July 2015

Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2015-01

Revision 14 Filing Instructions:
Changes to Florida Administrative Code (FAC) Chapter 64E-5

Changes to "Control of Radiation Hazard Regulations, "Part II Licensing of Radioactive Materials" FAC Rule 64E-5.220 and Part V "X-Ray in the Healing Arts" Rules 64E-5.508, 64E-5.510, 64E-5.511, 64E-5.801 and 64E-5.1601, which became effective June 3, 2015 (Revision 13) and changes to the radioactive materials regulations FAC Rules 64E-5.206 and 64E-5.217 which became effective July 1, 2015. **These changes are indicated as Revision 13 or 14 or (R13) (R14) in the margin.** Official versions of regulations may be found at the Florida Department of State website www.flrules.org/

These instructions (Table on next page) apply to the complete version (brown cover) of FAC Chapter 64E-5. Be sure that Revisions 1 through 12 changes have been inserted before making these changes. This may be verified by checking page iv of the index. Visit our website at http://www.floridahealth.gov/environmental-health/radiation-control/ to download R14 pages for replacement. (Includes R13 changes.)

A complete electronic copy of the chapter is also available on our website.

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

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PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Cover	Cover	Cover
Index	i through xvii	i through xvi
Part II (R13 and R14) Licensing of Radioactive Materials	Part II Index Part II Pages 5/6, 21/22, 25/26, 33/34, 35/36, 77/78, 79/80,85/86, 86/87, 88/90	Part II Index Part II Pages 5/6, 21/22, 25/26, 33/34, 35a/35b, 35c/36, 77/78, 79/80 85/86, 87/90 page 88 deleted (New at end Part II – Bond Risk Factors Worksheet – March 2014 4 pages) (New at end Part II Emergency Plan Isotopes and Quantities – July 2014 2 pages)
Part V (R13) X-Ray in the Healing Arts	Part V Index 43 through 70 (end of chapter)	Part III Index 43 through 62 (new end of chapter)
Part VIII (R13) Radiation Safety Requirements for Analytical Particle Accelerators	Part VIII Index Pages 1/2	Part VIII Index Pages 1/2
Part XVI (R13) Electronic Brachytherapy	Part XV1 I Index Pages 1/2, 3/4	Part XVI Index Pages 1/2, 3/4 (Note: Some printed versions may have a duplicate page 4 because the index was printed on the back page of the last part. You may keep the duplicate (identical) pages 4 or reprint all of Part XVI from the website.

The 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 NRC also identified other changes needed for Florida to be compatible with NRC regulations, updated forms and other documents incorporated by reference, changes to financial assurance mechanism authorized by Chapter 404, FS, changes to machine produced radiation with high energy therapy systems, mammographic systems and revisions to Radiation Machine Program Enforcement Manual.

You must read the rule changes and make appropriate adjustments if needed.

Questions regarding rules 64E-5.206, 64E-5.217 and 64E-5.220, call the Radioactive Materials Section at 850-245-4545

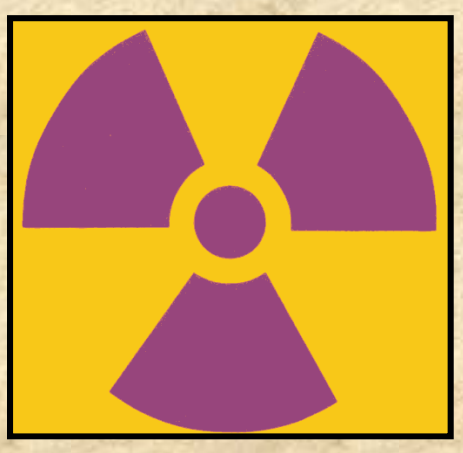
Questions regarding rules 64E-5.508, 64E-5.510, 64E-5.511, 64E-5.801 and 64E-5.1602, call the Radiation Machine Section at 904-278-5730

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

Rule Number(s)	Brief Summary of Changes
64E-5.203(2)(a)	Technical Change "(2)(b) through (d) changed to (2)(a) through (e)"
64E-5.206(11)	A new general license authorizing possession of products containing radium-226 such as antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanatory jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads, and many other products. Quantities and activities limits are listed as well as disposal and reporting requirements. (No fee for this general license.)
64E-5.217	Financial assurance (FA) calculation worksheet revised. New minimum amount requiring FA is change to greater than $30,000, educational and medical exemption were removed and FA mechanisms clarified as to what is acceptable by Chapter 404, F.S. FA requirements modeled after select sections 10 CFR 30.35 as authorized by Chapter 404, FS.
64E-5.220	List of Isotopes and Quantities are incorporated by reference instead of listing each one in the rule. (No changes were made to the existing list.)
64E-5.508	Deletes obsolete definitions and language related to requirements for x-ray and electron therapy systems.
64E-5.510	Deletes language related to mammographic screening system requirements.
64E-5.511	Updated forms DH 1107 09/14, DH Form 1113 09/14, DH Form 1114 replaces the existing forms, clarification when registration fees are due, and the section's enforcement's manual is updated.
64E-5.801	Revised form DH 1107 09/14 is referenced.
64E-5.1602	Revised form DH 1107 09/14 is referenced.

Attachments – R14 page replacements (78 pages) (Includes R13 changes).

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
Revision 13	June 3, 2015
Revision 14	July 1, 2015

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

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This is an “unofficial” copy that has been re-formatted for ease of use and to provide attachments. Electronic versions of these regulations are posted on the Bureau’s website: 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
R13	6-3-2015	64E-5.220, 64E-5.508, 64E-5.510, 64E-5.511, 64E-5.801, 64E-5.1602
R14	7-1-2015	64E-5.206, 64E-5.217

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

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PART II LICENSING OF RADIOACTIVE MATERIALS

SUBPART G RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

(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 (e), 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

(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.

(b)1. The general license in (4)(a), above, applies only to radioactive material
R8 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 21
R14 C.F.R. Part 179, section 179.21, April 1, 2013 edition, and is herein
R14 incorporated by reference and may be obtained from the internet at
R14 http://www.flrules.org/Gateway/reference.asp?No=Ref-05471 or at
R14 http://www.gpo.gov/fdsys/pkg/CFR-2013-title21-vol3/pdf/CFR-2013-title21-
R14 vol3-part179-subpartB.pdf

(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.
R6

(c) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in (4)(a), above;

1. Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

2. Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label. However,

   a. Devices containing only krypton need not be tested for leakage of radioactive material; and

   b. Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- and/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,

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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.

R8 R6 R6 R6 R6 R6 R8 R8 R6 R6 R14 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

R8 R8 15. Shall not export the device containing radioactive material except in accordance with 10 C.F.R. Part 110;

R8 R8 R8 R8 R8 R8 R14 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.

(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.

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.

R14 (11) Certain Items and Self-Luminous Products Containing Radium-226.

R14 (a) A general license is hereby issued to any person to acquire, receive, R14 possess, use, or transfer, in accordance with the provisions of subsections R14 64E-5.206(11)(b), (c), and (d), F.A.C., radium-226 contained in the R14 following products manufactured prior to November 30, 2007.

R14 1. Antiquities originally intended for use by the general public. For the R14 purposes of this paragraph, antiquities mean products originally R14 intended for use by the general public and distributed in the late 19th R14 and early 20th centuries, such as radium emanatory jars, revigators, R14 radium water jars, radon generators, refrigerator cards, radium bath R14 salts, and healing pads.

R14 2. Intact timepieces containing greater than 0.037 megabecquerel (1 R14 microcurie), nonintact timepieces, and timepiece hands and dials no R14 longer installed in timepieces.

R14 3. Luminous items installed in air, marine, or land vehicles.

R14 4. All other luminous products, provided that no more than 100 items are R14 used or stored at the same location at any one time

R14 5. Small radium sources containing no more than 0.037 megabecquerel R14 (1 microcurie) of radium-226. For the purposes of this paragraph, R14 ‘‘small radium sources’’ means discrete survey instrument check R14 sources, sources contained in radiation measuring instruments, R14 sources used in educational demonstrations (such as cloud chambers R14 and spinthariscopes), electron tubes, lightning rods, ionization sources, R14 static eliminators, or as designated by the NRC.

R14 (b) Persons who acquire, receive, possess, use, or transfer byproduct R14 material under the general license issued in paragraph 64E- 5.206(11)(a), R14 F.A.C., of this section are exempt from the provisions of Parts III and IX, to R14 the extent that the receipt, possession, use, or transfer of radioactive R14 materials is within the terms of the general license. This exemption shall R14 not apply to any such person specifically licensed under Chapter 64E-5, R14 F.A.C.

R14 (c) Any person who acquires, receives, possesses, uses, or transfers R14 byproduct material in accordance with the general license in subsection R14 64E-5.206(11)(a), F.A.C., must also comply with the following R14 requirements:

R14 1. Shall notify the Department should there be any indication of possible R14 damage to the product so that it appears it could result in a loss of the R14 radioactive material. A report containing a brief description of the R14 event, and the remedial action taken, must be furnished to the R14 Department within 30 days;

R14 2. Shall not abandon products containing radium-226. The product, and
R14 any radioactive material from the product, may only be disposed of
R14 according to Rule 64E-5.328, F.A.C., or by transfer to a person
R14 authorized by a specific license to receive the radium- 226 in the
R14 product or as otherwise approved by the Department;

R14 3. Shall not export products containing radium-226 except in accordance
R14 with 10 C.F. R. Part 110, 1-1-14 edition which is herein incorporated by
R14 reference and can be obtained from the internet at
R14 http://www.flrules.org/Gateway/reference.asp?No=Ref- 05472 or at
R14 http://www.gpo.gov/fdsys/pkg/CFR-2014-title10-vol2/pdf/CFR-2014-
R14 title10-vol2-part110.pdf;

R14 4. Shall dispose of products containing radium-226 at a disposal facility
R14 authorized to dispose of radioactive material in accordance with any
R14 Federal or State solid or hazardous waste law, including the Solid
R14 Waste Disposal Act, as authorized under the Energy Policy Act of
R14 2005, by transfer to a person authorized to receive radium-226 by a
R14 specific license issued under Part III, or equivalent regulations of an
R14 Agreement State or the NRC, as otherwise approved by the
R14 Department.

R14 5. Shall respond to written requests from the Department to provide
R14 information relating to the general license within 30 alendar days of the
R14 date of the request, or other time specified in the request. If the general
R14 licensee cannot provide the requested information within the allotted
R14 time, it shall, within that same time period, request a longer period to
R14 supply the information by providing the Department a written
R14 justification for the request.

R14 (d) Except for disassembly and repair of timepieces described in
R14 subparagraph 64E-5.206(11)(a)2., F.A.C., the general license in
R14 paragraph 64E-5.206(11)(a), F.A.C., does not authorize the manufacture,
R14 assembly, disassembly, repair, or import of products containing radium-
R14 226.

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.
R14 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, 7-1-15.

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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.

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 R14 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 R14 requirements of the Department. The Department shall use the Bond Risk R14 Factors Calculation Worksheet – March 2014 which is herein incorporated R14 by reference and which can be obtained from the internet at R14 http://www.flrules.org/Gateway/reference.asp?No=Ref-05470 or at R14 http://www.floridahealth.gov/prevention-safety-and-wellness/radiation-R14 control/, to determine the amount of the bond required for each applicant R14 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. (Click Here to go to Factors Calculation Worksheet – March 2014)

R14 (b) 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.

R14 (c) 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 R14 decreasing the amount required.

R14 (d) 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.

R14 1. The bond must contain, without limitation, the following conditions:

R14 a. The bond must be open-ended or, if written for a specific term, R14 such as five years, must be renewed automatically unless 90 R14 days or more prior to the renewal date, the issuer notifies the R14 Department's Bureau of Radiation Control, the beneficiary, and R14 the licensee of its intention not to renew;

R14 b. The bond must provide that the full face amount be paid to the
R14 beneficiary automatically prior to the expiration without proof
R14 forfeiture if the licensee fails to provide replacement acceptable
R14 to the Department within 30 days after receipt of notification of
R14 cancellation; and,

R14 c. he bond must be payable to the State of Florida;

R14 2. The bond must remain in effect until the Department has terminated
R14 the license or the requirements of sub-subparagraph
R14 64E-5.217(1)(d)1.b., F.A.C., are met.

R14 (e) 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.

R14 (f) 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;

R14 (b) Licensees who are only authorized for possession or use of radioisotopes
R14 with a half-life less than or equal to 120 days.

R14 (c) Any licensee whose mathematical product of the risk factors in the Bond
R14 Risk Factors Calculation Worksheet – March 2014 is less than or equal to
R14 30,000.

R14 (3) At the time of license application, license renewal and at intervals not to exceed 3
R14 years, the applicant or licensee must submit the bonding determination described
R14 in subsection 64E-5.217(1), F.A.C., above, with adjustments as necessary to
R14 account for changes in chemical and physical form of radioactive material,
R14 radioisotopes authorized, their radiotoxicity and quantity, authorized licensed
R14 activities, actual costs and the potential costs of decontamination, treatment, or
R14 disposal of radioactive materials and contaminated equipment or facilities.

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.
R14 History: New 7-17-85, Amended 4-4-89, 5-12-93, Formerly 10D-91.322, Amended 7-1-15.

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(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.

R13 (1) The list of quantities of radioactive materials requiring consideration of the need
R13 for an emergency plan for responding to a release as required in 64E-5.219, is
R13 provided in the Department publication “Emergency Plan Isotopes and
R13 Quantities,” July 2014 edition, which is incorporated by reference and can be
R13 obtained at http://www.floridahealth.gov/radiation, and at
R13 https://www.flrules.org/Gateway/reference.asp?No=Ref-05439.

(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
R13 May 12, 1993, Formerly 10D-91.327, Amended 6-3-2015.

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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.

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SUBPART G
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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.

Bond Risk Factors Calculation Worksheet - March 2014

If license authorized any radioisotopes with a half-life greater than 120 days, assign a risk factor for each A-F section based on radioactive materials license authorization and use.

A.

Half-Life of Radioisotope	Risk Multiplier	
Greater than 6 years	30	
6 months to 6 years	10	
120 days to 6 months	5	
Less than or equal to 120 days	0	
	Multiplier Used	

B.

Radioisotope	Risk Multiplier
Transuranic isotopes, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, Ac-225, I-129	50
Th-natural, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133, I-125, H-3, C-14	5
U-natural, U-235, U-238 and associated decay products	1
Any isotope not listed above	1
Multiplier Used	

C.

Activity	Risk Multiplier	
Greater than 100,000 curies	2000	
10,000 to 100,000 curies	1000	
100 to 10,000 curies	500	
10 to 100 curies	30	
1 to 10 curies	2	
Less than 1 curie	1	
	Multiplier Used	

Bond Risk Factors Calculation Worksheet - March 2014

D.

Facility - Radioactive Materials Use and Storage Area		Risk Multiplier	
Greater than 5,000 Ft^2			
	High Risk	30	
	Low Risk	10	
500 to 5,000 Ft^2			
	High Risk	10	
	Low Risk	5	
Less than 500 Ft^2			
	High Risk	5	
	Low Risk	1	
		Multiplier Used	

E.

Procedures - Radioactive Materials Use or Storage	Risk Multiplier	
License issued for manufacturing, benefaction or processing non-encapsulated radioactive materials	3	
Licensed issued for storage only	3	
Sealed sources not contained in a device with integral solid shielding	3	
Sealed sources contained in a device with integral solid shielding	1	
	Multiplier Used	

F.

Physical Form of Radioactive Materials	Risk Multiplier	
Non- encapsulated forms such as solid, powders, liquids, colloids, plasmas, gases (not to include noble gases).	20	
Single encapsulated source or source plated	3	
Double encapsulated source or noble gases	1	
	Multiplier Used	

Bond Risk Factors Calculation Worksheet - March 2014

Calculate using Assigned Risk Multipliers

A. Half-Life _____

B. Radioisotope x_____

C. Activity x_____

D. Facility x_____

E. Procedures x_____

F. Physical Form x_____

Product Total _____

If Product Total is greater than 30,000 then a bond is required. The dollar value of the required bond is the product of risk factors.

See Rule 64E-5.217, F.A. C., for additional options.

(Click Here to return to 64E-5.217)

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Emergency Plan Isotopes and Quantities - July 2014

Atomic No.	Material	Release Fraction	Curies
89	Actinium 228	0.001	4,000
95	Americium 241	0.001	2
95	Americium 242	0.001	2
95	Americium 243	0.001	2
51	Antimony 124	0.01	4,000
51	Antimony 126	0.01	6,000
56	Barium 133	0.01	10,000
56	Barium 140	0.01	30,000
56	Bismuth 207	0.01	5,000
56	Bismuth 210	0.01	600
49	Cadmium 109	0.01	1,000
49	Cadmium 113	0.01	80
20	Calcium 45	0.01	20,000
98	Californium 252	0.001	9
6	Carbon 14	0.01 (non CO_2)	50,000
58	Cerium 141	0.01	10,000
58	Cerium 144	0.01	300
55	Cesium 134	0.01	2,000
55	Cesium 137	0.01	3,000
17	Chlorine 36	0.5	100
24	Chromium 51	0.01	300,000
27	Cobalt 60	0.001	5,000
29	Copper 64	0.01	200,000
96	Curium 242	0.001	60
96	Curium 243	0.001	3
96	Curium 244	0.001	4

Atomic No.	Material	Release Fraction	Curies
96	Curium 245	0.001	2
63	Europium 152	0.01	500
63	Europium 154	0.01	400
63	Europium 155	0.01	3,000
64	Gadolinium 153	0.01	5,000
32	Germanium 68	0.01	2,000
79	Gold 198	0.01	30,000
105	Hafnium 172	0.01	400
105	Hafnium 181	0.01	7,000
67	Holmium 166m	0.01	100
1	Hydrogen 3	0.5	20,000
53	Iodine 125	0.5	10
53	Iodine 131	0.5	10
49	Indium 114m	0.01	1,000
49	Iridium 192	0.001	40,000
26	Iron 55	0.01	40,000
26	Iron 59	0.01	7,000
36	Krypton 85	1.0	6,000,000
82	Lead 210	0.01	8
25	Manganese 56	0.01	60,000
80	Mercury 203	0.01	10,000
42	Molybdenum 99	0.01	30,000
93	Neptunium 237	0.001	2
28	Nickel 63	0.01	20,000
41	Niobium 94	0.01	300
15	Phosphorus 32	0.5	100

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Atomic No.	Material	Release Fraction	Curies
15	Phosphorus 33	0.5	1,000
84	Polonium 210	0.01	10
19	Potassium 42	0.01	9,000
61	Promethium 145	0.01	4,000
61	Promethium 147	0.01	4,000
88	Radium 226	0.001	100
44	Ruthenium 106	0.01	200
62	Samarium 151	0.01	4,000
21	Scandium 46	0.01	3,000
34	Selenium 75	0.01	10,000
47	Silver 110m	0.01	1,000
11	Sodium 22	0.01	9,000
11	Sodium 24	0.01	10,000
38	Strontium 89	0.01	3,000
38	Strontium 90	0.01	90
16	Sulfur 35	0.5	900
43	Technetium 99	0.01	10,000
43	Technetium 99m	0.01	400,000
52	Tellurium 127m	0.01	5,000
52	Tellurium 129m	0.01	5,000
65	Terbium 160	0.01	4,000
69	Thulium 170	0.01	4,000
50	Tin 113	0.01	10,000
50	Tin 123	0.01	3,000
50	Tin 126	0.01	1,000
22	Titanium 44	0.01	100
23	Vanadium 48	0.01	7,000
54	Xenon 133	1.0	900,000
39	Yttrium 91	0.01	2,000
30	Zinc 65	0.01	5,000
40	Zirconium 93	0.01	400
40	Zirconium 95	0.01	5,000
	Any other beta-gamma emitter	0.01	10,000
	Mixed fission products	0.01	1,000
	Mixed corrosion products	0.01	10,000
	Contaminated equipment beta-gamma	0.001	10,000
	Irradiated material, any form other than solid noncombustible	0.01	1,000
	Irradiated material solid noncombustible	0.001	10,000
	Mixed radiological waste, beta-gamma	0.01	1,000
	Packaged mixed waste, beta-gamma	0.001	10,000
	Any other alpha emitter	0.001	2
	Contaminated equipment alpha	0.0001	20
	Package waste, alpha	0.0001	20

PART V X-RAYS IN THE HEALING ARTS

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

R13 (1) Definitions. In addition to the definitions in 64E-5.501, the following definitions shall apply to this section:

(a) "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.

(b) "Beam scattering filter" means a filter used in order to scatter a beam of electrons.

(c) "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

(d) "Dose monitoring system" means a system of devices for the detection, measurement and display of quantities of radiation.

(e) "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

R13 (f) "Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

R13 (g) "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

R13 (h) "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

R13 (i) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

R13 (j) "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beam passes in all conditions.

R13 (k) "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy and rotational therapy.

R13 (l) "Normal treatment distance" means:

1. For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

2. For x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

R13 (m) "Radiation head" means the structure from which the useful beam emerges.

(n) "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.

R13 (o) "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam or the patient during irradiation.

R13 (p) "Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation

R13 (q) "Virtual source" means a point from which radiation appears to originate.

(2) Requirements for Equipment.

(a) Leakage Radiation to the Patient Area.

1. New equipment shall meet the following requirement: For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons may be obtained from the manufacturer and shall be averaged over an area up to, but not exceeding, 200 square centimeters.

R13 2. The registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified and for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the department.

(b) Leakage of Radiation Outside the Patient Area for New Equipment.

1. The absorbed dose in rads (grays) due to leakage radiation, except in the area specified in (2)(a), above, when measured at any point one meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in (2)(a), above.

2. The registrant shall determine or obtain from the manufacturer the actual leakage radiation existing at the positions specified and for specified operating conditions. Radiation measurements, excluding neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters. Neutron measurements shall be averaged over an area up to, but not exceeding, 200 square centimeters.

(c) Beam Limiting Devices. Adjustable or interchangeable beam-limiting devices shall be provided, and such devices shall transmit no more than five percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.

(d) Filters.

1. Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

2. If the absorbed dose rate data indicated at the control panel relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.

3. For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters:

a. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

c. A display shall be provided at the treatment control panel showing the filter in use; and

d. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

(e) Beam Quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

1. The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten centimeters greater than the practical range of the electrons shall not exceed the values stated below. Linear interpolation shall be used for values not stated.

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

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

a. A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

b. The largest field size available which does not exceed 15 by 15 centimeters; and

c. A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.

(f) Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.

R13 1. The detectors shall be incorporated into two separate dose monitoring systems.

R13 2. The detector and the system into which that detector is incorporated shall meet the following requirements:

a. Each detector shall be removable only with tools and shall be designed to prevent incorrect positioning.

b. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

c. Each dose monitoring system shall be capable of independently monitoring, interrupting and terminating irradiation.

d. For new equipment, the design of the dose monitoring systems shall assure that:

(I) The malfunctioning of one system shall not affect the correct functioning of the second system; and

(II) The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

R13 3. Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall

R13 a. Maintain a reading until intentionally reset to zero;

R13 b. Have only one scale and no scale multiplying factors;

R13 c. Utilize a design such that increasing dose is displayed
R13 by increasing numbers in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

R13 d. In the event of power failure, the dose monitoring information required to be displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

R13 (g) Beam Symmetry. In equipment inherently capable of producing useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds five percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds ten percent, the irradiation is terminated.

(h) Selection and Display of Dose Monitor Units.

1. Irradiation shall not be possible until a selection of a number of dose monitor units or exposure time has been made at the treatment control panel.

2. The pre-selected number of dose monitor units or exposure time shall be displayed at the treatment control panel until reset manually for the next irradiation.

3. After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated

R13 4. After termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.

(i) Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy.

1. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

R13 2. The system shall be capable of terminating irradiation when not more than ten percent or 30 dose monitoring units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

R13 3. An indicator on the control panel shall show which dose monitoring system has terminated irradiation.

(j) Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(k) Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

(l) Timer.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.

2. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

R13

3. After termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

4. The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

(m) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following:

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1. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

2. An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.

3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

4. An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

6. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

(n) Selection of Energy. Equipment capable of generating radiation beams of
R13 different energies shall meet the following:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

2. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

3. The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

(o) Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam
R13 therapy shall meet the following:

1. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

2. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.

3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

4. The mode of operation shall be displayed at the treatment control panel.

R13 5. An interlock system shall be provided to terminate irradiation if:

a. Movement of the gantry occurs during stationary beam therapy; or

b. Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

6. Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

R13 a. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of arc differs by more than 20 percent from the selected value.

R13 b. Where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle relationship.

7. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by (2)(i), above.

R13 (p) Absorbed Dose Rate. A system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. In addition:

1. The dose monitor unit rate shall be displayed at the treatment R13 control panel, and

2. The radiation detectors specified in (2)(f), above, may form part of this system.

(q) Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

1. The x-ray target or the virtual source of x rays; and

2. The electron window or the virtual source of electrons if the system has electron beam capabilities.

(r) System Checking Facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

(3) Facility and Shielding Requirements. In addition to Part III, the following design requirements shall apply:

(a) Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.

(b) Control Panel. The control panel shall be located outside the treatment room.

(c) Viewing System. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.

(d) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

(e) Room Entrance. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors or other entrances to indicate when the useful beam is on.

(f) Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any barrier penetration or door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

(4) Surveys, Calibrations, Spot Checks and Operating Procedures.

(a) Surveys.

1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified person. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant shall obtain a written report of the survey from the qualified person, and a copy of the report shall be transmitted by the registrant to the department within 30 days of receipt of the report.

3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified person, is in violation of applicable regulations.

(b) Calibration.

1. The calibration of systems subject to 64E-5.508 shall be performed in accordance with an established calibration protocol acceptable to the department, such as the calibration protocol published by the American Association of Physicists in Medicine, before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution or other characteristics of the therapy beam.

2. The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.

3. Calibration radiation measurements required by (4)(b), above, shall be performed using a dosimetry system:

   a. Having a calibration factor for cobalt 60 gamma rays traceable to a national standard;

   b. Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;

   c. Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

   d. Which has had constancy checks performed on the system as specified by a radiological physicist.

4. Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent.

5. The calibration of the therapy beam shall include the following determinations:

   a. Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth.

   b. The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

   c. The uniformity of the radiation field and any dependency upon the direction of the useful beam.

   d. Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

   e. Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

6. Records of calibration measurements and dosimetry system calibrations required in (4)(b), above, shall be maintained for five years after completion of the full calibration.

7. A copy of the latest calibration performed shall be available in the facility for inspection by the department.

(c) Spot-checks. Spot-checks shall be performed on systems subject to this section during calibrations and thereafter at intervals not to exceed one month. Such spot-checks shall meet the following requirements:

1. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. Acceptable tolerance for each parameter measured in the spot-check shall not exceed manufacturer's recommendations.

2. If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.

3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot-check when compared to the value for that parameter determined in the calibration.

4. At intervals established in the spot-check procedures, spot-checks shall be made of absorbed dose measurements at a minimum of two depths in a phantom.

5. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.

6. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.

7. Whenever a spot-check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in (4)(b), above.

8. Records of spot-check measurements and any necessary corrective actions shall be maintained by the registrant for a period of two years.

9. Where a spot-check involves an absolute radiation measurement, such measurement shall be obtained using a system satisfying the requirements of (4)(b)3, above, or which has been compared with a system meeting those requirements within the previous year.

(d) Additional Operating Procedures.

1. No individual other than the patient shall be in the treatment room during treatment of a patient.

2. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used

3. The system shall not be used in the administration of radiation therapy unless the requirements of (4)(a), (4)(b) and (4)(c), above, have been met.

Specific Authority: 404.031, 404.051, 404.071, 404.081, 404.141, 404.22, F.S.
Law Implemented: 404.022, 404.031, 404.051(1)(4)(5)(6), 404.071(1), 404.081(1), 404.141, 404.22(1)(3), F.S.
R13 History: New 07-17-1985, amended 04-04-1989, 06-03-2015, Formerly 10D-91.609

64E-5.509 Veterinary Medicine X-ray Operations.

(1) Applicable Regulations. Veterinary medical x-ray operations shall conform with requirements of the following sections of these regulations:

(a) 64E-5.502, General Requirements, except 64E-5.502(1)(a)5., 64E-5.502(1)(a)6., 64E-5.502(1)(a)7. and 64E-5.502(1)(a)8.

(b) 64E-5.503, General Requirements for all Diagnostic X-Ray Systems.

(c) 64E-5.504, Fluoroscopic x-ray Systems.

(2) Additional Requirements.

(a) Positive means of beam alignment shall be provided in the form of accurate linear rulings, beam defining or beam centering lights, optical viewing devices or the equivalent. Such alignment means or devices shall be adjusted to indicate the beam center or beam area to within two percent of the SID.

(b) Means shall be provided to limit the useful beam to the area of diagnostic interest or to the area of the image receptor used in each particular case. Beam limitation may be accomplished by any of the means described in 64E-5.505(1).

(c) Each x-ray system shall be equipped with a device which will terminate the exposure after a preset time or exposure.

(d) Each exposure switch shall be of the dead-man type.

(e) Each exposure switch shall be located in such a way as to meet the following criteria:

1. The operator shall stand as far as practicable and at least six feet (1.8 m) from the animal and tube head and outside the useful beam or behind a protective barrier during exposures.

2. In lieu of distance or a protective barrier the operator shall wear a protective apron and monitoring device as provided in (3)(c), below.

(3) Operating Procedures.

(a) The operator shall stand in a protected position as indicated in (2)(e), above, during radiographic exposures with no other individuals in the x-ray room unless assistance of the nature described in (3)(c), below, is required.

(b) To the greatest practicable extent, animals must be immobilized by anesthetics, straps, sandbags, foam wedges, and other supporting or restraining devices.

(c) If an animal must be held by an individual, that individual shall be protected by appropriate shielding devices such as a protective apron and gloves, and the holder shall be so positioned that no part of his body will be struck by the useful beam. The exposure of that individual shall be monitored when engaged in such purposes.

Specific Authority: 404.051, 404.141, 404.22, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.
History: New July 17, 1985, amended April 4,1989, Formerly 10D-91.610

64E-5.510 Mammographic Systems.

(1) Mammographic medical x-ray systems shall meet the requirements of 64E-5.502 and 64E-5.503. Registrants who provide mammography services shall:

(a) Have a written quality assurance program specific to mammography imaging that includes an equipment quality control program for performance monitoring and an evaluation of all components of the equipment from the x-ray generator to the image processor.

(b) Establish standards for clinical image evaluations that include breast positioning, compression and overall image quality.

(c) Assign qualified and trained personnel to each part of the quality assurance program.

(d) Conduct a general review of the effectiveness of the quality assurance program annually and maintain a written report of the review.

(e) Have available the services of a medical physicist to furnish diagnostic x-ray physics support who is able to establish and conduct the equipment quality control program and who meets the requirements specified in (12), below. The specific duties of the medical physicist must include:

1. Monitoring equipment performance or verifying the qualifications and training of others to monitor equipment performance.

2. Evaluating the monitoring results to identify problems.

3. Verifying that corrections are effective and meet regulatory requirements.

R13 (2) The film processor shall be optimized for the specific mammography film used by the facility. Its performance shall be checked for consistency of speed, contrast, and base plus fog prior to processing patient films and after being idle more than six hours.

R13 (a) Performance checks shall be plotted and compared to established limits. If these limits are exceeded, documented corrective actions including an image quality check as specified in (8), below, are required.

(b) Corrective action shall be taken when:

1. Optical density deviates by more than 0.15 from established
R13 operating levels for readings of mid-density or density difference on the sensitometric control charts

2. Base plus fog exceeds the established operating level by more than 0.03 optical density.

(c) These records for processor optimization, performance, image quality checks and documented corrective actions shall be maintained for inspection by the department for at least one year.

R13 (3) Mammographic x-ray systems shall be monitored and evaluated using the following standards:

(a) The image quality shall be checked using a standard phantom approved
R13 by the FDA which meets the criteria below at least weekly and whenever service which could affect image quality is performed on the x-ray system or the film processor. The image quality shall be scored on the ability to image fibers, specks, and low density masses. If quality control limits are exceeded, image quality checks also must be performed after any corrective actions have been taken. This standard phantom must be
R13 designed to evaluate image quality in the 1.2 to 1.8 optical density range, shall not change more than 0.2 optical density from its previous reading, and must be composed of material that is equivalent to a nominal 4.5 centimeter compressed breast of average density of approximately 50 percent adipose and 50 percent glandular tissue. It shall contain the following objects:

1. Nylon fibers with thicknesses of 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 millimeters.

2. Aluminum oxide specks with diameters of 0.54, 0.40, 0.32, 0.24, and 0.16 millimeters.

3. Phenolic plastic spherical masses with thicknesses of 2.00, 1.00, 0.75, 0.50, and 0.25 millimeters.

(b) Phantom checks which indicate a decrease in image quality shall require immediate investigation of possible corrective actions.

(c) The minimum acceptable image quality of a standard phantom described in (8)(a), above, shall demonstrate the ability to image at least 0.75 millimeter fibers; 0.32 millimeter specks; and 0.75 millimeter spherical masses. Mammographic examinations shall not be performed on systems which do not meet the minimum image quality standard.

(d) The registrant must document in the annual review required in (1), above, that all equipment quality control items were performed under the direction and approval of the medical physicist.

(e) Mammography system performance must be evaluated regularly. Those components and parameters of the equipment quality control program tested for performance daily, weekly, monthly or quarterly shall be evaluated quarterly. The annual onsite survey by the medical physicist must include a summary of the quarterly evaluations.

(4) The following requirements apply to personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities.

(a) Interpreting physicians shall be licensed to practice medicine in the State of Florida, as specified in Chapters 458 and 459, F.S.

(b) Radiologic technologists shall be certified as a general radiographer in the state of Florida as specified in Chapter 64E-3, FAC

(c) A medical physicist qualified to conduct surveys of mammography facilities and provide oversight of the facility quality assurance program shall be licensed in Florida as a medical physicist as specified in Chapter 483, Florida Statutes.

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

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

1. Monitoring of mammograms repeated because of poor image quality; and

2. Maintaining records, analysis of results, and a description of any remedial action taken as a result of this monitoring.

(b) Clinical image interpretation. To ensure that quality clinical images are produced routinely at the facility, each facility shall submit clinical images to the department for review as required by the Department.

R13 (c) Surveys. A medical physicist who meets the qualifications specified in (4), above, and who establishes, monitors, evaluates, and directs the
R1 equipment quality control program must perform an on-site survey of the facility to assure that it meets quality control and equipment standards. These surveys shall be performed at least annually and shall be available for inspection by the department. Each survey report shall be retained by the facility until the next annual survey is completed satisfactorily.

R13 (6) In addition to the above requirements, effective October 1, 1994, no facility can conduct mammography procedures unless the facility also obtains and maintains a certificate issued by the FDA as described in Public Law 102-539, the Mammography Quality Standards Act of 199, and , and complies with all requirements of 21 CFR Part 900, April 1, 2014 edition, which is incorporated herein by reference and available from the internet at
R13 http://www.gpo.gov/fdsys/pkg/CFR-2014-title21-vol8/pdf/CFR-2014-title21-vol8-
R13 chapI-subchapI.pdf, and at
R13 https://www.flrules.org/Gateway/reference.asp?No=Ref-05440.

R1 Specific Authority: 404.051, 404.22, F.S.
R1 Law Implemented: 404.051(1)(4), 404.141, 404.22(1)(3)(6), F.S.
R13 History: New 03-17-1992, Amended 01-01-1994, 11-20-1994, Formerly 10D-91.611, Amended 05-18-1998, 06-03-2015

64E-5.511 Registration of Radiation Machines.

(1) Exemptions.

(a) Electronic equipment that produces radiation incidental to its operation for
R13 other purposes is exempt from registration requirements if the dose equivalent rate averaged over an area of ten square centimeters does not
R13 exceed 0.5 mR (five µSv) per hour at five centimeters from any accessible surface of the equipment. The production, testing or factory servicing of such equipment shall not be exempt.

R7 (b) Radiation machines that are non-operational and under the control of a
R7 registered vendor prior to final installation are exempt from the registration
R7 and fee requirements of this section.

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

(a) Each person who acquires a radiation machine or an additional radiation machine shall:

1. Apply for registration of the radiation machine with the department
R7 within 30 days after acquisition and before use.
R13 registration shall be DH Form 1107, 09/14, “Radiation Machine
R13 Facility Registration,” which is herein incorporated by reference and
R13 available from the internet at http://www.floridahealth.gov/radiation,
R13 or at https://www.flrules.org/Gateway/reference.asp?No=Ref-
R13 05441.

2. Designate an individual who will be responsible for radiation protection.

3. Prohibit any person who is not registered with the department as a provider of services as specified in (3), below, from furnishing radiation machine servicing or services to his radiation machine

R13 (b) Registration fees are due within 30 days after acquiring a radiation
R13 machine. If the machine is acquired within 120 days before the October 28
R13 annual renewal date, the registration fee will be due on or before October
R13 28 and will be the annual renewal fee. Otherwise, the renewal fee is due
R13 annually on or before October 28.

R13 (c) An annual fee for the registration and inspection of radiation machines shall be paid according to the following schedule:

R13	First Tube/Unit	Each Additional Tube/Unit
R13 Medical or Chiropractic or Osteopathic	$145	$ 85
Veterinary	$ 50	$ 34
Educational or Industrial	$ 47	$ 23
Dental or Podiatry	$ 31	$ 11
Medical Accelerator	$258	$148
Non-Medical	$ 81	$ 48

(3) Application for Registration of Servicing and Services.

(a) Each person who installs or offers to install radiation machines or furnishes or offers to furnish radiation machine servicing or services in Florida shall apply to the department to register such services before furnishing or offering to furnish such services.

R13 (b) Application for registration shall be completed on DH Form 1113, 09/14,
R13 "Radiation Machine Vendor Registration Form," which is herein
R13 incorporated by reference and which is available from the internet at
R13 http://www.floridahealth.gov/radiation, and at
R13 https://www.flrules.org/Gateway/reference.asp?No=Ref-05442.

(c) Services include the installation or servicing of radiation machines and associated radiation machine components.

(4) Report of Changes. The registrant shall report in writing within 30 days any changes to the information in the Certificate of Registration. The report shall include name, address of installation change, receipt, sale, transfer, or disposal of any radiation machine or major component.

(5) Assembler or Transferor Obligation.

(a) Any person who sells, leases, transfers, relocates, lends, assembles, installs or disposes of radiation machines or major components of such machines shall notify the department within 15 days after such action. Notification shall be made on DH Form 1114, 09/14, "Report of Assembly of Non-Certified X Ray Systems," which is herein incorporated by reference and available from the internet at http://www.floridahealth.gov/radiation and at https://www.flrules.org/Gateway/reference.asp?No=Ref-05443, or if the system contains certified components, on Form FDA 2579, which is herein incorporated by reference and which is available from the FDA at http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm.

(b) No person shall sell, offer to sell, lease, transfer, lend or install radiation machines unless such machines meet the requirements of these regulations.

(6) Out-of-State Radiation Machines.

(a) Any person proposing to bring a radiation machine into Florida shall notify the department in writing at least ten days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration and scope of use; and the exact location where the radiation machine will be used.

(b) Any person proposing to bring a radiation machine into Florida shall register the machine with the department and pay the registration fee.

(c) Any out-of-state person using a radiation machine in Florida shall notify the department when the use of the machine has been completed.

R13 (7) Enforcement. The General Statement of Policy and Procedure for Radiation
R13 Machine Enforcement Actions, September 2014, which is herein incorporated by reference, will be used to determine enforcement actions to be taken. This publication can be obtained from the internet at
R13 http://www.floridahealth.gov/radiation, and at
R13 https://www.flrules.org/Gateway/reference.asp?No=Ref-05444.

R7 Specific Authority 404.051, F.S.
R13 Law Implemented 404.071, 404.091, 404.101, 404.141, 404.161, 404.162, 404.163, 404.22, F.S.
History--New 12-12-1996, Formerly 10D-91.612, Amended 08-16-2007, 06-03-2015

PART VIII RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL PARTICLE ACCELERATORS

SUBPART A REGISTRATION PROCEDURE

SUBPART B RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

PART VIII

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL PARTICLE ACCELERATORS

SUBPART A
REGISTRATION PROCEDURE

64E-5.801 Registration Requirements.

(1) No person shall receive, possess, use, transfer, or acquire a particle accelerator facility or a particle accelerator except as authorized by a registration certificate issued by the department pursuant to these rules.

R13
R13 (2) Application for registration shall be made on DOH Form 1107, 09/14, “Radiation Machine Facility Registration,” (see Rule 64E-5.511, F.A.C.) and shall contain all information required by the form and accompanying instructions. Part V contains rules concerning registration and the payment of registration fees.

Specific Authority: 404.051, 404.22, F.S.
Law Implemented: 404.022, 404.051(1)(4)(9), 404.22(1), F.S.
R13 History: New 07-17-1985 Amended 05-15-1996, 06-03-2015 Formerly 10D-91.902.

64E-5.802 General Requirements for the Issuance of a Registration Certificate for Particle Accelerators. A registration application for acquisition and use of a particle accelerator or particle accelerator facility will be approved only if the department determines that:

(1) The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this part and Parts III and IX in such a manner as to minimize danger to public health and safety or property;

(2) The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

(3) The issuance of the registration certificate will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 64E-5.803;

(4) The applicant has appointed a radiation safety officer;

(5) The applicant or the applicant's staff have substantial experience in the use of particle accelerators and training sufficient to properly use the accelerator for accomplishment of the intended objectives; and

(6) The applicant has a radiation safety training program for operators of particle accelerators.

Specific Authority: 404.051, 404.22, F.S.
Law Implemented: 404.022, 404.051(1)(4)(8)(9), 404.22(1), F.S.
History: New July 17, 1985, Formerly 10D-91.903.

64E-5.803 Particle Accelerators for Therapeutic Use on Humans. In addition to the general registration requirements set forth in 64E-5.802, accelerators used for treatment of humans will be registered only if the department determines that:

(1) The applicant agrees to appoint a medical committee of at least two physicians, one of whom is expert in radiation therapy, plus a person experienced in depth dose calculations and radiation protection, for the purpose of evaluating and approving all proposed uses involving exposure of human beings;

(2) Persons designated on the application as the authorized users have had training and experience in treatment of humans utilizing radiations of the type and at energies near those produced by the accelerator to be employed;

(3) Individuals designated on the registration application as authorized users are physicians, as defined in 64E-5.101; and

(4) The applicable provisions of 64E-5.508 are met.

Specific Authority: 404.051, 404.081, 404.141, 404.22, F.S.
Law Implemented: 404.022, 404.081(1), 404.141, 404.051(1)(4)(8)(9), 404.22(1), F.S.
History: New July 17, 1985, Amended August 29, 1994, Formerly 10D-91.904.

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Part XVI ELECTRONIC BRACHYTHERAPY

Rules 64E-5.1601 — 64E 5.1604 are effective March 12, 2009 and are designated as Revision 9 (R9).

PART XVI
ELECTRONIC BRACHYTHERAPY

R9 **64E-5.1601 Definitions.** The following definitions apply only in this part.

R9 (1) "AAPM" means the American Association of Physicists in Medicine, R9 www.aapm.org.

R9 (2) "Authorized user" means a person who has met the requirements of subsection R9 64E-5.1603(1), F.A.C.

R9 (3) "Authorized medical physicist" means a person who has met the requirements of R9 subsection 64E-5.1603(2), F.A.C.

R9 (4) "Authorized operator" means a person who has met the requirements of R9 subsection 64E-5.1603(3), F.A.C.

R9 (5) "Electronic brachytherapy" means a method of radiation therapy using R9 electrically-generated x-rays to deliver a radiation dose at a distance of up to a R9 few centimeters by intracavitary, intraluminal or interstitial application, or by R9 applications with the source in contact with the body surface or very close to the R9 body surface.

R9 (6) "Electronic brachytherapy device" or "device" means the system used to produce R9 and deliver therapeutic radiation including the x-ray tube, the control mechanism, R9 the cooling system, and the power source.

R9 (7) "Electronic brachytherapy source" or "source" means the x-ray tube component R9 used in an electronic brachytherapy device.

R9 (8) "Medical event" means any event, except for an event that results from patient R9 intervention, in which the administration of radiation results in:

R9 (a) A total dose delivered that differs from the prescribed dose by 20 percent R9 or more;

R9 (b) A fractionated dose delivered that differs from the prescribed dose, for a R9 single fraction, by 50 percent or more; or

R9 (c) A dose to the wrong individual or the wrong treatment site.

R9 (9) "Mobile electronic brachytherapy device" means a device which is transported R9 from one address to be used at another address.

R9 (10) "Portable shielding" means shielding that can be easily moved into the primary or R9 secondary beam in order to reduce the radiation exposure to the patient, R9 occupational worker or a member of the public.

R9 Specific Authority: 404.051(4), 404.20, F.S.
R9 Law Implemented: 404.031, 404.051, 404.22, F.S
R9 History: New 03-12-2009

R9 **64E-5.1602 Administrative Requirements.**

R9 (1) Registration and Notification.

R9 (a) No electronic brachytherapy device may be used on a human without a
R9 current certificate of registration from the department.

R9 (b) An electronic brachytherapy device that is not operational and that is
R9 under the control of a registered vendor prior to final installation is exempt
R9 from the registration and fee requirements of this section.

R9 (c) A separate registration and radiation protection program are required for
R9 facilities for which one or more of the following applies:

R9 1. The facilities are not at the same physical address;

R9 2. The facilities are not under the same radiation safety program; or

R9 3. The facilities are not under the same management.

R9 (d) Each person who acquires an electronic brachytherapy device shall apply
R9 for registration of the radiation device with the department within 30 days
R13 after acquisition. Application for registration shall be on Form DH 1107,
R13 03/07, “Radiation Machine Facility Registration,” as incorporated in sub-
R9 paragraph 64E-5.511(2)(a)1., F.A.C. The application must include the
following documents:

R9 1. A list identifying the radiation safety officer and all authorized
R9 medical physicists, authorized operators, and authorized users
R9 except visiting authorized users, together with documentation of
R9 their training and education as described in Rule 64E-5.1603,
R9 F.A.C.;

R9 2. A copy of the most current record of surveys, calculations and
R9 quality assurance checks on each device;

R9 3. A current copy of the quality management program as described in
R9 subsection 64E-5.1604(3), F.A.C.;

R9 4. A current copy of the quality assurance program as described in
R9 subsection 64E-5.1604(4), F.A.C.; and

R9 5. A copy of the device manufacturer’s U.S. Food and Drug
R9 Administration certification; and

R9 6. Facility design information, which at a minimum must include:

R9 a. A diagram of the physical facility showing the location of the
R9 electronic brachytherapy treatment rooms;

R9 b. Whether the facility is a new structure or a modification to an
R9 existing structure; and

R9 c. The type and thickness of the portable shielding used for
R9 compliance and a procedure demonstrating the use of the
R9 shielding prior to treatment

R9 (e) The registrant shall update the registration on file with the department
R9 within 30 days of any change to any information reported in paragraph
R9 64E-5.1602(1)(d), F.A.C.

R9 (2) Installation, Maintenance or Repair.

R9 (a) Only a manufacturer's representative registered as a vendor under
R9 subsection 64E-5.511(3), F.A.C., shall install an electronic brachytherapy
R9 device.

R9 (b) Only a manufacturer's representative registered as a vendor under
R9 subsection 64E-5.511(3), F.A.C., or an authorized medical physicist shall
R9 adjust, repair, maintain, or service an electronic brachytherapy device in
R9 accordance with the manufacturer's guidelines.

R9 (c) A registrant shall retain a record of the installation, maintenance,
R9 adjustment, service and repair of an electronic brachytherapy device for 5
R9 years.

R9 (3) Fees. The registrant of an electronic brachytherapy device shall comply with the
R9 requirements of paragraph 64E-5.511(2)(b), F.A.C., and pay the fees for a
R9 medical accelerator unit.

Specific Authority: 404.051(4), 404.22, F.S.
Law Implemented: 404.051, 404.081(1), 404.22, F.S.
R13 History: New 03-12-2009, Amended 06-03-2015

64E-5.1603 Training And Education.

R9 (1) Qualification of Authorized User.

R9 (a) The registrant shall require the authorized user to be a physician who:

R9 1. Is licensed by the department as a medical doctor or doctor of
R9 osteopathy;

R9 2. Has completed a manufacturer’s device-specific training as
R9 specified in subsection 64E-5.1603(5), F.AC.; and

R9 3. Is certified in:

R9 a. Radiation oncology or therapeutic radiology by the American
R9 Board of Radiology;

R9 b. Radiation oncology by the American Osteopathic Board of
R9 Radiology;

R9 c. Radiology, with specialization in radiotherapy, as a British
R9 "Fellow of the Faculty of Radiology" or "Fellow of the Royal
R9 College of Radiology"; or

R9 d. Therapeutic radiology by the Canadian Royal College of
R9 Physicians and Surgeons.

R9 (b) A physician shall not act as an authorized user for any electronic
R9 brachytherapy device until such time as said physician's training has been
R9 reviewed and approved by the department.

R9 (2) Qualification of Authorized Medical Physicist.

R9 (a) The registrant shall require the authorized medical physicist to be a
R9 person who:

R9 1. Is currently licensed pursuant to Section 483.901, F.S., as a
R9 therapeutic radiological physicist; and

R9 2. Has completed a manufacturer’s device-specific training as
R9 specified in subsection 64E-5.1603(5), F.A.C.

R9 (b) A medical physicist shall not act as an authorized medical physicist for any
R9 electronic brachytherapy device until such time as said physicist’s training
R9 has been reviewed and approved by the department