECTED (beta, gamma, alpha, neutrons)	SENSITIVITY RANGE Low -High (mR/hr)	NUMBER AVAILABLE
Ex. XYZ Co. Model 1 survey meter with Model 33 probe	Monitoring & surveying for removable contamination	Beta & Gamma	0.1 mR/hr – 1 R/hr	2
<input type="checkbox"/> SEE ATTACHED LIST				

Florida Bureau of Radiation Control - Application For Radioactive Materials License
NON-HUMAN USE

10. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 9 ABOVE.

a. **Calibration by Licensed Service Company**

Calibration Frequency will be at Intervals Not to Exceed: _____ months

b. **Calibration by Applicant** (Attached is a separate sheet describing procedures, frequency and standards used for calibration of instruments.)

11. PERSONNEL MONITORING DEVICES. Complete Items a, b, & c. (Check all that are applicable)

a. Film OSLD TLD Other (See attached) (Provider Must be NVLAP Certified)

b. Whole Body: Exchange Frequency Not to Exceed: _____ Months

Extremity: Exchange Frequency Not to Exceed: _____ Months

c. Radiation Detected: Beta Gamma Neutron

12. FACILITIES AND EQUIPMENT. Attach a description of facilities where radioactive material, including waste, will be used or stored. **Attach an annotated diagram of the areas of use and/or storage, including adjacent areas.** Describe equipment such as remote handling devices, storage containers, shielding, fume hoods, etc. Describe security at your facility such as locks, chains, alarms, security camera, security services, etc.

Description of facilities and equipment also attached with annotated diagram of the areas of use or storage, including adjacent areas.

Attached is a description of security at facilities of the areas of radioactive materials are used or stored to prevent theft or unauthorized access to radioactive materials.

13. RADIATION PROTECTION PROGRAM. Attach a radiation protection program as appropriate for the material to be used, including general radiation safety procedures, emergency procedures, security, and bioassay procedures, etc. (Note that possession of large quantities of certain isotopes, such as those used in fixed gauges, industrial radiography, or irradiators for use in research or blood products, may require additional increased controls for security measures or national source tracking as required by 64E-5.350 and 64E-5.351, FAC.)

Radiation Protection Program Details Attached

Florida Bureau of Radiation Control - Application For Radioactive Materials License
NON-HUMAN USE

14. WASTE DISPOSAL. Describe the procedures for handling, storing and disposing of radioactive wastes (solid, liquid and/or gas). Name the commercial waste disposal service employed, if applicable. If sealed sources and/or devices will be returned to the manufacturer, so state.

See Attached for Details on Radioactive Waste Disposal

15. CERTIFICATE

The applicant and any official executing this certificate on behalf of the applicant named in Item 1, certify that this application has been prepared in accordance with Chapter 64E-5, Florida Administrative Code, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. *In addition, the applicant or executing official is acknowledging that they are aware that knowingly making false statements to a public servant is a violation of section 837.06, Florida Statutes, and is punishable by fine or imprisonment*

Certifying Official (Signature)

Name (typed or printed)

Title

Date

Warning: KNOWINGLY MAKING FALSE STATEMENTS TO A PUBLIC SERANT IS A VIOLATION OF SECTION 837.06, FLORIDA STATUTES, AND IS PUNISHABLE BY FINE OR IMPRISONMENT



**RADIOACTIVE MATERIALS SECTION
APPLICATION FOR RADIOACTIVE MATERIALS LICENSE
HUMAN USE**



INSTRUCTIONS - Complete Items 1 – 35 as applicable. Item 35 must be completed on all applications. Use supplemental sheets where necessary. **Mail the original and one copy to:** Department of Health, Bureau of Radiation Control, Radioactive Materials Section, 4052 Bald Cypress Way, Bin #C21, Tallahassee, FL 32399-1741. *Regulatory Guidance Documents are available from the Bureau of Radiation Control to assist in completing this application.*

1.a. LEGAL NAME, MAILING ADDRESS

(Include ZIP code), FEI #, Phone & Fax Numbers:

FEI # _____

Telephone # _____

Fax # _____

1.b. STREET ADDRESS WHERE RADIOACTIVE MATERIALS WILL BE USED OR STORED (Include ZIP Code)

Same as 1.a.

2.a. LICENSE FEE CATEGORY

(See 64E-5.204, F.A.C., for license descriptions)

b. LICENSE FEE ENCLOSED: \$ _____

3. THIS IS AN APPLICATION FOR:

- a. New License**
- b. Amendment To License Number:** _____
- c. Renewal Of License Number:** _____

4. INDIVIDUAL USERS & REQUESTED USES

(Name all Authorized Users & Authorized Medical Physicists, who may receive, possess, prepare, use or transfer radioactive materials or directly supervise others in these activities.)

SEE ATTACHED LIST

5.a. RADIATION SAFETY OFFICER (RSO):
(Name and Contact Information)

Name: _____

RSO Phone #: _____

RSO E-Mail: _____

5.b. ALTERNATE EMERGENCY CONTACT:

Name: _____

Contact Phone #: _____

Contact E-Mail: _____

Florida Bureau of Radiation Control - Application For Radioactive Materials License
HUMAN USE

6.a. Radioactive Materials For Medical Use By 64E-5, Florida Administrative Code	Y= <input checked="" type="checkbox"/>	Possession Limits
Both: 64E-5.626(1) & (2) Uptake, Dilution, Excretion (Written Directive Required) (Nal-131 \geq 30 μ Ci) <input type="checkbox"/> Capsule form ONLY I-131 or <input type="checkbox"/> I-131 Bioassay Program Attached	<input type="checkbox"/>	0.5 curies or _____ curies
Only 64E-5.626(1) Uptake, Dilution or Excretions (No Written Directive Required) (Nal-131 < 30 μ Ci)	<input type="checkbox"/>	0.5 curies or _____ curies
Only 64E-5.626(2) Uptake, Dilution or Excretions (Written Directive Required) (Nal-131 \geq 30 μ Ci) <input type="checkbox"/> Capsule form ONLY I-131 or <input type="checkbox"/> I-131 Bioassay Program Attached	<input type="checkbox"/>	0.5 curies or _____ curies
All: 64E-5.627(1), (2), & (3) Imaging & Localizations (Written Directive Required) (Nal-131 \geq 30 μ Ci) <input type="checkbox"/> Capsule form ONLY I-131 or <input type="checkbox"/> I-131 Bioassay Program Attached	<input type="checkbox"/>	2 curies or _____ curies
Only 64E-5.627(1) Imaging and Localizations (No Written Directive Required) (Nal-131 < 30 μ Ci)	<input type="checkbox"/>	2 curies or _____ curies
Both 64E-5.627(2) & (3) Imaging & Localizations (Written Directive Required) (Nal-131 \geq 30 μ Ci) <input type="checkbox"/> Capsule form ONLY I-131 or <input type="checkbox"/> I-131 Bioassay Program Attached	<input type="checkbox"/>	2 curies or _____ curies
<input type="checkbox"/> 64E-5.627 (4) Xe-133 Gas <input type="checkbox"/> Tc99m Aerosol	<input type="checkbox"/>	_____ millicuries
64E-5.628(1) Mo99/Tc99m Generator	<input type="checkbox"/>	5 curies
64E-5.628(2) or (3) Other Generators	<input type="checkbox"/>	Complete Item 6.b.
64E-5.630 Radiopharmaceutical Therapy (Written Directive Required) <input type="checkbox"/> Capsule form ONLY I-131 or <input type="checkbox"/> I-131 Bioassay Program Attached	<input type="checkbox"/>	2 curies or _____ curies
64E-5.632 Manual Brachytherapy	<input type="checkbox"/>	2 curies or _____ curies
64E-5.632(2) Sr-90 Eye Applicator ONLY	<input type="checkbox"/>	Complete Item 6.b.
64E-5.632(3)&(4) Pd-103 or I-125 for Permanent Implants ONLY	<input type="checkbox"/>	2 curies or _____ curies
64E-5.634(1) Gamma Stereotactic Radiosurgery	<input type="checkbox"/>	Complete Item 6.b.
64E-5.634(2) Remote Afterloaders	<input type="checkbox"/>	Complete Item 6.b.
64E-5.634(3) Teletherapy	<input type="checkbox"/>	Complete Item 6.b.
64E-5.664 Other Medical Uses Not Listed Above (Detailed Information Attached)	<input type="checkbox"/>	Complete Item 6.b.
64E-5.617 Quantities Exceeded: Calibration, Reference, or Transmission Sources or Other Radioactive Materials in Quantities Greater than Allowed by 64E-5.617	<input type="checkbox"/>	Complete Item 6.b.
64E-5.631 Sealed Sources for Diagnostic Uses	<input type="checkbox"/>	Complete Item 6.b.

**Florida Bureau of Radiation Control - Application For Radioactive Materials License
HUMAN USE**

6.b. Radioactive Materials Details Not Provided In Item 6.a.

Isotope	Chemical or Physical Form	Maximum number of sources, activity (curies) for each source and total activity	Purpose for which radioactive materials will be used:
Ex. Co-60	Sealed source XYZ Corp. Model XYZ for use in XYZ Corp Model AAA therapy device	30 sources, 2 curies each for a total of 60 curies.	64E-634(1). 15 sources for possession for source exchanges. See attached for procedure details

Item	Appendix	Title	Model Procedure Attached Or NA	Equivalent Procedure Attached
7	None	Facility Diagram	<input type="checkbox"/> NA	<input checked="" type="checkbox"/>
8	A	Radiation Safety Committee	<input type="checkbox"/>	<input type="checkbox"/>
9	B	Instrumentation	<input type="checkbox"/>	<input type="checkbox"/>
10	C	Quality Control	<input type="checkbox"/>	<input type="checkbox"/>
11	D	Dose Calibrator	<input type="checkbox"/>	<input type="checkbox"/>
12	E	Personnel Monitoring	<input type="checkbox"/>	<input type="checkbox"/>
13	F	Training Program	<input type="checkbox"/>	<input type="checkbox"/>
14	G	Ordering And Receiving	<input type="checkbox"/>	<input type="checkbox"/>
15	H	Opening Packages	<input type="checkbox"/>	<input type="checkbox"/>
16	I	Use Records	<input type="checkbox"/>	<input type="checkbox"/>
17	J	Rules Of Use	<input type="checkbox"/>	<input type="checkbox"/>
18	K	Emergency Procedures	<input type="checkbox"/>	<input type="checkbox"/>
19	L	Area Surveys	<input type="checkbox"/>	<input type="checkbox"/>
20	M	Members Of Public Dose Study	<input type="checkbox"/>	<input type="checkbox"/>
21	N	Radiopharmaceutical Therapy	<input type="checkbox"/>	<input type="checkbox"/>
22	O	Implant Therapy	<input type="checkbox"/>	<input type="checkbox"/>
23	P	Radioactive Gases & Aerosols	<input type="checkbox"/>	<input type="checkbox"/>
24	Q	Quality Management Program	<input type="checkbox"/>	<input type="checkbox"/>
25	R	ALARA Program (Radiation Safety Committee Required)	<input type="checkbox"/>	<input type="checkbox"/>
26	S	ALARA Program (No Radiation Safety Committee)	<input type="checkbox"/>	<input type="checkbox"/>
27	T	Leak Testing	<input type="checkbox"/>	<input type="checkbox"/>
28	U	Bioassay	<input type="checkbox"/>	<input type="checkbox"/>
29	V	Survey Meter Calibration	<input type="checkbox"/>	<input type="checkbox"/>
30	W	Waste	<input type="checkbox"/>	<input type="checkbox"/>
31	X	Inventory	<input type="checkbox"/>	<input type="checkbox"/>
32	Y	Diagnostic Radiopharmaceuticals	<input type="checkbox"/>	<input type="checkbox"/>
33	Z	Mobile Nuclear Medicine	<input type="checkbox"/>	<input type="checkbox"/>
34	Other		NA	<input type="checkbox"/>

35. CERTIFICATE

The applicant and any official executing this certificate on behalf of the applicant named in Item 1, certify that this application has been prepared in accordance with Chapter 64E-5, Florida Administrative Code, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. *In addition, the applicant or executing official is acknowledging that they are aware that knowingly making false statements to a public servant is a violation of section 837.06, Florida Statutes, and is punishable by fine or imprisonment*

Certifying Official (Signature)

Name (typed or printed)

Title

Date

State Boundaries



**Approximate Boundaries Shown
See Florida Constitution for Exact Boundaries**



0 40 80 120 Miles

1:4158925



**Florida Department of Health
Bureau of Radiation Control**

Disclaimer:
This product is for reference purposes only
and is not to be construed as a legal
document. Any reliance on the information
contained herein is at the user's own risk.
The Florida Department of Health and its
agents assume no responsibility for any
use of the information contained herein
or any loss resulting therefrom.

CONSTITUTION OF THE STATE OF FLORIDA – Article II, Section 1
State Boundaries
AS REVISED IN 1968 AND SUBSEQUENTLY AMENDED

ARTICLE II GENERAL PROVISIONS

SECTION 1. State boundaries.

- (a) The state boundaries are: Begin at the mouth of the Perdido River, which for the purposes of this description is defined as the point where latitude 30°16'53" north and longitude 87°31'06" west intersect; thence to the point where latitude 30°17'02" north and longitude 87°31'06" west intersect; thence to the point where latitude 30°18'00" north and longitude 87°27'08" west intersect; thence to the point where the center line of the Intracoastal Canal (as the same existed on June 12, 1953) and longitude 87°27'00" west intersect; the same being in the middle of the Perdido River; thence up the middle of the Perdido River to the point where it intersects the south boundary of the State of Alabama, being also the point of intersection of the middle of the Perdido River with latitude 31°00'00" north; thence east, along the south boundary line of the State of Alabama, the same being latitude 31°00'00" north to the middle of the Chattahoochee River; thence down the middle of said river to its confluence with the Flint River; thence in a straight line to the head of the St. Marys River; thence down the middle of said river to the Atlantic Ocean; thence due east to the edge of the Gulf Stream or a distance of three geographic miles whichever is the greater distance; thence in a southerly direction along the edge of the Gulf Stream or along a line three geographic miles from the Atlantic coastline and three leagues distant from the Gulf of Mexico coastline, whichever is greater, to and through the Straits of Florida and westerly, including the Florida reefs, to a point due south of and three leagues from the southernmost point of the Marquesas Keys; thence westerly along a straight line to a point due south of and three leagues from Loggerhead Key, the westernmost of the Dry Tortugas Islands; thence westerly, northerly and easterly along the arc of a curve three leagues distant from Loggerhead Key to a point due north of Loggerhead Key; thence northeast along a straight line to a point three leagues from the coastline of Florida; thence northerly and westerly three leagues distant from the coastline to a point west of the mouth of the Perdido River three leagues from the coastline as measured on a line bearing south 0°01'00" west from the point of beginning; thence northerly along said line to the point of beginning. The State of Florida shall also include any additional territory within the United States adjacent to the Peninsula of Florida lying south of the St. Marys River, east of the Perdido River, and south of the States of Alabama and Georgia.
- (b) The coastal boundaries may be extended by statute to the limits permitted by the laws of the United States or international law.

(one league = three statute miles)



FLORIDA DEPARTMENT OF HEALTH



NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION; NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

POSTING REQUIREMENT

THIS NOTICE MUST BE POSTED IN PLACES THAT PERMIT EMPLOYEES IN A RESTRICTED AREA TO SEE A COPY ON THE WAY TO OR FROM THEIR PLACE OF EMPLOYMENT.

The Department of Health has established standards for protection against radiation hazards in Chapter 64E-5, Florida Administrative Code.

YOUR EMPLOYER IS REQUIRED TO:

- Post or provide you a copy of the Department of Health rules and operating procedures that apply to your work and explain them to you.
- Apply the rules to work involving radiation sources.
- Post or provide you any Notice of Violation involving radiological working conditions, proposed civil penalties, and orders.

YOU ARE REQUIRED TO:

- Become familiar with the rules and the operating procedures that apply to your work.
- Observe the requirements to protect yourself and your co-workers.

WHAT IS IN THESE RULES:

- Limits on exposure to radiation and radioactive material in restricted and unrestricted areas
- Actions to take after accidental exposure
- Personnel monitoring, surveys, and equipment
- Caution signs, labels, and safety interlocks
- Exposure records and reports
- Options for workers about Department of Health inspections
- Related matters

REPORTS ON RADIATION EXPOSURE

Your employer must give you a written report if you receive an exposure above the limits in the rules or in the license. The maximum limits for exposure to employees are in Part III of the rules. However, your employer should keep your radiation exposure as low as reasonably achievable.

If you work where personnel monitoring is required:

- Your employer must give you a written annual report of your radiation exposures.
- Your employer must give you a written report of your radiation exposures when you terminate employment.

INSPECTIONS

Representatives of the Department of Health inspect all licensed and registered activities. Any worker or worker representative who believes that there is a violation of Chapter 404, Florida Statutes; Chapter 64E-5, Florida Administrative Code; or the terms of the employer's license or registration can request an inspection by contacting the Bureau of Radiation Control, Bin C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741 (850) 245-4266. The request must state specific reasons for the inspection. During inspections, Department of Health inspectors can confer privately with workers and any worker can bring to the attention of the inspectors any past or present condition that they believe contributed to or caused any violation.

Copies of Chapter 64E-5, F.A.C., the license or registration, operating procedures, any notice of violation about working conditions, penalty orders issued, and responses can be examined at:

Authorized Nuclear Pharmacist Training Requirements

64B16-28.903 Training Qualifications.

- (1) A pharmacist licensed to practice pharmacy in this state who performs a radiopharmaceutical service shall, prior to engaging in such specialized practice, be actively licensed as a nuclear pharmacist from the Board of Pharmacy.
- (2) A licensed pharmacist seeking licensure as a nuclear pharmacist in this state shall submit to the Board of Pharmacy a course outline from an accredited college of pharmacy or other program recognized by the Florida Department of Health and the Florida Board of Pharmacy (a program comparable to those offered by accredited colleges of pharmacy for the training of nuclear pharmacists), and a certificate of training which provides a minimum of 200 clock hours of formal didactic training, which includes:
 - (a) Radiation physics and instrumentation (85 hours);
 - (b) Radiation protection (45 hours);
 - (c) Mathematics pertaining to the use and measurement of radioactivity (20 hours);
 - (d) Radiation biology (20 hours);
 - (e) Radiopharmaceutical chemistry (30 hours).
- (3) Such academic training programs will be submitted to the Board for approval by an accredited educational institution which operates under the auspices of or in conjunction with an accredited college of pharmacy.
- (4) The minimum on-the-job training which shall be included in a radiopharmacy internship is five hundred (500) hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and experience shall include, but shall not be limited to the following:
 - (a) Ordering, receiving and unpackaging in a safe manner, radioactive material, including the performance of related radiation surveys;
 - (b) Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment;
 - (c) Calculating, preparing and verifying patient doses, including the proper use of radiation shields;
 - (d) Following appropriate internal control procedures to prevent mislabeling;
 - (e) Learning emergency procedures to safely handle and contain spilled materials, including related decontamination procedures and surveys;
 - (f) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals;
 - (g) Clinical practice concepts.
- (5) Guidelines for such programs are in a publication entitled "Guidelines for Florida Board of Pharmacy Internship Training in Radiopharmacy" (1988). Governmental and private radiopharmacy internship programs shall not apply to the pharmacy internship required under Rule 64B16-26.401, F.A.C.
- (6) If the didactic and experiential training required in this section have not been completed within the last seven years, the applicant must have been engaged in the lawful practice of nuclear pharmacy in another jurisdiction at least 1080 hours during the last seven years.
- (7) The Board of Pharmacy shall, subsequent to its review of the certificates of training, inform each applicant in writing as to whether or not licensure has been granted.

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL

Transfers of Industrial Devices Report 04/2007
64E-5.210(4)

**TRANSFERS OF INDUSTRIAL DEVICES REPORT
(TO GENERAL LICENSEES)**

Department of Health
Bureau of Radiation Control
4052 Bald Cypress Way - Bin #C21
Tallahassee Florida 32399-1741

(Also use below "FROM GENERAL LICENSES or LABEL CHANGES", as appropriate)

For each "licensee" to whom a device(s) has been transferred during the reporting period, supply the following:

NAME OF VENDOR	REPORTING PERIOD	
	FROM	TO
LICENSE NUMBER		

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE (No P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE (No., P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL

Transfers of Industrial Devices Report 04/2007 Continued
64E-5.210(4)

**TRANSFERS OF INDUSTRIAL DEVICES REPORT
(TO GENERAL LICENSEES)**

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE (No P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE (No P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL

Transfers of Industrial Devices Report 04/2007 Continued
64E-5.210(4)

**TRANSFERS OF INDUSTRIAL DEVICES REPORT
(TO GENERAL LICENSEES)**

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE (No P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE (No P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL

Transfers of Industrial Devices Report 04/2007 Continued
64E-5.210(4)

TRANSFERS OF INDUSTRIAL DEVICES REPORT (FROM GENERAL LICENSEES)

For each "licensee" from whom a device(s) has been received during the reporting period, supply the following:

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>
--------------------------	---

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>
--------------------------	---

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>
--------------------------	---

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>
--------------------------	---

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

STATE OF FLORIDA - DEPARTMENT OF HEALTH - BUREAU OF RADIATION CONTROL

Transfers of Industrial Devices Report 04/2007 Continued

64E-5.210(4)

TRANSFERS OF INDUSTRIAL DEVICES REPORT (FROM GENERAL LICENSEES)

For each "licensee" from whom a device(s) has been received during the reporting period, supply the following:

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE

MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE

MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE

MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE

MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)



Bureau of Radiation Control, Radiation Machine Program
RADIATION MACHINE FACILITY REGISTRATION

A. The information provided is to inform the bureau of:

Form with two checkboxes: 'New Facility Registration' and 'Changes to an existing registration - JR' followed by a blank line.

B. ADDRESS INFORMATION for the physical location of the radiation machine(s)

Form with two columns of input fields: Name of Facility, Doctor or other responsible party, Street Address, Facility Telephone Number, City, State and Zip code, Facility FAX Number, County, and E-mail address.

C. BILLING/MAILING INFORMATION if different from address information

Form with two columns of input fields: Billing/Mailing Name, Contact person for billing purposes, Billing/Mailing Address, Billing Telephone Number, Billing/Mailing City, State and Zip code, and Billing FAX Number.

D. COMPLIANCE INFORMATION if different from address information

Form with two columns of input fields: Organization Name, Contact person for compliance, Address, Telephone Number, and City, State and Zip code, FAX Number.

If you have questions or need guidance on the registration process, please contact this office at:

Department of Health
Bureau of Radiation Control, Radiation Machine Program
705 Wells Rd Ste 300, Orange Park, Florida 32073
Phone: (904)278-5730 Fax: (904)278-5737
www.myfloridaeh.com/radiation/ion1.htm

RADIATION MACHINE FACILITY REGISTRATION

E. New Registrants only: Identify the facility category you are registering. If you meet two or more categories, a separate registration form must be submitted for each facility category.

- HS Licensed as a Hospital under Chapter 395, Florida Statutes
- DI Diagnostic Imaging Center (accept outside referrals for diagnostic imaging services)
- MO Licensed as a Portable X-ray provider under 42 CFR, Part 486, Subpart C, sections 486.100 – 110 as administered by the Agency for Health Care Administration, State of Florida
- MA Screening/Diagnostic Mammography provider certified by the FDA under MQSA
- MB Biopsy Mammography only
- DS Dentist licensed under Chapter 466, Florida Statutes
- DC Chiropractic Physician licensed under Chapter 460, Florida Statutes
- DO Osteopathic Physician licensed under Chapter 459, Florida Statutes
- MD Medical Doctor licensed under Chapter 458, Florida Statutes
- PM Podiatric Physician licensed under Chapter 461, Florida Statutes
- AM Medical Accelerator
- TH Therapy treatment planners and other non-accelerator therapy related machines
- AN Industrial Particle Accelerator
- ED Educational Institution
- IN Industrial
- VM Veterinarian licensed under Chapter 474, Florida Statutes

RADIATION MACHINE FACILITY REGISTRATION

F. Radiation Machine Information (use additional copies of this page if necessary)

1.					
	Manufacturer's Name	Model Name	Control Serial Number	Installation Date	Room
	<input type="checkbox"/> Machine recently installed (attach copy of installation form)		<input type="checkbox"/> Machine present at time of occupancy of facility		
	<input type="checkbox"/> Machine removed from this location		<input type="checkbox"/> Machine rendered inoperable		
2.					
	Manufacturer's Name	Model Name	Control Serial Number	Installation Date	Room
	<input type="checkbox"/> Machine recently installed (attach copy of installation form)		<input type="checkbox"/> Machine present at time of occupancy of facility		
	<input type="checkbox"/> Machine removed from this location		<input type="checkbox"/> Machine rendered inoperable		
3.					
	Manufacturer's Name	Model Name	Control Serial Number	Installation Date	Room
	<input type="checkbox"/> Machine recently installed (attach copy of installation form)		<input type="checkbox"/> Machine present at time of occupancy of facility		
	<input type="checkbox"/> Machine removed from this location		<input type="checkbox"/> Machine rendered inoperable		
4.					
	Manufacturer's Name	Model Name	Control Serial Number	Installation Date	Room
	<input type="checkbox"/> Machine recently installed (attach copy of installation form)		<input type="checkbox"/> Machine present at time of occupancy of facility		
	<input type="checkbox"/> Machine removed from this location		<input type="checkbox"/> Machine rendered inoperable		

G. COMMENTS: Please use the following space to enter additional information

H. By the signature below the applicant acknowledges this is an accurate record of the machine(s) in their use and acknowledges their responsibility to inform the bureau of any future changes to this registration within thirty days.

Signature	Title or Position
Print Name	Date