October 2014

Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2014-01

Revision 12 Filing Instructions: Changes to Chapter 64E-5, Florida Administrative Code (F.A.C.)

Changes to "Control of Radiation Hazard Regulations," Part V "X-Ray in the Healing Arts" Rule 64E-5.504, F.A.C., became effective May 8, 2013 (Revision 11) and changes to the radioactive materials regulations became effective December 26, 2013. **These changes are indicated as Revision 11 or 12 or (R11) (R12) in the margin.** Official versions of regulations may be found at the Florida Department of State website www.flrules.org/

These instructions apply to the complete version (brown cover) of Chapter 64E-5, F.A.C. Be sure that Revisions 1 through 10 changes have been inserted before making these changes. This may be verified by checking page ii of the index. **Visit our website at http://www.floridahealth.gov/radiation to download R12 pages to replace. (Includes R11 changes.)**

Due to the large number of pages to be replaced, you may want to obtain a complete electronic copy of the chapter. This pdf file is also available on our website.

A brief summary of the changes is listed below the page replacement table.

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Cover	Cover	Cover
Index	i through xii	i through xvii
Part I (R11 & R12) General Provisions	Part I Index Part I Pages 1-27 (all)	Part I Index Part I Pages 1-29
Part II (R12) Licensing of Radioactive Materials	Part II Index Part II Pages 1-96 (all)	Part II Index Part II Pages 1-110
Part III (R12) Standards for Protection Against Radiation	Part III Index Part III Pages 3/4, 5/6, 11/12, 13/14, 21/22, 23/24, 25/26, 41/42, 43/44a, 47/48, 49/50, 51/52	Part III Index Part III Pages 3/4, 5/6, 11/12, 13/14, 21/22, 23/24, 25/26, 41/42, 43/44a, 47/48, 49/50, 51/52

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Part V (R11) X-Ray in the Healing Arts	Part III Index 23/24, 25/26, 27/28, 29/30	Part III Index 23/24, 25/26, 27/28, 29/30
Part VI (R12) Use of Radionuclides in the Healing Arts	Part VI Index Part VI Pages 3/4, 5/6, 11/13, 13/14, 15/16, 19/20, 21/22, 33/34, 35/36, 37/38, 41/42, 43/44, 45/46, 57/58, 59/60, 61/62, 63/64, 65/66, 67/68, 71/72, 73/74, 75/76, 77/78, 79/80, 81/82, 85/86, 87/88, 89/90, 91/92, 93/94	Part XV Index Part VI Pages 3/4, 5/6, 11/13, 13/14, 15/16, 19/20, 21/22, 33/34, 35/36, 37/38, 41/42, 43/44, 45/46, 57/58, 59/60, 61/62, 63/64, 65/66, 67/68, 71/72, 73/74, 75/76, 77/78, 79/80, 81/82, 85/86, 87/88, 89/90, 91/92, 93/94
Part XI (R12)	Part XI Index Pages 9/10	Part XI Index Pages 9/10
Part XIII (R12) Radiation Safety Requirements for Possession and Use of Sealed or Unsealed Sources of Radioactive Materials	Part XIII Index Part XIII Pages 9/10	Part XIII Index Part XIII Pages 9/10)
Part XIV (R12) Licensing and Radiation Safety Requirements for irradiators	Part XIV Index Pages 19/20	Part XIV Index Pages 19/20
Part XV (R12) Transportation of Radioactive Materials	Part XV Index Pages 1a/1b, 1c/2	Part XV Index Pages 1a/1b, 1c/1d(new), 1e(new)/2

The majority of changes are due to the changes to the Energy Policy Act of 2005 where the U.S. Nuclear Regulatory Commission (NRC) obtained authority to regulate accelerator produced radioactive materials (NARM) and discrete radium and also NRC identified other changes needed for Florida to be compatible with NRC regulations.

The table below provides a brief summary of the changes in each rule and not all changes are listed.

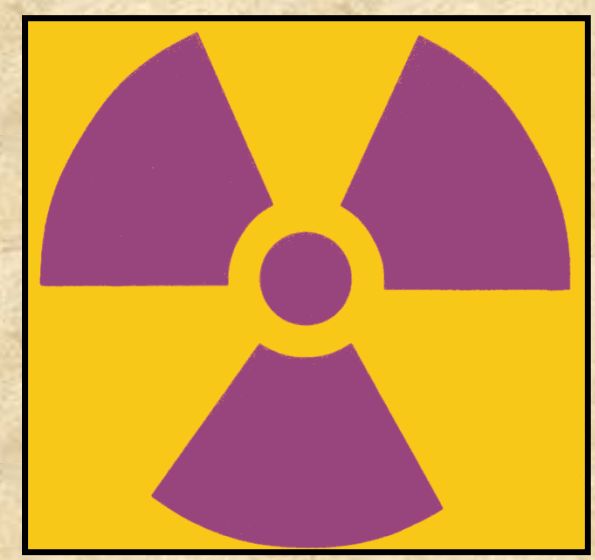
You must read the rule changes and make appropriate adjustments if needed. If you have any questions, please contact us at 850-245-4545

Rule Number(s)	Brief Summary of Changes
64E-5.101	New ALI/DAC tables are incorporated by reference to include NARM and discrete radium. Changes to definitions of Byproduct material, Medical Event, Dose, TEDE and new definitions for Discrete Source, PET, Consortium, and Waste. The changes are not new to the industry and have been used at the federal level since 2005.
64E-5.203	NRC retained the authority to regulate exempt items, quantities and concentrations of radioactive materials. This rule deletes obsolete exemptions and adds numerous new exemptions for certain isotopes and quantities of radioactive materials to include discrete radium sources.

Rule Number(s)	Brief Summary of Changes
64E-5.204	License category descriptions for medical use of HDR was clarified to include low, medium and pulsed rate remote dose afterloaders. The license fees were not changes and remain at the same level established in 2007.
64E-5.206	Relaxing the transfer requirements of generally licensed devices if certain criteria is met. Links to the forms for In Vivo and in Vitro use of radioactive materials under a general license are provided.
64E-5.210	Requirement for distributors of certain generally and specifically licensed radioactive materials are listed and links to existing documents incorporated by reference are provided.
64E-5.213	Requirement to follow the manufacturer's safety procedures identified in a national registry for the use of radioactive sources and devices and clarifying the requirement that one must maintain a fixed facility in the state to obtain a radioactive materials license.
64E-5.216	Clarifies that licenses operating under reciprocal recognition of an out of state radioactive materials license must transfer or dispose of radioactive materials to those licensed.
64E-5.304	Clarifies that when external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department.
64E-5.304, 64E-5.306, 64E-5.307, 64E-5.313. 64E-5.315, 64E-5.326, 64E-5.330, 64E-5.629, 64E-5.810, 64E-5.1115, 64E-5.1317, 64E-5.1419, 64E-5.1420	All reference the new ALI/DAC document incorporate by reference in 64E-5.101.
64E-5.504	Requirements for the use of X-ray fluoroscopic systems is listed.
64E-5 Part 6 Medical Use or Radioactive Materials	Majority of changes are those identified by NRC as needed for compatibility. The changes include revised cross references and to accept those listed on an NRC license to qualify as an authorized user.
64E-5.6422	Clarifies gamma knife spot checks that are to be performed only on a monthly basis and NOT before the first use of the unit on days of use.

Attachments – R12 page replacements (288 pages) (Includes R11 changes to Part 5).

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
Revision 11	May 8, 2013
Revision 12	December 26, 2013

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

This copy of the regulations do not contain certain parts applicable to a particular section. Contact the applicable Bureau of Radiation Control Section or the Bureau of Epidemiology – Radon and Indoor Air Quality Program 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 Program
Suite 300
705 Wells Road,
Orange Park, FL 32073

Telephone: (904) 278-5730 Fax: (904) 278-5737
RadiationControl@FLHealth.gov

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

Department of Health
Bureau of Radiation Control
Radioactive Materials Program
Bin #C21
4052 Bald Cypress Way
Tallahassee, FL 32399-1741

Telephone: (850) 245-4545 Fax: (850) 921-6364
RadiationContol@FLhealth.gov

PART X (Environmental Monitoring)

Department of Health
Bureau of Radiation Control
Environmental Radiation Programs
P.O. Box 680069
Orlando, FL 32868-0069

Telephone: (407) 297-2096 Fax: (407) 297-2085
RadiationContol@FLhealth.gov
24 Hour Emergency: (407)297-2095

PARTS XII (Radon)

Department of Health
Bureau of Epidemiology
Radon Program
Bin #A21
4052 Bald Cypress Way
Tallahassee, FL 32399-1720
Telephone: (850) 245-4288 phtoxicology@flhealth.gov

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: www.floridahealth.gov/environmental-health/radiation-control. 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	05-18-1998	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	10-8-2000	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	8-6-2001	64E-5.101, 64E-5.201, 64E-5.603, 64E-5.606. 64E-5.626, 64E-5.627, 64E-5.630
R4	9-11-2001	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	12-19-2001	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	9-28-2006	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	8-18-2007	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	2-28-2008	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	3-12-2009	New 64E-5.1601, 64E-51602, 64E-5.1603, 64E-5.1604

R10	02-11-2010	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, Application for Radioactive Materials License Non-Human Use, DH Form 1054 12/09, (See 64E-5.207), Application for Radioactive Materials Human Use DH Form 1322 12/09 (See 64E-5.207), **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)
R11	5-8-2013	64E-5.101, 64E-5.504
R12	12-26-2013	64E-5.101, 64E-5.203, 64E-5..204, 64E-5.206, 64E-5.210, 64E-5.213, 64E-5.216, 64E-5.304, 64E-5.306, 64E-5.307, 64E-5.313, 64E-5.315, 64E-5.326, 64E-5.330, 64E-5.331, 64E-5.344, 64E-5.350, 64E-5.351, 64E-5.6011, 64E-5.607, 64E-5.609, 64E-5.614, 64E-5.6251, 64E-5.626, 64E-5.627, 64E-5.629, 64E-5.630, 64E-5.632, 64E-5., 64E-5.633, 64E-5.6412, 64E-5.6422, 64E-5.643, 64E-5.645, 64E-5.649, 64E-5.650, 64E-5.652, 64E-5.653, 64E-5.654, 64E-5.655, 64E-5.656, 64E-5.660, 64E-5.661, 64E-5.662, 64E-5.663, 64E-5.810, 64E-5.1115, 64E-5.1317, 64E-5.1419, 64E-5.1420, 64E-5.1501, 64E-5.1502

PART I GENERAL PROVISIONS

PART II LICENSING OF RADIOACTIVE MATERIALS

SUBPART A LICENSE TYPES AND FEES

SUBPART B GENERAL LICENSES

SUBPART C SPECIFIC LICENSES

SUBPART D RECIPROCITY

SUBPART E BONDING

SUBPART F INSPECTION AND ENFORCEMENT

Part II Licensing of Radioactive Materials (continued)

SUBPART G RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

PART III STANDARDS FOR PROTECTION

SUBPART A GENERAL PROVISIONS

SUBPART B RADIATION PROTECTION PROGRAMS

SUBPART C OCCUPATIONAL DOSE LIMITS

SUBPART D RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

SUBPART E SURVEYS AND MONITORING

SUBPART F CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

Part III (Continued)

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

PART VI USE OF RADIONUCLIDES IN THE HEALING ARTS

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

PART XVI ELECTRONIC BRACHYTHERAPY

ATTACHMENTS

PART I GENERAL PROVISIONS

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) "A_1" means the maximum activity of special form radioactive material permitted in a Type A package.

(2) "A_2" 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:

R12 (a) In excess of the derived air concentrations (DACs) specified in State of
R12 Florida Bureau of Radiation Control ALIs, DACs, and Effluent
R12 Concentrations, June 2012, which is herein incorporated by reference and
R12 which can be obtained from the internet at
R12 http://www.flrules.org/Gateway/reference.asp?No=Ref-03449 or at
R12 http://www.doh.state.fl.us/environment/radiation/regs/64e-5tab.htm, 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
R12 by inhalation of selected radionuclides are given in State of Florida Bureau of
R12 Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, Table I,
R12 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.

(17) "Background radiation” means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the
R5 environment from the testing of nuclear explosive devices or from past nuclear
R5 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.

R12 (c) 1. Any discrete source of radium-226 that is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity; or

R12 2. Any material that meets the following:

R12 a. Has been made radioactive by use of a particle accelerator; and

R12 b. Is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity; and

R12 (d) Any discrete source of naturally occurring radioactive material, other than source material, that meets the following:

R12 1. The NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

R12 2. Is extracted or converted after extraction for use in a commercial, medical, or research activity.

R11 (193) "C-arm fluoroscope" means a fluoroscopic machine where the image receptor and the x-ray tube housing assembly are ganged allowing a change in the direction of the beam axis with respect to the patient without moving the patient.

R11 (188) "C-arm system" means a mobile C-arm used in the same room with the same patient support device.

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 ($H_{E,50} = \Sigma W_T H_{T,50}$).

R12 (197) “Consortium” means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

R10 R2 (30) “Constraint” or “dose constraint” means a value above which specified licensee actions are required.

R10 R5 (172) “Critical Group” means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

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
R6 every calendar day worked.

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
R2 the declaration in writing or is no longer pregnant.

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 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
R5 unrestricted use and termination of license or release of the property under
R5 restricted conditions and the termination of the license.

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
R12 in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent
R12 Concentrations, June 2012, 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).

R12 (195) “Discrete source” means a radionuclide that has been processed so that its
R12 concentration within a material has been purposely increased for use for
R12 commercial, medical, or research activities.

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
R12 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 ($H_E = \Sigma W_T H_T$).

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.

R11 (194) “Extremity-use-only fluoroscope” means a fluoroscope manufactured after
R11 June 10, 2006, having a maximum source-image receptor distance of less than
R11 45 centimeters and labeled “Extremity-use-only”

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/cm^2).

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 R6 R6 (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.

R10 R6 (179) “Fit test” means the use of a protocol to evaluate qualitatively or quantitatively the fit of a respirator on an individual.

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 R2 (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.

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
R2 individual for the assessment of dose equivalent such as film badges,
R2 thermoluminescence dosimeters, pocket ionization chambers, and personal or
R2 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
R2 (TLDs), optically stimulated luminescent devices (OSLDs), pocket ionization chambers, and personal air sampling devices.

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
R2 eye and is taken as the dose equivalent at the tissue depth of 0.3 centimeter
R2 (300 mg/cm^2).

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.

R12 (77) "Low specific activity material (LSA)" means that as defined in 49 C.F.R. section
R12 173.403, 10-1-12 edition, which is herein incorporated by reference and may be
R12 obtained at https://www.flrules.org/Gateway/reference.asp?No=Ref-03472 or at
R12 http://www.myfloridaeh.com/radiation/radmat1.htm.

R10 (78) "Lung class" (see "Class").

R10 (79) "Major processor" means a user processing, handling or manufacturing radioactive material exceeding A_2 quantities as unsealed sources or material, or exceeding 4 times A_1 quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers or small industrial programs. A_1 and A_2 quantities can be found in Part XV.

R10 (80) "Management" means the chief executive officer or other individual, or a delegate
R10 or the delegates of the chief executive officer or other individual, having the
R10 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 a written directive that result in either of 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; and

a. When the total dose delivered differs from the prescribed dose by 20 percent or more;

b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range;

c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more; or

2. 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; and

a. An administration of a wrong radioactive drug containing radioactive material;

b. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

c. An administration of a dose or dosage to the wrong individual or human research subject;

d. An administration of a dose or dosage delivered by the wrong mode of treatment; or

e. A leaking sealed source where the patient or human research subject is contaminated.

3. 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.

(c) Radiation from a therapeutic x-ray machine or particle accelerator that result in any of the following:

1. 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;

2. An administration of a dose to the wrong individual or human research subject;

3. An administration of a dose delivered by the wrong mode of treatment, wrong treatment, or wrong treatment site;

4. When treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

5. When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

6. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

R11 (187) “Mobile C-arm” means a mobile c-arm fluoroscope designed for use without a
R11 specific patient support device. This includes machines moved from room to
R11 room to assist in surgical procedures.

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.

R12 (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.

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
R2 radiation, from any medical administration the individual has received, from
R2 exposure to individuals administered radioactive material and released as
R2 specified in Rule 64E-5.622, F.A.C., from voluntary participation in medical research programs, or as a member of the public.

R10 R4 (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.

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.

R12 (96) "Package" means that as defined in 49 C.F.R. section 173.403, 10-1-12 edition.

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 R4 R4 (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.

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.

R12 R12 R12 (196) “Positron Emission Tomography (PET) radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

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 R10 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;

R10 (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
R10 dose and dose per fraction as documented in the written directive; or

R10 (d) For remote brachytherapy afterloaders, the total dose and dose per
R10 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
R1 to achieve the purpose for which the department issued or amended the license.
R1 Storage during which no licensed material is accessed for use or disposal and
R1 activities incidental to decontamination or decommissioning are not principal
R1 activities.

R10 (106) "Public dose" means the dose received by a member of the public from exposure
R2 to radiation or radioactive materials released by a licensee or registrant, or to any
R2 other sources of radiation under the control of the licensee or registrant. Public
R2 dose does not include occupational dose or doses received from background
R2 radiation, from any medical administration the individual has received, from
R2 exposure to individuals administered radioactive materials and released as
R2 specified in Rule 64E-5.622, F.A.C., or from voluntary participation in medical 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 R4 (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.

R10 R4 R4 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.

R10 R8 R8 R8 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.

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 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;

(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 R5 R5 R5 R5 R5 (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.

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 R8 (129) "Sealed source" means radioactive material that is encased in a capsule designed to prevent release or escape of the radioactive material.

R10 R10 R10 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 R6 R6 (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.

R10 (185) Semiannual or Semiannually means an interval not to exceed six months.

R10 R6 R6 (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).

R10 R4 R4 (131) "Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

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:

R1
$$\frac{\text{175 (grams contained U-235)}}{350} + \frac{\text{50 (grams U-233)}}{200} + \frac{\text{50 (grams Pu)}}{200} = 1$$

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
R10 with a stereotactic guidance device to very precisely deliver a therapeutic dose to
R10 a tissue volume.

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
R10 impart particular knowledge and practical education through interrelated studies
R10 and supervised training.

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
R6 respirator for which the source of breathing air is not designed to be carried by
R6 the user.

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
R6 neutron generator tube to produce neutrons for use in well logging applications.

R12 (151) "Total effective dose equivalent" (TEDE) means the sum of the effective 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 R6 R6 R6 (183) “User seal check” or “fit check” means an action conducted by the respirator user to determine if the respirator is seated to the face properly. Examples include negative pressure check, positive pressure check, irritant smoke check, and isoamyl acetate check.

R10 R2 (156) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess to 500 rad (5 gray) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

R10 (157) "Visiting authorized user" means an authorized user who is not identified on the license.

R12 R12 R12 R12 R12 R12 (198) “Waste” or “Radioactive Waste” means those low-level radioactive wastes containing source, special nuclear or other radioactive material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or radioactive material as defined in paragraphs 64E-5.101(21)(b), (c) and (d).

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
R10 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
R10 radiopharmaceutical, dosage, and route of administration;

R10 (b) For any administration of iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels), the dosage;

R10 (c) For gamma stereotactic radiosurgery, target coordinates settings per
R10 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
R10 dose, dose per fraction, treatment site, number of fractions and overall treatment period;

(e) For high dose rate remote afterloading brachytherapy, the radioisotope,
R10 treatment site, dose per fraction, number of fractions, and total dose; and

R10 (f) For all other brachytherapy, including low, medium, and pulsed dose rate
R10 remote afterloaders,

R10 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.

R11 Editor's Note: Definitions have been alphabetized effective, 12-26-13.

Rulemaking Authority: 404.051, 404.061, F.S.

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

R1-R12 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, 9-11-01, 12-18-01, 9-28-06, 8-16-07, 2-28-08, 2-11-10, 5-8-13, 12-26-13.

Page left Intentionally Blank

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:

(a) Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

(b) Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).

(c) Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

(d) Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(3) As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown below:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

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

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

(4) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 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})
	2.5×10^{-8}	2	980×10^{6}	980×10^{8}
	1.0×10^{-7}	2	980×10^{6}	980×10^{8}
	1.0×10^{-6}	2	810×10^{6}	810×10^{8}
	1.0×10^{-5}	2	810×10^{6}	810×10^{8}
	1.0×10^{-4}	2	840×10^{6}	840×10^{8}
	1.0×10^{-3}	2	980×10^{6}	$980x\ 10^{8}$
	1.0×10^{-2}	2.5	1010×10^{6}	1010×10^{8}
	1.0×10^{-1}	7.5	170×10^{6}	170×10^{8}
	5.0×10^{-1}	11	39×10^{6}	39×10^{8}
	1	11	27×10^{6}	$27\ x10^{8}$
	2.5	9	29×10^{6}	29×10^{8}
	5	8	23×10^{6}	23×10^{8}
	7	7	24×10^{6}	24×10^{8}
	10	6.5	24×10^{6}	24×10^{8}
	14	7.5	17×10^{6}	17×10^{8}
	20	8	16×10^{6}	16×10^{8}
	40	7	14×10^{6}	14×10^{8}
	60	5.5	16×10^{6}	16×10^{8}
	100	4	20×10^{6}	20×10^{8}
	200	3.5	19×10^{6}	19×10^{8}
	300	3.5	16×10^{6}	16×10^{8}
	400	3.5	14×10^{6}	14×10^{8}

[a] Value of quality factor at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

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

PART II LICENSING OF RADIOACTIVE MATERIALS

SUBPART G RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

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.

R12 (a) 1. 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.

R12 2. A manufacturer, processor, or producer of a product or material is
R12 exempt from the requirements for a license to the extent that this
R12 person transfers radioactive material contained in a product or
R12 material in concentrations not in excess of those specified in
R12 Schedule A and introduced into the product or material by a
R12 licensee holding a specific license issued by the NRC expressly
R12 authorizing such introduction. This exemption does not apply to the
R12 transfer of radioactive material contained in any food, beverage,
R12 cosmetic, drug, or other commodity or product designed for
R12 ingestion or inhalation by, or application to, a human being.

(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
R12 accordance with a specific license issued by the NRC pursuant to 10 CFR
R12 section 32.11.

(2) Exempt Quantities.

R12 (a) Except as provided in (2)(b) through (d), 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.

R12 (d) No person may, for purposes of producing an increased radiation level,
R12 combine quantities of byproduct material covered by this exemption so
R12 that the aggregate quantity exceeds the limits set forth in Schedule B,
R12 except for radioactive material combined within a device placed in use
R12 before May 3, 1999, or as otherwise permitted by the regulations in this
R12 part.

(e) 1. Any person, who possesses radioactive material received or acquired before September 25, 1971, under the then existing general license issued to transfer, receive, acquire, own, possess, use and import quantities of radioactive materials listed in subparagraph 64E-5.203(2)(e)2., F.A.C., Table of General Licensed Quantities prior to September 25, 1971 below, or similar general license of a State, or provided that no person shall at any one time possess or use, pursuant to the general license provisions of this section, more than a total of ten such quantities.

2. Below is the Table of General Licensed Quantities prior to September 25, 1971

	Radioactive material	Column No. I Not as a sealed source (microcuries)	Column No. III As a sealed source (microcuries)
a.	Antimony (Sb 124)	1	10
b.	Arsenic 76 (As 76)	10	10
c.	Arsenic 77 (As 77)	10	10
d.	Barium 140 – Lanthanum 140 (Ba La 140)	1	10
e.	Beryllium 7 (Be 7)	50	50
f.	Cadmium 109 – Silver 109 (Cd Ag 109)	10	10
g.	Calcium 45 (Ca 45)	10	10
h.	Carbon 14 (C 14)	50	50
i.	Cerium 144 – Praseodymium (Ce Pr 144)	1	10
j.	Cesium – Barium 137 (Cs Ba 137)	1	10
k.	Chlorine 36 (Cl 36)	1	10
l.	Chromium 51 (Cr 51)	50	50
m.	Cobalt 60 (Co 60)	1	10
n.	Copper 64 (Cu 64)	50	50
o.	Europium 154 (Eu 154)	1	10
p.	Fluorine 18 (F 18)	50	50
q.	Gallium 72 (Ga 72)	10	10
r.	Germanium 71 (Ge 71)	50	50

	Radioactive material	Column No. I Not as a sealed source (microcuries)	Column No. III As a sealed source (microcuries)
t.	Gold 199 (Au 199)	10	10
u.	Hydrogen 3 (Tritium) (H 3)	250	250
v.	Indium 114 (In 114)	1	10
w.	Iodine 131 (I-131)	10	10
x.	Iridium 192 (Ir 192)	10	10
y.	Iron 55 (Fe 55)	50	50
z.	Iron 59 (Fe 59)	1	10
aa.	Lanthanum 140 (La 140)	10	10
bb.	Manganese 52 (Mn 52)	1	10
cc.	Manganese 56 (Mn 56)	50	50
dd.	Molybdenum 99 (Mo 99)	10	10
ee.	Nickel 59 (Ni 59)	1	10
ff.	Nickel 63 (Ni 63)	1	10
gg.	Niobium 95 (Nb 95)	10	10
hh.	Palladium 109 (Pd 109)	10	10
ii.	Palladium 103 – Rhodium 103 (Pd-Rh 103)	50	50
jj.	Phosphorus 32 (P 32)	10	10
kk.	Polonium 210 (Po 210)	0.1	1
ll.	Potassium 42 (K 42)	10	10
mm.	Praseodymium 143 (Pr 143)	10	10
nn.	Promethium 147 (Pm 147)	10	10
oo.	Rhenium 186 (Re 186)	10	10
pp.	Rhodium 105 (Rh 105)	10	10
qq.	Rubidium 86 (Rb 86)	10	10
rr.	Ruthenium 106 – Rhodium 106 (Ru Rh 106)	1	10
ss.	Samarium 153 (Sm 153)	10	10
tt.	Scandium 46 (Sc 46)	1	10
uu.	Silver 105 (Ag 105)	1	10
vv.	Silver 111 (Ag 111)	10	10

	Radioactive material	Column No. I Not as a sealed source (microcuries)	Column No. III As a sealed source (microcuries)
xx.	Sodium 24 (Na 24)	10	10
yy.	Strontium 89 (Sr 89)	1	10
zz.	Strontium 89 – Yttrium 90 (Sr Y 90)	0.1	1
aaa.	Sulfur 35 (S 35)	50	50
bbb.	Tantalum 182 (Ta 182)	10	10
ccc.	Technetium 96 (Tc 96)	1	10
ddd.	Technetium 99 (Tc 99)	1	10
eee.	Tellurium 127 (Te 127)	10	10
fff.	Tellurium 129 (Te 129)	1	10
ggg.	Thallium 204 (Tl 204)	50	50
hhh.	Tin 112 (Sn 113)	10	10
iii.	Tungsten 185 (W 185)	10	10
jjj.	Vanadium 48 (V 48)	1	10
kkk.	Yttrium 90 (Y 90)	1	10
lll.	Yttrium 91 (Y 91)	1	10
mmm.	Zinc 65 (Zn 65)	10	10
nnn.	Beta or Gamma emitting radioactive material not listed above	1	10

(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 NRC, 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 µGy) per hour at 10 centimeters from any surface;

      (II) For pocket watches, 0.1 millirad (1 µGy) 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 µGy) per hour at 10 centimeters from any surface.

   h. One microcurie (37 kBq) of radium 226 per timepiece in
R12 intact timepieces manufactured prior to November 30, 2007

R12 2. Ionization chamber smoke detectors containing not more than 1
R12 microcurie (µCi) of americium-241 per detector in the form of a foil
R12 and designed to protect life and property from fires.

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
R12 tritium per balance part manufactured before December 17, 2007.

R12 4. Marine compasses containing not more than 750 millicuries (27.8
R12 GBq) of tritium gas and other marine navigational instruments
R12 containing not more than 250 millicuries (9.25 GBq) of tritium gas
R12 manufactured before December 17, 2007.

R12 5. 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 µGy) 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.

R12 6. 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.

(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.

R12 1. Except for persons who manufacture, process, produce, or initially
R12 transfer for sale or distribution 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
R12 been manufactured, processed, produced, imported or initially transferred in accordance with a specific license issued by the NRC pursuant to Section 32.26 of 10 C.F.R. Part 32. 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 NRC, Washington, D.C. 20555.

R12 2. This exemption also covers gas and aerosol detectors
R12 manufactured or distributed before November 30, 2007 in
R12 accordance with a specific license issued by a State under
R12 comparable 10 CFR, section 32.26 authorizing distribution to
R12 persons exempt from regulatory requirements.

R2 (4) Radioactive drug: capsules containing carbon 14 urea for in vivo diagnostic use
R2 for humans.

R2 (a) Except as provided in paragraphs (b) and (c) of this section, any person is
R2 exempt from the requirements for a license set forth in these regulations if
R2 such person receives, possesses, uses, transfers, owns, or acquires
R2 capsules containing 1 microcurie (37 kBq) carbon 14 urea each, allowing
R2 for nominal variation that can occur during the manufacturing process, for
R2 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

Rulemaking Authority: 404.051, 404.061, F.S.
Law Implemented: 404.022, 404.051(1)(4)(10), 404.141, F.S.
R12 History: New 7-17-85, Amended 4-4-89, Formerly 10D-91.303, Amended 10-8-00, Amended 12-26-13.

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
R7 applications with the department or the issuance of licensing documents to the
R7 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
R6 particular general licensee prior to the receipt of radioactive material and the
R7 department requires registration of certain general licenses described in
R6 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
R7 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
R7 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
R7 as described in 64E-5.206(1)(a). ..... $30.00 per unit.

2. Measuring, gauging, and control devices
R7 as described in 64E-5.206(4)..... $30.00 per unit.

3. *In Vivo* testing
R7 as described in 64E-5.206(7)..... $150.00 per license.

4. *In Vitro* testing
R7 as described in 64E-5.206(8)..... $150.00 per license.

5. Depleted uranium
R7 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
R12 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
R2 addressed to or delivered in person to the Department of Health, Bureau
R2 of Radiation Control, Bin #C21, 4052 Bald Cypress Way, Tallahassee, FL
R2 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.

3. Method of payment. Checks, drafts or money orders for payment

of fees shall be payable to DOH, Bureau of Radiation Control; and
R2 sent to: Department of Health, Bureau of Radiation Control, Bin
R2 #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 forthe 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 OCCURING 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 OCCURING 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	**l.(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 OCCURING 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 R7	a.(I)	Teletherapy or gamma stereotactic radiosurgery including gamma knife devices;	$1,838	$1,791
R12 R12	a.(II)	High, medium, low or pulsed dose rate remote afterloader devices;	$1,697	$1,654
R12 R12 R7	a.(III)	High, medium, low or pulsed dose rate remote afterloader devices and gamma stereotactic radiosurgery including gamma knife devices or teletherapy devices;	$1,838	$1,791
R7 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 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 R7 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
R12 R12 R7	f.(II)	Mobile, medium, low or pulsed dose rate remote afterloader 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 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 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, 404.131, 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.
R12 Amended September 28, 2006, Amended 5-18-98, 9-28-06, 8-16-07, 12-26-13.

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 R8 by the NRC, or an agreement state, which authorizes distribution of R8 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 R8 Section 179.21 of 21 CFR Part 179. (Pursuant to 120.54(6) Florida R8 Statutes, 64E-5.206(4)(b)1. is substantively identical to 10 CFR 31.5(b)(1) R8 published on 01/01/2007.)

R6 (b)2. The devices must have been received from one of the specific licenses R6 described in (b)1., above or through a transfer made under subparagraph R6 6E-5.206(4)(c)8., F.A.C.

(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

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

6. Shall not abandon the device containing radioactive material;

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

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

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

b. Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

9. Shall comply with the provisions of 64E-5.343 and 64E-5.344 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Parts III and IX.

R6 10. Shall be required to obtain written Department authorization before
R6 transferring the device to any other specific license not specifically
R6 identified in subparagraph 64E-5.206(4)(c)7, F.A.C. A holder of a
R12 specific license may transfer a device for possession and use under
R12 its own specific license without prior approval if the specific license
R12 holder satisfies the following requirements:

R12 a. Verifies that the specific license authorizes the possession
R12 and use, or applies for and obtains an amendment to the
R12 license authorizing the possession and use;

R12 b. Removes, alters, covers, or clearly and unambiguously
R12 augments the existing label otherwise required by
R12 subparagraph 64E-5.206(4)(c)1., F.A.C., so that the device
R12 is labeled in compliance with Rule 64E-5.325, F.A.C.,
R12 provided the manufacturer, model number, and serial
R12 number is retained;

R12 c. Obtains manufacturer's or initial transferor's information
R12 concerning maintenance that would be applicable under the
R12 specific license such as leak testing procedures;

R12 d. Reports the transfer under subparagraph 64E-5.206(4)(c)7.,
R12 F.A.C.

R6 11. Shall appoint an individual responsible for having knowledge of the
R6 appropriate regulations and requirements and the authority for
R6 taking required actions to comply with appropriate regulations and
R6 requirements. The general licensee, through this individual, shall
R6 ensure the day-to-day compliance with the appropriate regulations
and requirements. This appointment does not relieve the general licensee of any of its responsibility in the regard.

R6 12. a. Shall register, in accordance with sub-subparagraphs
R6 64E-5.206(4)(c)12.b., and 64E-5.206(4)(c)12.c., F.A.C., all
R6 devices except exit signs containing tritium. Each address
R6 for a location of use as described in sub-subparagraph
R6 64E-5.206(4)(c)12.c.(IV), F.A.C., represents a separate
R6 general license and requires a separate registration.

R6 b. Shall annually register with the Department the possession
R6 of a device meeting the criteria in sub-subparagraph
R6 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;

(III) Name, title, and telephone number of the responsible person designated a representative of the general licensee under paragraph 64E-5.206(4)(c) and subsection (11), F.A.C.;

(IV) Address or location at which the device(s) are used or stored. For portable devices, the address of the primary place of storage;

(V) Certification by the responsible representative of the general licensee that the information concerning the devices(s) have been verified through a physical inventory and checking the label information; and

(VI) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

d. Persons generally licensed by other Agreement States, Licensing States, or the U.S. Nuclear Regulatory Commission with respect to devices meeting the criteria in 10 CFR 31.5(c)(13)(i) are not subject to registration requirements if the devices are used in areas subject to the Department jurisdiction for less than 180 days in any calendar year. The Department will not request registration from such licensees.

13. Shall report to the Department changes in the general licensee name and the mailing address for each location of use within 30 days of the effective date of the change. For a portable device, a report of address change is required for a change in the device's primary place of storage.

14. Shall not hold devices that are not in use longer than 2 years. If the devices with shutters are not being used, the shutters must be locked in the closed position. The testing required by subparagraph 64E-5.206(4)(c)2., F.A.C., need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two year time limit if the general licensee performs physical inventories at intervals not to exceed three months while they are in standby. (Pursuant to 120.54(6) Florida Statutes, 64E-5.206(4)(c)14. is substantively identical to 10 CFR 31.5(c)(15) published on 01/01/2007.)

15. Shall not export the device containing radioactive material except in accordance with 10 C.F.R. Part 110;

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.)

(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 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 original and one copy of the completed form DH 361, 10/12 and received from the Department a validated copy of this form with a certification number assigned. DH 361 10/12, entitled, “Certificate – Medical Use of Radioactive Material under General License,” is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03450 or at http://www.doh.state.fl.us/environment/radiation/matform.htm.

R12
R12
R12
R12
R12
R12
R12

(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
R12 he has submitted the original and one copy of the completed form DH 360
R12 10/12, and received from the Department a validated copy of this form
R12 with a certification number assigned. DH 360 10/12 entitled, “Certificate –
R12 *In Vitro* Testing with Radioactive Material under General License” is herein
R12 incorporated by reference and can be obtained from the internet at
R12 http://www.flrules.org/Gateway/reference.asp?No=Ref-03451 or at
R12 http://www.doh.state.fl.us/environment/radiation/matform.htm.

(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.

Rulemaking Authority: 404.051, 404.061, 404.071, 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.
R12 History: New 7-17-85, Amended 4-4-89, 1-1-94, Formerly 10D-91.306, Amended 9-28-06, 2-28-08, 12-26-13.

Page Left Intentionally Blank

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, 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
R10 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.

R12 (1) Licensing the Distribution of Radioactive Material in Exempt Concentrations. 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 NRC, Washington, D.C. 20555. No person may introduce radioactive materials into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subsection 64E-5.203(1), F.A.C., NRC or equivalent regulations of an Agreement State, except in accordance with a license issued by the NRC under 10 CFR section 32.11.

(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 NRC, Washington, D.C. 20555. No person may introduce radioactive materials into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subsection 64E-5.203(1), F.A.C., NRC or equivalent regulations of an Agreement State, except in accordance with a license issued by the NRC under 10 CFR section 32.11.

R12 (3) Licensing the Distribution of Radioactive Material in Exempt Items. 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 NRC, Washington, D.C. 20555. No person may introduce radioactive materials into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subsection 64E-5.203(1), F.A.C., NRC or equivalent regulations of an Agreement State, except in accordance with a license issued by the NRC under 10 CFR section 32.11.

(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 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 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.

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

1. A copy of the general license contained in subsection 64E-5.206(4), subparagraphs 64E-5.206(4)(c)2.,3. and 4. or subparagraph 64E-5.206(4)(c)12., F.A.C., do not apply to the particular device, those paragraphs may be omitted;

2. A copy of Rules 64E-5.103, 64E-5.343, and 64E-5.344, F.A.C.;

3. A list of services that can only be performed by a specific licensee;

4. Information on acceptable disposal options including costs of disposal; and

5. An indication that department policy is to issue high civil penalties for improper disposal.

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

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;

2. A list of services that can only be performed by a specific licensee;

3. Information on acceptable disposal options including costs of disposal; and

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.

(f) Each device that is transferred must meet the labeling requirements in subparagraphs 64E-5.210(4)(d)3. through 5., F.A.C.

(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.

(h) Each person licensed under subsection 64E-5.210(4), F.A.C., shall comply with the following reporting and record keeping requirements.

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” which is herein incorporated by reference and is available at the address listed in paragraph 64E-5.204(2)(b), F.A.C., or can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03452 or at http://www.doh.state.fl.us/environment/radiation/regs/64e-5tab.htm.

2. This 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;

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;

c. The date of transfer;

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

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

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 4. For devices received from a subsection 64E-5.206(4), F.A.C., general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial 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 5. If the licensee makes changes to the device possessed by a subsection 64E-5.206(4), F.A.C., general licensee, such that the label must be changed to update required information, this report must identify the general licensee, the device, and the changes to information on the device label.

R6 6. The report must clearly identify the specific licensee submitting the report and include the licenses number of the specific licensee.

R6 7. If no transfers have been made to or from persons generally licensed under subsection 64E-5.206(4), F.A.C., during the reporting period, the report must so indicate.

R6 (i) Each person licensed under subsection 64E-5.210(4), F.A.C., shall comply with the following additional reporting and record keeping requirements for transfers and receipt of devices to Agreement States or R8 the NRC.

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

R6 2. The report must be clear and legible and contain the following data:

R6 a. The identity of each general licensee by name and mailing 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 b. The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

R6 c. The date of transfer;

R6 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 general licensee, the report must
R6 include the identity of the general licensee by name and address,
R6 the type, model number, and serial number of the device received,
R6 the date of receipt, and, in the case of devices not initially
R6 transferred by the reporting licensee, the name of the manufacturer
R6 or initial transferor.

R6 5. If the licensee makes changes to the device possessed by a
R6 general licensee, such that the label must be changed to update
R6 required information, this report must identify the general licensee,
R6 the device, and the changes to information on the device label.

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 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

(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.

R12 (f) The applicant satisfies the requirements specified in paragraph
R12 64E-5.210(10)(b), F.A.C.

(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:

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.

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

(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

(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:

R3 1. Perform tests before initial use, periodically, and following repair on
R3 each instrument for accuracy, linearity, and geometry dependence
R3 appropriate for the use of the instrument and make adjustments
R3 when needed; and

R3 2. Check each instrument for constancy and proper operation at the
R3 beginning of each day of use.

R12 (f) An application from a medical facility, educational institution, or Federal
R12 facility to produce Positron Emission Tomography (PET)
R12 radiopharmaceuticals containing for noncommercial transfer to licensees
R12 in its consortium licensed for medical pursuant to Part VI, or equivalent
R12 Agreement State, or NRC rules will be approved if:

R12 1. The requirements of paragraphs 64E-5.210(10)(a), (b), and (e),
R12 F.A.C., are satisfied;

R12 2. The information required of paragraphs 64E-5.210(10)(c) and (d),
R12 F.A.C., indicates the PET drugs to be noncommercially transferred
R12 to members of its consortium.

(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
R10 persons licensed pursuant to Part VI for the uses listed in 64E-5.627 or
R10 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.

(a) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant
R10 to Part VI for use as a calibration, transmission or reference source or for
R10 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.

R12 (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
R12 herein incorporated by reference and can be obtained from the
R12 internet at https://www.flrules.org/gateway/reference.asp?No=Ref-
R12 03508 or at
R12 http://www.doh.state.fl.us/environment/radiation/matform.htm
R12 which is available from the department.

R12 2. NRC Guide 10.10 March 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations and Registration of
R12 Devices Containing By-product Material, which is herein
R12 incorporated by reference and can be obtained from the internet at
R12 http://www.flrules.org/Gateway/reference.asp?No=Ref-03453 or at
R12 http://pbadupws.nrc.gov/docs/ML0037/ML003740220.pdf or at
R12 http://www.doh.state.fl.us/environment/radiation/.

R12 3. NRC Regulatory Guide 10.11 June 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations of Sealed Sources
R12 Containing By-product Material, which is herein incorporated by
R12 reference and and can be obtained from the internet at
R12 http://www.flrules.org/Gateway/reference.asp?No=Ref-03454 or at
R12 http://pbadupws.nrc.gov/docs/ML0037/ML003740233.pdf or at
R12 http://www.doh.state.fl.us/environment/radiation/.

R12 4. American National Standards Institute (ANSI) Standard, ANSI-HPS N43.8-2008, Classification of Industrial Ionizing Radiation Gauging
R12 Devices, which is herein incorporated by reference and can be
R12 obtained from the internet at
R12 http://hps.org/hpssc/documents/ansi_standards_order_form.pdf.

R12 5. ANSI Standard, ANSI-HPS N43.4-2005, Classification of
R12 Radioactive Self-Luminous Light Sources, which is herein
R12 incorporated by reference and can be obtained from the internet at
R12 http://hps.org/hpssc/documents/ansi_standards_order_form.pdf.

6. ANSI Standard N432-1980, NBS Handbook 136, as issued in January 1981, Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography, which is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03455 or at http://pbadupws.nrc.gov/docs/ML0508/ML050840139.pdf or at http://www.doh.state.fl.us/environment/radiation/matform.htm which is available from the department.

7. ANSI Standard, ANSI-HPS N43.6-2007, Sealed Radioactive Sources Classification, which is herein incorporated by reference and can be obtained from the internet at http://hps.org/hpssc/documents/ansi_standards_order_form.pdf. The ANSI publications referenced in this rule section: ANSI-HPS N43.8-2008; ANSI-HPS N43.4-2005; ANSI-HPS N43.6-2007; are copyrighted materials. These materials are available for public inspection and examination at the Florida Department of State, Room 701, The Capitol, Tallahassee, Florida 32399-0250, and at the Florida Department of Health, Bureau of Radiation Control, 4042 Bald Cypress Way, Tallahassee, Florida 32399-1741.

(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.

(15) Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

Rulemaking Authority: 404.051, 404.061, 404.071, 404.081, F.S.
Law Implemented: 404.022, 404.051, 404.061, 404.081, 404.141, F.S.
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, 2-28-08, 2-11-10, 12-26-13.

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 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.

R12 (4) (a) 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.

R12 (b) Each person specifically licensed by the Department shall maintain a fixed
R12 facility located within the state of Florida.

(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 (6) A separate license is not required for temporary job sites lasting less than two
R10 years or for each facility that is authorized under a broad scope license.

R1 (7) A licensee shall notify the department in writing within 30 days after a radiation
R1 safety officer permanently discontinues performance of radiation safety officer
R1 duties.

R12 (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.

R12 R12 R12 R12 (g) Identifying all sources or devices by manufacturer and model number as registered by the sealed source and device registry or for sources or devices not registered by the sealed source and device registry provide the information in subsection 64E-5.210(14), F.A.C.

R10 Rulemaking Authority: 404.051, 404.061,F.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, 2-11-10,
R12 12-26-13.

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

(1) Except as provided in Part II, each specific license shall expire at the end of the
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.

(3) No less than 30 days before the expiration date specified in the license, the licensee shall either:

(a) Submit an application for license renewal on the same form used for the initial application under Part II, or

(b) Notify the department, in writing, if the licensee decides not to apply for license renewal.

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

1. Terminate the use of radioactive material;

R5 2. Remove residual radioactivity to the extent acceptable to the department;

3. Properly dispose of the radioactive material;

4. Submit a properly completed DH Form 1059, which is herein incorporated by reference effective July 17, 1985; and

5. Submit a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual
R5 radioactivity, unless the licensee demonstrates the absence of
R5 residual radioactivity in some other manner. The licensee shall, as appropriate:

a. For gamma radiation, report levels of radiation in units of microroentgens per hour at 10 centimeters and at 1 meter from surfaces.

b. For alpha and beta radiation, report levels of radioactivity in units of transformations per minute or microcuries per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

c. Specify the instruments used and certify that each instrument is properly calibrated or tested.

R5 (b) 1. If no residual radioactivity attributable to activities conducted under the license is detected, the licensee shall submit a
R5 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
R5 release for unrestricted use or satisfies the
R5 requirements specified in Rules 64E-5.221,
R5 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
R5 suitable for release for unrestricted use or satisfies the
R5 requirements specified in Rules 64E-5.221,
R5 64E-5.222, 64E-5.223, or 64E-5.224, F.A.C.

R2 d. Department has received the following records, if
R2 requested:

R2 (I) Disposal records specified in Rules 64E-5.330,
R2 64E-5.331(1)(a)(c), (2), (3), or 64E-5.336(2)(d),
R2 F.A.C.; and

R2 (II) Records specified in Rule 64E-5.214(6), F.A.C.

Space intentionally left blank

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
R5 suitable for release for unrestricted use or does not satisfy the
R5 requirements specified in Rules 64E-5.221, 64E-5.222, 64E-5.223,
R5 or 64E-5.224, F.A.C., the department will inform the licensee of the appropriate further actions required for termination of the license.

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

(a) Limit actions involving radioactive material to those related to
R1 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
R5 decontaminate the area to unrestricted release levels or satisfy the
R5 requirements specified in Rules 64E-5.221, 64E-5.222, 64E-5.223,
R5 or 64E-5.224, F.A.C.; and

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

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

R1 Specific Authority: 404.051, 404.061, 404.081, 404.141, F.S.
R1 Law Implemented: 404.051(1),(4),(9), 404.061(2), 404.081(1), 404.141, F.S.
R1 History: New July 17, 1985, Amended May 12, 1993, Amended August 14, 1996, Formerly 10D-91.315,
R2, R5 Amended May 18, 1998, Amended October 8, 2000, Amended December 19, 2001.

64E-5.215 Transfer of Material.

(1) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(2) Except as otherwise provided in his license and subject to the provisions of (3) and (4), below, a licensee may transfer radioactive material:

(a) To the department after receiving approval from the department;

(b) To the U.S. Department of Energy;

(c) To any person exempt from these regulations to the extent permitted under such exemption;

(d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the U.S. Nuclear Regulatory Commission, an agreement state, a licensing state, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the department, an agreement state or a Licensing State.

(3) Before transferring radioactive material to a specific licensee of the department, the U.S. Nuclear Regulatory Commission, an agreement state, a licensing state or to a general licensee who is required to register with the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(4) Any of the following methods for the verification required by (3), above, are applicable:

(a) The transferor may possess and read a current copy of the transferee's specific or general license.

(b) The transferor may possess a written certification by the transferee that the transferee is authorized by license to receive the type, form and quantity of radioactive material to be transferred, specifying the license number, issuing agency and expiration date.

(c) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license to receive the type, form and quantity of radioactive material to be transferred, specifying the license number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.

(d) The transferor may obtain other information compiled by a reporting service from official records of the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state regarding the identity of licensees and the scope and expiration dates of the licenses.

(e) When none of the methods of verification described in (4)(a) through (d), above, are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation for the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state that the transferee is licensed to receive the radioactive material.

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

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

SUBPART D
RECIPROCITY

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

(1) Subject to these regulations, any person who holds a specific license from the
R12 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
R2 license by the Department to conduct the activities authorized in such licensing
R8 document within the State of Florida, except for areas of exclusive federal
R10 jurisdiction, for a period not in excess of 180 consecutive days provided that:

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

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

(c) The out-of-state licensee complies with these applicable regulations and with all the terms and conditions of the licensing document, except any
R2 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
R12 section except by transfer to a person who is specifically licensed by the
R12 Department, by the NRC, an Agreement State or a Licensing State to
R21 receive such material.

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), F.S.
Law Implemented: 404.051(1),(2),(4),(6),(11), 404.061(2), 404.081(1), F.S.
R12 History: New 7-17-85, Amended 4-4-89, Formerly 10D-91.321, Amended 10-8-00, 2-28-08, 2-11-10, 12-26-13.

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:

Page left Intentionally Blank

(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
Europium 154	0.01	400

Material	Release Fraction	Curies
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
Silver 110m	0.01	1,000

Material	Release Fraction	Curies
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
Conntaminated 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

SUBPART G
RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

R5 **64E-5.221 Radiological criteria for license termination.** The criteria in this subpart apply to the decommissioning of facilities licensed under this chapter but do not apply to uranium and thorium recovery facilities as specified in Rule 64E-5.211, F.A.C., or to sites which previously have submitted and received department approval of a license termination 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 with the criteria in this subpart, the department will require additional cleanup only if based on new information or if it determines that the criteria of this subpart were not met and residual activity remaining at the site could result in significant threat to public health and safety.

R5 (2) When calculating total effective dose equivalent to the average member of the critical group, the licensee shall determine the peak annual total effective dose 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 unrestricted use if the total effective dose equivalent to an average member of the critical group from the residual radioactivity that is distinguishable from background radiation does not exceed 25 millirem (0.25 mSv) per year including radioactivity from groundwater sources of drinking water and the residual radioactivity levels are as low as reasonably achievable. Determination of the ALARA levels must take into account any detriments such as deaths from transportation accidents potentially expected to result from decontamination and waste 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 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 licensee can demonstrate that further reductions in residual radioactivity to comply with the provisions of Rule 64E-5.222, F.A.C., would result in an increase in public or environmental harm. Determination of the ALARA levels must take into account any detriments such as traffic accidents potentially expected to result from decontamination and waste disposal.

R5 (2) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of 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 independent third party including a governmental custodian of a site to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

R5 (a) Funds sufficient to pay decommissioning costs placed into an account segregated from the licensee's assets and outside the licensee's 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 assuming custody and ownership of a site.

R5 (4) The licensee has submitted a decommissioning or license termination plan as specified in Rule 64E-5.214(2), F.A.C., to the department indicating the licensee's intent to decommission in accordance with this part and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the license termination or decommissioning plan how the advice of individuals and institutions in the community who could be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

R5 (a) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters:

R5 1. Whether provisions for institutional controls proposed by the licensee:

R5 (I) Will provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group 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 other affected parties.

R5 2. Whether the licensee has provided sufficient financial assurance to enable an independent third party including a governmental custodian of a site to assume and carry out responsibilities for any 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.(I), F.A.C., if the licensee:

R5 (1) Provides assurance that public health and safety would continue to be protected
R5 and that it is unlikely that the total effective dose equivalent from all combined
R5 man-made sources other than medical sources would be more than 100 millirem
R5 per year (1 millisievert per year) by submitting an analysis of possible sources of
R5 exposure;

R5 (2) Has employed restrictions to the extent practical on site use according to the
R5 provisions of Rule 64E-5.223, F.A.C., in minimizing exposures at the site;

R5 (3) Reduces doses to ALARA levels considering any detriments such as traffic
R5 accidents potentially expected to result from decontamination and waste
R5 disposal; and

R5 (4) Has submitted a decommissioning or license termination plan to the department
R5 indicating the licensee's intent to decommission as specified in Rule
R5 64E-5.214(2), F.A.C., and specifying that the licensee proposes to 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 (µCi per ml)	Column II Liquid and Gas Concentration (µCi 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 (µCi per ml)	Column II Liquid and Gas Concentration (µCi per ml)
Technetium (43)	Tc-96m Tc-96		1×10^{-1} 1×10^{-3}
Tellurium (52)	Te-125m Te-127m Te-127 Te-129m Te-131m Te-132		2×10^{-3} 6×10^{-4} 3×10^{-3} 3×10^{-4} 6×10^{-4} 3×10^{-4}
Terbium (65	Tb-160		4×10^{-4}
Thallium (81)	Tl-200 Tl-201 Tl-202 Tl-204		4×10^{-3} 3×10^{-3} 1×10^{-3} 1×10^{-3}
Thulium (69)	Tm-170 Tm-171		5×10^{-4} 5×10^{-3}
Tin (50)	Sn-113 Sn-125		9×10^{-4} 2×10^{-4}
Tungsten (Wolfram) (74)	W-181 W-187		4×10^{-3} 7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m Xe-133 Xe-135	4×10^{-6} 3×10^{-6} 1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90 Y-91m Y-91 Y-92 Y-93		2×10^{-4} 3×10^{-2} 3×10^{-4} 6×10^{-4} 3×10^{-4}
Zinc (30)	Zn-65 Zn-69m Zn-69		1×10^{-3} 7×10^{-4} 2×10^{-2}
Zirconium (40)	Zr-95 Zr-97		6×10^{-4} 2×10^{-4}
Beta and gamma emitting radioative 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
Cobalt 58m (Co 58m)	10

Radioactive Material (Symbol)	Microcuries
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
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10

Radioactive Material (Symbol)	Microcuries
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
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100

Radioactive Material (Symbol)	Microcuries
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
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10

Radioactive Material (Symbol)	Microcuries
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
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

Radioactive Material (Symbol)	Microcuries
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
Cobalt 58	1	0.01

Radioactive Material	Column I (curies)	Column II (curies)
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
Iron 59	1	0.01

Radioactive Material	Column I (curies)	Column II (curies)
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
Praseodymium 142	10	0.1
Praseodymium 143	10	0.1

Radioactive Material	Column I (curies)	Column II (curies)
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
Technetium 97m	10	0.1
Technetium 97	10	0.1
Technetium 99m	100	1.0

Radioactive Material	Column I (curies)	Column II (curies)
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
Zirconium 95	1	0.01
Zirconium 97	1	0.01

Radioactive Material	Column I (curies)	Column II (curies)
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

SUBPART B RADIATION PROTECTION PROGRAMS

SUBPART C OCCUPATIONAL DOSE LIMITS

SUBPART D..RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

SUBPART E SURVEYS AND MONITORING

SUBPART F CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

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

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

SUBPART I PRECAUTIONARY PROCEDURES

SUBPART J WASTE MANAGEMENT

SUBPART K RECORDS

SUBPART L REPORTS

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

(3) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Department. The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements to demonstrate compliance with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable.

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, 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, June 2012 (see 64E-5.101, F.A.C.).

(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).

Rulemaking Authority: 404.051, F.S.
Law Implemented: 404.022, 404.051(1)(4), F.S.
History: New January 1, 1994, Formerly 10D-91.435, Amended 10-8-00, 9-28-06, 12-26-13.

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.
R12 See State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent
R12 Concentrations, June 2012, (see 64E-5.101, F.A.C.) 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.

Rulemaking Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
R12 History: New January 1, 1994, Formerly 10D-91.437, Amended 12-26-13.

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
R12 equivalent. See State of Florida Bureau of Radiation Control ALIs, DACs,
R12 and Effluent Concentrations, June 2012.

(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,
R12 that is D, W, or Y, from State of Florida Bureau of Radiation Control ALIs,
R12 DACs, and Effluent Concentrations, June 2012, for each radionuclide in
R12 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
R12 (0.05 sievert), that is, the stochastic ALI, as listed in parentheses in State
R12 of Florida Bureau of Radiation Control ALIs, DACs, and Effluent
R12 Concentrations, June 2012. (See 64E-5.101, F.A.C.) 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.

Rulemaking Authority: 404.051, F.S.
Law Implemented: 404.022, 404.051(1)(4), F.S.
R12 History: New January 1, 1994, Formerly 10D-91.308, Amended 12-26-13.

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

(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.

R10 (5) A licensee or applicant for a license may permit visitors to an individual who
R10 cannot be released under Rule 64E-5.622, F.A.C., to receive a radiation dose
R10 greater than 0.1 rem (1 millisievert) provided the following are satisfied:

R10 (a) The radiation dose received does not exceed 0.5 rem (5 millisievert);

R10 (b) The authorized user, as defined in Rule 64E-5.6011, F.A.C., has
R10 determined before the visit that it is appropriate.

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
R12 area do not exceed the values specified in State of Florida Bureau
R12 of Radiation Control ALIs, DACs and Effluent Concentrations,
R12 June 2012, 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
R12 concentration values in State of Florida Bureau of Radiation Control ALIs, DACs,
R12 and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) 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.

Rulemaking Authority: 404.051, F.S.
Law Implemented: 404.022, 404.051(1)(4), F.S.
R12 History: New 1-1-94, Amended 11-20-94, 5-15-96, Formerly 10D-91.444, Amended 12-26-13.

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:

(a) Adults likely to receive in 1 year from sources external to the body a dose
R2 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
R2 body a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose
R2 equivalent in excess of 0.15 rem (1.5 mSv) or a shallow dose equivalent to
R2 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
R2 from radiation sources external to the body a deep dose equivalent in
R2 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,
R2 F.A.C., the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(a) Adults likely to receive in 1 year an intake in excess of 10 percent of the
R12 applicable ALI in State of Florida Bureau of Radiation Control ALIs, DACs,
R12 and Effluent Concentrations June 2012 (see 64E-5.101, F.A.C.), Table I,
R12 Columns 1 and 2; and

R2 (b) Minors likely to receive in 1 year a committed effective dose equivalent in
R2 excess of 0.10 rem (1.0 millisievert); and

R2 (c) Declared pregnant women likely to receive during the entire pregnancy a
R2 committed effective dose equivalent in excess of 0.1 rem (1 mSv).

Rulemaking Authority: 404.051, F.S.
Law Implemented: 404.022, 404.051(1)(4), F.S.
R12 History: New 1-1-94, Formerly 10D-91.446, Amended 10-8-00, 12-26-13.

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.

(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:

(1) Containers holding licensed material in quantities less than the quantities listed in State of Florida Bureau of Radiation Control Radioactive Material Requiring
R2 Labeling, May 2000;

(2) Containers holding licensed material in concentrations less than those specified
R12 in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent
R12 Concentrations, July 2012 (See 64E-5.101, F.A.C.), 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.

Rulemaking Authority: 404.051, F.S.
Law Implemented: 404.022, 404.051(1)(4), F.S.
R12 History: New 1-1-94, Formerly 10D-91.459, Amended 10-8-00, 12-26-13.

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
R12 listed in State of Florida Bureau of Radiation Control ALIs, DACs, and
R12 Effluent Concentrations, June 2012, 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
R12 sewer by the concentration of that radionuclide listed in State of
R12 Florida Bureau of Radiation Control ALIs, DACs, and Effluent
R12 Concentrations, June 2012, (See 64E-5.101, F.A.C.) 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).

Rulemaking Authority: 404.051, F.S.
Law Implemented: 404.022, 404.051(1)(4), F.S.
R12 History: New 1-1-94, Formerly 10D-91.463, Amended 12-26-13.

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-
R10 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;

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.

R12 (d) Licensed material as defined in paragraphs 64E-5.101(21)(c) and (d), F.A.C., may be disposed of at a licensed low-level radioactive waste disposal facility, even though it is not defined as low-level radioactive waste provided the requirements of Rule 64E-5.332, F.A.C., are satisfied or at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

(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.

Rulemaking Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
R12 History: New 1-1-94, Formerly 10D-91.465, Amended 2-11-10, 12-26-13.

(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);

R2 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, June 2012 (see 64E-5.101, F.A.C.); 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, June 2012; and

2. The damage affects the integrity of the licensed material or its container.

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

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

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

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

Rulemaking Authority: 404.051, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
R12 History: New 1-1-94, Amended 5-15-96, Formerly 10D-91.481, Amended 10-8-00, 2-11-10, 12-26-13.

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

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

(a) Incidents for which notification is required by Rule 64E-5.344, F.A.C.,; or

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

1. The occupational dose limits for adults in Rule 64E-5.304, F.A.C.;

2. The occupational dose limits for a minor in Rule 64E-5.310, F.A.C.;

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

4. The limits for an individual member of the public in Rule 64E-5.312, F.A.C.;

5. Any applicable limit in the license or registration;

6. The ALARA constraints for air emissions specified in subsection 64E-5.303(5), F.A.C.; or

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

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

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

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 (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 submit a National Source Tracking Transaction Report. The report must include the following information:

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

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

R8 (c) The name, address, and license number of the person that provided the source;

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

R8 (e) The radioactive material in the source;

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

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

R8 (h) The date of receipt; and

R8 (i) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

R8 (4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

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

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

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

R8 (d) The radioactive material in the source;

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

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

R8 (g) The disassemble date of the source.

R8 (5) Each licensee who disposes of a nationally tracked source shall complete 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
R8 file a 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 its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009 or as specified in 10 C.F.R. section 20.2207(h), 1-1-13 edition, which is herein incorporated by reference and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-03456 or http://www.gpo.gov/fdsys/pkg/CFR-2013-title10-vol1/pdf/CFR-2013-title10-vol1-sec20-2207.pdf. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009 or as specified in 10 C.F.R. section 20.2207(h), 1-1-13 edition. The information may be submitted by using any of the methods identified by paragraph (6)(a) through (6)(e) of this section. The initial inventory report 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 manufacturer, model, and serial number of each nationally tracked 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 Rulemaking Authority: 404.051, F.S.
R8 Law Implemented: 404.022, 404.051, 404.081, F.S.
R12 History: New 2-28-08, Amended 12-26-13.

R8 **64E-5.351 Nationally Tracked Source Thresholds.** The nationally tracked source thresholds are listed in table 1 below with the Terabecquerel (TBq) values as the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

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

R12 Rulemaking Authority: 404.051, F.S.
R8 Law Implemented: 404.022, 404.051, 404.081, F.S.
R12 History: New 2-28-08, Amended 12-26-13

Page intentionally left blank

PART V X-RAYS IN THE HEALING ARTS

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.

R1 R7 R1 R1 R1 R7 R1

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.

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.

R11 (e) Compliance with the dose limits will be determined as follows:

R11 1. Movable grids and compression devices willl be removed from the
R11 useful beam during the measurement.

R11 2. The fluoroscope's radiation output will be maximized.

R11 a. Systems with automatic exposure controls such as
R11 automatic brightness control will have sufficient lead or lead
R11 equivalent materials placed in the useful beam to produce
R11 the maximum output.

R11 b. Systems without automatic exposure controls or systems
R11 with a manual mode in addition to automatic exposure
R11 control modes will have the current and potential set to
R11 produce the maximum output. Attenuating material will be
R11 placed in the useful beam to protect the imaging system. If
R11 the registrant has a written radiation protection program
R11 restricting the range of current and potential the tests will be
R11 performed within the range of allowed values.

R11 c. Patient support device height and SID, where adjustable, will
R11 be varied to produce the maximum output. If the registrant
R11 has a written radiation protection program restricting the
R11 range of patient support device heights or SIDs the tests will
R11 be performed within the range of allowed values.

R11 3. The exposure rate will be measured at the following points on the
R11 centerline of the beam unless the specified geometry is prohibited
R11 by a written radiation protection program.

R11 a. At least one centimeter above the patient support device and
R11 corrected for distance to show the actual entrance exposure
R11 rate at the top surface of the patient support device for:
R11

R11 (I) Fluoroscopes where the x-ray tube is fixed under the
R11 patient support device.

R11 (II) C-arm systems or stationary c-arm fluoroscopes
R11 where the x-ray tube can be rotated under the patient
R11 support device. The x-ray tube will be positioned as
R11 close to the patient support device as possible.

R11 b. At 30 centimeters above the patient support device with
R11 the end of the beam-limiting device or spacer assembly
R11 positioned as close as possible to the point of measurement
R11 for:

R11 (I) Fluoroscopes where the x-ray tube is fixed above the
R11 patient support device.

R11 (II) C-arm systems or stationary c-arm fluoroscopes
R11 where the x-ray tube can be rotated above the patient
R11 support device.

R11 c. At a point 15 centimeters laterally from the centerline of the patient support device or from the centerline of the patient if the registrant has a written radiation protection program specifying placement of the patient not on the centerline of the patient support device in the direction of the x-ray tube with the input surface of the fluoroscopic imaging assembly positioned as close to the edge of the patient support device as possible but no closer than 15 cm for:

R11 (I) Fluoroscopes where the x-ray tube is fixed laterally to the patient support device.

R11 (II) C-arm systems or stationary c-arm fluoroscopes where the x-ray tube can be rotated lateral to the patient support device.

R11 d. At 30 centimeters from the input surface of the fluoroscopic imaging assembly, 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, for mobile c-arm fluoroscopes. Spacers or other attachments normally used can not be removed to allow measuring from a point closer to the actual input surface.

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 barrier and frame assembly with the attenuation block in the useful beam combined with radiation from the image intensifier if provided shall not exceed 2 milliroentgens (0.516 μC per kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic image assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

R1 (b) Measuring Compliance with Barrier Transmission Limits

R1 1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area no greater than 100 square centimeters with no linear dimension greater than 20 centimeters.

R1 2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly position 30 centimeters above the tabletop.

R1 3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam limiting device or spacer assembly as close to the table top as it can be placed but not closer than 30 centimeters.

R1 4. Movable grids and compression devices shall be removed from the useful beam during the measurements.

R1 5. The attenuation block shall be positioned in the useful beam 10 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:

(a) Thirty-eight centimeters on stationary fluoroscopes installed after January 1, 1977,

(b) Thirty-five and one-half centimeters on stationary fluoroscopes installed prior to January 1, 1977,

(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.

R11 (e) Nineteen centimeters for extremity-use-only fluoroscopes.

R11 (f) Ten centimeters for extremity-use-only fluoroscopes used for specific
R11 surgical applications. Written safety procedures must be provided to the
R11 operator of the fluoroscope and precautionary measures followed during
R11 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, photo-fluorographic 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:

R11 (a) The remote control panel shall be installed as to require the operator to
R11 stand behind a permanent protective barrier meeting the requirements of
R11 paragraph 64E-5.502(2)(a)-(c), F.A.C. The barrier must be wide enough to
R11 prevent the secondary scatter radiation from striking the operator directly
R11 when the machine is operated from the remote control panel.

R11 (b) The operator must be able to see and hear the patient when behind the
R11 barrier.

R11 (c) The barrier shall be constructed of material of sufficient density to meet or
R11 exceed the barrier requirements of sub-subparagraph 64E-5.502(1)(a)4.b., F.A.C.

Specific Authority: 404.051, 404.22, F.S.
R7 Law Implemented: 404.05, 404.22, F.S.
R11 History: New 7-17-85, amended 4-4-89, 3-17-92, 1-5-95, Formerly 10D-91.605, amended 5-18-98, 8-16-07, 5-8-13.

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.

PART VI USE OF RADIONUCLIDES IN THE HEALING ARTS

SUBPART A GENERAL ADMINISTRATIVE REQUIREMENTS

SUBPART B GENERAL TECHNICAL REQUIREMENTS

SUBPART C UPTAKE, DILUTION, AND EXCRETION

SUBPART D IMAGING AND LOCALIZATION

SUBPART E RADIOPHARMACEUTICALS FOR THERAPY

SUBPART F SEALED SOURCES FOR DIAGNOSIS

SUBPART G SOURCES FOR BRACHYTHERAPY

R10 SUBPART H PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.

SUBPART I TRAINING AND EXPERIENCE REQUIREMENTS

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

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:

R12 (a) A physician, dentist, or podiatrist who meets the requirements in Rule
R12 64E-5.658 and subsection 64E-5.649(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, intralumimnal 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.
R12 History: New 02-11-10, Amended 12-26-13..

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
R10 an 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 institutions, management and all authorized users shall participate in the program
R10 as required by the RSO.

(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.

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

R12 (c) Require and verify implementation of corrective actions; and

R12 (d) Stop unsafe operations.

(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: 404.051, 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.
R12 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.713,Amended 2-11-10, 12-26-13.

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, preparation, or transfer of radioactive material by a physician in training under the supervision of an authorized user as allowed by paragraph 64E-5.601(3)(a), F.A.C., shall:

R10 1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

R10 2. Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

R10 3. Require the preparation of radioactive materials use only under the supervision of an authorized user or authorized nuclear pharmacist;

R10 4. Require the authorized user to be immediately available to communicate with the supervised individual; and

R10 5. Require that only those individuals specifically designated by the authorized user be permitted to administer radionuclides or radiation to patients.

R10 (b) A licensee shall require the supervised individual receiving, possessing, acquiring, preparing, using or transferring radioactive material specified in 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 procedures established by the licensee; and

R10 3. Comply with these regulations and the license conditions regarding the use of radioactive material.

R10 (c) The licensee’s management or radiation safety committee shall provide written approval prior to any training of a physician to receive, acquire, prepare, possess or use radioactive material under the supervision of an authorized user. After the training has been completed, the licensee shall provide documentation to the supervised individual that the individual received the training and experience required by this section. The licensee shall maintain records that identify physicians currently in training and the physicians who have completed training for 7 years after the last date training was received; and

(2) Supervision of an individual in training to become an authorized medical physicist:

(a) A licensee who permits the receipt, preparation, acquisition, possession, use, or transfer of radioactive material to an individual in training under the supervision of an authorized medical physicist as allowed by paragraph 64E-5.601(3)(c), F.A.C., shall:

1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

2. Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use; and

3. Require the authorized medical physicist to be immediately available to communicate with the supervised individual.

(b) A licensee shall require the supervised individual receiving, acquiring or preparing, possessing, using or transferring radioactive material specified in paragraph 64E-5.601(3)(c), F.A.C., to:

1. Follow the instructions of the supervising authorized medical physicist;

2. Follow the written radiation and quality management program procedures established by the licensee; and

3. Comply with these regulations and the license conditions regarding the use of radioactive material.

(c) The licensee’s management or radiation safety committee shall provide written approval prior to any individual to receive, possess or use radioactive material under the supervision of an authorized medical physicist. After the training has been completed, the licensee shall provide documentation to the supervised individual that the individual received the training and experience required by this section. The licensee shall maintain records that identify individuals currently in training and the individuals who have completed training for 7 years after the last date training was received.

(3) A licensee that permits any supervised activities regarding the use of radioactive materials or radiation from radioactive materials is responsible for the acts and omissions of the supervised individual.

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

64E-5.609 Visiting Authorized User, Visiting Authorized Medical Physicist, or 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 respective 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.

Rulemaking Authority: 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-91.715, Amended 02-11-10, 12-26-13.

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

(1) The mobile medical licensee shall obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive materials at the client's address and clearly delineates the authority and responsibility of the licensee and the client. A licensee providing mobile medical services shall retain this letter for 3 years after the provision of service.

(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.

(3) The mobile medical licensee shall check instruments used to measure the activity of unsealed or sealed radioactive materials for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check and shall perform all daily quality control tests on all equipment used to obtain images or information from radionuclide studies before medical use at each location of use.

(4) Before leaving a client location, mobile medical service licensees shall perform a survey of all areas where radioactive materials are used with a radiation survey instrument in order to ensure that they have complied with the requirements in Rule 64E-5.621, F.A.C., that radiation dose rates are at background levels, and that removable contamination is below 2000 disintegrations per minute per 100 square centimeters sampled. A licensee shall check each survey instrument for proper operation with a dedicated check source before each use at each location. The licensee is not required to keep records of these dedicated source survey instrument checks.

(5) Mobile medical service licensees shall retain a record of each survey required for 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.

(6) A physician shall be on site at each client's address at the time radioactive materials are administered. An authorized user shall be immediately available to communicate with the supervised individuals or individuals under their direction.

(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:

(a) Assemble the relevant facts including the cause;

(b) Identify any corrective action required to prevent recurrence;

(c) 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
R10 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:

(1) 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;

(2) 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.

(3) Teletherapy sources manufactured and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the
R10 NRC; or

R10 (4) Sealed sources or devices containing radioactive materials that are either;

R10 (a) Manufactured, labeled, packaged, and distributed as specified in a license
R10 issued by the department or by another agreement state, a licensing state
R10 or the NRC; or

R10 (b) Noncommercially transferred from a medical use licensee authorized by
R10 Chapter 64E-5, Part VI, F.A.C., or equivalent medical use license issued
R10 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 8-25-9191, 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
R10 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
R10 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

R12 (g) The name or initials of the individual performing the check.

(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
R10 by the manufacturer who has compared their source to a source calibrated by the
R10 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 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, 404.071, 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.
R12 History: New 8-25-91, Formerly 10D-91.720, Amended 2-11-10, 12-26-13.

R10 **64E-5.615 Use, Calibration and Check of Survey Instruments.** A licensee shall ensure that the survey instruments used to comply with this part have been calibrated before 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; 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:

(7) Individuals receiving radiopharmaceutical therapy shall be provided a private room with a private sanitary facility or a room with another individual who is receiving unsealed radioactive materials who cannot be released under Rule 64E-5.622, F.A.C. Individuals receiving manual brachytherapy shall be provided a private room or a room with another individual who is receiving manual brachytherapy and cannot be released under Rule 64E-5.622, F.A.C. The licensee shall not place an individual receiving manual brachytherapy in the same room with a patient who is not receiving manual brachytherapy.

(8) A licensee shall take these additional safety precautions for radiopharmaceutical therapy patients or human research subjects who cannot be released by Rule 64E-5.622, F.A.C.:

(a) Monitor material and items removed from the patient's or human research 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/cm^2 and a minimum probe diameter of 1.5 inches.

(9) For manual brachytherapy patients or human research subjects who cannot be released by Rule 64E-5.622, F.A.C., the licensee shall have the applicable emergency response equipment available near each treatment room to respond to the following:

(a) A source that is dislodged from the patient or human research subject; and

(b) A sealed source lodged within the patient following removal of the source applicators.

(10) The licensee shall establish a bioassay program to measure the thyroid burden of each individual who helps prepare, prepares or administers a dosage of unsealed iodine 131 or iodine 125 in accordance with Rule 64E-5.1320, F.A.C.

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.
History: New 5-15-96, Formerly 10D-91.721, Amended 02-11-10.

R12 **64E-5.6251 Manual Therapy Related Computer Systems.** The licensee shall perform
R12 acceptance testing on the treatment planning system of manual brachytherapy therapy-related
R10 computer systems in accordance with published protocols accepted by nationally recognized
R10 bodies. At a 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.
R12 History: New 02-11-10, Amended 12-26-13.

SUBPART C
UPTAKE, DILUTION, AND EXCRETION

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

(Entire section Changed) A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for medical use under the following conditions:

(1) When a written directive is not required by subsection 64E-5.607(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 a NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol, or a Notice of Claimed Investigational Exemption for a New Drug (IND) protocol accepted by U.S. Food and Drug Administration (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. Except for sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C.; or

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.626(1)(d)2., F.A.C., and specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or;

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.649 or 64E-5.657, F.A.C.

(2) When a written directive is required by subsection 64E-5.607(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 64E-5.660, F.A.C.; or

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.626(1)(d)2., F.A.C., and 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-5.657, 64E-5.660, 64E-5.661, 64E-5.662 or 64E-5.663, F.A.C.

Rulemaking Authority: 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-91.733, Amended 8-6-01, *8-6-01, 2-11-10, 12-26-13.*.

SUBPART D
IMAGING AND LOCALIZATION

64E-5.627 Use of Unsealed Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies. A licensee is allowed to use any radioactive material in a diagnostic radiopharmaceutical, or any generator, or reagent kit, for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for medical use under the following conditions: **(Entire section Changed)**

(1) When a written directive is not required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

(a) Obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations; or

(b) Radioactive material is obtained from and prepared by a 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. Except for sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rules 64E-5.650 or 64E-5.660 and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C.;

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.626(1)(d)2., F.A.C., and specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.; or

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.650 or 64E-5.657, F.A.C.

(2) When a written directive is required by subsection 64E-5.607(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 64E-5.660, F.A.C.; or

3. An individual under the supervision a physician who is an authorized user under subparagraph 64E-5.627(2)(d)2., F.A.C., and 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 Rules 64E-5.657, 64E-5.660, 64E-5.661, 64E-5.662 or 64E-5.663, F.A.C.

(3) For oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) and when a written directive is required by 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;

R12 2. A physician who is an authorized user and meets the training
R12 requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.;

R12 3. An individual under the supervision of a physician who is an
R12 authorized user under subparagraph 64E-5.627(1)(d)2., F.A.C., and
R10 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.

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: 404.051, 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.
R12 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.735, 8-6-01, 2-11-10, 12-26-13.

4. The ratio of the measures expressed as microcuries of parent isotope(s) and other contaminates per millicurie of daughter isotope (kilobecquerels of parent isotope(s) per megabecquerel of daughter isotope);

5. The date of the test; and

6. The initials of the individual who performed the test.

(d) A licensee shall report immediately to the department each occurrence of parent isotope(s) or other contaminates concentrations exceeding the limits specified in paragraph 64E-5.628(3)(a), F.A.C.

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.
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 ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) 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 ALIs, DACs, and Effluent Concentrations, June 2012. 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.

Rulemaking Authority: 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 1-1-94, Formerly 10D-91.737, Amended 2-11-10, 12-26-13.

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 a physician who is an authorized user under subparagraph 64E-5.630(1)(d)2., F.A.C., 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) 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

(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 64E-5.660, F.A.C.; or

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.626(1)(d)2., F.A.C., and 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 training and experience specified in Rule 64E-5.661 or 64E-5.657, F.A.C.

(3) For oral administration of sodium iodide I-131 in quantities greater than 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 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 64E-5.660, F.A.C.; or

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.626(1)(d)2., F.A.C., and 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 training and experience specified in Rule 64E-5.662 or 64E-5.657, F.A.C.

(4) For parenteral use of radioactive materials 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 64E-5.660, F.A.C.; or

3. An individual under the supervision of a physician who is an authorized user under subparagraph 64E-5.626(1)(d)2., F.A.C., and 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 training and experience specified in Rule 64E-5.663 or 64E-5.657, F.A.C.

Rulemaking Authority: 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 5-12-93, Formerly 10D-91.739, Amended 8-6-01, 2-11-10, 12-26-13.

SUBPART F
SEALED SOURCES FOR DIAGNOSIS

64E-5.631 Use of Sealed Sources for Diagnosis. The licensee is allowed to use the sealed sources listed below, provided they are approved by and used as specified in, the Sealed Source and Device Registry, for diagnostic medical uses, or in research in accordance with an active IDE application accepted by the FDA and the requirements of Rule 64E-5.612, 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;

(3) Gadolinium 153 as a sealed source in a device for bone mineral analysis;

(4) Americium 241 as a sealed source in a device for bone mineral analysis; or

(5) For isotopes or uses not listed in subsections 64E-5.631(1) through (4), F.A.C., above, the licensee must amend their radioactive materials license.

In order to use isotopes in accordance this Rule, an authorized user must satisfy the training and experience requirements specified in Rule 64E-5.654 or 64E-5.657, F.A.C.

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.
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
R12 specified in, the Sealed Source and Device Registry, for medical uses, or in research in
R10 accordance with an active IDE application accepted by the FDA and the requirements of Rule
R10 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: 404.051, 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.
R12 History: New 8-25-91, Formerly 10D-91.745 Amended 2-11-10, 12-26-13.

64E-5.633 Manual Brachytherapy Sources Inventory and Surveys.

(1) The licensee shall maintain accountability at all times for all manual brachytherapy sources in storage or use.

(a) 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; and

(b) As soon as possible after removing the sources from a patient or a human research subject, the licensee shall immediately count or otherwise verify the number of sources and return them to a secure storage area.

(2) A licensee shall make a record of the use of manual brachytherapy sources which includes:

(a) For temporary implants;

1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage; and

2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage.

(b) For permanent implants;

1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage;

2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage; and

3. The number and activity of sources permanently implanted in the patient or human research subject.

(3) Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey. This record shall contain the date and results of the survey, the survey instrument used and the name of the individual who performed the survey.

(4) A licensee shall maintain the records required in 64E-5.633(2) and (3) for 3 years.

Rulemaking Authority: 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-91.748, Amended 2-11-10, 12-26-13.

(5) A licensee shall correct mathematically the outputs determined in paragraph 64E-5.641(2)(a), F.A.C., for physical decay at intervals consistent with 1 percent physical decay.

(6) Full calibration measurements required by subsection 64E-5.6411(1), F.A.C., and physical decay corrections required by subsection 64E-5.641(5), F.A.C., shall be performed by the authorized medical physicist.

(7) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection 64E-5.6411(2), F.A.C., a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(8) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsections 64E-5.6411(1)-(5), F.A.C.

(9) A licensee shall maintain a record of each remote afterloader unit calibration for three years. The record shall include the following:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for both the remote afterloader unit and the source;

(c) The model numbers and serial numbers of the instruments used to calibrate the remote afterloader unit;

(d) The results and an assessment of the full calibrations.

(e) The results of the audiograph required for low dose-rate remote afterloaders; and

(f) The signature of the authorized medical physicist.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History: New 02-11-10.

64E-5.6412 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units. (Entire section New)

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each gamma stereotactic radiosurgery:

(a) Before the first medical use of the unit;

(b) 1. 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;

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;

R12 (e) On-off errors;

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.

(7) A licensee shall maintain a record of each gamma stereotactic radiosurgery unit calibration 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 gamma stereotactic radiosurgery unit and the source;

(c) The model numbers and serial numbers of the instruments used to calibrate the gamma stereotactic radiosurgery unit;

(d) The results and an assessment of the full calibrations; and

(e) The signature of the authorized medical physicist.

Rulemaking Authority: 404.051, 404.061, 404.071, 404.081, 404.141 FS..
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History: New 02-11-10, Amended 12-26-13..

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.

(6) A licensee authorized to use a teletherapy unit for medical use shall perform
R10 safety spot-checks of each teletherapy facility monthly and after each source
R10 installation.

(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
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.

(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.

(10) A licensee shall maintain a record of each spot-check required by 64E-5.642(1)
R10 and (6) for 3 years and a copy of the procedures required by subsection
R10 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
R10 afterloader unit; 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), 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 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 (6) A licensee shall retain a copy of the procedures required by subsection 64E-5.6421(4), F.A.C., until the licensee no longer possesses the remote afterloader unit.

R10 (7) A licensee shall maintain a record of each spot-check required by subsection 64E-5.6421(2), F.A.C., for 3 years and a copy of the procedures required by subsections 64E-5.6421(4) and (5), F.A.C., until the licensee no longer 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 remote afterloader unit and source;

R10 (c) An assessment of timer accuracy;

R10 (d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

R10 (e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of 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 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.

R12 (2) To satisfy the requirements of paragraph 64E-5.6422(1)(a), F.A.C., spot checks shall include the determination of:

R10 (a) Assure the proper operation of the:

1. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

2. Helmet microswitches;

3. Emergency timing circuits; and

4. Stereotactic frames and localizing devices (trunnions).

(b) Determine the following elements:

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.;

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;

3. Source output against computer calculation;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. Trunnion centricity.

(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.

(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

(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:

(a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Timer termination;

(e) Radiation monitors used to indicate room exposures; and

(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
R10 intercom systems, timer termination, treatment table retraction
R10 mechanism, and stereotactic frames and localizing devices (trunnions);
R10 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: 404.051, 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.
R12 History: New 02-11-10, Amended 12-26-13.

R10 **64E-5.6423 Additional Technical Requirements for Mobile Remote Afterloader Units. (Entire section New)**

R10 (1) A licensee providing mobile remote afterloader service for medical use shall perform the following:

R10 (a) Check survey instruments before medical use at each address of use or 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 licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a 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 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 safe shielded position.

R10 (3) In addition to the requirements for checks in subsection 64E-5.6423(2), F.A.C., a licensee shall ensure overall proper operation of the remote afterloader unit by 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 the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

R10 (5) The licensee shall keep a copy of each check for mobile remote afterloader unit required by subsection 64E-5.6423(2), F.A.C., for three years. The records shall include:

R10 (a) The date of the check;

R10 (b) The manufacturer's name, model number, and serial number of the remote afterloader unit;

R10 (c) Notations accounting for all sources before the licensee departs from a 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.

(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,
R12 after each installation of a teletherapy source; following repairs to the source(s)
R12 driving unit, or other electronic or mechanical component that could expose the
R12 source(s), reduce shielding around the source(s), or compromise the radiation
R12 safety of the unit or the source(s); and after making any change for which an amendment is required by Rule 64E-5.636, F.A.C.

R12 (a) The maximum and average radiation levels levels from the surface of the
R12 main source(s) safe with the source(s) in the shielded position do not
R12 exceed the levels stated in the Sealed Source and Device Registry.

(b) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, radiation levels in restricted areas shall be unlikely to
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: 404.051, 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.
R12 History: New 8-25-91, Amended 1-1-994, Formerly 10D-91.762, Amended 10-8-00, 2-11-10, 12-26-13.

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
R10 instrument calibrated as provided in Rule 64E-5.615, F.A.C., to ensure that the
R10 maximum radiation levels and average radiation levels from the surface of the
R10 main source safe with the source(s) in the shielded position do not exceed the
R10 levels stated in the Sealed Source and Device Registry.
R10

R10 (2) The licensee shall make the survey specified in subsection 64E-5.644(1), F.A.C.,
R10 at the installation of a new source and following repairs to the source(s)
R10 shielding, the source(s) driving unit, or other electronic or mechanical component
R10 that could expose the source, reduce the shielding around the source(s), or
R10 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
R10 64E-5.644(1), F.A.C., for the duration of the license. These records shall include:
R10

R10 (a) The date of the measurements;

R10 (b) The manufacturer's name, model number and serial number of the
R10 treatment unit, source, and instrument used to measure radiation levels;

R10 (c) Each dose rate measured around the source while the unit is in the off
R10 position and the average of all measurements; and

R10 (d) The signature of the RSO or authorized medical physicist who performed
R10 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.

64E-5.645 Remote Afterloader, Gamma Stereotactic and Teletherapy Therapy-Related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system of high, medium, low, pulsed dose-rate remote afterloaders, gamma stereotactic, and teletherapy therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. An example of a nationally recognized body is the American Association of Physicists in Medicine. At a minimum, the acceptance testing must include, as applicable, verification of the following:

(1) The source-specific input parameters required by the dose calculation algorithm;

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) The accuracy of isodose plots and graphic displays;

(4) The accuracy of the software used to determine sealed source positions from radiographic images; and

(5) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Rulemaking Authority: 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 1-1-94, Formerly 10D-91.764, Amended 10-8-00, 2-11-10, 12-26-13..

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.

(1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery 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.

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 R10 whose certification process has been recognized by the NRC or an R10 agreement state under subsection 64E-5.656(1), F.A.C., and has R10 experience in radiation safety for similar types of use of radioactive R10 material for which the licensee is seeking the approval of the individual as R10 RSO and who meets the requirements in subsections 64E-5.648(4) and R10 (5), F.A.C., of 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
R10 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

R12 (2) Be an authorized user under Rule 64E-5.650 or 64E-5.660, F.A.C., NRC 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;

R12 d. Chemistry of radioactive material for medical use;

R12 e. Radiation biology; 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., NRC or equivalent Agreement State requirements, involving the following:

R10 a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Administering dosages of radioactive drugs to patients or human research subjects.

(b) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657, 64E-5.649, 64E-5.650 or 64E-5.660, F.A.C., NRC or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.649(1)(a) or 64E-5.649(3)(a), F.A.C., of this section and has demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses authorized under subsection 64E-5.626(1), F.A.C.

Rulemaking Authority: 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-91.769, Amended 02-11-10, 12-26-13.

64E-5.650 Training for Imaging and Localization Studies for Which a Written Directive Is Not Required. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user specified in subsection 64E-5.627(1), F.A.C., to:
(Entire section Changed)

(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-5.650(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:

(a) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in subparagraphs 64E-5.650(3)(a)1. and 64E-5.650(3)(a)2., F.A.C., of this section; and

(b) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) Be an authorized user under Rule 64E-5.660, F.A.C., and meet the requirements in sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C., NRC or equivalent Agreement State requirements; or paragraph 64E-5.650(3)(a), F.A.C.; or

(3) (a) Have completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum the following:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use;

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.650 or 64E-5.660, and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C., NRC or equivalent Agreement State requirements, involving the following:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

f. Administering dosages of radioactive drugs to patients or human research subjects; and

g. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(3) (b) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657, 64E-5.650, 64E-5.660, and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C., NRC or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.650(1)(a) or 64E-5.650(3)(a) or 64E-5.650(3)(a), F.A.C., of this section and has demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses authorized under subsections 64E-5.626(1) and 64E-5.627(1), F.A.C.

Rulemaking Authority: 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-91.770, Amended 2-11-10, 12-26-13, 12-26-13.

64E-5.651 Repealed 02-11-10 (See Rules 64E-5.660, 64E-5.661, 64E-5.662 & 64E-5.663)

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.
History: New 8-25-91, Formerly 10D-91.771, Repealed 02-11-10.

64E-5.652 Training for Use of Manual Brachytherapy Sources. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a brachytherapy source specified in 64E-5.632, F.A.C., to: **(Entire section Changed)**

(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-5.652(2)(c), 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:

(a) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2) (a) Have completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes-

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657 or 64E-5.652, F.A.C., NRC or equivalent Agreement State requirements at a medical institution, clinic, or private practice facility**,** involving the following:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Checking survey meters for proper operation;

c. Preparing, implanting, and removing brachytherapy sources;

d. Maintaining running inventories of material on hand;

e. Using administrative controls to prevent a medical event involving the use of radioactive material;

f. Using emergency procedures to control radioactive material; and

(b) Have completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule 64E-5.657 or 64E-5.652, F.A.C., NRC or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph 64E-5.652(2)(a)2., F.A.C., of this section; and

(c) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.652, F.A.C., NRC or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.652(1)(a) or 64E-5.652(2)(a) and 64E-5.652(2)(b), F.A.C., of this section and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses of manual brachytherapy sources authorized under Rule 64E-5.632, F.A.C.

Rulemaking Authority: 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-91.772, Amended 2-11-10, 12-26-13..

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 radiotherapy to: **(Entire section Changed)**

(1) Be authorized user under Rule 64E-5.652, F.A.C., NRC or equivalent Agreement State requirements; or

(2) (a) Have completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include the following:

1. Radiation Protection and instrumentation;

2. Radiation Protection;

3. Mathematics pertaining to the use and measurement of radioactivity: and

4. Radiation biology; and

(b) Have supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve the following:

1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

4. Follow-up and review of each individual's case history; and

(c) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.652, 64E-5.653, F.A.C., NRC or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs 64E-5.653(2)(a) and 64E-5.653(2)(b), F.A.C., of this section and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized for strontium-90 for ophthalmic use.

Rukemaking Authority: 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-91.773, Amended 2-11-10, 12-26-13.

64E-5.654 Training for Use of Sealed Sources for Diagnosis. Except as provided in 64E-5.657, F.A.C., the licensee shall require the authorized user of a sealed source in a device specified in 64E-5.631, F.A.C., to be a physician, dentist, or podiatrist:

(1) Be certified by a specialty board whose certification process includes all of the requirements in subsections 64E-5.654(2) and (3), F.A.C., of this section and whose certification has been recognized by the NRC or an agreement state. (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.); or

(2) Have completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include the following:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology; and

(3) Have completed training in the use of the device for the uses requested.

Rulemaking Authority: 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-91.774, Amended 2-11-10, 12-26-13.

64E-5.655 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. Except as provided in 64E-5.657, the licensee shall require the authorized user of a sealed source specified in 64E-5.634. F.A.C., to:

(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-5.655(2)(c) and subsection 64E-5.655(3), 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:

(a) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2) (a) Have completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes the following:

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657 or 64E-5.655, F.A.C., NRC or equivalent Agreement State requirements at a medical institution, clinic, or private practice facility, involving the following:

a. Reviewing full calibration measurements and periodic spot-checks;

b. Preparing treatment plans and calculating treatment doses and times;

c. Using administrative controls to prevent a medical event involving the use of radioactive material;

d. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

e. Checking and using survey meters;

f. Selecting the proper dose and how it is to be administered; and

(b) Have completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in Rule 64E-5.657 or 64E-5.655, F.A.C., NRC or equivalent Agreement State requirements as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph 64E-5.655(2)(a)2., F.A.C., of this section; and

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 64E-5.655(1)(a) or 64E-5.655(2)(a) and 64E-5.655(2)(b) and subsection 64E-5.655(3), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee for each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.655, F.A.C., NRC or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(3) Have received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Rulemaking Authority: 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-91.775, Amended 2-11-10, 12-26-13.

64E-5.656 Training for an Authorized Medical Physicist. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized medical physicist to: **(Entire section Changed)**

(1) Be certified by a specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.656(2)(b) and subsection 64E-5.656(3), 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:

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have 2 years of full-time practical training and/or supervised experience in medical physics:

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the NRC or an agreement state; or

2. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in Rule 64E-5.657, 64E-5.652 or 64E-5.655, F.A.C.; and

(c) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2) (a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal 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 beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

R10 4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

R10 (b) Have obtained written attestation that the individual has satisfactorily completed the requirements in subsection 64E-5.656(3) and paragraphs 64E-5.656(1)(a) and (b) or 64E-5.656(2)(a) and subsection 64E-5.656(3), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized medical physicist to fulfill the radiation safety related duties for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.656 or 64E-5.657, F.A.C., or NRC equivalent Agreement State requirements, for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

R10 (3) Have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

R10 Rulemaking Authority: 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.
R12 History: New 8-25-91, Formerly 10D-91.776, Amended 2-11-10, 12-26-13.

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

64E-5.660 Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of unsealed radioactive materials specified in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., which require a written directive to: **(Entire section New)**

(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 sub-subparagraphs 64E-5.660(2)(a)2.g. and paragraph 64E-5.660(2)(b), F.A.C., of this section. (Specialty boards whose certification processes 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 be recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subparagraph 64E-5.660(2)(a)1. through sub-subparagraph 64E-5.660(2)(a)2.e., F.A.C., of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(2) (a) Have completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include the following:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657 or 64E-5.660, F.A.C., NRC or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages in the same dosage category or categories (i.e., sub-subparagraph 64E-5.660(2)(a)2.g., F.A.C.,) as the individual requesting authorized user status. The work experience must involve the following:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

f. Performing checks for proper operation of survey meters; and

g. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status as listed below:

(I) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required or sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.;

(II) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

(III) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(IV) Parenteral administration of any other radionuclide, for which a written directive is required; and

(b) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 64E-5.660(1)(a) and subparagraph 64E-5.660(2)(a)2.g., or paragraph 64E-5.660(2)(a), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., that require a written directive. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.660, F.A.C., NRC or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must have experience in administering dosages in the same dosage category or categories specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C., as the individual requesting authorized user status.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS.
Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History-New 02-11-10, Amended 12-26-13.

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). Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user 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), to: **(Entire section New)**

(1) Be certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 64E-5.661(3)(a) and 64E-5.661(3)(b), F.A.C., of this section and whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.661(3)(c), 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.); or

(2) Be an authorized user under Rule 64E-5.660, F.A.C., or uses listed in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), or Rule 64E-5.662, F.A.C., or equivalent agreement state requirements; or

(3) (a) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include the following:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(b) Have work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.660, 64E-5.661 or 64E-5.662, F.A.C., NRC or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), F.A.C. The work experience must involve the following:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

6. Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 64E-5.661(3)(a) and 64E-5.661(3)(b), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee that required a written directive under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657, 64E-5.660, 64E-5.661 or 64E-5.662, F.A.C., NRC or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), F.A.C.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS.
Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History-New 02-11-10, Amended 12-26-13.

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). Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to: **(Entire section New)**

(1) Be certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 64E-5.662(3)(a) and 64E-5.662(3)(b), F.A.C., of this section, and whose certification has been recognized by the NRC or an agreement state, and who meets the requirements in paragraph 64E-5.662(3)(c), 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.); or

(2) Be an authorized user under Rule 64E-5.660, F.A.C., for uses listed in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C., NRC or equivalent Agreement State requirements; or

(3) (a) Have successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(b) Have work experience, under the supervision of an authorized user who meets the requirements in Rules 64E-5.657, 64E-5.660 or 64E-5.662, F.A.C., NRC or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C. The work experience must involve the following:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

6. Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 64E-5.662(3)(a) and 64E-5.662(3)(b), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., that require written directives. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.660, 64E-5.662, F.A.C., NRC or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS.
Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History-New 02-11-10, Amended 12-26-13.

64E-5.663 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the parenteral administration requiring a written directive, to: **(Entire section New)**

(1) Be an authorized user under Rule 64E-5.660, F.A.C., for uses listed in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C., NRC or equivalent Agreement State requirements; or

(2) Be an authorized user under Rule 64E-5.652 or 64E-5.655, F.A.C., NRC or equivalent Agreement State requirements and who meets the requirements in subsection 64E-5.663(4), F.A.C. of this section; or

(3) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under Rule 64E-5.652 or 64E-5.655, F.A.C., and who meets the requirements in subsection 64E-5.663(4), F.A.C., of this section.

(4) (a) Have successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include the following:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(b) Have work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.660 or 65E-5.663, F.A.C., NRC or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in Rule 64E-5.660, F.A.C., or equivalent agreement state requirements, must have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C., NRC or equivalent Agreement State requirements. The work experience must involve the following:

1. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

2. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

5. Using procedures to contain spilled radioactive material safely, and 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,
R12 F.A.C., NRC 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 404.051, 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.
R12 History-New 02-11-10, Amended 12-26-13.

SUBPART J
OTHER MEDICAL USES OR RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

64E-5.664 Other Medical Uses of Radioactive Material or Radiation From Radioactive Material . A licensee may use radioactive materials or a radiation source from radioactive materials approved for medical use which is not specifically addressed in Rule 64E-5.626, 64E-5.627, 64E-5.630, 64E-5.631, 64E-5.632 or 64E-5.634, F.A.C., provided the following are satisfied: **(Entire section New)**

(1) The applicant or licensee has received written approval from the department in a license or license amendment and uses the material in accordance with the regulations and specific license conditions the department considers necessary for the medical use of the material;

(2) The applicant or licensee has submitted the information required by Rules 64E-5.207 and 64E-5.208, F.A.C.; and

(3) The licensee shall provide specific information on the following:

(a) Radiation safety precautions and instruction;

(b) Methodology for measuring dosages or doses to be administered to patients or human research subjects;

(c) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(d) Security of radioactive materials, training or experience of individuals involved in these uses or other information not specified in paragraph 64E-5.664(3)(a)(b) or (c), F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
History-New 02-11-10

PART VIII RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL PARTICLE ACCELERATORS

SUBPART A REGISTRATION PROCEDURE

SUBPART B RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

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
R12 excess of the limits specified in State of Florida Bureau of Radiation Control ALIs,
R12 DACs, and Effluent Concentrations, (see 64E-5.101, F.A.C.) June 2012, Table I.,
R12 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
R12 specified in State of Florida Bureau of Radiation Control ALIs, DACs, and
R12 Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) Table II, 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.
R12 History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.912, Amended 12-26-13.

PART XI RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS

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

Specific Authority: 404.051, 404.061, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.081(1)(2), F.S.
R6 History: New July 17, 1985, Amended May 15, 1996, Formerly 10D-91.1213, Amended October 8, 2000, Amended September
R6 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
R12 Control ALIs, DACs, and Effluent Concentrations, June 2012,
R12 (see 64E-5.101, F.A.C.) Table II, Column 2, shall apply.

(b) For liquids, the water concentration values in State of Florida Bureau of
R12 Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012,
R12 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.
R12 History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.1216, Amended 12-26-13.

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.

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

SUBPART A GENERAL REQUIREMENTS

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

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

SUBPART D REQUIREMENTS FOR THE POSSESSION AND USE OF UNSEALED SOURCES OF RADIOACTIVE MATERIALS

(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.

Rulemaking 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 μSv) per hour to 200 millirem (2 mSv) per hour. The instruments shall be operable and calibrated as provided in 64E-5.314.

Rulemaking Authority: 404.051, 404.061, 404.071, 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, 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.

Rulemaking Authority: 404.051, 404.061, 404.071, 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, 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.

Rulemaking Authority: 404.051, 404.061, 404.071, 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, 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
R12 that will maintain airborne concentrations within the limits prescribed by State of
R12 Florida Bureau of Radiation Control, ALIs, DACs, and Effluent Concentrations,
R12 June 2012, (see 64E-5.101, F.A.C.) 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.

Rulemaking Authority: 404.051, 404.061, 404.071, 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.
R12 History: New May 12, 1993, Amended January 1, 1994, Formerly 10D-91.1423, Amended 12-26-13.

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;

PART XIV LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

SUBPART A GENERAL PROVISIONS

SUBPART B SPECIFIC LICENSE FOR LARGE IRRADIATORS

SUBPART C DESIGN AND PERFORMANCE REQUIREMENTS FOR LARGE IRRADIATORS

SUBPART D OPERATION OF IRRADIATORS

SUBPART E RECORDS AND REPORTS

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,
R12 DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) 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.
R12 History: New August 14, 1996, Formerly 10D-91.1519., Amended 12-26-13.

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, NRC, 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, NRC, 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,
R12 June 2012, (see 64E-5.101, F.A.C.) 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.
R12 History: New August 14, 1996, Formerly 10D-91.1520, Amended 12-26-13..

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

ATTACHMENTS

PART XV

TRANSPORTATION OF RADIOACTIVE MATERIALS

R8 **64E-5.1501 Purpose and Scope.**

(1) The packaging and transportation of radioactive material are also subject to the requirements of other agencies such as the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission and the U.S. Postal Service. The requirements of this part are in addition to, and not in substitution for, other requirements.

(2) Determinations and listings of A_1 and A_2 values are found in 10 CFR Part 71,
R12 Appendix A as published 01/01/2012 which is herein incorporated by reference
R12 and can be obtained from the internet at
R12 http://www.flrules.org/Gateway/reference.asp?No=Ref-03457 or at
R12 http://www.gpo.gov/fdsys/pkg/CFR-2012-title10-vol2/pdf/CFR-2012-title10-vol2-
R12 part71.pdf.

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.
R12 History: New July 17, 1985, Amended May 15, 1996, Formerly 10D-91.2001,Amended 2-28-08, 12-26-13.

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
R12 01/01/2012 which is herein incorporated by reference and can be obtained
R12 from the internet http://www.flrules.org/Gateway/reference.asp?No=Ref-
R12 03458, https://www.flrules.org/Gateway/reference.asp?No=Ref-03473,
R12 https://www.flrules.org/Gateway/reference.asp?No=Ref-03474,

R12 https://www.flrules.org/Gateway/reference.asp?No=Ref-03475, and
R12 https://www.flrules.org/Gateway/reference.asp?No=Ref-03476 or at
R12 http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CF
R12 R&searchPath=Title+49%2FSubtitle+B&oldPath=Title+49&isCollapsed=tr
R12 ue&selectedYearFrom=2012&ycord=1546 and 10 C.F.R. Part 71
R12 published on 01/01/2012 which is herein incorporated by reference and
R12 can be obtained from the internet at
R12 http://www.flrules.org/Gateway/reference.asp?No=Ref-03459 or at
R12 http://www.gpo.gov/fdsys/pkg/CFR-2012-title10-vol2/pdf/CFR-2012-title10-
R12 vol2-part71.pdf, and 10 C.F.R. Parts 73.72 through 73.74 published on
R12 01/01/2012 which is herein incorporated by reference and can be obtained
R12 from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-
R12 03460 or at
R12 http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CF
R12 R&searchPath=Title+10%2FChapter+I%2FPart+73%2FSubjgrp&oldPath=
R12 Title+10%2FChapter+I%2FPart+73%2FSubjgrp&isCollapsed=true&select
R12 edYearFrom=2012&ycord=1772.

(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.
R12 History: New July 17, 1985, Formerly 10D-91.2003,Amended 10-8-00, 9-28-06, 2-28-08, 12-26-13.

Page intentional left blank

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.