February 2010

Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2010-01

Revision 10 Filing Instructions:
Changes to Chapter 64E-5, Florida Administrative Code (F.A.C.)

Changes to "Control of Radiation Hazard Regulations," Chapter 64E-5, F.A.C., became effective February 11, 2010. **These changes are indicated as Revision 10 or (R10) in the margin and rose highlighting.**

These instructions apply to the complete version (brown cover) of Chapter 64E-5, F.A.C. Be sure that Revisions 1 through 9 changes have been inserted before making these changes. This may be verified by checking page ii of the index. **Visit our website at www.doh.state.fl.us/environment/radiation/ to download R10 pages to replace. An electronic copy of the chapter is also available**

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Cover	Cover	Cover
Index	i through xii	i through xvi
Part I General Provisions	Part I Index Part I Pages 1-26 (all)	Part I Index Part I Pages 1-27
Part II Licensing of Radioactive Materials	Part II Index Part II Pages 29/30, 45/46, 47/48, 53/54, 59/60, 65/66	Part II Index Part II Pages 29/30, 45/46, 47/48, 53/54, 59/60, 65/66
Part III Standards for Protection Against Radiation	Part III Index Part III Pages 11/12, 25/26, 41/42, 43/44, 45/46	Part III Index Part III Pages 11/12, 25/26, 41/42, 43/44a, 44b/44c (new), 44d/44e, 45/46
Part VI Use of Radionuclides in the Healing Arts	Part VI Index Part VI Pages 1-48 (all)	Part XV Index Part VI Pages 1-94
Part XIII Radiation Safety Requirements for Possession and Use of Sealed or Unsealed Sources of Radioactive Materials	Part XIII Index Part XIII Pages 1/2, 3/4	Part XIII Index Part XIII Pages 1/2, 3/4, 13/14 (new), 15/16 (new)

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
Attachment - 7 Radioactive Materials Application License Non-Human Use Form DH-1054 12/09	Radioactive Materials License Application Non-Human Use Form DH-1054 05/1997	Radioactive Materials License Application Non-Human Use Form DH-1054 12/09
		New Radioactive Materials License Application Human Use Form DH-1322 12/09
		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)

Below is a brief summary of the substantial changes. Please see rule text for details.

Part I: Definitions to support the terms for the medical use of radiations to include medical events, authorized nuclear pharmacist. Note the definition of misadministration is now called a medical event and several definitions were moved to Part VI.

Part II: New applications forms for both medical use and non-human use of radioactive materials have been developed and only one copy and an original application needs to be submitted to the department. Nuclear pharmacy and sealed source distribution rules were changed to include the equivalent to 10 CFR Part 1000 (Other medical uses or radioactive materials not previously listed), as well as remote afterloaders. Reciprocity time frames reduced from 365 days to 180 days to comply with NRC requirements. Provisions to exceed this time frame are described.

Part III: Member of the public radiation dose limits increased to include higher doses from patients containing radioactive materials, isotopes with half-life 120 days or less may now be disposed of by decay in storage (DIS) methodology provided it is not a sealed source, reporting requirements added should an embryo/fetus receive 5 rem dose equivalent from radiation received from radioactive materials or a nursing child exceeds 5 rem total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

Part VI MAJOR REWRITE: Training and experience requirement changed to be listed on a license as a physician authorized users, authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), Radiation Safety Officer (RSO). Recentness of training expanded from 5 to 7 years, Grandfathering of existing uses expanded to include RSO's, medical physicists, nuclear pharmacists currently listed on a medical use license (certain restrictions apply). Requirements for the medical use of remote afterloaders and gamma knife added. Definitions added to support this use. Concept of visiting authorized user expanded to include authorized medical physicists and RSO, expanded duties for RSO's, expanded duties for and requirements to have a Radiation Safety Committee, higher possession limits for calibration, reference and transmission sources, DIS half-life isotopes increased from 90 to 120 days, acceptance testing required on treatment planning systems for therapy-related computer systems, brachytherapy inventory frequency expanded from 3 months to 6 months, and the RSO must agree in writing to the licensee to accept RSO duties and responsibilities for implementation of the radiation safety program, use of I-123 does not require a written directive as long as its use is listed in the diagnostic clinical procedures manual signed off on by all the authorized users. Authorized Users and Authorized Medical Physicists at High Dose Rate Remote Afterloader facilities and Gamma Stereotactic Radiosurgery facilities have very specific new rules requiring their physical presence during the treatment.

Part XIII: Tritium and Iodine 125/131 bioassay requirements are specified.

Visit our website at www.doh.state.fl.us/environment/radiation/ to download pages to replace in your "brown cover" version of the "Control of Radiation Hazard Regulations", 64E-5, F.A.C. or to download a complete copy of 64E-5, F.A.C.

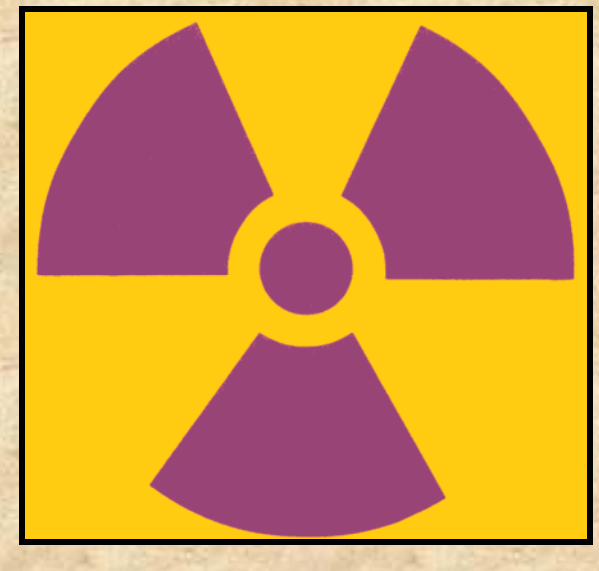
No specific actions nor written response is required to this information notice. However, we urge you to carefully review those changes applicable to your license and procedures. It may be necessary for you to revise your procedures to be compliant with the rule changes. If you have any questions or need additional information, please call us at (850) 245-4545.

FLORIDA DEPARTMENT OF HEALTH

Bureau of Radiation Control

Division of Environmental Health

CONTROL OF RADIATION HAZARD REGULATIONS



Chapter 64E-5
Florida Administrative Code

Effective Date July 3, 1997 Includes

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

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

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

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

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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: http://www.doh.state.fl.us/environment/radiation. Chapter 64E-5 and all other Florida Administrative Codes are available at https://www.flrules.org/.

Chronology of Rule Revisions

Revision	Effective Date	Sections Affected
R1	May 18, 1998	64E-5.101, 64E-5.204, 64E-5.213, 64E-5.214, 64E-5.319, 64E-5.332, 64E-5.333, 64E-5.334, 64E-5.347, 64E-5.402, 64E-5.422, 64E-5.502, 64E-5.504, 64E-5.510, 64E-5.617, 64E-5.902, 64E-5.1513, Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997.
R2	October 8, 2000	64E-5.101, 64E-5.201, 64E-5.203, 64E-5.204, 64E-5.214, 64E-5.216, 64E-5.301, 64E-5.303, 64E-5.304, 64E-5.309, 64E-5-311, 64E-5.312, 64E-5.314, 64E-5.315, 64E-5.323, 64E-5.326, 64E-5.334, 64E-5.339, 64E-5.344, 64E-5.345, 64E-5.414, 64E-5.420, 64E-5.422, 64E-5.505, 64E-5.622, 64E-5.625, 64E-5.643, 64E-5.645, 64E-5.1103, 64E-5.1112, 64E-5.1310, 64E-5.1406, 64E-5.1418, 64E-5.1502, 64E-5.1513 Radioactive Material Requiring Labeling, May 2000
R3	August 6, 2001	64E-5.101, 64E-5.201, 64E-5.603, 64E-5.606. 64E-5.626, 64E-5.627, 64E-5.630
R4	September 11, 2001	64E-5.401 - 64E-5.422 repealed and replaced with sections 64E-5.423, 64E-5.424, 64E-5.425, 64E-5.426, 64E-5.427, 64E-5.428, 64E-5.429, 64E-5.430, 64E-5.431, 64E-5.432, 64E-5.433, 64E-5.434, 64E-5.435, 64E-5.436, 64E-5.437, 64E-5.438, 64E-5.439, 64E-5.440, 64E-5.441
R5	December 19, 2001	64E-5.101, 64E-5.214, 64E-5.221, 64E-5.222, 64E-5.223, 64E-5.224, 64E-5.225, 64E-5.226, 64E-5.901, Notice to Employees 3/01
R6	September 28, 2006	64E-5.101, 64E-5.204, 64E-5.206, 64E-5.210 , 64E-5.213, 64E-5.304, 64E-5.318, 64E-5.319, 64E-5.427, 64E-5.429, 64E-5.434, 64E-5.440, 64E-5.441, 64E-5.1104, 64E-5.1107, 64E-5.11071, 64E-5.11072, 64E-5.11073, 64E-5.1112, 64E-5.1119, 64E-5.1311, 64E-5.1502, Bureau of Radiation Control Respiratory Protection Factors May 2006, Transfers of Industrial Devices Report 10-2003
R7	August 16, 2007	64E-5.101, 64E-5.204, 64E-5.210, 64E-5.502, 64E-5.504, 64E-5.506, 64E-5.511, 64E-5.1508, Transfers of Industrial Devices Report 04/2007, Radiation Machine Facility Registration DH 03/2007
R8	February 28, 2008	64E-5.101, 64E-5.206, 64E-5.206, 64E-5.210, 64E-5.216, **New** 64E-5.350, **New** 64E-5.351, 64E-5.430, 64E-5.440, 64E-5.441, 64E-5.1003, 64E-5.11702, 64E-5.1501, 64E-5.1502
R9	March 12, 2009	New 64E-5.1601, 64E-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)

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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 I GENERAL PROVISIONS

PART I

GENERAL PROVISIONS

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

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

(2) "A_2" means the maximum activity of radioactive material, other than special form or low specific activity radioactive material, permitted in a Type A package.

(3) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(4) "Accelerator-produced material" means any material made radioactive by a particle accelerator.

(5) "Act" means the Florida Radiation Protection Act, Chapter 404, Florida Statutes.

(6) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

(7) "Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, used, or stored.

(8) "Adult" means an individual 18 or more years of age.

(9) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors or gases.

(10) "Airborne radioactivity area" means a room, enclosure or operating area in which airborne radioactive materials exist in concentrations:

(a) In excess of the derived air concentrations (DACs) specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, which is herein incorporated by reference and which is available from the department, or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(11) "ALARA" means as low as reasonably achievable making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to use of nuclear energy and licensed or registered sources of radiation in the public interest.

(12) "Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

(13) "Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

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

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

(15) "Area of use" means a portion of a physical structure that has been set aside to receive, use, or store radioactive material.

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

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

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

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

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

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

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

R10 4. A permit issued by a NRC master material broad scope licensee
R10 that authorizes medical use or the practice of nuclear pharmacy; or

R10 (c) Is identified as an authorized nuclear pharmacist by a commercial nuclear
R10 pharmacy that has been authorized to identify authorized nuclear
R10 pharmacists; or

R10 (d) Is designated as an authorized nuclear pharmacist in accordance with
R10 paragraph 64E-5.210(10)(b)3., F.A.C.

R10 (176) “Atmosphere-supplying respirator” means a respirator that supplies the respirator
R6 user with breathing air from a source independent of the ambient atmosphere
R6 and includes supplied-air respirators and self-contained breathing apparatus
R6 units.

R10 (16) "Authorized user" means an individual who is identified on a department, NRC,
R10 agreement state, or licensing state specific license that authorizes the use of
R10 radioactive material.

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

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

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

R4 (20) "Bioassay" means the determination of kinds, quantities or concentrations, and in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

R10 (21) "Byproduct material" means:

(a) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface waste resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute byproduct material within this definition.

R10 (188) "C-arm system" means a fluoroscopic C-arm routinely used with the same patient
R7 support device which will have interlocks, detents or positioning marks to allow
R7 reproducible geometry. Measurements of patient entrance exposure for this type
R7 of system will be measured in accordance with subparagraph
R7 64E-5.504(3)(e)2., 3., and 5., F.A.C.

R10 (22) "Cabinet x-ray system or Cabinet x-ray" means an x-ray system with the x-ray
R7 tube installed in an enclosure independent of existing architectural structures. A
R7 cabinet x-ray system is intended to contain the material being irradiated, and
R7 exclude personnel from its interior during generation of radiation. To be certified
R7 as a cabinet x-ray, the cabinet must be shielded so that every location on the
R7 exterior meets the conditions of 0.5 mRem (0.005 millisievert) in any one hour, at
R7 a distance of 5 cm. An x-ray tube used within a shielded part of a building or x-
R7 ray equipment that may temporarily or occasionally incorporate portable shielding
R7 is not considered a cabinet x-ray system.

R10 (23) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin on January 1 and subsequent calendar quarters shall be arranged so that no day is included in more than 1 calendar quarter, no calendar quarter, or part thereof, is included in more than 1 calendar year, and no day in any 1 year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him to determine calendar quarters for purposes of these rules except at the beginning of a calendar year.

R10 (24) "Calibration" means:

(a) The determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(b) The determination of the strength of a source of radiation relative to a standard.

R10 (25) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier or by civil aircraft.

R10 (26) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

R10 (27) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

R10 (28) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

R10 (29) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).

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

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

R10 (31) "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps).

R10 R6 (186) Daily means an interval not to exceed a consecutive 24 hour period or once every calendar day worked.

R10 (32) "Declared pregnant woman" means a woman who has voluntarily informed her employer in writing of her pregnancy and the estimated date of conception.
R2 R2 The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

R10 (33) "Dedicated check source" means a radioactive source that is used to assure the consistent operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

R10 (34) "Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1,000 mg/cm^2).

R10 (35) "Decommission" means to remove a facility safely from service and reduce residual radioactivity to a level that permits release of the property for
R5 R5 unrestricted use and termination of license or release of the property under restricted conditions and the termination of the license.

R10 (36) "Depleted uranium" means the source material uranium in which the isotope uranium 235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

R10 (37) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3.

R10 (38) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee can take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rem (0.05 sievert).

R10 R5 R5 R5 (173) “Distinguishable from background” means that the detectable concentration of a radionuclide is statistically different from the background concentrations of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

R4 (39) "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. For the purposes of these rules, "radiation dose " is an equivalent term.

R10 (40) "Dose equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

R10 (41) "Dose limits" means the permissible upper bounds of radiation doses established as specified in these rules. For purposes of these rules, "limits" is an equivalent term.

R10 (42) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices to determine the radiation dose delivered to the monitoring devices.

R10 (43) "Effective dose equivalent" (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

R10 (44) "Embryo" or "fetus" means the developing human organism from conception until birth.

R10 R6 R6 R6 (177) “Energy compensation source” or “ECS” means a small sealed source with an activity not exceeding 100 microcuries (3.7 MBq) used within a logging tool or other tool components to provide a reference standard to maintain the tool’s calibration when in use.

R10 (45) "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

R10 (46) "Exposure", when used as a noun, means the quotient of dQ by dm, where "dQ" is the absolute value of the total charge of the ions of 1 sign produced in air when all the electrons, negatrons and positrons, liberated by photons in a volume element of air having mass "dm" are completely stopped in air. "Exposure", when used as a verb, means being exposed to ionizing radiation or to radioactive material. The special unit of exposure is the roentgen (R).
See Rule 64E-5.106, F.A.C., for the SI equivalent.

R10 (47) "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

R10 (48) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

R10 (49) "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

R10 (50) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).

R10 (51) "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

R10 (52) "Field station" means a temporary or portable facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.

R10 R6 R6 (178) “Fit factor” means a quantitative estimate of the fit of a particular respirator to a specific individual and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

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

R10 (53) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

R10 (54) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

R10 (55) "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

R10 (56) "Healing arts" means professions concerned with diagnosis or treatment of human and animal maladies, including the practice of medicine, dentistry, veterinary medicine, osteopathy, chiropractic, podiatry and naturopathy.

R10 R2 (57) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates. For purposes of these rules, rooms or areas in which diagnostic x-ray systems are used for healing arts purposes are not considered high radiation areas.

R10 (58) "Human use" means the internal or external administration of radiation or radioactive material to human beings.

R10 (59) "Individual" means any human being.

R10 (60) "Individual monitoring" means the assessment of:

(a) Dose equivalent by the use of individual monitoring devices or by the use of survey data; or

(b) Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed.

R10 (61) "Individual monitoring devices" means devices designed to be worn by a single
R2 individual for the assessment of dose equivalent such as film badges,
R2 thermoluminescence dosimeters, pocket ionization chambers, and personal or
R2 lapel air sampling devices. For purposes of these rules, individual monitoring equipment and personnel monitoring equipment are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters
R2 (TLDs), optically stimulated luminescent devices (OSLDs), pocket ionization chambers, and personal air sampling devices.

R10 (62) “Industrial radiography” means nondestructive testing using ionizing radiation to make radiographic images or radiographs to detect flaws in objects.

R10 (63) "Inhalation class" (see "Class").

R10 (64) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

R10 (65) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

R10 (66) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

R10 (67) "Large irradiator" means an irradiator where radiation dose rates exceeding 500 rems (5 sieverts) per hour exist at 1 meter from the sealed radioactive sources in air or in water. This does not include irradiators in which both sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel, or to radioactive materials used for medical radiology, teletherapy, industrial radiography, gauging, calibration of radiation detection instruments, or open-field agricultural irradiations.

R10 (68) “Lens dose equivalent (LDE)” applies to the external exposure of the lens of the
R2 eye and is taken as the dose equivalent at the tissue depth of 0.3 centimeter
R2 (300 mg/cm^2).

R10 (69) "License" means a license issued by the Department in accordance with the rules adopted by the Department.

R10 (70) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the department.

R10 (71) "Licensee" means any person who is licensed by the Department in accordance with these rules and the Act.

R10 (72) "Licensing State" means any state with rules equivalent to the Suggested State Regulations for Control of Radiation for the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

R10 (73) "Local components" means parts of an analytical x-ray system and includes areas that are struck by x-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but does not include power supplies, transformers, amplifiers, readout devices and control panels.

R10 (74) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.

R10 (75) "Logging tool" means a device used subsurface to perform well-logging.

R10 (76) "Lost or missing licensed material" means licensed material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

R10 (77) "Low specific activity material (LSA)" means that as defined in 49 C.F.R.
R8 173.403. (Pursuant to Section 120.54(6) Florida Statutes, subsection
R8 64E-5.101(79), F.A.C., is substantively identical to 49 CFR 173.403 published on 10/01/2007.)

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

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

R10 (80) "Management" means the chief executive officer or other individual, or a delegate
R10 or the delegates of the chief executive officer or other individual, having the
R10 authority to manage, direct, or administer the licensee's activities.

R10 (81) "Medical institution" means any establishment that:

(a) Offers services more intensive than those required for room, board, personal services, and general nursing care, and offers facilities and beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care for illness, injury, deformity, infirmity, abnormality, disease, or pregnancy; and

(b) Regularly makes available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or

other definitive medical treatment of similar extent.

R10 (82) "Member of the public" means any individual except when that individual is receiving an occupational dose.

R10 (83) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

R10 (84) "Minor" means an individual less than 18 years of age.

R10 (85) "Medical event" means the administration of:

R10 (a) Radioactive materials or radiation from radioactive materials requiring a written directive that results in the following:

R10 1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin;

R10 2. When the total dose delivered differs from the prescribed dose by 20 percent or more;

R10 3. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range;

R10 4. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

R10 5. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin;

R10 6. An administration of a wrong radioactive drug containing radioactive material;

R10 7. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

R10 8. An administration of a dose or dosage to the wrong individual or human research subject;

R10 9. An administration of a dose or dosage delivered by the wrong mode of treatment;

R10 10. A leaking sealed source where the patient or human research subject is contaminated;

R10 11. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or

R10 12. Any medical use that results or will result in unintended permanent functional damage to an individual's organ or a physiological system, as determined by a physician.

(b) Radioactive materials or radiation from radioactive materials not requiring a written directive that result in either of the following:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

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

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

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

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

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

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

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

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

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

f. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or

g. Any medical use that results or will result in unintended permanent functional damage to an individual's organ or a physiological system, as determined by a physician.

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

1. Any medical use that results or will result in unintended permanent functional damage to an individual's organ or a physiological system, as determined by a physician;

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

R10 3. An administration of a dose delivered by the wrong mode of
R10 treatment, wrong treatment, or wrong treatment site;

R10 4. When treatment consists of three or fewer fractions and the
R10 calculated total administered dose differs from the total prescribed
R10 dose by more than 10 percent of the total prescribed dose;

R10 5. When the calculated weekly administered dose is 30 percent
R10 greater than the weekly prescribed dose; or

R10 6. When the calculated total administered dose differs from the total
R10 prescribed dose by more than 20 percent of the total prescribed
R10 dose.

R10 (187) “Mobile C-arm” means a mobile fluoroscopic machine that is designed for and
R7 used without a patient support device such as a radiographic table, cradle or
R7 radiolucent stretcher. This would include machines moved from room to room to
R7 assist in surgical procedures. Measurements of patient entrance exposure for
R7 this type of system will be measured in accordance with subparagraph
R7 64E-5.504(3)(e) 2, 3, and 4, F.A.C.

R10 (86) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, radiation monitoring and radiation protection monitoring are equivalent terms.

R10 (87) "NARM" means any naturally occurring or accelerator-produced radioactive material. To meet the definition of licensing state, NARM only refers to discrete sources of NARM. Diffuse sources of NARM, which are large in volume and low in activity, are excluded from consideration by the Conference of Radiation Control Program Directors, Inc., for licensing state designation purposes.

R10 (189) “Nationally tracked source” means a sealed source containing a quantity equal to
R8 or greater than Category 1 or Category 2 levels of any radioactive material listed
R8 in Rule 64E-5.351, F.A.C. In this context a sealed source is defined as
R8 radioactive material that is sealed in a capsule or closely bonded, in a solid form,
R8 and which is not exempt from regulatory control. It does not mean material
R8 encapsulated solely for disposal, or nuclear material contained in any fuel
R8 assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked
R8 sources are those containing radioactive material at a quantity equal to or greater
R8 than the Category 1 threshold. Category 2 nationally tracked sources are those
R8 containing radioactive material at a quantity equal to or greater than the Category
R8 2 threshold but less than the Category 1 threshold. (Pursuant to Section
R8 120.54(6) Florida Statutes, subsection 64E-5.101(194), F.A.C, is substantively
R8 identical to 10 CFR 20.1003 published on 01/01/2007).

R10 (88) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

R10 (89) "Nonstochastic effect" means a health effect the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

R10 (90) "Normal form" means radioactive material which has not been demonstrated to qualify as "special form"; also referred to as "nonspecial form."

R10 (91) "Normal operating procedures" means operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.

R10 (92) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

R10 (93) "Occupational dose" means the dose received by an individual in the course of employment which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background
R2 radiation, from any medical administration the individual has received, from
R2 exposure to individuals administered radioactive material and released as
R2 specified in Rule 64E-5.622, F.A.C., from voluntary participation in medical research programs, or as a member of the public.

R10 (94) “Offshore” means within the territorial waters of the State of Florida as specified
R4 in Article II, Section 1 of the Constitution of the State of Florida.

R10 (95) “Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

R10 (96) "Package" means that as defined in 49 C.F.R. 173.403. (Pursuant to Section
R8 120.54(6) Florida Statutes, subsection 64E-5.101(100), F.A.C., is substantively
R8 identical to 49 CFR 173.403 published on 10/01/2007).

R10 (97) "Packaging" means, for radioactive materials, the assembly of components necessary to ensure compliance with the packaging requirements of the U.S. Nuclear Regulatory Commission and the U.S. Department of Transportation. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The conveyance, tie-down system, and auxiliary equipment may sometimes be designated as part of the packaging.

R10 (98) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

R10 (99) "Permanent radiographic installation" means an enclosed shielded room, cell, or
R4 vault, as specified in Rule 64E-5.431, F.A.C., in which industrial radiography is
R4 performed.

R10 (100) "Permit" means the written authorization issued by the Department for the transportation of radioactive waste as described in Rule 64E-5.1509, F.A.C.

R10 (101) "Personal supervision" means supervision in which the radiographer or logging supervisor is physically present at the site where sources of radiation and associated equipment are being used, watching the performance of the radiographer's assistant or supervised individual and in such proximity that immediate assistance can be given if required.

R10 (102) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

R10 (103) "Prescribed Dosage" means the quantity of radiopharmaceutical activity as documented:

(a) In a written directive; or

(b) Either in the diagnostic clinical procedures manual or in any appropriate record as specified in the directions of the authorized user for diagnostic
R10 procedures in which a written directive is not required.

R10 (104) "Prescribed Dose" means:

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

R10 (b) For manual brachytherapy, either the total source strength and exposure time or the total dose as documented in the written directive;

(c) For teletherapy, particle accelerator or therapeutic x-ray machine, the total
R10 dose and dose per fraction as documented in the written directive; or

R10 (d) For remote brachytherapy afterloaders, the total dose and dose per
R10 fraction as documented in the written directive.

R10 (105) "Primary beam" means the radiation which passes through an aperture of the source housing in a direct path from the x-ray tube located in the radiation source housing.

R10 (170) “Principal activities” means activities authorized by the license that are essential
R1 to achieve the purpose for which the department issued or amended the license.
R1 Storage during which no licensed material is accessed for use or disposal and
R1 activities incidental to decontamination or decommissioning are not principal
R1 activities.

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

R10 (107) "Quality factor" (Q) means the modifying factor listed in the tables in subsections 64E-5.106(3) and (4), F.A.C., used to derive dose equivalent from absorbed dose.

R10 (108) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee or registrant of approximately 13 consecutive weeks. The beginning of the first quarter in a year shall coincide with the starting date of the year and no day shall be omitted or duplicated in consecutive quarters.

R10 (109) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).

R10 (110) "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, "ionizing radiation" is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radio waves or microwaves, visible, infrared, or ultraviolet light.

R10 (111) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual's receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

R10 (112) "Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

R10 (113) "Radiation Safety Officer or RSO" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules.

R10 (114) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

R10 (115) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

R10 R4 (116) "Radiographer" means any individual who has completed successfully the training and testing requirements specified in subsection 64E-5.434(2), F.A.C., performs or personally supervises radiographic operations and is responsible to the licensee or registrant for assuring compliance with the requirements of these rules and all license or certificate of registration conditions.

R10 R4 R4 R4 (117) "Radiographer's assistant or assistant radiographer " means any individual who has completed successfully the training and testing requirements specified in subsection 64E-5.434(1), F.A.C., and who, under the personal supervision of a radiographer, conducts radiographic operations.

R10 R8 R8 R8 R8 R8 (118) "Radiographic exposure device" means any instrument containing a sealed source, fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed from a shielded position to an unshielded position for the purpose of making a radiographic exposure. It also is known as a camera or a projector. (Pursuant to Section 120.54(6) Florida Statutes, subsection 64E-5.101(122), F.A.C., is substantively identical to 10 CFR 34.3 published on 01/01/2007).

R10 (119) "Recordable event" means the administration of:

(a) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(b) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

R10 (c) Iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels) when;

1. The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage; and

2. The difference between the administered dosage and the prescribed dosage exceeds 15 microcuries.

R10 (d) A therapeutic administration of a radiopharmaceutical other than iodine
R10 131 as sodium iodide, when the administered dosage differs from the prescribed dosage by more than 10 percent from the prescribed dosage;

(e) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose; or

R10 (f) A teletherapy, particle accelerator, gamma stereotactic radiosurgery or therapeutic x-ray machine radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

R10 (120) "Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics can be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

R10 (121) "Registrant" means any person who is registered with the Department and is legally obliged to register with the Department pursuant to these rules and the Act.

R10 (122) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR, Parts 100-189.

R10 (123) "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

R10 (124) "Research and development" means:

(a) Theoretical analysis, exploration or experimentation; or

(b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

R10 (125) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

R10 R5 R5 R5 R5 R5 (174) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee but excludes background radiation. It also includes radioactive material as a result of routine or accidental releases of radioactive material at the site and previous burials at the site even if those burial sites were made as specified in Part III of this Chapter.

R10 (126) "Restricted area" means an area, access to which is limited by the licensee or registrant to protect individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building can be set apart as a restricted area.

R10 (127) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air.

R10 (128) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

R10 R8 R8 R8 (129) "Sealed source" means radioactive material that is encased in a capsule designed to prevent release or escape of the radioactive material. (Pursuant to Section 120.54(6) Florida Statutes, subsection 64E-5.101(133), F.A.C., is substantively identical to 10 CFR 30.4 published on 01/01/2007).

R10 R10 R10 R10 R10 (190) "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both NRC and the agreement states, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

R10 R6 R6 (180) "Self-contained breathing apparatus" or "SCBA" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

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

R10 R6 R6 (130) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

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

R10 (132) "Shipping paper" means a shipping order, bill of lading, manifest or other shipping document serving a similar purpose and containing the information required by 49 CFR, Parts 172.202, 172.203 and 172.204.

R10 (133) "SI" means an abbreviation of the International System of Units.

R10 (134) "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

R10 (135) “Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

R10 (136) "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

R10 (137) "Source material" means:

(a) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(b) Ores which contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

R10 (138) "Source material milling" means any activity that results in the production of byproduct material as defined by Rule 64E-5.101, F.A.C.

R10 (139) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

R10 (140) "Special form" means radioactive material which satisfies all of the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than 5 millimeters; and

(c) It satisfies the test requirements of 49 CFR, Part 173.469. Special form encapsulations designed in accordance with the requirements of 49 CFR, Part 173.389 in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. Special form encapsulations either designed or constructed after June 30, 1985, must meet the requirements of this part.

R10 (141) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

R10 (142) "Specific activity" means the activity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the activity per unit mass of the material.

R10 (191) “Stereotactic radiosurgery” means the use of external radiation in conjunction
R10 with a stereotactic guidance device to very precisely deliver a therapeutic dose to
R10 a tissue volume.

R10 (143) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For the purposes of these rules, "probabilistic effect" is an equivalent term.

R10 (144) "Storage area" means any location, facility, or vehicle which is used to store, transport, or secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

R10 (145) "Storage container" means a container in which sealed sources are secured and stored.

R10 (192) “Structured educational program” means an educational program designed to
R10 impart particular knowledge and practical education through interrelated studies
R10 and supervised training.

R10 (146) "Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

R10 (181) “Supplied-air respirator” or “air-line respirator” means an atmosphere-supplying
R6 respirator for which the source of breathing air is not designed to be carried by
R6 the user.

R10 (147) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal or presence of sources of radiation. When appropriate, such evaluation includes tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

R10 (148) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

R10 (149) "Temporary job site" means a site, base or facility that is created and maintained to support a single job.

R10 (150) "Test" means the process of verifying compliance with an applicable rule.

R10 R6 (182) "Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

R10 (151) "Total effective dose equivalent" means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

R10 (152) "Type B packaging" means a packaging designed to retain the integrity of containment and shielding required by U.S. Nuclear Regulatory Commission and U.S. Department of Transportation regulations when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR, Part 71.

R10 (153) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating or refining.

R10 (154) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

R10 (155) "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof as specified in sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy as specified in section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

R10 R6 R6 R6 (183) "User seal check" or "fit check" means an action conducted by the respirator user to determine if the respirator is seated to the face properly. Examples include negative pressure check, positive pressure check, irritant smoke check, and isoamyl acetate check.

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

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

R10 (158) "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

R10 (159) "Weighting factor" (W_T) for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

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

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

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

R10 (160) "Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed

R10 (161) "Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

R10 (162) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

R10 (163) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

R10 (164) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

R10 (165) "Worker" means an individual engaged in work in a restricted area under the authority of a license or registration issued by the Department.

R10 (166) "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3 x 10^5 MeV of potential alpha particle energy. The short-lived radon daughters are:

(a) For radon 222: polonium 218, lead 214, bismuth 214, and polonium 214;

(b) For radon 220: polonium 216, lead 212, bismuth 212, and polonium 212.

R10 (167) "Working level month" (WLM) means an exposure to 1 working level for 170 hours. Two thousand working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

R10 (168) "Written directive" means a written order for a specific patient or human research
R10 subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, which shall contain the following information:

(a) For a therapeutic administration of a radiopharmaceutical, the
R10 radiopharmaceutical, dosage, and route of administration;

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

R10 (c) For gamma stereotactic radiosurgery, target coordinates settings per
R10 treatment for each anatomically distinct treatment site, collimator size, plug pattern, and total dose;

(d) For teletherapy, particle accelerator or therapeutic x-ray machine, the total
R10 dose, dose per fraction, treatment site, number of fractions and overall treatment period;

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

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

R10 1. Prior to implantation, the radioisotope, treatment site, dose, number of sources, and source strengths; and

2. After implantation but prior to completion of the procedure, the radioisotope, treatment site, total source strength and exposure time or total dose.

R10 (169) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant can change the starting date of the year used to determine compliance by the licensee or registrant if the change is made at the beginning of the year and if no day is omitted or duplicated in consecutive years.

R10 Editor's Note: Definitions have been alphabetized effective, 02-11-10.
Rulemaking Authority: 404.051, 404.061, F.S.
Law Implemented: 404.031, 404.061, 404.20, 404.22, 404.30, F.S.
R1-R10 History: New 7-17-85, Amended 4-4-89,5-12-93,1-1-94, 5-15-96, Formerly 10D-91.102, Amended 5-18-98, 10-8-00, 8-6-01, 9-11-01, 12-18-01, 9-28-06, 8-16-07, 2-28-08, Amended 02-11-10.

64E-5.102 Exemptions.

(1) The Department may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property or the environment.

(2) Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, transports or acquires sources of radiation:

(a) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(b) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

(c) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

(d) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine:

1. That the exemption of the prime contractor or subcontractor is authorized by law; and

2. That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health, safety and environment.

Specific Authority: 404.051, 404.061, F.S.
Law Implemented: 404.051(10), 404.061(4), 404.111(3), 404.121(1), 404.20, F.S.
History: New 7-17-85, Amended 5-12-93, Formerly 10D-91.103.

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

Specific Authority: 404.051, 404.061, 404.081, F.S.
Law Implemented: 404.022, 404.061(2), 404.081, 404.20(2), 404.22(2), F.S.
History: New 7-17-85, Formerly 10D-91.104.

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

(1) Sources of radiation;

(2) Facilities wherein sources of radiation are used or stored;

(3) Radiation detection and monitoring instruments; and

(4) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

Specific Authority: 404.051, 404.061, F.S.
Law Implemented: 404.022, 404.051(1)(7), 404.061(2), 404.22(1), F.S.
History: New July 17, 1985, Formerly 10D-91.106.

64E-5.105 Prohibited Uses.

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

(2) A shoe-fitting fluoroscopic device shall not be used.

Specific Authority: 404.051, 404.061, 404.141, F.S.
Law Implemented: 404.022, 404.051, 404.061(2), 404.141, 404.22(3), F.S.
History: New 7-17-85, Amended 1-1-94, Formerly 10D-91.110.

64E-5.106 Units of Exposure and Dose.

(1) As used in these regulations, the unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58 x 10^{-4} coulomb per kilogram of air.

(2) As used in these regulations, the units of dose are:

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

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

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

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

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

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

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

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

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

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FORM MONOENERGETIC NEUTRONS

(thermal)	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons) (cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent[b] (neutrons) (cm^{-2} rem^{-1})
	2.5×10^{-8}	2	980×10^{6}	980×10^{8}
	1.0×10^{-7}	2	980×10^{6}	980×10^{8}
	1.0×10^{-6}	2	810×10^{6}	810×10^{8}
	1.0×10^{-5}	2	810×10^{6}	810×10^{8}
	1.0×10^{-4}	2	840×10^{6}	840×10^{8}
	1.0×10^{-3}	2	980×10^{6}	$980x\ 10^{8}$
	1.0×10^{-2}	2.5	1010×10^{6}	1010×10^{8}
	1.0×10^{-1}	7.5	170×10^{6}	170×10^{8}
	5.0×10^{-1}	11	39×10^{6}	39×10^{8}
	1	11	27×10^{6}	$27\ x10^{8}$
	2.5	9	29×10^{6}	29×10^{8}
	5	8	23×10^{6}	23×10^{8}
	7	7	24×10^{6}	24×10^{8}
	10	6.5	24×10^{6}	24×10^{8}
	14	7.5	17×10^{6}	17×10^{8}
	20	8	16×10^{6}	16×10^{8}
	40	7	14×10^{6}	14×10^{8}
	60	5.5	16×10^{6}	16×10^{8}
	100	4	20×10^{6}	20×10^{8}
	200	3.5	19×10^{6}	19×10^{8}
	300	3.5	16×10^{6}	16×10^{8}
	400	3.5	14×10^{6}	14×10^{8}

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

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

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

PART II LICENSING OF RADIOACTIVE MATERIALS

SUBPART G RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

(9) Ice Detection Devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium 90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium 90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the department or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(b) Persons who own, receive, acquire, possess, use or transfer strontium 90 contained in ice detection devices pursuant to the general license in (9)(a), above;

1. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 64E-5.328;

2. Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

3. Are exempt from the requirements of Parts III and IX except that such persons shall comply with the provisions of 64E-5.328, 64E-5.343 and 64E-5.344.

(c) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium 90 in ice detection devices.

(d) This general license is subject to the provisions of 64E-5.103 through 64E-5.104, 64E-5.213, 64E-5.215 and Part XV.

(10) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

Specific Authority: 404.051, 404.061, 404.071, 404.081, F.S
Law Implemented: 404.022, 404.051(1),(4),(6),(8),(9),(10),(11), 404.061(2), 404.071(1),(3), 404.081(1), 404.141, F.S.
R6 History: New July 17, 1985, amended April 4, 1989, Amended January 1, 1994, Formerly 10D-91.306, Amended September
R8 28, 2006, Amended February 28, 2008.

SUBPART C
SPECIFIC LICENSES

64E-5.207 Filing Application for Specific Licenses.

R10 (1) An original and one copy of an application for specific licenses, license renewals, 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.

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

_____
Name of Manufacturer

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

_____
Name of Manufacturer

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine 125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Part III.

(9) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to general licensees under subsection 64E-5.206(9), F.A.C., will be approved if:

(a) The applicant satisfies the general requirements of Rule 64E-5.208, F.A.C.; and

(b) The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32, are met.

(10) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Part VI for the uses listed in Rules 64E-5.626,
R10 64E-5.627, 64E-5.630 and 64E-5.664, F.A.C. will be approved if:

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

(b) The applicant submits evidence that:

R3 1. The applicant is registered or licensed with the U.S. Food and Drug
R3 Administration as a drug manufacturer; or

R3 2. The applicant is registered or licensed as a drug manufacturer as
R3 specified in Chapter 499, F.S.; or

R3 3. The applicant has a nuclear pharmacy permit and only authorized
R3 nuclear pharmacists compound or dispense radiopharmaceuticals
R3 as specified in Section 465.0193, F.S.

(c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by
R3 medical use licensees;

R3 (d) The applicant satisfies the following labeling requirements:

R3 1. The label affixed to each transport radiation shield of any material
R3 of a radioactive drug transferred for commercial distribution
R3 includes the radiation symbol and the words “Caution, Radioactive
R3 Material” or “Danger, Radioactive Material”; the name of the
R3 radioactive drug or its abbreviation; and the quantity of the
R3 radioactive material at a specified date and time. The time can be
R3 omitted for radioactive drugs with a half life greater than 100 days.

R3 2. A label affixed to each syringe, vial, or other container used to hold
R3 a radioactive drug transferred for commercial distribution includes
R3 the words “Caution, Radioactive Material” or “Danger, Radioactive
R3 Material” and an identifier that correlates the syringe, vial, or other
R3 container with the information on the transport radiation shield
R3 label; and

R3 (e) A licensee shall possess and use instruments to measure the radioactivity
R3 of radioactive drugs. The licensee shall have procedures for use of the
R3 instruments. The licensee shall measure by direct measurements or by
R3 combination of measurements and calculations the amount of radioactivity
R3 in doses of alpha-emitting, beta-emitting, or photon-emitting radioactive
R3 drugs before transfer for commercial distribution. In addition, the licensee
R3 shall:

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

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

(11) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by
R10 persons licensed pursuant to Part VI for the uses listed in 64E-5.627 or
R10 Rule 64E-5.664, F.A.C., will be approved if:

(a) The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.;

(b). The applicant submits evidence that:

1. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or

2. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(d) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity and date of assay; and

(e) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

1. Adequate information pertaining to radiation safety on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the department pursuant to Part VI for uses listed in Rule 64E-5.627, F.A.C., or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing State. The labels, leaflets, or brochures required by this section are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA

(12) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.

(a) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant
R10 to Part VI for use as a calibration, transmission or reference source or for
R10 the uses listed in 64E-5.631, 64E-5.634, 64E-5.664 or 64E-5.632, F.A.C., will be approved if:

1. The applicant satisfies the general requirements in 64E-5.208;

2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

a. The radioactive material contained, its chemical and physical form, and amount,

b. Details of design and construction of the source or device,

c. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

d. For devices containing radioactive material, the radiation profile of a prototype device,

e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

f. Procedures and standards for calibrating sources and devices,

g. Legend and methods for labeling sources and devices as to their radioactive content, and

h. Instructions pertaining to radiation safety for handling and storing the source or device; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

1. U. S. Department of Health and Human Services Publication FDA 81-8025 June 1981, Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM), which is herein incorporated by reference and which is available from the department.

2. U. S. Nuclear Regulatory Commission Regulatory Guide 10.10 March 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations and Registration of Devices Containing By-product Material, which is herein incorporated by reference and which is available from the department

3. U. S. Nuclear Regulatory Commission Regulatory Guide 10.11 June 1987, Guide for the Preparation of Applications for Radiation Safety Evaluations of Sealed Sources Containing By-product Material, which is herein incorporated by reference and which is available from the department.

4. American National Standards Institute Standard N538, Classification of Industrial Ionizing Radiation Gauging Devices October 1979, which is herein incorporated by reference and which is available from the department.

5. American National Standards Institute Standard N540, Classification of Radioactive Self-Luminous Light Sources January 1976, which is herein incorporated by reference and which is available from the department.

6. American National Standards Institute Standard N432, Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography January 1980, which is herein incorporated by reference and which is available from the department.

7. American National Standards Institute Standard N542, Sealed Radioactive Sources Classification July 1978, which is herein incorporated by reference and which is available from the department.

(d) The licensee or applicant shall not distribute devices or products containing sealed sources unless the devices or sealed sources are manufactured and distributed in accordance with the registration and as authorized by a specific radioactive materials license issued by the department for such manufacture or distribution.

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

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

R10 Rulemaking Authority: 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
R7 Law Implemented: 404.022, 404.051, 404.061, 404.081, 404.141, F.S.
R3,R6-7 History:7-17-85, Amended 8-25-91, 5-12-93, 1-1-94, 5-15-96, Formerly 10D-91.311, Amended 8-6-01, 9-28-06, 8-16-07
R7,R10 2-28-08, Amended 02-11-10.

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

(1) An application for a license to

(2) receive title to, receive, possess and use source material for milling or by-product material as defined in Part I shall address the following:

(a) Description of the proposed project or action;

(b) Area or site characteristics including geology, topography, hydrology and meteorology;

(c) Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;

(d) Environmental effects of accidents;

(e) Long-term impacts including decommissioning, decontamination and reclamation; and

(f) Site and project alternatives.

(2) The applicant shall not commence construction of the project until the department has weighed the environmental, economic, technical and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

(3) At least 1 full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential longterm effects.

(4) Prior to issuance of the license, the applicant shall establish financial surety arrangements consistent with the requirements of 64E-5.217.

(b) Facilities for which one or more of the following applies:

1. The facilities are not contiguous;

2. The facilities are not under a single radiation safety program; or

3. The facilities are not under the same management.

R10 4. Temporary job sites lasting more than two years.

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

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

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

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

R1 (8) A licensee shall apply and receive a license amendment or department approval:

R1 (a) Before using radioactive material for a method or type or use not permitted
R1 by the license;

R1 (b) Before permitting anyone to use radioactive material as an authorized
R1 user as authorized by the license;

R1 (c) Before changing a radiation safety officer

R1 (d) Before ordering or receiving radioactive materials in excess of the amount
R1 authorized on the license

R1 (e) Before adding to or changing the areas of use or address or addresses of
R1 use identified in the application or on the license; and

R1 (f) Before changing statements, representations, and procedures which are
R1 incorporated into the license.

R10 Rulemaking Authority: 404.051, 404.061, 404.141F.S.
R1 Law Implemented: 404.051(1)(4), 404.061(2)(3), 404.081(1), 404.141, F.S.
R6 History: New 7-17-85, Amended 4-4-89, 5-12-93, 8-29-94, Formerly 10D-91.314, Amended 5-18-98., 9-28-06,
R10 Amended 02-11-10

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

(1) Except as provided in Part II, each specific license shall expire at the end of the
R1 specified day in the month and year stated therein. Each specific license
R1 revoked by the department expires at the end of the day on the date of the
R1 department's final order revoking the license or on the expiration date stated in
R1 the final order.

R1 (2) (a) Each licensee shall notify the department in writing within 60 days of the
R1 occurrence of any of the following and either begin decommissioning its
R1 site or any separate building or outdoor area that contains residual
R1 radioactivity so that the building or outdoor area is suitable for release as
R1 specified in these rules or send a notice of a decommissioning plan within
R1 12 months as specified in (4)(c) below and begin decommissioning upon
R1 approval of that plan.

R1 1. The license has expired as specified in (1), above.

R1 2. The licensee has ceased principal activities permanently at the
R1 entire site or in any separate building or outdoor area.

R1 3. The licensee has conducted no principal activities under the license
R1 for 24 months.

R1 4. The licensee has conducted no principal activities for 24 months in
R1 any separate building or outdoor area that contains residual
R1 radioactivity to the extent that the building or outdoor area is
R1 unsuitable for release as specified in these rules.

R1 (b) The notification and request for termination of the license shall include the
R1 reports and information specified in (4)(a)4. and 5., below.

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

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

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

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

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

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

SUBPART D
RECIPROCITY

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

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

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

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

(c) The out-of-state licensee complies with these applicable regulations and with all the terms and conditions of the licensing document, except any
R2 such terms and conditions that are inconsistent with these applicable regulations; and

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

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

2. Exempt from the requirements for a license for such material under
R2 Rule 64E-5.203(1)(a), F.A.C.

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

R10 (2) In addition to the provisions of subsection (1), above, any person who holds a
R10 specific license issued by the NRC, an agreement state, or a licensing state authorizing the holder to manufacture, transfer, install or service a device described in paragraph 64E-5.206(4)(a), F.A.C., within areas subject to the jurisdiction of the licensing body may be granted a general license by the department to install, transfer, demonstrate or service such a device in this State provided that:

(a) Such person shall file a report with the Department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of radioactive material contained in the device;

(b) The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State;

(c) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(d) The holder of the specific license shall furnish to each general licensee to whom he transfers such device, or on whose premises he installs such device, a copy of the general license contained in subsection 64E-5.206(4), F.A.C., or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(3) The Department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health, safety or property.

R10 Rulemaking Authority: 404.051(4),(11) 404.061(2), 404.081(1), 404.141, F.S.
Law Implemented: 404.051(1),(2),(4),(6),(11), 404.061(2), 404.081(1), F.S.
R10 History: New 7-17-85, Amended 4-4-89, Formerly 10D-91.321, Amended 10-8-00, 2-28-08, Amended 02-11-10.

PART III STANDARDS FOR PROTECTION

SUBPART A GENERAL PROVISIONS

SUBPART B RADIATION PROTECTION PROGRAMS

SUBPART C OCCUPATIONAL DOSE LIMITS

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SUBPART E SURVEYS AND MONITORING

SUBPART F CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

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

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SUBPART K RECORDS

SUBPART L REPORTS

(2) If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

(3) A licensee, registrant, or an applicant for a license or registration can apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 millisievert). This application shall include the following information:

(a) Demonstration of the need for and the expected duration of operations in excess of the limit in 64E-5.304(1);

(b) The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 millisievert) annual limit; and

(c) The procedures to be followed to maintain the dose ALARA.

(4) In addition to the requirements of this part, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

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

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

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

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

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

(1) The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in 64E-5.312.

(2) A licensee or registrant shall show compliance with the annual dose limit in 64E-5.312 by:

(a) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual who is likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(b) Demonstrating that:

1. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in State of Florida Bureau of Radiation Control ALIs, DACs and Effluent Concentrations, July 1993, Table II; and

2. The dose from external sources would not exceed 0.002 rem (0.02 millisievert) in an hour and 0.05 rem (0.5 millisievert) in a year if an individual were continually present in an unrestricted area.

(3) Upon approval from the department, the licensee can adjust the effluent concentration values in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, for members of the public to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

(4) Dental and podiatry registrants are exempt from (1), (2), and (3), above.

(5) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public until the department terminates each pertinent license or registration requiring the record.

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Amended November 20, 1994, Amended May 15, 1996, Formerly 10D-91.444.

SUBPART E
SURVEYS AND MONITORING

64E-5.314 General.

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

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

(b) Are necessary under the circumstances to evaluate:

R2 1. The magnitude and extent of radiation levels;

2. Concentrations or quantities of radioactive material; and

R2 3. The potential radiological hazards.

(2) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements such as dose rate and effluent monitoring are calibrated annually for the radiation measured.

(3) All personnel dosimeters except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 64E-5.304, with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

1. The licensee shall determine the fraction of the limit in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table III represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table III; and

2. The sum of the fractions for each radionuclide required by 64E-5.330(1)(c)1. does not exceed unity; and

(d) The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 5 curies (185 gigabecquerels) of hydrogen 3, 1 curie (37 gigabecquerels) of carbon 14, and 1 curie (37 gigabecquerels) of all other radioactive materials combined.

(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 64E-5.330(1).

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.463.

64E-5.331 Disposal of Specific Wastes.

(1) A licensee can dispose of the following licensed material without regard to its radioactivity:

(a) 0.05 microcurie (1.85 kBq) or less of hydrogen 3 or carbon 14 per gram of medium used for liquid scintillation counting;

(b) 0.05 microcurie (1.85 kBq) or less of hydrogen 3 or carbon 14 per gram of animal tissue, averaged over the weight of the entire animal.

(c) Any radioactive material which is not a sealed source with a physical half-
R10 life of less than 120 days if all of the following are met:

1. Radioactive material to be disposed is held for decay in storage a minimum of 10 half-lives;

2. The radioactive material is monitored at the container surface before disposal as ordinary trash and its radioactivity cannot be distinguished from the background radiation level in a low background radiation area with an appropriate radiation survey instrument set on its most sensitive scale and with no interposed shielding;

3. All radiation labels are removed or obliterated, unless specifically authorized in writing or license condition by the department;

4. Each generator column is separated and monitored individually with all radiation shielding removed to ensure that its contents have decayed to background levels before disposal; and

5. The licensee shall retain a record of each disposal for 3 years. The record shall include:

a. The date of the disposal;

b. The date on which the radioactive material was placed in storage;

c. The radionuclides disposed;

d. The model and serial number of the radiation survey instrument used;

e. The background dose rate;

f. The radiation dose rate measured at the surface of each container; and

g. The name of the individual who performed the disposal.

(2) A licensee shall not dispose of tissue as specified in 64E-5.331(1) in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee shall maintain records as specified in 64E-5.340.

R10 Rulemaking Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
R10 History: New1-1-94, Formerly 10D-91.465, Amended 02-11-10.

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

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

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

R2 2. A lens dose equivalent exceeding 15 rem (0.15 sievert); or

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

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

(3) The licensee or registrant shall prepare each report filed with the department as specified in Rule 64E-5.344, F.A.C., so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(4) Licensees or registrants shall make the reports required by subsections 64E-5.344(1) and (2), F.A.C., to the department by telephone, telegram, mailgram, or facsimile to the department.

(5) The provisions of Rule 64E-5.344, F.A.C., do not apply to doses that result from planned special exposures if such doses are within the limits for planned special exposures and are reported as specified in Rule 64E-5.346, F.A.C.

(6) Immediate notification. In addition to the other reporting requirements in these regulations, each licensee shall notify the department as soon as possible but not later than 4 hours after the discovery of an event, such as a fire, explosion, or toxic gas release, that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or to avoid releases of licensed material that could exceed regulatory limits.

(7) Twenty-four hour report. Each licensee shall notify the department within 24 hours after the discovery of any of the following events involving licensed material:

(a) An unplanned contamination event that:

1. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

2. Involves a quantity of material greater than five times the lowest annual limit on intake of materials as specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993; and

3. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(b) An event in which equipment is disabled or fails to function as designed when:

1. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposure to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

2. The equipment is required to be available and operable when it is disabled or fails to function; and

3. No redundant equipment is available and operable to perform the required safety function.

(c) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body;

(d) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed materials when:

1. The quantity of material involved is five times the lowest annual limit on intake for material specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993; and

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

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

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

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

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

(8) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(a) Licensees shall make reports required by subsections 64E-5.344(6) and (7), F.A.C., by telephone to the department. If the information is available at the time of notification, the information provided in these reports must include:

1. The caller's name and call back telephone number;

2. A description of the event, including date and time;

3. The exact location of the event;

4. The isotopes, quantities, and chemical and physical forms of the licensed material involved; and

5. Any personnel radiation exposure data available.

(b) Written report. Each licensee who makes a report required by subsections 64E-5.344(6) and (7), F.A.C., shall submit a written follow-up report within 30 days of the initial report. Written reports prepared as required by other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information. The reports must include the following:

1. A description of the event, including the probable cause and the manufacturer and model number of any equipment that failed or malfunctioned;

2. The exact location of the event;

3. The isotopes, quantities, and chemical and physical form of the licensed material involved;

4. Date and time of the event;

5. Corrective actions taken or planned and the results of any evaluations or assessments; and

6. The extent of exposure of individuals to radiation or to radioactive materials without identification of the individuals by name.

R10 Rulemaking Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
R10 History: New 1-1-94, Amended , 5-15-98, Formerly 10D-91.481, Amended 10-8-00, Amended 02-11-10.

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

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

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

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

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

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

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

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

5. Any applicable limit in the license or registration;

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

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

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

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

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

(2) Contents of Reports.

R2 (a) Each report required by subsection 64E-5.345(1), F.A.C., shall describe the extent of exposure of individuals to radiation and radioactive material, including as appropriate:

1. Estimates of each individual's dose;

2. The levels of radiation and concentrations of radioactive material involved;

3. The cause of the elevated exposures, dose rates, or concentrations; and

4. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable R2 limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.

R2 (b) Each report filed as specified in subsection 64E-5.345(1), F.A.C., shall R2 include for each occupationally overexposed individual: the name, social security account number, and date of birth. With respect to the limit for R2 the embryo or fetus in Rule 64E-5.311, F.A.C., the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(3) All licensees or registrants who make reports as specified in subsection 64E-5.345(1), F.A.C., shall submit the report in writing to the department.

R10 (4) Reports of Medical Events.

(a) The licensee or registrant shall notify the department by telephone no later R10 than the next calendar day after the discovery of the medical event. The licensee or registrant shall also notify the referring physician of the R2 affected individual and the individual or a responsible relative or guardian, unless the referring physician personally informs the licensee either that R2 he will inform the individual or believes, based on medical judgment, that R2 telling the individual or the individual's responsible relative or guardian would be harmful to either. These notifications shall be made within 24 R10 hours after the licensee or registrant discovers the medical event. If the R10 referring physician, individual or the individual's responsible relative or R2 guardian cannot be reached within 24 hours, the licensee or registrant shall notify them as soon as practicable. The licensee is not required to R2 notify the individual or the individual's responsible relative or guardian R2 without first consulting the referring physician; however, the licensee or registrant shall not delay medical care for the individual because of this. If R10 a verbal notification is made, the licensee shall inform the individual, or R10 appropriate responsible relative or guardian, that a written description of R10 the event can be obtained from the licensee upon request. The licensee R10 shall provide such a written description if requested.

R10 (b) Written Report. Within 15 days after the medical event report to the department, the licensee or registrant shall report in writing to the department and to the referring physician and furnish a copy of the report
R2 to the individual or the individual's responsible relative or guardian if either was previously notified by the licensee or registrant as specified in (4)(a), above, or a brief description of both event and consequences as they
R2 affect the individual or the individual's responsible relative or guardian if a statement is included that the report submitted to the department can be obtained from the licensee or registrant. The written report shall include the licensee's or registrant's name; the prescribing physician's name; the referring physician's name; a brief description of the event; why the event
R2 occurred; the effect on the individual; the action taken to prevent recurrence; whether the licensee or registrant informed the individual or
R2 the individual's responsible relative or guardian and what information was
R2 provided to the individual or individual's responsible relative or guardian, and if not, a written medical justification. The report shall not include the
R2 individual's name or other information that could lead to identification of
R2 the individual.

R10 (5) Records of medical event. Each licensee or registrant shall retain a record of
R10 each medical event for 20 years. The record shall contain the names of all individuals involved in the event, including the prescribing physician, the allied health personnel, the individual, and the individual's referring physician, the
R2 individual's identification number if one has been assigned, a brief description of
R2 the event, why it occurred, the effect on the individual, what improvements are
R2 needed to prevent recurrence, and the actions taken, if any, to prevent recurrence.

(6) Rights and Duties of Licensees or Registrants. Aside from the notification requirement, nothing in this section shall affect any rights or duties of licensees,
R2 registrants or physicians in relation to each other, the individual, or responsible relatives or guardians.

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

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

R10 (b) Written Report.

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

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

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

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

R10 Rulemaking Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
R10 History: New 1-1-94, Formerly 10D-91.482, Amended 10-8-00, Amended 02-11-10.

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

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.483.

64E-5.347 Notifications and Reports to Individuals.

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

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

Specific Authority: 404.051, 404.081, F.S.
R1 Law Implemented: 404.051(1)(4), 404.081, F.S.
R1 History: New January 1, 1994, Formerly 10D-91.484, Amended May 18, 1998.

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

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.485.

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

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.486.

PART VI USE OF RADIONUCLIDES IN THE HEALING ARTS

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PART VI

USE OF RADIONUCLIDES IN THE HEALING ARTS

64E-5.601 License Required.

(1) Radioactive materials shall not be manufactured, produced, acquired, received, possessed, prepared, used, or transferred for medical use except as provided in a specific license.

(2) Any licensee who is licensed for one or more of the medical uses in Rule 64E-5.626, 64E-5.627, 64E-5.630, or 64E-5.632, F.A.C., also is authorized to use radioactive material under a general license in subsection 64E-5.206(8), F.A.C., for specified in vitro uses without filing the certificate required by paragraph 64E-5.206(8)(b), F.A.C., but is subject to the other provisions of subsection 64E-5.206(8), F.A.C.

(3) (a) Unless prohibited by license condition, a physician in training may receive, possess, acquire, prepare, use, or transfer radioactive materials as provided in these regulations under the supervision of an authorized user as provided in subsections 64E-5.608(1) and 64E-5.608(3), F.A.C.

(b) Current and active certified radiologic technologists as authorized in Part IV Chapter 468, F.S., may receive, possess, acquire, prepare, use, or transfer radioactive materials as provided in these regulations under the supervision of an authorized user as provided in paragraph 64E-5.607(3)(e) and subsection 64E-5.608(3), F.A.C.

(c) Unless prohibited by license condition, a medical physicist in training may receive, acquire, prepare, use, possess, or transfer radioactive materials as provided in these regulations under the supervision of an authorized medical physicist as provided in subsections 64E-5.608(2) and 64E-5.608(3), F.A.C.

(4) Unless authorized by the department, no individual shall manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive materials for medical use unless:

(a) That individual is listed on the licensee's specific license as an authorized user, authorized medical physicist, or an authorized nuclear pharmacist;

(b) Authorized by Rule 64E-5.609, F.A.C.;

(c) Authorized by subsection 64E-5.601(2), F.A.C., with approval of the radiation safety committee at medical institutions or by management for licensees that are not medical institutions; or

(d) That individual is in training, authorized by subsection 64E-5.601(3), F.A.C., and subpart I of Part VI.

R10 (5) Provisions for the protection of human research subjects are:

R10 (a) A licensee may conduct research involving human research subjects only R10 if it uses the radioactive materials specified on its license for the uses R10 authorized on its license.

R10 (b) If the research is conducted, funded, supported, or regulated by another R10 federal agency that has implemented the **"**Federal Policy for the R10 Protection of Human Subjects (Federal Policy)", as described in 45 CFR R10 Part 46, dated 11/9/2009, which is herein incorporated by reference, and R10 may be accessed at http://www.doh.state.fl.us/environment/radiation/, or R10 requested in writing from the Department of Health, Bureau of Radiation R10 Control, Bin C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741, R10 the licensee shall, before conducting research:

R10 1. Obtain review and approval of the research from an "Institutional R10 Review Board (IRB)," as defined and described in the Federal R10 Policy; and

R10 2. Obtain "informed consent," as defined and described in the Federal R10 Policy, from the human research subject.

R10 (c) If the research will not be conducted, funded, supported, or regulated by R10 another federal agency that has implemented the Federal Policy, the R10 licensee shall, before conducting research, apply for and receive a specific R10 amendment to its radioactive materials medical use license. The R10 amendment request must include a written commitment that the licensee R10 will, before conducting research:

R10 1. Obtain review and approval of the research from an IRB as defined and R10 described in the Federal Policy; and

R10 2. Obtain "informed consent", as defined and described in the Federal R10 Policy, from the human research subject.

R10 (d) Nothing in this section relieves licensees from complying with the other R10 requirements in this part.

R10 (6) Authorized nuclear pharmacists must be actively licensed as a nuclear R10 pharmacist by the Department of Health, Division of Medical Quality Assurance R10 as specified in Rule 64B16-28.903, F.A.C., and authorized medical physicists R10 must have an active medical physicist license**,** in the area they are practicing, R10 issued by the Department of Health, Division of Medical Quality Assurance.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.707, Amended 8-6-01, Amended 02-11-10.

64E-5.6011 Definitions. (Entire section New)

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

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

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

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

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

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

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

(2) "Authorized user" means:

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

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

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

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

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

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

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

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

(5) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method by which the licensee shall perform diagnostic clinical procedures, and provides other instructions and precautions related thereto. Each diagnostic clinical procedure shall be approved by the authorized user and shall include the radiopharmaceutical, dosage, and route of administration.

(6) "High dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(7) "Low dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

(8) "Manual brachytherapy," as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually delivered.

(9) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or humans research subjects under the supervision of an authorized user.

(10) "Medium dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(11) "Mobile medical service" means the ability to transport and use radioactive materials for medical use at the client's address.

(12) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(13) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user under Chapter 64E-5, Part VI, F.A.C., an authorized medical physicist, an authorized nuclear pharmacist or a RSO under Chapter 64E-5 Part VI, F.A.C.

(14) "Pulsed dose-rate remote afterloader," as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, provided that the source is:

(a) Approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(b) Used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

R10 (15) "Radiation Safety Officer" or "RSO" means an individual who:

R10 (a) Meets the requirements in subsection 64E-5.648(1) or paragraph
R10 64E-5.648(3)(a) and Rule 64E-5.658, F.A.C.; or

R10 (b) Is identified as a RSO on a specific medical use license issued by the
R10 NRC or an agreement state or a medical use permit issued by a NRC master material licensee.

R10 (16) "Teletherapy physicist" means an individual identified as the qualified teletherapy
R10 physicist on a department license.

R10 (17) "Therapeutic dosage" means a dosage of unsealed radioactive materials that is
R10 intended to deliver a radiation dose to a patient or human research subject for
R10 palliative or curative treatment.

R10 (18) "Therapeutic dose" means a radiation dose delivered from a source containing
R10 radioactive materials to a patient or human research subject for palliative or
R10 curative treatment.

R10 (19) "Treatment site" means the anatomical description of the tissue intended to
R10 receive a radiation dose, as described in a written directive.

R10 (20) "Unit dosage" means a dosage prepared for medical use for administration as a
R10 single dosage to a patient or human research subject without any further
R10 manipulation of the dosage after it is initially prepared.

R10 Rulemaking Authority: 404.051, 404.061.
R10 Law Implemented: 404.031, 404.061(2), 404.20, 404.22, 404.30 FS.
R10 History: New 02-11-10.

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

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

R10 (2) Before permitting anyone, except a visiting authorized user, visiting authorized
R10 medical physicist, or visiting authorized nuclear pharmacist described in Rule
R10 64E-5.609, F.A.C., to work as an authorized user, authorized nuclear pharmacist,
R10 or authorized medical physicist.

R10 (3) Before changing a RSO or authorized medical physicist;

R10 (4) Before ordering or receiving radioactive material in excess of the amount, in a
R10 different form, or receiving a different radionuclide than is authorized on the license;

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

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

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1) (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.708, Amended 02-11-10.

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

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.709, Amended August 6, 2001, Amended 02-11-10.

SUBPART A

GENERAL ADMINISTRATIVE REQUIREMENTS

64E-5.604 ALARA Program.

(1) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable as provided in Rule 64E-5.303, F.A.C.

(2) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the radiation safety committee.

R10 (3) For licensees that are not required to have a radiation safety committee, medical institutions, management and all authorized users shall participate in the program
R10 as required by the RSO.

(4) The ALARA program shall include an annual review by the radiation safety
R10 committee for medical licensees required to have a radiation safety committee, or
R10 by management and the RSO for licensees that are not required to have a
R10 radiation safety committee. The review shall include summaries of the types, amounts and purposes of radioactive material used; occupational dose reports; and continuing education and training of all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology and the cost of improvements in relation to benefits.

(5) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(a) A commitment by management to keep occupational doses as low as reasonably achievable;

(b) A requirement that the radiation safety officer annually report to management in writing on the radiation safety program; and

(c) Categories of personnel exposure levels that, when exceeded, will initiate investigation by the radiation safety officer of the cause of the exposure and actions taken to reduce the probability of recurrence.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.710, Amended 02-11-10.

64E-5.605 Radiation Safety Officer.

R10 (1) A licensee shall appoint a RSO who agrees in writing to be responsible for
R10 implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are performed with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive materials program.

(2) The radiation safety officer shall promptly investigate and implement corrective actions as necessary regarding:

(a) Overexposures;

(b) Accidents;

(c) Spills;

(d) Losses;

(e) Thefts;

(f) Unauthorized receipts, uses, transfers, and disposals; and

(g) Other deviations from approved radiation safety practice. A written report of these investigations and the corrective actions taken shall be given to management.

(3) The radiation safety officer shall implement written policies and procedures to:

(a) Authorize the purchase of radioactive material;

(b) Receive and open packages of radioactive material;

(c) Store radioactive material;

(d) Keep an inventory record of radioactive material;

(e) Use radioactive material safely;

(f) Take emergency action if control of radioactive material is lost;

(g) Perform periodic radiation surveys;

(h) Perform checks of survey instruments and other safety equipment;

(i) Dispose of radioactive material;

(j) Train personnel who work in or frequent areas where radioactive material is used or stored; and

(k) Keep a copy of all records and reports required by department regulations, a copy of these regulations, a copy of each licensing request and license including amendments, and the written policies and procedures required by the regulations.

(4) The radiation safety officer shall approve radiation safety program changes for medical use not at a medical institution with the consent of management prior to sending to the department for licensing action.

(5) The radiation safety officer shall assist the radiation safety committee for medical use at a medical institution.

R10 (6) The RSO shall review, sign and date, at least every 3 months the occupational radiation exposure records of all personnel working with radioactive material.

R10 (7) The licensee shall retain a copy of both authority, duties, and responsibilities of
R10 the RSO and a signed copy of each RSO's agreement to be responsible for
R10 implementing the radiation safety program for the duration of the license. The
R10 records must include the signature of the RSO and licensee management.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.711, Amended 02-11-10.

R10 **64E-5.606 Radiation Safety Committee.**

R10 (1) Each license listed below shall establish a radiation safety committee to oversee the use of radioactive materials;

R10 (a) Medical institutions as defined in Rule 64E-5.101, F.A.C.; or

R10 (b) Other licenses authorized for any of the following medical uses:

R10 1. Subsection 64E-5.627(2), F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

R10 2. Subsection 64E-5.627(3), F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

R10 3. Subsection 64E-5.627(4), F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

R10 4. Any subsection of Rule 64E-5.630, F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

R10 5. Subsections 64E-5.634(1) and 64E-5.634(2), F.A.C.;

R10 6. Subsections 64E-5.634(1) and 64E-5.634(3), F.A.C.; or

R10 7. Subsections 64E-5.634(2) and 64E-5.634(3), F.A.C.

R10 (2) Membership of the radiation safety committee shall include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. Other members who are experienced in the assay of radioactive material and protection against radiation, such as an authorized medical physicist or a nuclear medicine technologist employed by or working under contract with the institution may be included as appropriate.

R10 (3) The committee shall meet at least every 6 months. To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the RSO, or designee and the management representative, or designee.

R10 (4) The minutes of each radiation safety committee meeting shall include:

(a) The date of the meeting;

(b) Members present;

(c) Members absent;

(d) Summary of deliberations and discussions;

(e) Recommended actions and the numerical results of all ballots; and

(f) Documentation of any reviews required in Rules 64E-5.604 and 64E-5.606, F.A.C.

R10 (5) The committee shall provide each member with a copy of the meeting minutes and shall retain a copy for 5 years or until the department authorizes its disposition.

R10 (6) The committee shall be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable.

R10 (7) The committee shall review and approve any individual to be an authorized user,
R10 an authorized nuclear pharmacist, the RSO, or an authorized medical physicist based on safety and the training and experience standards of this part before sending a license application or request for amendment or renewal.

R10 (8) The committee shall review and approve each proposed method of use of radioactive material based on safety.

R10 (9) The committee shall review and approve procedures and radiation safety
R10 program changes based on safety and with the advice of the RSO and the management representative prior to sending to the department for licensing action.

R10 (10) The committee shall review occupational radiation exposure records of all personnel working with radioactive material and all incidents involving radioactive
R10 material at least every 6 months, with the assistance of the RSO, to determine cause and review subsequent actions taken.

R10 (11) The committee shall review the radioactive materials program at least every
R10 12 months with the assistance of the RSO as described in subsection 64E-5.604(4), F.A.C.

R10 (12) The committee shall establish levels for occupational dose that will result in
R10 investigations and considerations of action by the RSO when exceeded.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.712, Amended 8-6-01, Amended 02-11-10.

64E-5.607 Authority and Responsibilities.

(1) A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:

(a) Identify radiation safety problems;

(b) Initiate, recommend, or provide solutions; and

(c) Require and verify implementation of corrective actions.

(2) A licensee shall establish in writing and keep current the authority, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.

(3) Authorized users shall have the following special responsibilities:

R10 (a) For written directives;

R10 1. A written directive must be dated and signed by an authorized user
R10 before the administration of I-131 as sodium iodide greater than
R10 1.11 megabecquerels (MBq) (30 microcuries ([micro]Ci)), any
R10 therapeutic dosage of unsealed radioactive material or any
R10 therapeutic dose of radiation from material; or

R10 2. Due to the emergent nature of the patient's condition, a delay in
R10 order to provide a written directive would jeopardize the patient's
R10 health, an oral directive is acceptable provided:

R10 a. The information contained in the oral directive must be
R10 documented as soon as possible in writing in the patient's
R10 record; and

R10 b. A written directive must be prepared within 48 hours of the
R10 oral directive.

R10 3. The written directive must contain the patient or human research
R10 subject's name and the following information:

R10 a. For any administration of quantities greater than 1.11 MBq
R10 (30 [micro]Ci) of sodium iodide I-131: the dosage;

R10 b. For an administration of a therapeutic dosage of unsealed
R10 radioactive material other than sodium iodide I-131: the
R10 radioactive drug, dosage, and route of administration;

R10 c. For gamma stereotactic radiosurgery: the total dose,
R10 treatment site, and values for the target coordinate settings
R10 per treatment for each anatomically distinct treatment site;

R10 d. For teletherapy: the total dose, dose per fraction, number of
R10 fractions, and treatment site;

R10 e. For high dose-rate remote afterloading brachytherapy: the
R10 radionuclide, treatment site, dose per fraction, number of
R10 fractions, and total dose; and

R10 f. For all other brachytherapy;

R10 (I) Before implantation: treatment site, the radionuclide,
R10 and dose; and

R10 (II) After implantation but before completion of the
R10 procedure: the radionuclide, treatment site, number of
R10 sources, and total source strength and exposure time
R10 (or the total dose).

R10 4. A written revision to an existing written directive may be made if the
R10 revision is dated and signed by an authorized user before the
R10 administration of the dosage of unsealed radioactive material, the
R10 brachytherapy dose, high dose remote afterloader dose, the
R10 gamma stereotactic radiosurgery dose, the teletherapy dose, or the
R10 next fractional dose; or

R10 5. Due to the emergent nature of the patient's condition, a delay in
R10 order to provide a written directive would jeopardize the patient's
R10 health, an oral directive is acceptable provided:

R10 a. The information contained in the oral directive must be
R10 documented as soon as possible in the patient's record; and

R10 b. A written directive must be prepared within 48 hours of the
R10 oral directive.

(b) Review personally the patient's case to assure that the therapeutic radiation procedure is appropriate;

R10 (c) Review personally the patient's case or develop and implement adequate
R10 written procedures to assure that the diagnostic radiation procedure is
R10 appropriate.

R10 (d) Prior to administration, the authorized user must document deviations
R10 from the diagnostic clinical procedures manual for each patient.

(e) Use radioactive material or direct technologists and physicians in training in using radioactive material;

(f) Interpret results of diagnostic procedures; and

(g) Review regularly the progress of the patient receiving therapy and modify the originally prescribed dose if needed.

R10 (4) The licensee shall retain a copy of the written directives specified in paragraph
R10 64E-5.607(3)(a), F.A.C., for three years.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.713, Amended 02-11-10.

64E-5.608 Supervision. (Entire section Changed)

R10 (1) Supervision of a physician in training to become an authorized user:

R10 (a) A licensee who permits the receipt, acquisition, possession, use, preparation, or transfer of radioactive material by a physician in training under the supervision of an authorized user as allowed by paragraph 64E-5.601(3)(a), F.A.C., shall:

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

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

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

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

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

R10 (b) A licensee shall require the supervised individual receiving, possessing, acquiring, preparing, using or transferring radioactive material specified in paragraph 64E-5.601(3)(a), F.A.C., to:

R10 1. Follow the instructions of the supervising authorized user;

R10 2. Follow the written radiation and quality management program procedures established by the licensee; and

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

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

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

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

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

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

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

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

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

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

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

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

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

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.714, Amended 02-11-10.

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

(1) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(a) The licensee has a copy of a license issued by the department, the NRC, or an agreement state that identifies the visiting authorized user by name as an authorized user for medical use; and

(b) The visiting authorized user performs only those procedures for which he is specifically authorized by the license described in paragraph 64E-5.609(1)(b), F.A.C., above.

(2) For up to 60 days each year, a licensee may permit an authorized medical physicist or an individual qualified under Rules 64E-5.656 and 64E-5.658, F.A.C., to function as a visiting authorized medical physicist as authorized by the license.

(3) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a RSO, under Rules 64E-5.648 and 64E-5.658, F.A.C., to function as a visiting RSO and to perform the functions of a RSO, as provided in Rule 64E-5.605 and subsection 64E-5.607(1), F.A.C.

(4) A license amendment is not needed to permit a visiting authorized user, visiting authorized medical physicist, or visiting RSO to use licensed material or perform functions in accordance with this section.

(5) The visiting authorized user, visiting authorized medical physicist, or visiting RSO shall have the prior written permission of the licensee's management and, if the use or function occurs on behalf of a medical institution, the institution's radiation safety committee.

(6) Licensee records shall include a copy of the record described in Rule 64E-5.657, F.A.C., or some other form of documentation that verifies the individual has met the perspective training and experience requirements listed in Subpart I. A licensee shall retain copies of the records specified in Rule 64E-5.609, F.A.C., for 3 years after the last visit.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.715, Amended 02-11-10.

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

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

(2) Mobile medical service licensees shall secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use.

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

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

(5) Mobile medical service licensees shall retain a record of each survey required for 3 years. The record must include the date of the survey, a diagram of each area that was surveyed, the measured dose rate at several points in each area of use in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

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

(7) Radioactive material will be received at the permanent location of the mobile medical service or delivered directly to an authorized individual in the vehicle at a place of use. A mobile medical service may not have radioactive materials delivered from the manufacturer or the distributor to the client unless the client has a radioactive materials license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

(8) Restrooms contained in mobile vehicles shall not routinely be used by patients who have been administered radioactive material.

(9) Radioactive gases or aerosols shall not be used by mobile medical service licenses.

(10) Prior to administration, the mobile medical service licensee shall assure that individuals or human research subjects meet the patient release criteria specified in Rule 64E-5.622, F.A.C.

(11) A licensee authorized to use mobile remote afterloaders for medical use shall follow the requirements specified in Rule 64E-5.6423, F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New8-25-91, Formerly 10D-91.716, Amended 02-11-10.

64E-5.611 Quality Management Program and Notifications, Records and Reports of Medical Events.

(1) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide a high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following objectives:

(a) Except where a delay to provide a written directive would jeopardize the patient's health as specified in paragraphs (b) and (c) of this section, a written directive is prepared prior to administration for the following:

1. Any teletherapy radiation dose;

2. Any gamma stereotactic radiosurgery radiation dose;

3. Any brachytherapy radiation dose;

4. Any administration of iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels);

5. Any therapeutic administration of a radiopharmaceutical other than iodine 131 as sodium iodide; or

6. Any high dose rate remote afterloader radiation dose.

(b) An oral directive is acceptable when a delay to provide a written directive would jeopardize the patient's health because of the emergent nature of the patient's condition. The information contained in the oral directive must be documented immediately in the patient's record and a written
R10 directive prepared within 48 hours of the oral directive.

(c) An oral revision to an existing written directive is acceptable when a delay to provide a written revision to an existing written directive would jeopardize the patient's health. The oral revision must be documented immediately in the patient's record and a revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) A written directive which changes an existing written directive can be made for any diagnostic or therapeutic procedure if the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma
R10 stereotactic radiosurgery dose, high dose rate remote afterloader dose,
R10 the teletherapy dose, or the next fractional dose.

R10 (e) The patient's or human research subject's identity is verified by more than one method as the individual named in the written directive prior to administration;

R10 (f) The final plans of treatment and related dose calculations, manually or
R10 computer generated, for brachytherapy, teletherapy, high dose rate
R10 remote afterloader, and gamma stereotactic radiosurgery agree with the respective written directives:

R10 (g) Verify that any computer-generated calculations are correctly transferred
R10 into the consoles of therapeutic medical units authorized by
R10 Rule 64E-5.634, F.A.C.;

R10 (h) Each administration agrees with the written directive; and

R10 (i) Any unintended deviation from the written directive is identified and
R10 evaluated and appropriate action is taken.

(2) The licensee shall develop procedures for and conduct a review of the quality management program including an evaluation of the following:

(a) A representative sample of patient administrations within the review period;

(b) All recordable events within the review period; and

R10 (c) All medical events within the review period to verify compliance with all aspects of the quality management program.

(3) The review of the quality management program specified in (2) above shall be conducted at intervals not to exceed 12 months. A record of each review shall be maintained for inspection by the department in an auditable form for 3 years and shall include evaluations and findings of the review.

(4) The licensee shall evaluate each of these reviews to determine the effectiveness of the quality management program and make modifications to meet the objectives in subsection 64E-5.611(1), F.A.C.

(5) Within 30 days of discovery of each recordable event, the licensee shall:

(a) Assemble the relevant facts including the cause;

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

(c) Retain a record in an auditable form for 3 years of the relevant facts and any corrective action taken.

(6) The licensee shall retain in an auditable form for 3 years each written directive and a record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required by subsection 64E-5.611(1), F.A.C.

R10 (7) Each applicant for a new license shall submit to the department a quality management program as part of the application for a license and implement the program upon issuance of the license by the department.

R10 (8) Each licensee shall maintain copies of the quality management program for the
R10 duration of the license.

R10 (9) Each licensee shall submit and maintain records and reports of medical events as required by subsections 64E-5.345(4) and (5), F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.717, Amended 02-11-10.

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

(1) Radioactive material manufactured, labeled, packaged, and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission;

(2) Generators and reagent kits that have been manufactured, labeled, packaged, and distributed as specified in an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration unless the kits are not subject to the Federal Food, Drug, and Cosmetics Act and the Public Health Services Act.

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

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

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

R10 (b) Noncommercially transferred from a medical use licensee authorized by
R10 Chapter 64E-5, Part VI, F.A.C., or equivalent medical use license issued
R10 by another agreement state or the NRC.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.718, Amended 02-11-10.

SUBPART B
GENERAL TECHNICAL REQUIREMENTS

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

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-9191, Amended 5-13-93, Formerly 10D-91.719.

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

(1) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity
R10 administered to each patient or human research subject.

R10 (2) A licensee shall check each dose calibrator before use each day of use, or during
R10 an assigned shift for facilities operating continuously, for constancy with a dedicated check source. The check shall be performed on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium 226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days. A record shall be made of each check, which shall include:

(a) The model and serial number of the dose calibrator;

(b) The identity and decay corrected activity of the radionuclide contained in the check source;

(c) The date of the check;

(d) The activity measured;

(e) The percent error;

(f) The instrument settings; and

(g) The initials of the individual who performed the check.

(3) The licensee shall test each dose calibrator for accuracy at the time of installation and at least every 12 months. The test shall be completed by assaying at least two sealed sources containing different radionuclides, the activity of which has been determined by the National Institute of Standards and Technology (NIST) or
R10 by the manufacturer who has compared their source to a source calibrated by the
R10 NIST. The sources shall have a minimum activity of 10 microcuries (370 kBq) for radium 226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide. At least one of the sources shall have a principal photon energy between 100 kilo-electron volts and 500 kiloelectron volts. A record shall be made of each test, which shall include:

(a) The model and serial number of the dose calibrator;

(b) The model and serial number of each source used and the identity of the radionuclide contained in the source and its activity;

(c) The date of the test;

(d) The results of the test;

(e) The instrument settings; and

R10 (f) The name of the individual performing this test.

(4) The licensee shall test each dose calibrator for linearity at the time of installation and at least every 3 months over the range of use between 10 microcuries (370 kBq) and the highest dosage that will be administered. A record shall be made of each test, which shall include:

(a) The model and serial number of the dose calibrator;

(b) The calculated activities;

(c) The measured activities;

(d) The date of the test; and

R10 (e) The name of the individual performing this test.

(5) The licensee shall test each dose calibrator for geometry dependence at the time of installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator. A record shall be made of each test, which shall include:

(a) The model and serial number of the dose calibrator;

(b) The configuration of the source measured;

(c) The activity measured and the instrument setting for each volume measured;

(d) The date of the test; and

R10 (e) The name of the individual performing this test.

(6) A licensee shall correct mathematically dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(7) A licensee shall also perform checks and tests required by Rule 64E-5.614, F.A.C., following adjustment or repair of the dose calibrator.

(8) A licensee shall retain a record of each check and test required by Rule 64E-5.614, F.A.C., for 3 years.

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

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.720, Amended 02-11-10.

R10 **64E-5.615 Use, Calibration and Check of Survey Instruments.** A licensee shall R10 ensure that the survey instruments used to comply with this part have been calibrated before R10 first use, at least every 12 months, and after repair.

R10 (1) A record shall be made of each calibration, which shall include:

(a) A description of the source used;

(b) The certified dose rates from the source;

(c) The rates indicated by the instrument being calibrated;

(d) The correction factors deduced from the calibration data;

R10 (e) The name of the individual who performed the calibration;

(f) The date of calibration.

R10 (g) The model number and serial number of the instrument being calibrated; R10 and

R10 (h) The results of the calibration.

(2) The licensee shall:

(a) Calibrate all required scale readings up to 1,000 millirems (10 mSv) per hour with a radiation source;

(b) Calibrate each linear scale instrument at two points located approximately 1/3 and 2/3 of full-scale, calibrate each logarithmic scale instrument at midrange of each decade and at two points of at least one decade, and calibrate each digital instrument at appropriate points; and

R10 (c) Conspicuously note on the instrument the date of calibration.

(3) The licensee shall:

(a) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(b) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent and a correction chart or graph is attached conspicuously to the instrument.

(4) A licensee shall check each survey instrument for proper operation with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(5) The licensee shall retain a record of each calibration required in subsection 64E-5.615(1), F.A.C., for 3 years.

(6) The licensee may use persons licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations required by subsection 64E-5.615(1), F.A.C., shall be maintained by the licensee.

(7) A licensee authorized to use radioactive material for uptake, dilution, and excretion studies or sealed sources for diagnostic purposes shall possess a portable radiation survey instrument with a range from 0.1 millirem (1.0 μSv) per
R10 hour to at least 1,000 millirem (10 mSv) per hour.

(8) A licensee authorized to use radioactive material for imaging and localization studies, radiopharmaceutical therapy or implant therapy shall possess portable radiation survey instruments with a range from 0.1 millirem (1.0 μSv) per hour to
R10 at least 1,000 millirem (10 mSv) per hour.

R10 (9) A licensee authorized to use radioactive material in Rule 64E-5.634, F.A.C., shall possess a radiation survey instrument as described in subsection (7) or (8), above.

R10 (10) The licensee shall not use survey instruments if the difference between the
R10 indicated exposure rate and the calculated exposure rate is more than 20
R10 percent.

R10 (11) A licensee may calibrate instrumentation used in Rule 64E-5.615, F.A.C., using
R10 nationally recognized standards or the manufacturer's instructions. The
R10 standards or instructions used by the licensee must be available for inspection by
R10 the department

R10 Rulemaking Authority: 404.051, 404.061 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.
R10 History: New 8-2591, Amended 5-15-96, Formerly 10D-91.721, Amended 02-11-10.

64E-5.616 Determination of Dosages of Unsealed Radioactive Material for Medical Use.

(1) The licensee shall determine by assay or direct measurement within 30 minutes before each radiopharmaceutical dosage and record the activity of each dosage before medical use. A record of the assay shall be made which shall include:

(a) The generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number; expiration date; and the radionuclide;

(b) The patient's or human research subject's name or identification number if one has been assigned;

(c) The prescribed dosage and activity of the dosage at the time of assay or a notation that the total activity assayed is less than 10 microcuries (370 kBq);

(d) The date and time of the assay and administration; and

(e) The name of the individual who performed the assay.

(2) Unless directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(3) A licensee shall retain a record of the assays listed in Rule 64E-5.616, F.A.C., for 3 years.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.722, Amended 02-11-10.

64E-5.617 Authorization for Calibration, Transmission and Reference Sources.

Any person authorized by Rule 64E-5.601, F.A.C., for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission and reference use:

(1) Sealed sources that:

(a) Do not exceed 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed by the department, the NRC, an agreement state; or

(b) Do not exceed 1.11 GBq (30 mCi) each, which are redistributed by a licensee that is authorized to redistribute sealed sources that are manufactured and distributed by a person licensed by the department, the NRC, or an agreement state, provided the redistributed sealed sources are in the original packaging and shielding, and are accompanied by the manufacturer's approved instructions;

(2) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 15 millicuries (555 MBq) each;

R10 (3) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and

R10 (4) Unless approved by the department, the maximum possession limit of radioactive
R10 materials described in subsections 64E-5.617(1), (2) and (3), F.A.C., above, shall
R10 not exceed a combined activity of 1 curie (37 GBq), This includes radioactive
R10 materials as waste in storage.

R10 (5) Unless approved by the department, the maximum possession limit for
R10 Technetium 99m in individual amounts shall not exceed 300 millicuries
R10 (11.1 GBq) each and a combined activity of 900 millicuries (33.3 GBq).

R10 Rulemaking Authority: 404.051, 404.061, 404.141, F.S.
R1 Law Implemented: 404.051(1)(4)(6)(10), 404.061(2), 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.723, Amended 5-18-98, Amended 02-11-10.

64E-5.618 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee who possesses any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the department and shall maintain the instructions for the duration of source use in a legible form and convenient to users.

(2) A licensee in possession of a sealed source shall assure that:

(a) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(b) The source is tested for leakage at least every 6 months or at intervals approved by the department, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

(c) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample, or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) each 24 hours;

(d) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(e) Teletherapy and other device source samples are taken when the source is in the off position.

(f) Leak tests are analyzed by individuals who are licensed by the department, U.S. Nuclear Regulatory Commission, an agreement state or licensing state to perform leak test services.

(3) A licensee shall retain leak test records for 3 years. The records shall contain the model number and serial number if assigned of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), the date of
R10 the test, and the name of the individual who performed the test analysis.

(4) If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(a) Immediately withdraw the sealed source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with these regulations; and

R10 (b) File a written report with the department within 5 days of receiving the leak test results describing the equipment involved, the test results, the action
R10 taken, the model number and serial number or the leaking source if
R10 assigned, the radioisotope and its estimated activity, and the date of the
R10 test.

(5) A leak test is not required on the following sources:

(a) Sources containing only radioactive material with a half-life of less than 30 days;

(b) Sources containing only radioactive material as a gas;

(c) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; and

(d) Seeds of iridium 192 encased in nylon ribbon.

(6) Leak tests are not required on calibration and reference sources stored and not being used. The licensee shall, however, clearly indicate on the inventory records that these sources are for storage only and the date placed in storage. The licensee shall test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

(7) Leak tests are not required on brachytherapy and teletherapy sources that are listed on a department license for storage only. The licensee shall test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

R10 (8) A licensee who possesses sealed sources or brachytherapy sources, except
R10 gamma stereotactic radiosurgery sources, shall conduct a physical inventory of
R10 all such sources at intervals not to exceed six months. The licensee shall retain each inventory record for 3 years. The inventory records shall contain the model number of each source and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each
R10 source, the date of the inventory, and the name of the individual who performed
R10 the inventory.

(9) A licensee who possesses a sealed source or brachytherapy source shall survey all areas where such sources are stored with a radiation survey instrument at least every 3 months. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(10) A licensee shall retain a record of each survey required in subsection 64E-5.618(9), F.A.C., for 3 years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the
R10 survey, and the name of the individual who performed the survey.

R10 (11) Sealed sources designated as radioactive waste and held for decay in storage as
R10 in Rule 64E-5.624, F.A.C., are not required to be leak tested or inventoried as
R10 required by this section.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.724, Amended 02-11-10.

64E-5.619 Syringe Shields and Labels.

(1) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield. Each individual who prepares or administers radiopharmaceuticals shall use a syringe radiation shield unless the use of the shield is contraindicated for that patient.

(2) Unless used immediately, a licensee shall label conspicuously each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical with the patient's name or the radiopharmaceutical name or its abbreviation and the type of diagnostic study or therapy procedure to be performed.

Specific Authority: 404.051, 404.061, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.725.

64E-5.620 Vial Shields and Labels. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield and conspicuously label each vial with the radiopharmaceutical name or its abbreviation.

Specific Authority: 404.022, 404.051, 404.061, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.727.

64E-5.621 Surveys for Contamination and Ambient Radiation Dose Rate.

(1) A licensee shall survey with a radiation survey instrument at the end of each day
R10 of use, or during an assigned shift for facilities operating continuously, all areas where radiopharmaceuticals are routinely prepared for use or administered.

(2) A licensee shall survey all areas where radiopharmaceuticals or radioactive wastes are stored with a radiation survey instrument at least once each week.

(3) A licensee shall conduct the surveys required by subsections 64E-5.621(1) and (2), F.A.C., with an instrument capable of measuring dose rates as low as 0.1 millirem (1 µSv) per hour.

(4) A licensee shall establish dose rate action levels for the surveys required by subsections 64E-5.621(1) and (2), F.A.C., and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

(5) A licensee shall perform a wipe survey for removable contamination weekly of all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.

(6) A licensee shall analyze the wipe surveys required by subsection 64E-5.621(5), F.A.C., with an instrument capable of detecting contamination of 2,000 disintegrations per minute (33.3 Bq) or shall monitor each wipe sample in a low background area with a radiation survey instrument using a probe with a maximum window thickness of 2.0 mg/cm^2 and a minimum probe diameter of 1.5 inches.

(7) A licensee shall establish removable contamination action levels for the wipe surveys required by subsection 64E-5.621(5), F.A.C., and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

(8) A licensee shall retain a record of each survey required by subsection subsections 64E-5.621(1), (2), and (5), F.A.C., for 3 years. The record shall include:

(a) The date of the survey;

R10 (b) A diagram of each area surveyed;

(c) Action levels established for each area;

(d) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, or counts per minute if performed with a radiation survey instrument as described in subsection 64E-5.621(6), F.A.C.;

(e) The serial number and the model number of the instrument used to make the survey or analyze the samples; and

R10 (f) The name of the person who performed the survey.

R10 (9) The licensee does not need to perform the radiation surveys in subsection
R10 64E-5.621(1) or (2), F.A.C., in areas where patients or human research subjects
R10 are currently confined when such patients or subjects cannot be released under
R10 Rule 54E-5.622, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 04.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.729, Amended 02-11-10.

R10 **64E-5.622 Release of Patients or Human Research Subjects Treated with**
R10 **Radiopharmaceuticals, Implants or Remote Afterloader Units.**

R2 (1) Except as authorized by subsection 64E-5.622(4), F.A.C., a licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:

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

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

R2 (2) Except as authorized by subsection 64E-5.622(4), F.A.C., a licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 5 millirems (50 µSv) per hour at a distance of 1 meter.

(3) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation survey instrument to confirm that all sources have been removed. The licensee shall not release a patient treated by temporary implant from confinement for medical care until all sources have been removed.

R2 (4) Licensees and license applicants whose proposed procedures to release
R2 individuals who have been administered radiopharmaceuticals or permanent
R2 implants containing radioactive material from the control of licensees differ from
R2 those specified in subsections (1) and (2), above, must submit their proposed
R2 procedures to the department for approval. The procedures must:

R2 (a) Demonstrate that the total effective dose equivalent to any other individual
R2 from exposure to the released individual is not likely to exceed 500
R2 millirem (5 µSv);

R2 (b) Contain a copy of the instructions including written instructions to be given
R10 to the released individual, or the individual's parent or guardian, on
R2 actions recommended to maintain doses to other individuals as low as is
R2 reasonably achievable if the total effective dose equivalent to another
R2 individual is likely to exceed 100 millirem (1 µSv). If the dose to a breast-
R2 feeding infant or child could exceed 100 millirem (1 µSv) if there were no
R2 interruption of breast-feeding, the instructions also shall include:

R2 1. Guidance on the interruption or discontinuance of breast-feeding
R2 and

R2 2 Information on the consequences of failing to follow the guidance.

R2 (c) Specify that the licensee shall maintain a record of the basis for
R2 authorizing the release of an individual from their control who has been
R2 administered radiopharmaceuticals or permanent implants containing
R2 radioactive material for 3 years after the date of release.

R2 (5) A licensee shall maintain a record of patient surveys which demonstrates
R10 compliance with subsections 64E-5.622(3) and (6), F.A.C., for 3 years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirems (microsieverts) per hour and measured
R10 within 1 meter from the patient, and the initials of the individual who performed the survey.

R10 (6) Before releasing a patient or human research subject from licensee control, a
R10 licensee shall survey the patient or the human research subject and the remote
R10 afterloader unit with a portable radiation detection survey instrument to confirm
R10 that the source(s) has been removed from the patient or human research subject
R10 and returned to the safe shielded position.

R10 Rulemaking Authority: 404.051, 404.061, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.730, Amended 10-8-00, Amended 02-11-10.

64E-5.623 Storage of Volatiles and Gases. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container or an equivalent shield and container. A licensee shall store and use a multidose container in a properly functioning fume hood.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.731.

64E-5.624 Decay In Storage.

(1) A licensee shall hold radioactive material with a physical half life of less than
R10 120 days for decay in storage before disposal as ordinary trash. A licensee is
R10 exempt from the requirements of paragraph 64E-5.331(1)(c), F.A.C., of these regulations if:

(a) The radioactive material is held for decay a minimum of 10 half-lives;

(b) The radioactive material is monitored at the container surface before disposal as ordinary trash and its radioactivity cannot be distinguished from the background radiation level in a low background radiation area with a radiation survey instrument set on its most sensitive scale and with no interposed shielding;

(c) All radiation labels are removed or obliterated; and

(d) Each generator column is separated and monitored individually with all radiation shielding removed to ensure that its contents have decayed to background radiation levels before disposal.

(2) The licensee shall retain a record of each disposal for 3 years. The record shall include:

(a) The date of the disposal;

(b) The date on which the radioactive material was placed in storage;

(c) The radionuclides disposed;

(d) The model and serial number of the radiation survey instrument used;

(e) The background dose rate;

(f) The radiation dose rate measured at the surface of each waste container; and

(g) The name of the individual who performed the disposal.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.732, Amended 02-11-10.

64E-5.625 Safety Instructions and Precautions for Liquid Iodine,
R10 **Radiopharmaceutical Therapy, Manual Brachytherapy, Remote Afterloader Units,**
R10 **Teletherapy Units, and Gamma Stereotactic Radiosurgery.**

(1) A licensee shall provide oral and written radiation safety instructions to all
R10 personnel caring for patients or human research subjects, who cannot be
R10 released under Rule 64E-5.622, F.A.C., undergoing radiopharmaceutical therapy
R10 or manual brachytherapy. This training shall be provided initially prior to caring
R10 for patients and refresher training shall be provided at least every 12 months. The instruction shall describe the licensee's procedures for notification of the RSO
R10 and an authorized user in case of the patient’s death or medical emergency.

R10 (2) The instruction for radiopharmaceutical therapy shall be commensurate with the
R10 duties of the personnel and describe the procedures for:

R10 (a) Patient or human research subject control;

R10 (b) Visitor control, including;

R10 1. Routine visitation to hospitalized individuals in accordance with
R10 paragraph 64E-5.312(1)(a), F.A.C.; and

R10 2. Visitation authorized in accordance with subsection 63E-5.312(5),
R10 F.A.C.

(c) Contamination control; and

(d) Waste control.

(3) The instruction for manual brachytherapy shall be commensurate with the duties of the personnel and describe:

(a) Size and appearance of the brachytherapy sources;

(b) Safe handling and shielding instructions;

(c) Procedures for patient or human research subject control; and

(d) Procedures for visitor control, including;

1. Routine visitation to hospitalized individuals in accordance with paragraph 64E-5.312(1)(a), F.A.C.; and

2. Visitation authorized in accordance with paragraph 64E-5.312(5), F.A.C.

(4) A licensee shall provide instruction for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as described in Rule 64E-5.636, F.A.C.

(5) A licensee shall keep a record of individuals receiving instruction required by subsections (1), (2), (3), and (4) above, which includes a list of topics covered, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the department for 3 years.

(6) A licensee shall take the following safety precautions for each patient or human research subject receiving manual brachytherapy or radiopharmaceutical therapy who cannot be released under Rule 64E-5.622, F.A.C.

(a) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room.

(b) Measure promptly, after administration of the dosage, the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Rule 64E-5.312, F.A.C. Retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(c) Provide the patient with radiation safety guidance before authorizing release of the patient that will help to keep radiation dose to household members and the public as low as reasonably achievable.

(d) Notify the RSO and an authorized user immediately if the patient dies or has a medical emergency.

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

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

(a) Monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste.

(b) Survey the patient's room and private sanitary facility for removable contamination before assigning another patient to the room. The room shall not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters or the wipe samples are equal to background when surveyed with an instrument using a probe with a maximum window thickness of 2.0 mg/cm^2 and a minimum probe diameter of 1.5 inches.

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

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

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

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

Rulemaking Authority 404.051, 404.061, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), (3), 404.081, 404.141 F.S.
History: New 5-15-96, Formerly 10D-91.721, Amended 02-11-10.

64E-5.6251 Therapy Related Computer Systems. (Entire section New) The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

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

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

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

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

The licensee shall maintain records of this acceptance testing and protocols used in performing these tests for inspection by the department.

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

SUBPART C
UPTAKE, DILUTION, AND EXCRETION

64E-5.626 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies. **(Entire section Changed)** A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for medical use under the following conditions:

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

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by a NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol, or a Notice of Claimed Investigational Exemption for a New Drug (IND) protocol accepted by U.S. Food and Drug Administration (FDA); or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application, or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

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

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

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

(2) When a written directive is required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application, or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. For sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.657, 64E-5.660, 64E-5.661, 64E-5.662 or 64E-5.663, F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.733, Amended 8-6-01, Amended 02-11-10.

SUBPART D
IMAGING AND LOCALIZATION

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

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

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

(b) Radioactive material is obtained from and prepared by a NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

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

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

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

(2) When a written directive is required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. For sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq) a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the applicable training and experience specified in Rules 64E-5.657, 64E-5.660, 64E-5.661, 64E-5.662 or 64E-5.663, F.A.C.

(3) Only for oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) and when a written directive is required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

R10 (a) Radioactive material is obtained from a manufacturer or pharmacy
R10 licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent
R10 NRC or agreement state regulations; or

R10 (b) Radioactive material is obtained from and prepared by a NRC or
R10 agreement state licensee for use in research in accordance with a
R10 Radioactive Drug Research Committee-approved protocol or an IND
R10 protocol accepted by FDA; or

R10 (c) Radioactive material is prepared by the licensee for use in research in
R10 accordance with a Radioactive Drug Research Committee-approved
R10 application or an IND protocol accepted by FDA; or

R10 (d) Radioactive material is prepared by:

R10 1. An authorized nuclear pharmacist;

R10 2. For sodium iodide I-131 in quantities greater than 30 microcuries
R10 (1.11 MBq), a physician who is an authorized user and meets the
R10 training requirements specified in Rule 64E-5.650 or 64E-5.660,
F.A.C.; or

R10 3. An individual under the supervision of an authorized user as
R10 specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or
R10 subsection 64E-5.608(1), F.A.C.

R10 (e) The authorized user must satisfy the applicable training and experience
R10 specified in Rules 64E-5.657, 64E-5.660 or 64E-5.661, F.A.C.

R10 (4) A licensee shall use radioactive aerosols or gases only if application on
R10 DH Form 1322 12/09 is made to and approved by the department and the
R10 requirements of Rule 64E-5.629, F.A.C., are met.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.735, Amended 8-6-01, Amended 02-11-10.

R10 **64E-5.628 Generators. (Entire section Changed)**

R10 (1) Permissible Molybdenum/Technetium Concentration.

R10 (a) A licensee shall not administer a radiopharmaceutical containing more
R10 than 0.15 microcurie of molybdenum 99 per millicurie of technetium 99m
R10 (5.55 kilo-becquerel of molybdenum 99 per 37 megabecquerel of
R10 technetium 99m).

R10 (b) A licensee preparing technetium 99m radiopharmaceuticals from
R10 molybdenum 99/technetium 99m generators shall measure the
R10 molybdenum 99 concentration in each eluate or extract.

R10 (c) A licensee who is required to measure molybdenum concentrations shall
R10 retain a record of each measurement for 3 years. The record shall include
R10 for each elution or extraction of technetium 99m:

R10 1. The measured activity of the technetium expressed in millicuries
R10 (megabecquerels);

R10 2. The measured activity of molybdenum expressed in microcuries
R10 (kilobecquerels);

R10 3. The ratio of the measures expressed as microcuries of
R10 molybdenum per millicurie of technetium (kilobecquerels of
R10 molybdenum per megabecquerel of technetium);

R10 4. The date of the test; and

R10 5. The initials of the individual who performed the test.

R10 (d) A licensee shall report immediately to the department each occurrence of
R10 molybdenum 99 concentration exceeding the limits specified in subsection
R10 64E-5.628(1), F.A.C.

R10 (2) Permissible Strontium/Rubidium Concentration.

R10 (a) A licensee shall not administer a radiopharmaceutical containing more
R10 than 0.02 microcurie of strontium 82 per millicurie of rubidium 82
R10 (0.74 kilobecquerel of strontium 82 per 37 megabecquerel of rubidium 82)
R10 or more than 0.2 microcurie of strontium 85 per millicurie of rubidium 82
R10 (7.4 kilobecquerel of strontium 85 per 37 megabecquerel of rubidium 82).

R10 (b) A licensee preparing rubidium 82 radiopharmaceuticals from
R10 strontium 82/rubidium 82 generators shall measure and calculate the
R10 strontium 82 and strontium 85 concentration on each day of use prior to
R10 the use of rubidium chloride for injection.

R10 (c) A licensee who is required to measure strontium 82 and strontium 85
R10 concentrations shall retain a record of each measurement for 3 years.
R10 The record shall include for each day of use assay:

R10 1. The measured activity of the rubidium 82 expressed in millicuries
R10 (megabecquerels);

R10 2. The measured activity of strontium 82 expressed in microcuries
R10 (kilobecquerels);

R10 3. The calculated activity of strontium 85 expressed in microcuries
R10 (kilobecquerels);

R10 4. The ratio of the measures expressed as microcuries of strontium 82
R10 per millicurie of rubidium 82 (kilobecquerels of strontium 82 per
R10 megabecquerel of rubidium 82) and the ratio of the measures
R10 expressed as microcuries of strontium 85 per millicurie of
R10 rubidium 82 (kilobecquerels of strontium 85 per megabecquerel of
R10 rubidium 82);

R10 5. The date of the test; and

R10 6. The initials of the individual who performed the test.

R10 (d) A licensee shall report immediately to the department each occurrence of
R10 strontium 82 or strontium 85 concentrations exceeding the limits specified
R10 in subsection 64E-5.628(2), F.A.C.

R10 (3) Other Permissible Parent/Daughter Concentration.

R10 (a) If a licensee seeks to utilize a Parent/Daughter concentration other that
R10 those listed in subsection (1) or (2) above, the licensee must submit a
R10 license amendment to the department for review and approval of the
R10 maximum parent isotope or other contaminate concentrations
R10 breakthrough per daughter isotope concentration allowed for
R10 administration to patients or human research subjects, and the
R10 instrumentation and procedures used in determining parent isotope or
R10 other contaminate breakthrough concentrations;

R10 (b) Each license must perform the determination listed in paragraph (3)(a),
R10 above, on each day of use prior to the administration to patients or human
R10 research subjects;

R10 (c) Retain a record of each measurement for 3 years. The record shall
R10 include for each day of use assay:

R10 1. The measured activity of the daughter isotope expressed in
R10 millicuries (megabecquerels);

R10 2. The measured activity of parent isotope(s) and other contaminates
R10 expressed in microcuries (kilobecquerels);

R10 3. The calculated activity of parent isotope(s) and other contaminates
R10 expressed in microcuries (kilobecquerels) as applicable;

R10 4. The ratio of the measures expressed as microcuries of parent
R10 isotope(s) and other contaminates per millicurie of daughter isotope
R10 (kilobecquerels of parent isotope(s) per megabecquerel of daughter isotope);

R10 5. The date of the test; and

R10 6. The initials of the individual who performed the test.

R10 (d) A licensee shall report immediately to the department each occurrence of
R10 parent isotope(s) or other contaminates concentrations exceeding the
R10 limits specified in paragraph 64E-5.628(3)(a), F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.736., Amended 02-11-10

64E-5.629 Control of Aerosols and Gases.

(1) A licensee shall only administer radioactive aerosols or gases when airborne concentrations are within the limits prescribed by State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3, and Table II.

(2) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(3) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(4) Before receiving, using, or storing radioactive gas, the licensee shall calculate the time needed after a release to reduce the concentration in the area of use to the occupational limit listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(5) A licensee shall post the time calculated in subsection 64E-5.629(4), F.A.C., at the area of use and require that individuals evacuate the room until the posted time has elapsed if a gas spill occurs.

R10 (6) A licensee shall check the operation of collection systems prior to use each
R10 month of use and measure the ventilation rates in areas of use every 6 months. Records of these checks and measurements shall be maintained for 3 years.

(7) A copy of the calculations required in subsection 64E-5.629(4), F.A.C., shall be recorded and retained for the duration of the license.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.737, Amended 02-11-10.

SUBPART E
RADIOPHARMACEUTICALS FOR THERAPY

64E-5.630 Use of Radiopharmaceuticals for Therapy. A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical that requires a written directive as described in subsection 64E-5.607(3), F.A.C., and for a therapeutic medical use provided the following is met **(Entire section Changed)**

(1) For any unsealed radiopharmaceutical including parenteral use listed in subsection 64E-5.630(4), F.A.C., and sodium iodide I-131 use listed in subsections 64E-5.630(2) and (3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 54E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.660 or 64E-5.657, F.A.C.

(2) Only for oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

R10 (c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

R10 (d) Radioactive material is prepared by:

R10 1. An authorized nuclear pharmacist;

R10 2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

R10 3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

R10 (e) The authorized user must satisfy the training and experience specified in Rule 64E-5.661 or 64E-5.657, F.A.C.

R10 (3) Only for oral administration of sodium iodide I-131 in quantities greater than 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

R10 (a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

R10 (b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

R10 (c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or.

R10 (d) Radioactive material is prepared by:

R10 1. An authorized nuclear pharmacist;

R10 2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

R10 3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

R10 (e) The authorized user must satisfy the training and experience specified in Rule 64E-5.662 or 64E-5.657, F.A.C.

R10 (4) Only parenteral use of radioactive materials the licensee must satisfy the following:

R10 (a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

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

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.663 or 64E-5.657, F.A.C.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.739, Amended 8-6-01, Amended 02-11-10.

SUBPART F
SEALED SOURCES FOR DIAGNOSIS

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

(1) Iodine 125 as a sealed source in a device for bone mineral analysis;

(2) Iodine 125 as a sealed source in a portable device for imaging;

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

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

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

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

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.743, Amended 02-11-10.

SUBPART G
SOURCES FOR BRACHYTHERAPY

R10 **64E-5.632 Use of Sources for Manual Brachytherapy**. The licensee is allowed to use the brachytherapy sources listed below, provided they are approved by and used as specified in, the Sealed Source and Device Registry, for diagnostic medical uses, or in research in accordance with an active IDE application accepted by the FDA and the requirements of Rule 64E-5.612, F.A.C., are met.

(1) Cobalt 60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(2) Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions;

(3) Palladium 103 as a sealed source in seeds for interstitial treatment of cancer;

(4) Iodine 125 as a sealed source in seeds for interstitial treatment of cancer;

(5) Cesium 137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(6) Iridium 192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(7) Gold 198 as a sealed source in seeds for interstitial treatment of cancer;

R10 (8) Radon 222 as seeds for interstitial treatment of cancer;

R10 (9) Radium 226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;

R10 (10) Cesium 131 as a sealed source in seeds for interstitial treatment of cancer; or

R10 (11) For isotopes or uses not listed in subsections 64E-5.632(1) through (10), F.A.C., above, the licensee must amend their radioactive materials license.

R10 In order to use isotopes in accordance with Rule 64E-5.632, F.A.C., an authorized user must satisfy the training and experience requirements specified in Rule 64E-5.652 or 64E-5.657, F.A.C. An authorized user of only Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions listed in subsection 64E-5.632(2), F.A.C., above must satisfy the training and experience specified in Rule 64E-5.652, 64E-5.653 or 64E-5.657, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.745, Amended 02-11-10.

R10 **64E-5.633 Manual Brachytherapy Sources Inventory and Surveys.**

R10 (1) The licensee shall maintain accountability at all times for all manual brachytherapy sources in storage or use. As soon as possible each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

R10 (2) A licensee shall make a record of the use of manual brachytherapy sources which includes:

R10 (a) For temporary implants;

R10 1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage; and

R10 2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage.

R10 (b) For permanent implants;

R10 1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage;

R10 2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage; and

R10 3. The number and activity of sources permanently implanted in the patient or human research subject.

R10 (3) Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey. This record shall contain the date and results of the survey, the survey instrument used and the name of the individual who performed the survey.

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

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.748, Amended 02-11-10.

R10 **64E-5.6331 Calibration Measurements of Manual Brachytherapy Sources.**
(Entire section New)

R10 (1) Before the first medical use of a brachytherapy source, the licensee shall, using published protocols currently accepted by nationally recognized bodies, determine the following:

R10 (a) Source output or activity using a dosimetry system that meets the requirements of subsection 64E-5.640(1), F.A.C.; and

R10 (b) Source positioning accuracy within applicators.

R10 (2) Instead of a licensee making its own measurements as required in subsection 64E-5.6331(1), F.A.C., the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM) that are made in accordance with subsection 64E-5.6331(1), F.A.C.

R10 (3) A licensee shall mathematically correct the outputs or activities determined in subsection 64E-5.6331(1), F.A.C., for physical decay at intervals consistent with 1 percent physical decay.

R10 (4) For each brachytherapy source the licensee shall retain the following records for three years after the last use of the source:

R10 (a) The date of calibration;

R10 (b) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

R10 (c) The source output or activity;

R10 (d) The source positioning accuracy within the applicators; and

R10 (e) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
R10 Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 02-11-10.

R10 **64E-5.6332 Decay of Strontium-90 Sources for Ophthalmic Treatments.**
(Entire section New)

R10 (1) Only an authorized medical physicist or authorized user qualified to perform procedures described in subsection 64E-5.632(2), F.A.C., shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Rule 64E-5.6331, F.A.C.

R10 (2) For each Strontium 90 source the licensee shall retain the following records for the life of the source:

(a) The date and activity of the source as determined under Rule 64E-5.6331, F.A.C.; and

(b) For each decay calculation, the date and the source activity as determined under Rule 64E-5.6332, F.A.C.

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

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

64E-5.634 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit. (Entire section Changed)

(1) A licensee shall use sealed sources in photon emitting gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of Rule 64E-5.612, F.A.C. are met.

(2) A licensee shall use sealed sources in photon emitting remote afterloader units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of Rule 64E-5.612, F.A.C., are met.

(3) A licensee shall use sealed sources in photon emitting teletherapy units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of Rule 64E-5.612, F.A.C., are met.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.751, Amended 02-11-10.

R10 **64E-5.635 Installation, Adjustment, Maintenance and Repair Restrictions.**
(Entire section Changed)

R10 (1) Only a person specifically licensed by the NRC or an agreement state shall
R10 install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or
R10 gamma stereotactic radiosurgery unit that involves work on the source(s)
R10 shielding, the source(s) driving unit, or other electronic or mechanical component
R10 that could expose the source(s), reduce the shielding around the source(s), or
R10 compromise the radiation safety of the unit or the source(s).

R10 (2) Except for low dose-rate remote afterloader units, only a person specifically
R10 licensed by the NRC or an agreement state shall install, replace, relocate, or
R10 remove a sealed source or source contained in other remote afterloader units,
R10 teletherapy units, or gamma stereotactic radiosurgery units.

R10 (3) For a low dose-rate remote afterloader unit, only a person specifically licensed by
R10 the NRC or an agreement state or an authorized medical physicist shall install,
R10 replace, relocate, or remove a sealed source(s) contained in the unit.

R10 (4) A licensee shall retain a record of the installation, maintenance, adjustment, and
R10 repair of remote afterloader units, teletherapy units, and gamma stereotactic
R10 radiosurgery units for 3 years. For each installation, maintenance, adjustment
R10 and repair, the record must include the date, description of the service, and
R10 name(s) of the individual(s) who performed the work.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.752, Amended 02-11-10.

R10 **64E-5.636 Safety Procedures and Instructions for Remote Afterloader Units,**
R10 **Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**
(Entire section Changed)

R10 (1) Listed below are the safety and instruction requirements for a licensee:;

R10 (a) Secure the unit, the console, the console keys, and the treatment room
R10 when not in use or unattended;

R10 (b) Permit only individuals approved by the authorized user, RSO, or
R10 authorized medical physicist to be present in the treatment room during
R10 treatment with the source(s);

R10 (c) Prevent dual operation of more than one radiation producing device in a
R10 treatment room if applicable; and

R10 (d) Develop, implement, and maintain written procedures for responding to an
R10 abnormal situation when the operator is unable to place the source(s) in
R10 the shielded position, or remove the patient or human research subject
R10 from the radiation field with controls from outside the treatment room.
R10 These procedures must include the following:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by paragraph 64E-5.636(1)(d), F.A.C., of this section must be physically located at the unit console.

(3) A licensee shall post instructions at the unit console to inform the operator of the following:

(a) The location of the procedures required by paragraph (4)(a) of this section; and

(b) The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

(4) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in the following:

(a) The procedures identified in paragraph 64E-5.636(1)(d), F.A.C., of this section; and

(b) The operating procedures for the unit.

(5) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(6) A licensee shall retain a record of individuals receiving instruction required by paragraph 64E-5.636(4), F.A.C., of this section. These records shall be maintained for 3 years and must include the list of topics covered, the date of the instruction, the name(s) of the attendee(s) and the name(s) of the individual(s) who provided the instruction.

(7) A licensee shall retain a copy of the procedures required by paragraphs 64E-5.636(1)(d) and 64E-5.636(4)(b), F.A.C., until the licensee no longer possesses the remote afterloader, teletherapy unit or gamma stereotactic radiosurgery unit.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.753, Amended 02-11-10.

64E-5.637 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units . (Entire section Changed)

(1) A licensee shall control access to the treatment room by a door at each entrance.

(2) A licensee shall equip each entrance to the treatment room with an electrical interlock system that shall:

(a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) Cause the source(s) to be shielded when an entrance door is opened; and

(c) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(3) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(4) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(6) In addition to the requirements specified in paragraphs 64E-5.637(1) through (5), F.A.C., of this section, a licensee shall:

(a) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

1. An authorized medical physicist and either, an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either, an authorized user or an individual under, the supervision of an authorized user, who have been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(b) For high dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either, an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(c) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(d) Notify the RSO, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(7) A licensee shall have applicable emergency response equipment available near each treatment room in order to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.755, Amended 02-11-10.

64E-5.638 Radiation Monitoring Devices.

(1) A licensee shall have a permanent radiation monitor in each teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room capable of continuously monitoring radiation levels.

(2) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit, medium or high dose rate remote afterloader unit, or gamma stereotactic radiosurgery unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room.

(3) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit, medium or high dose rate remote afterloader unit, or gamma stereotactic radiosurgery unit. This backup power supply may be a battery system.

(4) Each radiation monitor shall be checked daily with a dedicated check source for proper operation before the teletherapy unit, medium or high dose rate remote afterloader unit, or gamma stereotactic radiosurgery unit is used.

(5) A licensee shall maintain a record of the check required by subsection 64E-5.638(4), F.A.C., for 3 years. The record shall include the date of the check, notation what the monitor indicates when its detector is and is not exposed to the source, and the initials of the individual who performed the check.

(6) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room to use a radiation survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The radiation survey instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in subsection 64E-5.638(5), F.A.C.

(7) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.757, Amended 02-11-10.

64E-5.639 Viewing Systems. A licensee shall construct or equip each teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room to permit continuous observation of the patient, or human research subject from the teletherapy unit console during irradiation.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.758, Amended 02-11-10.

64E-5.640 Dosimetry Equipment Used With Remote Afterloading Units, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units.

(1) Except for low dose-rate remote afterloader source output or where the activity is determined by the manufacturer, a licensee shall have a dosimetry system available for use calibrated by paragraph (a) or (b) below.

(a) The system must have been calibrated using a system or source traceable to the NIST and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the AAPM. The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration.

(b) The system shall have been calibrated within the previous 4 years and shall have been intercompared 18 to 30 months after the calibration at an intercomparison meeting with another dosimetry system that has been calibrated within the previous 2 years by the NIST or by a calibration laboratory accredited by the AAPM. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The calibration factor of the licensee's system shall not have changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(2) The licensee shall have available for use a dosimetry system for spot-check measurements. The spot-check system shall be the same system used to meet the requirement in 64E-5.640(1), or shall be a system that has been compared with a system that has been calibrated as provided in subsection 64E-5.640(1), F.A.C. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration.

(3) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:

R10 (a) The date, the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subsections 64E-5.640(1) and (2), F.A.C.;

(b) The correction factors that were determined;

(c) The names of the individuals who performed the calibration, intercomparison, or comparison; and

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.759, Amended 02-11-10.

R10 **64E-5.641 Full Calibration Measurements on Teletherapy Units..**

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

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

(b) Before medical use whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(c) Before medical use following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(d) Before medical use following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(e) At least every 12 months.

(2) Full calibration measurements shall include the determination of:

(a) The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) Timer constancy and linearity over the range of use;

(e) On-off error; and

(f) The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C., to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 64E-5.641(2)(a), F.A.C., may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by subsection 64E-5.641(1), F.A.C., using the manufacturer's published protocols, published protocols as accepted by nationally recognized bodies or equivalent procedures that have been submitted to the department. An example of a nationally recognized body is the American Association of Physicists in Medicine.

(5) A licensee shall correct mathematically the outputs determined in paragraph 64E-5.641(2)(a), F.A.C., for physical decay monthly for cobalt 60 and at least every 6 months for cesium 137.

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

(7) A licensee shall maintain a record of each calibration of each teletherapy unit for three years. The record shall include:

(a) The date of the calibration;

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

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

(d) The results and an assessment of the full calibration to include the following:

1. The tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy;

2. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The measured timer accuracy for a typical treatment time;

4. The calculated on-off error;

5. The estimated accuracy of each distance measuring or localization device; and

6. The signature of the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 5-12-93, Formerly 10D-91.760, Amended 02-11-10.

R10 **64E-5.6411 Full Calibration Measurements on Remote Afterloader Units.**
(Entire section New)

R10 (1) A licensee authorized to use a remote afterloader unit for medical use shall
R10 perform full calibration measurements on each remote afterloader unit:

R10 (a) Before the first medical use of the unit;

R10 (b) 1. Before medical use following replacement of the source or following
R10 reinstallation of the unit in a new location outside the facility; and
R10

R10 2. Before medical use following any repair of the unit that includes
R10 removal of the source or major repair of the components associated
R10 with the source exposure assembly; and

R10 (c) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate,
R10 and pulsed dose-rate remote afterloader units with sources whose half-life
R10 exceeds 75 days; and

R10 (d) At intervals not exceeding 1 year for low dose-rate remote afterloader
R10 units.

R10 (2) Full calibration measurements of remote afterloader unit shall include the
R10 determination of:

R10 (a) The output within 5 percent;

R10 (b) Source positioning accuracy to within 1 millimeter;

R10 (c) Source retraction with backup battery upon power failure;

R10 (d) Timer constancy and linearity over the range of use;

R10 (e) Length of the source transfer tubes;

R10 (f) Length of the applicators; and

R10 (g) Function of the source transfer tubes, applicators, and transfer tube-
R10 applicator interfaces.

R10 (3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C.,
R10 to measure the output for one set of exposure conditions. The remaining
R10 radiation measurements required in paragraph 64E-5.6411(2)(a), F.A.C., may be
R10 made using a dosimetry system that indicates relative dose rates.

R10 (4) A licensee shall make full calibration measurements required by subsection
R10 64E-5.6411(1), F.A.C., in accordance with published protocols accepted by
R10 nationally recognized bodies.

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

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

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

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

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

(a) The date of the calibration;

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

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

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

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

(f) The signature of the authorized medical physicist.

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

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

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

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

(b) 1. Before medical use whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

R10 2. Before medical use following replacement of the source or following
R10 reinstallation of the gamma stereotactic radiosurgery unit in a new
R10 location;

R10 3. Following any repair of the gamma stereotactic radiosurgery unit that
R10 includes removal of the sources or major repair of the components
R10 associated with the source assembly; and

R10 (c) At intervals not exceeding 1 year, with the exception that relative helmet
R10 factors need only be determined before the first medical use of a helmet
R10 and following any damage to a helmet.

R10 (2) Full calibration measurements of the gamma stereotactic radiosurgery unit shall
R10 include the determination of:

R10 (a) The output within 3 percent;

R10 (b) Relative helmet factors;

R10 (c) Isocenter coincidence;

R10 (d) Timer constancy and linearity over the range of use;

R10 (e) On-off timers;

R10 (f) Trunnion centricity;

R10 (g) Treatment table retraction mechanism, using backup battery power or
R10 hydraulic backups with the unit off;

R10 (h) Helmet microswitches;

R10 (i) Emergency timing circuits; and

R10 (j) Stereotactic frames and localizing devices (trunnions).

R10 (3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C.,
R10 to measure the output for one set of exposure conditions. The remaining
R10 radiation measurements required in paragraph 64E-5.6412(2)(a), F.A.C., may be
R10 made using a dosimetry system that indicates relative dose rates.

R10 (4) A licensee shall make full calibration measurements required by subsection
R10 64E-5.6412(1), F.A.C., in accordance with published protocols accepted by
R10 nationally recognized bodies.

R10 (5) A licensee shall correct mathematically the outputs determined in paragraph
R10 64E-5.6412(2)(a), F.A.C., at intervals not exceeding 1 month for cobalt-60 and at
R10 intervals consistent with 1 percent physical decay for all other radionuclides.

R10 (6) Full calibration measurements required by subsection 64E-5.6412(1), F.A.C., and
R10 physical decay corrections required by subsection 64E-5.6412(5), F.A.C., shall
R10 be performed by the authorized medical physicist.

R10 (7) A licensee shall maintain a record of each gamma stereotactic radiosurgery unit
R10 calibration for three years. The record shall include:

R10 (a) The date of the calibration;

R10 (b) The manufacturer's name, model number, and serial number for both the
R10 gamma stereotactic radiosurgery unit and the source;

R10 (c) The model numbers and serial numbers of the instruments used to
R10 calibrate the gamma stereotactic radiosurgery unit;

R10 (d) The results and an assessment of the full calibrations; and

R10 (e) The signature of the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
R10 Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History: New 02-11-10.

R10 **64E-5.642 Periodic Spot-Checks of Teletherapy Units.**

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at least every month.

(2) Spot-checks shall include the determination of:

(a) Timer constancy and timer linearity over the range of use;

(b) On-off error;

(c) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) The accuracy of all distance measuring and localization devices used for medical use;

(e) The output for one typical set of operating conditions; and

(f) The difference between the measurement made in paragraph 64E-5.642(2)(e), F.A.C., and the anticipated output, expressed as a percentage of the anticipated output, which is the value obtained at the last full calibration corrected mathematically for physical decay.

(3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C., to make the spot-check required in paragraph 64E-5.642(2)(e), F.A.C.

(4) A licensee shall perform spot-checks required by subsection 64E-5.642(1),
R10 F.A.C., following procedures established by the authorized medical physicist.

R10 (5) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days and promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification for 3 years.

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

(7) Safety spot-checks shall assure proper operation of:

(a) Electrical interlocks at each teletherapy room entrance;

(b) Electrical or mechanical stops installed to limit use of the primary beam of radiation, restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam on-off mechanism;

R10 (c) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

R10 (d) Viewing and intercom systems;

(e) Treatment room doors from inside and outside the treatment room; and

(f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

R10 (8) If the results of the checks required in subsection 64E-5.642(7), F.A.C., of this
R10 section indicate the malfunction of any system, a licensee shall lock the control
R10 console in the off position and not use the unit.

(9) A licensee shall promptly repair any system identified in subsection 64E-5.642(7), F.A.C. that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.

(10) A licensee shall maintain a record of each spot-check required by 64E-5.642(1)
R10 and (6) for 3 years and a copy of the procedures required by subsection
R10 64E-5.641(4), F.A.C., until the licensee no longer possesses the teletherapy unit. The record shall include:

(a) The date of the spot-check;

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

(c) The manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit;

(d) The timer linearity and constancy;

(e) The calculated on-off error;

(f) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(g) The determined accuracy of each distance measuring or localization device;

(h) The difference between the anticipated output and the measured output;

(i) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors; and

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

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.761, Amended 02-11-10.

R10 **64E-5.6421 Periodic Spot-Checks for Remote Afterloader Units. (Entire section New)**

R10 (1) A licensee authorized to use a remote afterloader unit for medical use shall
R10 perform the following spot-checks:

R10 (a) Before the first use of a high dose-rate, medium dose-rate, or pulsed
R10 dose-rate remote afterloader unit on a given day;

R10 (b) Before each patient treatment with a low dose-rate remote afterloader unit;
R10 and

R10 (c) After each source installation.

R10 (2) Spot-checks shall include the determination of:

R10 (a) Electrical interlocks at each remote afterloader unit room entrance;

R10 (b) Source exposure indicator lights on the remote afterloader unit, on the
R10 control console, and in the facility;

R10 (c) Viewing and intercom systems in each high dose-rate, medium dose-rate,
R10 and pulsed dose-rate remote afterloader facility;

R10 (d) Emergency response equipment;

R10 (e) Radiation monitors used to indicate the source position;

R10 (f) Timer accuracy;

R10 (g) Clock (date and time) in the unit's computer; and

R10 (h) Decayed source(s) activity in the unit's computer.

R10 (3) If the results of the checks required in subsection 64E-5.6421(2), F.A.C., of this
R10 section indicate the malfunction of any system, a licensee shall lock the control
R10 console in the off position and not use the unit except as may be necessary to
R10 repair, replace, or check the malfunctioning system.

R10 (4) A licensee shall perform spot-checks required by subsection 64E-5.6421(2), F.A.C., following procedures established by the authorized medical physicist.

R10 (5) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days and promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for 3 years.

R10 (6) A licensee shall retain a copy of the procedures required by subsection 64E-5.6421(4), F.A.C., until the licensee no longer possesses the remote afterloader unit.

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

R10 (a) The date of the spot-check;

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

R10 (c) An assessment of timer accuracy;

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

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

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
R10 Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History: New 02-11-10.

R10 **64E-5.6422 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units (Entire section New)**

R10 (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform the following spot-checks:

R10 (a) Monthly:

R10 (b) Before the first use of the unit on a given day; and

R10 (c) After each source installation.

R10 (2) Spot-checks shall include the determination of:

R10 (a) Assure the proper operation of the:

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

2. Helmet microswitches;

3. Emergency timing circuits; and

4. Stereotactic frames and localizing devices (trunnions).

(b) Determine the following elements:

1. The output for one typical set of operating conditions measured with the dosimetry system described in subsection 64E-5.640(2), F.A.C.;

2. The difference between the measurement made in subparagraph 64E-5.6422(2)(b)1, F.A.C., and the anticipated output, expressed as a percentage of the anticipated output value obtained at last full calibration corrected mathematically for physical decay;

3. Source output against computer calculation;

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

5. On-off error; and

6. Trunnion centricity.

(3) A licensee shall perform spot-checks required by subsection 64E-5.6422(1), F.A.C., following procedures established by the authorized medical physicist.

(4) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days and promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for 3 years

(5) To satisfy the requirements of paragraphs 64E-5.6422(1)(b) and (c), F.A.C., the licensee's spot-checks must assure proper operation of the following:

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

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

(c) Viewing and intercom systems;

(d) Timer termination;

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

(f) Emergency off buttons.

R10 (6) If the results of the checks required in subsection 64E-5.6422(5), F.A.C., of this
R10 section indicate the malfunction of any system, a licensee shall lock the control
R10 console in the off position and not use the unit except as may be necessary to
R10 repair, replace, or check the malfunctioning system.

R10 (7) A licensee shall arrange for the repair of any system identified in subsection
R10 64E-5.6422(2), F.A.C., that is not operating properly as soon as possible.

R10 (8) A licensee shall maintain a record of each spot-check required by subsections
R10 64E-5.6422(2) and (5), F.A.C., for 3 years and a copy of the procedures required
R10 in subsections 64E-5.5422(2) and (3), F.A.C., until the licensee no longer
R10 possesses the gamma stereotactic radiosurgery unit. The record shall include:

R10 (a) The date of the spot-check;

R10 (b) The manufacturer's name, model number, and serial number for the
R10 gamma stereotactic radiosurgery unit;

R10 (c) The manufacturer's name, model number and serial number of the
instrument used to measure the output of the gamma stereotactic
radiosurgery unit;

R10 (d) The timer linearity and constancy;

R10 (e) The calculated on-off error;

R10 (f) A determination of trunnion centricity;

R10 (g) The difference between the anticipated output and the measured output;

R10 (h) An assessment of source output against computer calculations;

R10 (i) Notations indicating the operability of radiation monitors, helmet
R10 microswitches, emergency timing circuits, emergency off buttons,
R10 electrical interlocks, source exposure indicator lights, viewing and intercom
R10 systems, timer termination, treatment table retraction mechanism, and
R10 stereotactic frames and localizing devices (trunnions); and
R10

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

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
R10 Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History: New 02-11-10.

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

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

R10 (a) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

R10 (b) Account for all sources before departure from a client's address of use.

R10 (2) In addition to the periodic spot-checks required by Rule 64E-5.6421, F.A.C., a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of the following:

R10 (a) Electrical interlocks on treatment area access points;

R10 (b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

R10 (c) Viewing and intercom systems;

R10 (d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

R10 (e) Radiation monitors used to indicate room exposures;

R10 (f) Source positioning (accuracy); and

R10 (g) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

R10 (3) In addition to the requirements for checks in subsection 64E-5.6423(2), F.A.C., a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

R10 (4) If the results of the checks required in subsection 64E-5.6423(2), F.A.C., indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

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

R10 (a) The date of the check;

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

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

R10 (d) Notations indicating the operability of each entrance door electrical
R10 interlock, radiation monitors, source exposure indicator lights, viewing and
R10 intercom system, applicators, source transfer tubes, and transfer tube
R10 applicator interfaces, and source positioning accuracy; and

R10 (e) The signature of the individual who performed the check.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS..
R10 Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History: New 02-11-10.

64E-5.643 Radiation Surveys for Teletherapy Facilities.

(1) The licensee shall perform radiation surveys with an operable radiation survey
R2 instrument calibrated as provided in Rule 64E-5.615, F.A.C., before medical use,
after each installation of a teletherapy source, and after making any change for
R2 which an amendment is required by Rule 64E-5.636, F.A.C.

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

(b) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, radiation levels in restricted areas shall be unlikely to
R2 cause any occupationally exposed individuals to receive a dose in excess
R2 of the limits specified in Rule 64E-5.304, F.A.C.; and radiation dose rates
R2 of any individual member of the public in unrestricted areas shall not
R2 exceed the limits specified in paragraph 64E-5.312(1)(c), F.A.C.

(2) If the results of the surveys required in subsection 64E-5.643(1), F.A.C., indicate any radiation levels in excess of the limits specified, the licensee shall lock the control in the off position and shall not use the unit:

(a) Except to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

(b) Until the licensee has received a specific exemption from the department.

(3) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include:

(a) The date of the measurements;

(b) The reason the survey is required;

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

(d) Each dose rate measured around the teletherapy source while in the off position and the average of all measurements;

(e) A plan of the areas surrounding the treatment room that were surveyed;

(f) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;

(g) The calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and

R10 (h) The signature of the RSO or the authorized medical physicist.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Amended 1-1-994, Formerly 10D-91.762, Amended 10-8-00, Amended 02-11-10.

R10 **64E-5.644 Radiation Surveys for Remote Afterloader and Gamma Stereotactic**
R10 **Radiosurgery Facilities. (Entire section Changed)**

R10 (1) The licensee shall perform radiation surveys with an operable radiation survey
R10 instrument calibrated as provided in Rule 64E-5.615, F.A.C., to ensure that the
R10 maximum radiation levels and average radiation levels from the surface of the
R10 main source safe with the source(s) in the shielded position do not exceed the
R10 levels stated in the Sealed Source and Device Registry.
R10

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

R10 (3) A licensee shall retain a record of the radiation surveys required by subsection
R10 64E-5.644(1), F.A.C., for the duration of the license. These records shall include:
R10

R10 (a) The date of the measurements;

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

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

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

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.763, Amended 02-11-10.

64E-5.645 Therapy-Related Computer Systems. (Entire section Changed) The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. An example of a nationally recognized body is the American Association of Physicists in Medicine. At a minimum, the acceptance testing must include, as applicable, verification of the following:

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

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

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

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

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

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Amended 1-1-94, Formerly 10D-91.764, Amended 10-8-00, Amended 02-11-10.

64E-5.646 Reports of Teletherapy Surveys, Checks, Tests, and Measurements. A licensee shall furnish a copy of the records required in Rules 64E-5.643, 64E-5.644, and 64E-5.645, F.A.C., and the output from the teletherapy source expressed as rads (grays) per hour at 1 meter from the source as determined during the full calibration required in Rule 64E-5.641, F.A.C., to the department within 30 days following completion of the action that initiated the record requirement.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.765.

64E-5.647 Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at least every 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) This inspection and servicing shall only be performed by persons specifically licensed to do so by the department, an agreement state, or the U.S. Nuclear Regulatory Commission.

(3) A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain:

(a) The inspector's name;

R10 (b) The inspector's radioactive materials license number;

(c) The date of inspection;

(d) The manufacturer's name and model number and serial number for both
R10 the treatment unit and source;

(e) A list of components inspected;

(f) A list of components serviced and the type of service;

(g) A list of components replaced; and

(h) The signature of the inspector.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.766, Amended 02-11-10.

SUBPART I
TRAINING AND EXPERIENCE REQUIREMENTS

64E-5.648 Radiation Safety Officer. Except as provided in Rule 64E-5.657, F.A.C.,
R10 the licensee shall require the RSO as provided in Rule 64E-5.605, F.A.C., to be an individual who: **(Entire section Changed)**

R10 (1) Is certified by a specialty board whose certification process has been recognized
R10 by the NRC or an agreement state and who meets the requirements in
R10 subsections 64E-5.648(4) and (5), F.A.C., of this section. (The names of board
R10 certifications which have been recognized by the NRC or an agreement state will
R10 be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-
R10 use-toolkit/spec-board-cert.html.) To have its certification process recognized, a
R10 specialty board shall require all candidates for certification to:

R10 (a) 1. Hold a bachelor's or graduate degree from an accredited college or
R10 university in physical science or engineering or biological science
R10 with a minimum of 20 college credits in physical science;

R10 2. Have 5 or more years of professional experience in health physics
R10 (graduate training may be substituted for no more than 2 years of
R10 the required experience) including at least 3 years in applied health
R10 physics; and

R10 3. Pass an examination administered by diplomates of the specialty
R10 board, which evaluates knowledge and competence in radiation
R10 physics and instrumentation, radiation protection, mathematics
R10 pertaining to the use and measurement of radioactivity, radiation
R10 biology, and radiation dosimetry; or

(b) 1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have 2 years of full-time practical training and/or supervised experience in medical physics either:

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

b. In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in Rule 64E-5.657, 64E-4.650 or 64E-5.660, F.A.C.;

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) Have completed a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Radiation biology; and

5. Radiation dosimetry.

(b) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a NRC or agreement state license or permit issued by a NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

3. Securing and controlling radioactive material;

4. Using administrative controls to avoid mistakes in the administration of radioactive material;

R10 5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

R10 6. Using emergency procedures to control radioactive material; and

R10 7. Disposing of radioactive material; or

R10 (3) (a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an agreement state under subsection 64E-5.656(1), F.A.C., and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO and who meets the requirements in subsections 64E-5.648(4) and (5), F.A.C., of this section; or

R10 (b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities; and

R10 (4) Have obtained written attestation, signed by a preceptor RSO, or residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category as designated by the applicant seeking authorized status) who meets the requirements in subsection 64E-5.648(5) and in subparagraphs 64E-5.648(1)(a)1., and 64E-5.648(1)(a)2., or 64E-5.648(1)(b)1., and 64E-5.648(1)(b)2., or subsection 64E-5.648(2) or paragraph 64E-5.648(3)(a), F.A.C., of this section, and has demonstrated the ability to function independently as a RSO to fulfill the radiation safety related duties for a medical use licensee; and

R10 (5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.767, Amended 02-11-10.

64E-5.649 Training for Uptake, Dilution, or Excretion Studies. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a
R10 radiopharmaceutical listed in subsection 64E-5.626(1), F.A.C., to: **(Entire section Changed)**

R10 (1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.649(3)(b), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

R10 (a) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraph 64E-5.649(3)(a) and subparagraph 64E-5.649(3)(a)2., F.A.C., of this section; and

R10 (b) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

R10 (2) Be an authorized user under Rule 64E-5.650 or 64E-5.660, F.A.C., or equivalent agreement state requirements; or

R10 (3) (a) Have completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include the following:

R10 1. Classroom and laboratory training in the following areas:

R10 a. Radiation physics and instrumentation;

R10 b. Radiation protection;

R10 c. Mathematics pertaining to the use and measurement of radioactivity;

R10 d. Chemistry of radioactive material for medical use; and

R10 2. Work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.649, 64E-5.650 or 64E-5.660, F.A.C., or equivalent agreement state requirements, involving the following:

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

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

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

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

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

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

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

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.769, Amended 02-11-10.

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

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.650(3)(b), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

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

d. Chemistry of radioactive material for medical use;

e. Radiation biology; and

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

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

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

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

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

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

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

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

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

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.770, Amended 02-11-10.

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

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.771, Repealed 02-11-10.

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

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and who meets the requirements in paragraph 64E-5.652(2)(c), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

a. Radiation physics and instrumentation;

b. Radiation protection;

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

d. Radiation biology; and

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

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

b. Checking survey meters for proper operation;

c. Preparing, implanting, and removing brachytherapy sources;

d. Maintaining running inventories of material on hand;

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

f. Using emergency procedures to control radioactive material; and

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

R10 (c) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.652, F.A.C., or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.652(1)(a) or 64E-5.652(2)(a) and 64E-5.652(2)(b), F.A.C., of this section and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses of manual brachytherapy sources authorized under Rule 64E-5.632, F.A.C.

R10 Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
R10 History: New 8-25-91, Formerly 10D-91.772, Amended 02-11-10.

64E-5.653 Training for Ophthalmic Use of Strontium 90. Except as provided in 64E-5.657, the licensee shall require the authorized user of only strontium 90 for ophthalmic R10 radiotherapy to: **(Entire section Changed)**

R10 (1) Be authorized user under Rule 64E-5.652, F.A.C., or equivalent agreement state requirements; or

R10 (2) (a) Have completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include the following:

R10 1. Radiation Protection and instrumentation;

R10 2. Radiation Protection;

R10 3. Mathematics pertaining to the use and measurement of radioactivity: and

R10 4. Radiation biology; and

R10 (b) Have supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve the following:

1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

R10 4. Follow-up and review of each individual's case history; and

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

Rukemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.773, Amended 02-11-10.

64E-5.654 Training for Use of Sealed Sources for Diagnosis. Except as provided in 64E-5.657, the licensee shall require the authorized user of a sealed source in a device specified in 64E-5.631, F.A.C., to: **(Entire section Changed)**

(1) Be certified by a specialty board whose certification process includes all of the requirements in subsections 64E-5.654(2) and (3), F.A.C., of this section and whose certification has been recognized by the NRC or an agreement state. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

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

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.774, Amended 02-11-10.

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

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.655(2)(c) and subsection 64E-5.655(3), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

a. Radiation physics and instrumentation;

b. Radiation protection;

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

d. Radiation biology; and

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

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

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

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

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

e. Checking and using survey meters;

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

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

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

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

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.775, Amended 02-11-10.

R10 **64E-5.656 Training for an Authorized Medical Physicist.** Except as provided in
R10 Rule 64E-5.657, F.A.C., the licensee shall require the authorized medical physicist to:
(Entire section Changed)

R10 (1) Be certified by a specialty board whose certification process has been
R10 recognized by the NRC or an agreement state and who meets the requirements
R10 in paragraph 64E-5.656(2)(b) and subsection 64E-5.656(3), F.A.C., of this
R10 section. (The names of board certifications which have been recognized by the
R10 NRC or an agreement state will be posted on the NRC's Web page at
R10 http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To
R10 have its certification process recognized, a specialty board shall require all
R10 candidates for certification to:

R10 (a) Hold a master's or doctor's degree in physics, medical physics, other
R10 physical science, engineering, or applied mathematics from an accredited
R10 college or university;

R10 (b) Have 2 years of full-time practical training and/or supervised experience in
R10 medical physics:

R10 1. Under the supervision of a medical physicist who is certified in
R10 medical physics by a specialty board recognized by the NRC or an
R10 agreement state; or

R10 2. In clinical radiation facilities providing high-energy, external beam
R10 therapy (photons and electrons with energies greater than or equal
R10 to 1 million electron volts) and brachytherapy services under the
R10 direction of physicians who meet the requirements for authorized
R10 users in Rule 64E-5.657, 64E-5.652 or 64E-5.655, F.A.C.; and

R10 (c) Pass an examination, administered by diplomates of the specialty board,
R10 that assesses knowledge and competence in clinical radiation therapy,
R10 radiation safety, calibration, quality assurance, and treatment planning for
R10 external beam therapy, brachytherapy, and stereotactic radiosurgery; or

R10 (2) (a) Hold a master's or doctor's degree in physics, medical physics, other
R10 physical science, engineering, or applied mathematics from an accredited
R10 college or university; and has completed 1 year of full-time training in
R10 medical physics and an additional year of full-time work experience under
R10 the supervision of an individual who meets the requirements for an
R10 authorized medical physicist for the type(s) of use for which the individual
R10 is seeking authorization. This training and work experience must be
R10 conducted in clinical radiation facilities that provide high-energy, external
R10 beam therapy (photons and electrons with energies greater than or equal
R10 to 1 million electron volts) and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;

2. Performing decay corrections;

3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

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

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

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

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.776, Amended 02-11-10.

64E-5.657 Training for Experienced RSO, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist. (Entire section Changed)

(1) (a) An individual identified as a RSO, a teletherapy or medical physicist, or a nuclear pharmacist on a NRC or agreement state license or a permit issued by a NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope, need not comply with the training requirements of Rule 64E-5.648, 64E-5.656 or 64E-5.659, F.A.C., respectively.

(b) An individual identified as a RSO, an authorized medical physicist, or an authorized nuclear pharmacist on a NRC or agreement state license or a permit issued by a NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope, need not comply with the training requirements of Rule 64E-5.648, 64E-5.656 or 64E-5.659, F.A.C., respectively.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or agreement state, a permit issued by a NRC master material licensee, a permit issued by a NRC or agreement state broad scope licensee, or a permit issued by a NRC master material license broad scope permittee who perform only those medical uses for which they were authorized, need not comply with the training requirements of Rule 64E-5.649, 64E-5.650, 64E-5.660, 64E-5.661, 64E-5.662, 64E-5.663, 64E-5.652, 64E-5.653, 64E-5.654 or 64E-5.655, F.A.C.

(3) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on department radioactive materials licenses for the same uses for which these individuals are authorized.

Rulemaking Authority: 404.051, 404.061, 404.071, F.S.
Law Implemented: 404.022, 404.051(1)(4)(10)(11), 404.061(2)(3), 404.071(3) 404.141, F.S.
History: New 8-25-91, Amended 5-15-96, Formerly 10D-91.777, Amended 02-11-10.

64E-5.658 Recentness of Training. The training and experience specified in Rules 64E-5.648 , 64E-5.649, 64E-5.650, 64E-5.652, 64E-5.653, 64E-5.654, 64E-5.655, 64E-5.656, 64E-5.657,64E-5.659, 64E-5.660, 64E-5.661,64E-5.662 and 64E-5.663, F.A.C., shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education or experience since the required training and experience was completed and within the 7 years preceding the date of application.

Rulemaking Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New 8-25-91, Formerly 10D-91.779, Amended 02-11-10.

R10 **64E-5.659 Training for an Authorized Nuclear Pharmacist.** Except as provided in Rule
R10 64E-5.657, F.A.C., the licensee shall require the authorized nuclear pharmacist to:
(Entire section New)

R10 (1) Be certified by a specialty board whose certification process has been
R10 recognized by the NRC or an agreement state and who meets the requirements
R10 in paragraph 64E-5.659(2)(b), F.A.C., of this section. (The names of board
R10 certifications which have been recognized by the NRC or an agreement state will
R10 be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-
R10 use-toolkit/spec-board-cert.html.) To have its certification process recognized, a
R10 specialty board shall require all candidates for certification to:

R10 (a) Have graduated from a pharmacy program accredited by the American
R10 Council on Pharmaceutical Education (ACPE) or have passed the Foreign
R10 Pharmacy Graduate Examination Committee (FPGEC) examination;

R10 (b) Hold a current, active license to practice pharmacy;

R10 (c) Provide evidence of having acquired at least 4000 hours of
R10 training/experience in nuclear pharmacy practice. Academic training may
R10 be substituted for no more than 2000 hours of the required training and
R10 experience; and

R10 (d) Pass an examination in nuclear pharmacy administered by diplomats of
R10 the specialty board, that assess knowledge and competency in
R10 procurement, compounding, quality assurance, dispensing, distribution,
R10 health and safety, radiation safety, provision of information and
R10 consultation, monitoring patient outcomes, research and development; or

R10 (2) (a) Have completed 700 hours in a structured educational program consisting
R10 of both:

R10 1. 200 hours of classroom and laboratory training in the following
R10 areas:

R10 a. Radiation physics and instrumentation;

R10 b. Radiation protection;

R10 c. Mathematics pertaining to the use and measurement of
R10 radioactivity;

R10 d. Chemistry of radioactive material for medical use; and

R10 e. Radiation biology; and

R10 2. Supervised practical experience in a nuclear pharmacy involving:

R10 a. Shipping, receiving, and performing related radiation
R10 surveys;

R10 b. Using and performing checks for proper operation of
R10 instruments used to determine the activity of dosages,
R10 survey meters, and, if appropriate, instruments used to
R10 measure alpha or beta-emitting radionuclides;

R10 c. Calculating, assaying, and safely preparing dosages for
R10 patients or human research subjects;

R10 d. Using administrative controls to avoid medical events in the
R10 administration of radioactive material; and

R10 e. Using procedures to prevent or minimize radioactive
R10 contamination and using proper decontamination
R10 procedures; and

R10 (b) Have obtained written attestation, signed by a preceptor authorized user
R10 or a residency program director who represents a consensus of residency
R10 program faculties (as long as at least one member of the residency
R10 program faculty is an authorized individual in the same category
R10 designated by the applicant seeking authorized status) who meets the
R10 requirements in paragraphs 64E-5.659(1)(a), 64E-5.659(1)(b) and
R10 64E-5.659(1)(c) or 64E-5.659(2)(a), F.A.C., of this section and have
R10 demonstrated the ability to function independently as an authorized
R10 nuclear pharmacist to fulfill the radiation safety related duties for a medical
R10 use licensee.

R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
R10 Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History-New 02-11-10

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

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in sub-subparagraphs 64E-5.660(2)(a)2.g. and paragraph 64E-5.660(2)(b), F.A.C., of this section. (Specialty boards whose certification processes have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To be recognized, a specialty board shall require all candidates for certification to:

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

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

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

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

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

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

R10 2. Work experience, under the supervision of an authorized user who
R10 meets the requirements in Rule 64E-5.657 or 64E-5.660, F.A.C., or
R10 equivalent agreement state requirements. A supervising authorized
R10 user, who meets the requirements in subsection
R10 64E-5.660(2), F.A.C., must also have experience in administering
R10 dosages in the same dosage category or categories (i.e., sub-
R10 subparagraph 64E-5.660(2)(a)2.g., F.A.C.,) as the individual
R10 requesting authorized user status. The work experience must
R10 involve the following:

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

R10 b. Performing quality control procedures on instruments used
R10 to determine the activity of dosages, and performing checks
R10 for proper operation of survey meters;

R10 c. Calculating, measuring, and safely preparing patient or
R10 human research subject dosages;

R10 d. Using administrative controls to prevent a medical event
R10 involving the use of unsealed radioactive material;

R10 e. Using procedures to contain spilled radioactive material
R10 safely and using proper decontamination procedures;

R10 f. Performing checks for proper operation of survey meters;
R10 and

R10 g. Administering dosages of radioactive drugs to patients or
R10 human research subjects involving a minimum of three
R10 cases in each of the following categories for which the
R10 individual is requesting authorized user status as listed
R10 below:

R10 (I) Oral administration of less than or equal to
R10 1.22 gigabecquerels (33 millicuries) of sodium iodide
R10 I-131, for which a written directive is required or sub-
R10 sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.;

R10 (II) Oral administration of greater than 1.22
R10 gigabecquerels (33 millicuries) of sodium iodide I-131;

R10 (III) Parenteral administration of any beta emitter, or a
R10 photon-emitting radionuclide with a photon energy
R10 less than 150 keV, for which a written directive is
R10 required; and/or

R10 (IV) Parenteral administration of any other radionuclide,
R10 for which a written directive is required; and

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

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

64E-5.661 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries). Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to: **(Entire section New)**

(1) Be certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 64E-5.661(3)(a) and 64E-5.661(3)(b), F.A.C., of this section and whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.661(3)(c), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or

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

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

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

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

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

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

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

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

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

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

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

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

64E-5.662 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries). Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to: **(Entire section New)**

(1) Be certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 64E-5.662(3)(a) and 64E-5.662(3)(b), F.A.C., of this section, and whose certification has been recognized by the NRC or an agreement state, and who meets the requirements in paragraph 64E-5.662(3)(c), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or

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

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

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

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

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

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

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

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

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

R10 6. Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

R10 (c) Have obtained written attestation that the individual has satisfactorily completed the requirements in subsection 64E-5.663(2) or 64E-5.663(3), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized for the parenteral administration of unsealed radioactive material requiring a written directive. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657, 64E-5.660 or 65E-5.663, F.A.C., or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements in Rule 64E-5.660, F.A.C., must have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C.

R10 Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS.
R10 Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS.
R10 History-New 02-11-10

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

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

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

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

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

(a) Radiation safety precautions and instruction;

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

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

(d) Security of radioactive materials, training or experience of individuals involved in these uses or other information not specified in paragraph 64E-5.665(3)(a)(b) or (c), F.A.C.

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

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

SUBPART A GENERAL REQUIREMENTS

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

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PART XIII

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

64E-5.1301 Sealed or Unsealed Sources of Radioactive Material. The rules in this part establish radiation safety requirements for licensees possessing or using sealed or unsealed sources of radioactive materials not otherwise specified in a license or addressed in these rules. The requirements of this part are in addition to and not in substitution for other applicable requirements of these rules. Licenses of broad scope are exempt from the
R10 requirements of Rule 64E-5.1313, subsections 64E-5.1318(2), and 64E-5.1319(1), (2), (3) and
R10 (4), F.A.C. Except for Rule 64E-5.1320, F.A.C., the requirements of this part do not apply to persons licensed as specified in Parts IV, VI, and XI. General licensees as specified in subsections 64E-5.206(7) and (8), F.A.C., are exempt from the requirements of this part.

R10 Rulemaking Authority: 404.051, 404.061, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(10), 404.061(2)(3), 404.081(1), F.S.
R10 History: New 5-12-93, Amended 5-15-96, Formerly 10D-91.1401, Amended 02-11-10.

SUBPART A
GENERAL REQUIREMENTS

64E-5.1302 Operating and Emergency Procedures. The licensee's operating and emergency procedures shall be posted in accordance with 64E-5.901 and shall accompany portable devices at all times. The procedures shall include instructions in the following as applicable to the type of use:

(1) The uses of sources of radiation so that exposures are maintained as low as reasonably achievable and no individual is likely to be exposed to radiation doses in excess of the standards in Part III;

(2) Methods and occasions for conducting radiation surveys;

(3) Methods and occasions for locking and securing sources of radiation;

(4) Personnel monitoring and the use of personnel monitoring equipment;

(5) Minimizing exposure of individuals in the event of an accident;

(6) Notifying proper personnel in the event of damage, loss, theft, or accident involving sources of radiation;

(7) General guidelines for the safe handling and use of unsealed sources of radioactive materials;

(8) Maintenance of records;

(9) Procedures for picking up, receiving and opening packages containing radioactive materials; and

(10) The transportation of radioactive sources to temporary job sites, including the packaging, marking, labeling and placing of such sources in vehicles, placarding of vehicles, securing the sources during transportation and possessing proper shipping papers and emergency response information.

Specific Authority: 404.051, 404.061, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.
History: New May 12, 1993, Amended January 1, 1994, Amended May 15, 1996, Formerly 10D-91.1403.

64E-5.1303 Leak Test Requirements for Possession of Sealed Sources.

(1) A licensee in possession of a sealed source shall assure that:

(a) The sealed source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the sealed source was tested semiannually before transfer to the licensee;

(b) The sealed source is tested for leakage at least semiannually or at intervals approved by the department;

(c) Leak tests are capable of detecting 0.005 microcurie (185 Bq) of radioactive material on the test sample, or, in the case of radium, the escape of radon of 0.001 microcurie (37 Bq) each 24 hours;

(d) Test samples are taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(e) Device test samples are taken when the sealed source is in the off or shielded position.

(f) Leak tests are analyzed by individuals who are licensed by the department, U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform leak test services.

(2) A licensee shall retain leak test records for 3 years. The records shall contain the manufacturer's name, the model and serial numbers of each sealed source tested, the identity of each sealed source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), the date of the test, and the signature of the radiation safety officer or designee.

(3) If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(a) Immediately withdraw the sealed source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with these regulations; and

(b) File a report with the department within 5 days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

(4) A leak test is not required on the following sealed sources:

(a) Sealed sources containing only radioactive material with a half-life of less than 30 days;

(b) Sealed sources containing only radioactive material as a gas;

(c) Sealed sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; and

(d) Sealed sources that are listed on a department license for storage only. The licensee shall test each such sealed source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

(5) The department is authorized to approve leak test frequencies other than semiannually. Criteria used to determine these frequencies include:

(a) The isotope and activity;

(b) The requested usage;

(c) The environmental hazards to which the sealed sources may potentially be exposed;

(d) The manufacturer's recommended frequency; and

(e) Specific information on the sealed source or device provided by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, including:

1. Sealed Source and Device Registry sheets;

2. Naturally Occurring or Accelerator Produced Radioactive Materials Sealed Source and Device Registry sheets.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.
Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.
History: New May 12, 1993, Formerly 10D-91.1404.

64E-5.1304 Inventory Requirements. A licensee who possesses sealed sources shall conduct a physical inventory of all such sealed sources semiannually unless another interval is specified in the license. Inventory records shall be retained for 3 years. Inventory records shall contain the following:

(1) The model and serial number of each sealed source;

(2) The identity of each sealed source radionuclide and its estimated activity;

(3) The location of each sealed source;

(4) The date of the inventory; and

(5) The signature of the radiation safety officer or designee.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.
Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.
History: New May 12, 1993, Formerly 10D-91.1405.

64E-5.1305 Training Requirements, Authority, Duties and Responsibilities of the Radiation Safety Officer.

(1) The licensee shall appoint a radiation safety officer with the authority to fulfill the duties and responsibilities listed in this part.

(2) The radiation safety officer shall have sufficient training and experience with radioactive materials to be a user of the requested licensed materials, unless otherwise specified in the license. This training shall include practical experience in the safe use of radioactive materials and knowledge of procedures, facilities and equipment.

(3) The duties and responsibilities of the radiation safety officer shall include the following:

(a) Ensure that all terms and conditions of the license and these regulations are complied with;

(b) Ensure that the sealed sources are leak tested timely and as prescribed by the manufacturer or by the license;

(c) Ensure that radioactive materials are used only by individuals who are authorized by the license and that all individuals wear required personnel monitoring equipment;

(d) Maintain all records required by the license and these regulations. These records shall include personnel monitoring records, leak test records, inventory records, training records for users and receipt, transfer and disposal records;

(e) Ensure that radioactive materials are properly secured against unauthorized access or removal;

64E-5.1320 Bioassay Program. The licensee shall establish and submit for department approval a bioassay program used to evaluate internal doses. At a minimum an acceptable program shall include the following action levels for organ uptakes, corresponding actions taken if these levels are exceeded, frequency of measurement and maintenance of records.

(1) Routine bioassay is required when an individual handles in open form unsealed quantities of radioactive iodine that exceed those shown in the table 1 below. The quantities shown apply to both the quantity handled at any one time or integrated as the total amount of activity introduced into a process by an employee over any 3-month period.

TABLE 1

I-125 or I-131 Activity Handled in Unsealed Form Requiring Bioassay

Type of Operation	Volatile or Dispersible	Bound to Nonvolatile Agent
Processes in open room or bench, with possible escape of iodine from process vessels	1.0 mCi (37 MBq)	1.0 mCi (37 MBq)
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	1.0 mCi (37 MBq)	10.0 mCi (370 MBq)
Processed carried out within glove boxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	10.0 mCi (370 MBq)	100.0 mCi (3700 MBq)

(a) A bioassay shall be taken within 72 hours of initial use of radioiodine and every 2 weeks thereafter. When radioiodine use is on an infrequent basis (less than every 2 weeks), a bioassay shall be taken within 10 days of the last day of use.

(b) If the thyroid burden at the time of measurement exceeds 0.12 microcurie (4.44 KBq) of iodine 125 or 0.04 microcurie (1.48 KBq) of iodine 131, the following actions shall be taken:

1. An investigation of the operations involved, including air and other facility surveys, shall be carried out to determine the cause(s);

2. Corrective actions that will eliminate or lower the potential for further exposures shall be implemented;

3. A repeat bioassay shall be taken within 2 weeks of the previous measurement and shall be evaluated within 24 hours after the measurement in order to confirm the presence of internal radioiodines; and

4. Notification reports must be provided as required by Rules 64E-5.345, and 64E-5.347, F.A.C., or as required by conditions of the license; and

(c) A record of each bioassay shall be maintained for inspection by the department in an auditable form for 3 years and shall include the date of the bioassay, the name of the individual, and the thyroid burden at the time of the measurement.

(2) Routine bioassay is required when an individual handles in open form unsealed quantities of tritium that exceed those shown in table 2 below. The quantities shown apply to both the quantity handled at any one time or integrated as the total amount of activity introduced into a process by an employee over a 1-month period.

TABLE 2

Tritium Activity Handled in Levels or Concentrations Requiring Bioassay

Type of Operation	HTO and Other Tritiated Compounds (Including Nucleotide Precursors)	Tritium (HT or T) Gas in Sealed Process Vessels
Processes in open room or bench with possible escape of tritium from process vessels	0.1 Ci (3.70 GBq)	100 Ci (3.7 TBq)
Processes with possible escape of tritium carried out within a fume hood of adequate design, face velocity, and performance reliability	1 Ci (37 GBq)	1,000 Ci (37 TBq)
Processes carried out within glove boxes that are ordinarily closed but with possible release of tritium1 from process vessels and occasional exposure to contaminated box and leakage	10 Ci (370 GBq)	10,000 Ci (370 TBq)

(a) A bioassay shall be taken within 72 hours of initial use of tritium and every 2 weeks thereafter. When work with tritium is on an infrequent basis (less frequent than every 2 weeks), a bioassay shall be taken within 10 days of the last day of use.

(b) If the urinary tritium concentration exceed 5 microcuries (185 KBq) per liter at the time of the measurement the following actions shall be taken:

1. An investigation of the operations involved, including air and other facility surveys, shall be carried out to determine the cause(s);

2. Corrective actions that will eliminate or lower the potential for further exposures shall be implemented;

R10 3. A repeat bioassay shall be taken within 1 week of the previous
R10 measurement and shall be evaluated within 1 week after the
R10 measurement. Internal dose commitments shall be estimated using
R10 at least two bioassays and other survey data, including the
R10 probable times of intake of tritium; and

R10 4. Notification reports must be provided as required by Rules
R10 64E-5.345, and 64E-5.347, F.A.C., or as required by conditions of
R10 the license; and

R10 (c) A record of each bioassay shall be maintained for inspection by the
R10 department in an auditable form for 3 years and shall include the date of
R10 the bioassay, the name of the patient, and the urinary tritium concentration
R10 at the time of the measurement.

R10 Rulemaking Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081 FS.
R10 Law Implemented: 404.022, 404.042, 404.051(1), (4), (6), (9), (10), 404.061(2), (3), 404.071(1), 404.081(1) FS..
R10 History: New 02-11-10

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Federal Policy as described in 45 CFR Part 46 dated 11/09/2009 which is herein incorporated by reference in 64E-5.601(5)(b), F.A.C

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Title 45: Public Welfare

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PART 46—PROTECTION OF HUMAN SUBJECTS

Section Contents

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).

Editorial Note: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost—sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

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Authority: 5 U.S.C. 301; 42 U.S.C. 289, 42 U.S.C. 300v–1(b).

Source: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§ 46.101 To what does this policy apply?

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(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in theFederal Registeror will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in theFederal Registeror in such other manner as provided in department or agency procedures.[1]

[1] Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A–D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.102 Definitions.

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(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation,* and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

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(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

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[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§§ 46.104-46.106 [Reserved]

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§ 46.107 IRB membership.

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(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall

be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

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In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in §46.103(b)(4) and, to the extent required by, §46.103(b)(5).

(b) Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 46.109 IRB review of research.

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(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

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(a) The Secretary, HHS, has established, and published as a Notice in theFederal Register,a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in theFederal Register. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.111 Criteria for IRB approval of research.

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(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

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Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

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An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.114 Cooperative research.

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Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ 46.115 IRB records.

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(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described is §46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.116 General requirements for informed consent.

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Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.117 Documentation of informed consent.

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(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116.

This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

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Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 46.119 Research undertaken without the intention of involving human subjects.

 top

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

 top

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department

or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 [Reserved]

 top

§ 46.122 Use of Federal funds.

 top

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 46.123 Early termination of research support: Evaluation of applications and proposals.

 top

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragarph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 46.124 Conditions.

 top

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

 top

Source: 66 FR 56778, Nov. 13, 2001, unless otherwise noted.

§ 46.201 To what do these regulations apply?

 top

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS

employees.

(b) The exemptions at §46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of §46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in §46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Definitions.

top

The definitions in §46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in theFederal Registerguidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

§ 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

top

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§ 46.204 Research involving pregnant women or fetuses.

top

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

§ 46.205 Research involving neonates.

top

(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

(3) Individuals engaged in the research will have no part in determining the viability of a neonate.

(4) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if

the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the neonate will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the neonate;

(3) There will be no added risk to the neonate resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

top

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§ 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

top

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of §§46.204 or 46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in theFederal Register,has determined either:

(1) That the research in fact satisfies the conditions of §46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or

alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

top

Source: 43 FR 53655, Nov. l6, l978, unless otherwise noted.

§ 46.301 Applicability.

top

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

top

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

top

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) *DHHS* means the Department of Health and Human Services.

(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

top

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8386, Jan. 26, 1981]

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

top

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under §46.306 (a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

top

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in theFederal Register,of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in theFederal Register,of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research

top

Source: 48 FR 9818, Mar. 8, 1983, unless otherwise noted.

§ 46.401 To what do these regulations apply?

top

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of §46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of Subpart A are applicable to this subpart.

[48 FR 9818, Mar. 8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991]

§ 46.402 Definitions.

top

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

top

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

top

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

top

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

top

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

top

HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) That the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

top

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

top

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Subpart E—Registration of Institutional Review Boards

top

Source: 74 FR 2405, Jan. 15, 2009, unless otherwise noted.

§ 46.501 What IRBs must be registered?

top

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under §46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§ 46.502 What information must be provided when registering an IRB?

top

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an “active protocol” is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§ 46.503 When must an IRB be registered?

top

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under §46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

§ 46.504 How must an IRB be registered?

top

Each IRB must be registered electronically through *http://ohrp.cit.nih.gov/efile* unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

§ 46.505 When must IRB registration information be renewed or updated?

top

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with §46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must

be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

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FLORIDA DEPARTMENT OF HEALTH

Bureau of Radiation Control
Division of Environmental Health

RADIOACTIVE MATERIALS PROGRAM
APPLICATION FOR RADIOACTIVE MATERIALS LICENSE
NON-HUMAN USE

INSTRUCTIONS - Complete Items 1 – 15 as applicable. Item 15 must be completed on all applications. Use supplemental sheets where necessary. **Mail the original and one copy to:** Department of Health, Bureau of Radiation Control, Radioactive Materials Program, 4052 Bald Cypress Way, Bin #C21, Tallahassee, FL 32399-1741. *Regulatory Guidance Documents are available from the Bureau of Radiation Control to assist in completing this application.*

1.a. LEGAL NAME, MAILING ADDRESS (Include ZIP code), FEI #, Phone & Fax Numbers:

FEI #_____

Telephone # _____

Fax # _____

1.b. STREET ADDRESS WHERE RADIOACTIVE MATERIALS WILL BE USED OR STORED (Include ZIP Code)

☐ Same as 1.a.

2.a. LICENSE APPLICATION FEE CATEGORY
(See 64E-5.204, F.A.C., for license descriptions)

_____

b. LICENSE FEE ENCLOSED: $_____

3. THIS IS AN APPLICATION FOR:

☐ **a.** New License

☐ **b.** Amendment To License Number:_____

☐ **c.** Renewal Of License Number:_____

4. INDIVIDUAL USERS & REQUESTED USES
(Name all individuals who may receive, possess, prepare, use or transfer radioactive materials or directly supervise others in these activities.)

☐ SEE ATTACHED LIST

5.a. RADIATION SAFETY OFFICER (RSO):
(Name and Contact Information)

Name: _____

RSO Phone #:_____

RSO E-Mail: _____

5.b. ALTERNATE EMERGENCY CONTACT:

Name: _____

Contact Phone #: _____

Contact E-Mail: _____

6. TRAINING AND EXPERIENCE IN RADIATION SAFETY

a. FORMAL TRAINING IN RADIATION SAFETY: Describe the formal training for each individual named in Items 4 and 5, including principles and practices of radiation protection, radioactivity measurement, monitoring techniques and the use of instruments, mathematics and calculations basic to the use and measurement of radioactivity, and biological effects of radiation. Include the name of the person or institution providing the training, duration of training and when training was received. Attach a copy of any training certificate received if applicable.

☐ **SEE ATTACHED LIST**

b. EXPERIENCE: Describe the radiation work experience for each individual named in Items 4 and 5, including where the experience was obtained or attach a copy of a radioactive materials license that identifies them by name as an authorized user. Include a list of radioisotopes and the maximum activity of each use. Work experience or on-the-job training should be commensurate with the proposed use.

☐ **SEE ATTACHED LIST**

7. RADIOACTIVE MATERIAL

a. Isotope	b. Chemical or Physical Form (If sealed sources, include manufacturer name and model numbers)	c. Maximum Amount Or Activity Possessed At Any One Time. (If sealed source, state the number of sources, maximum activity per source and total activity)
Ex. Co-60	Sealed source XYZ Corp. Model XYZ for use in XYZ Corp Model AAA therapy device or liquid/gas/powder.	30 sources, 2 curies each for a total of 60 curies.
☐ SEE ATTACHED LIST		

8. DESCRIBE THE PURPOSE FOR WHICH EACH RADIOACTIVE MATERIAL LISTED IN ITEM 7, ABOVE WILL BE USED.

(For each sealed source, include the manufacturer's name and model number of the device, gauge or storage container where the source will be used or stored. List a line item for each different type of use for the same or different isotopes.

Ex. Co-60 to be used in a xyz corporation model AAA device in a BBB source holder for the measuring of density of materials in a process vessel.

☐ SEE ATTACHED LIST

9. LIST EACH TYPE OF RADIATION DETECTION INSTRUMENT (i.e., survey meters, counters, etc.)

TYPE OF INSTRUMENTS (include manufacturer and model number of each)	**USE** (e.g., monitoring, surveying, measuring)	**RADIATION DETECTED** (beta, gamma, alpha, neutrons)	**SENSITIVITY RANGE Low –High** (mR/hr)	**NUMBER AVAILABLE**
Ex. XYX Co. Model 1 survey meter with Model 33 probe	Monitoring & surveying for removable contamination	Beta & Gamma	0.1 mR/hr – 1 R/hr	2
☐ SEE ATTACHED LIST				

10. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 9 ABOVE.

a. ☐ **Calibration by Licensed Service Company**
Calibration Frequency will be at Intervals Not to Exceed: _____ months

b. ☐ **Calibration by Applicant** (Attached is a separate sheet describing procedures, frequency and standards used for calibration of instruments.)

11. PERSONNEL MONITORING DEVICES. Complete Items a, b, & c. (Check all that are applicable)

a. ☐ Film ☐ OSLD ☐ TLD ☐ Other (See attached) (Provider Must be NVLAP Certified)

b. ☐ Whole Body: Exchange Frequency Not to Exceed: _____ Months
☐ Extremity: Exchange Frequency Not to Exceed: _____ Months

c. Radiation Detected: ☐ Beta ☐ Gamma ☐ Neutron

12. FACILITIES AND EQUIPMENT. Attach a description of facilities where radioactive material, including waste, will be used or stored. **Attach an annotated diagram of the areas of use and/or storage, including adjacent areas.** Describe equipment such as remote handling devices, storage containers, shielding, fume hoods, etc. Describe security at your facility such as locks, chains, alarms, security camera, security services, etc.

☐ Description of facilities and equipment also attached with annotated diagram of the areas of use or storage, including adjacent areas.

☐ Attached is a description of security at facilities of the areas of radioactive materials are used or stored to prevent theft or unauthorized access to radioactive materials.

13. RADIATION PROTECTION PROGRAM. Attach a radiation protection program as appropriate for the material to be used, including general radiation safety procedures, emergency procedures, security, and bioassay procedures, etc. (Note that possession of large quantities of certain isotopes, such as those used in fixed gauges, industrial radiography, or irradiators for use in research or blood products, may require additional increased controls for security measures or national source tracking as required by 64E-5.350 and 64E-5.351, FAC.)

☐ Radiation Protection Program Details Attached

14. WASTE DISPOSAL. Describe the procedures for handling, storing and disposing of radioactive wastes (solid, liquid and/or gas). Name the commercial waste disposal service employed, if applicable. If sealed sources and/or devices will be returned to the manufacturer, so state.

☐ See Attached for Details on Radioactive Waste Disposal

15. CERTIFICATE

The applicant and any official executing this certificate on behalf of the applicant named in Item 1, certify that this application has been prepared in accordance with Chapter 64E-5, Florida Administrative Code, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. *In addition, the applicant or executing official is acknowledging that they are aware that knowingly making false statements to a public servant is a violation of section 837.06, Florida Statutes, and is punishable by fine or imprisonment*

Certifying Official (Signature)

Name (typed or printed)

Title

Date

Warning: KNOWINGLY MAKING FALSE STATEMENTS TO A PUBLIC SERANT IS A VIOLATION OF SECTION 837.06, FLORIDA STATUTES, AND IS PUNISHABLE BY FINE OR IMPRISONMENT

FLORIDA DEPARTMENT OF HEALTH

Bureau of Radiation Control
Division of Environmental Health

RADIOACTIVE MATERIALS SECTION
APPLICATION FOR RADIOACTIVE MATERIALS LICENSE
HUMAN USE

INSTRUCTIONS - Complete Items 1 – 35 as applicable. Item 35 must be completed on all applications. Use supplemental sheets where necessary. **Mail the original and one copy to:** Department of Health, Bureau of Radiation Control, Radioactive Materials Section, 4052 Bald Cypress Way, Bin #C21, Tallahassee, FL 32399-1741. *Regulatory Guidance Documents are available from the Bureau of Radiation Control to assist in completing this application.*

1.a. LEGAL NAME, MAILING ADDRESS (Include ZIP code), FEI #, Phone & Fax Numbers:

FEI #_____

Telephone # _____

Fax # _____

1.b. STREET ADDRESS WHERE RADIOACTIVE MATERIALS WILL BE USED OR STORED (Include ZIP Code)

☐ Same as 1.a.

2.a. LICENSE FEE CATEGORY
(See 64E-5.204, F.A.C., for license descriptions)

_____

b. LICENSE FEE ENCLOSED: $_____

3. THIS IS AN APPLICATION FOR:

☐ **a.** New License

☐ **b.** Amendment To License Number:_____

☐ **c.** Renewal Of License Number:_____

4. INDIVIDUAL USERS & REQUESTED USES
(Name all Authorized Users & Authorized Medical Physicists, who may receive, possess, prepare, use or transfer radioactive materials or directly supervise others in these activities.)

☐ SEE ATTACHED LIST

5.a. RADIATION SAFETY OFFICER (RSO):
(Name and Contact Information)

Name: _____

RSO Phone #:_____

RSO E-Mail: _____

5.b. ALTERNATE EMERGENCY CONTACT:

Name: _____

Contact Phone #: _____

Contact E-Mail: _____

6.a. Radioactive Materials For Medical Use By 64E-5, Florida Administrative Code	Y=☒	Possession Limits
Both: 64E-5.626(1) & (2) Uptake, Dilution, Excretion (Written Directive Required) (NaI-131 ≥ 30 µCi) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	0.5 curies or _____ curies
Only 64E-5.626(1) Uptake, Dilution or Excretions (No Written Directive Required) (NaI-131 < 30 µCi)	☐	0.5 curies or _____ curies
Only 64E-5.626(2) Uptake, Dilution or Excretions **(Written Directive Required)** (NaI-131 ≥ 30 µCi) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	0.5 curies or _____ curies
All: 64E-5.627(1), (2), & (3) Imaging & Localizations (Written Directive Required) (NaI-131 ≥ 30 µCi) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	2 curies or _____ curies
Only 64E-5.627(1) Imaging and Localizations (No Written Directive Required) (NaI-131 < 30 µCi)	☐	2 curies or _____ curies
Both 64E-5.627(2) & (3) Imaging & Localizations **(Written Directive Required)** (NaI-131 ≥ 30 µCi) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	2 curies or _____ curies
☐ 64E-5.627 (4) Xe-133 Gas ☐ Tc99m Aerosol	☐	_____ millicuries
64E-5.628(1) Mo99/Tc99m Generator	☐	5 curies
64E-5.628(2) or (3) Other Generators	☐	Complete Item 6.b.
64E-5.630 Radiopharmaceutical Therapy (Written Directive Required) ☐ Capsule form ONLY I-131 or ☐ I-131 Bioassay Program Attached	☐	2 curies or _____ curies
64E-5.632 Manual Brachytherapy	☐	2 curies or _____ curies
64E-5.632(2) Sr-90 Eye Applicator ONLY	☐	Complete Item 6.b.
64E-5.632(3)&(4) Pd-103 or I-125 for Permanent Implants ONLY	☐	2 curies or _____ curies
64E-5.634(1) Gamma Stereotactic Radiosurgery	☐	Complete Item 6.b.
64E-5.634(2) Remote Afterloaders	☐	Complete Item 6.b.
64E-5.634(3) Teletherapy	☐	Complete Item 6.b.
64E-5.664 Other Medical Uses Not Listed Above (Detailed Information Attached)	☐	Complete Item 6.b.
64E-5.617 Quantities Exceeded: Calibration, Reference, or Transmission Sources or Other Radioactive Materials in Quantities Greater than Allowed by 64E-5.617	☐	Complete Item 6.b.
64E-5.631 Sealed Sources for Diagnostic Uses	☐	Complete Item 6.b.

6.b. Radioactive Materials Details Not Provided In Item 6.a.

Isotope	Chemical or Physical Form	Maximum number of sources, activity (curies) for each source and total activity	Purpose for which radioactive materials will be used:
Ex. Co-60	Sealed source XYZ Corp. Model XYZ for use in XYZ Corp Model AAA therapy device	30 sources, 2 curies each for a total of 60 curies.	64E-634(1). 15 sources for possession for source exchanges. See attached for procedure details

Item	Appendix	Title	Model Procedure Attached Or NA	Equivalent Procedure Attached
7	None	Facility Diagram	☐ **NA**	☒
8	A	Radiation Safety Committee	☐	☐
9	B	Instrumentation	☐	☐
10	C	Quality Control	☐	☐
11	D	Dose Calibrator	☐	☐
12	E	Personnel Monitoring	☐	☐
13	F	Training Program	☐	☐
14	G	Ordering And Receiving	☐	☐
15	H	Opening Packages	☐	☐
16	I	Use Records	☐	☐
17	J	Rules Of Use	☐	☐
18	K	Emergency Procedures	☐	☐
19	L	Area Surveys	☐	☐
20	M	Members Of Public Dose Study	☐	☐
21	N	Radiopharmaceutical Therapy	☐	☐
22	O	Implant Therapy	☐	☐
23	P	Radioactive Gases & Aerosols	☐	☐
24	Q	Quality Management Program	☐	☐
25	R	ALARA Program (Radiation Safety Committee Required)	☐	☐
26	S	ALARA Program (No Radiation Safety Committee)	☐	☐
27	T	Leak Testing	☐	☐
28	U	Bioassay	☐	☐
29	V	Survey Meter Calibration	☐	☐
30	W	Waste	☐	☐
31	X	Inventory	☐	☐
32	Y	Diagnostic Radiopharmaceuticals	☐	☐
33	Z	Mobile Nuclear Medicine	☐	☐
34	Other		**NA**	☐

35. CERTIFICATE

The applicant and any official executing this certificate on behalf of the applicant named in Item 1, certify that this application has been prepared in accordance with Chapter 64E-5, Florida Administrative Code, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. *In addition, the applicant or executing official is acknowledging that they are aware that knowingly making false statements to a public servant is a violation of section 837.06, Florida Statutes, and is punishable by fine or imprisonment*

Certifying Official (Signature)

Name (typed or printed)

Title

Date

Warning: KNOWINGLY MAKING FALSE STATEMENTS TO A PUBLIC SERANT IS A VIOLATION OF SECTION 837.06, FLORIDA STATUTES, AND IS PUNISHABLE BY FINE OR IMPRISONMENT