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FLORIDA DEPARTMENT OF HEALTH

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August 2001

Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2001-04

Revisions 3 and 4 Filing Instructions: Changes to Chapter 64E-5, Florida Administrative Code (F.A.C.)

Changes were made to "Control of Radiation Hazard Regulations," Chapter 64E-5, F.A.C., that became effective August 8 and September 11, 2001. **These changes are indicated as Revision 3 or (R3) and Revision 4 (R4) in the margin.** Enclosed are copies of the pages to be inserted. This update is printed on blue paper.

These instructions apply to the complete version (brown cover) of Chapter 64E-5, F.A.C. Be sure that Revision 1 and Revision 2 changes have been made before making these changes. This can be verified by checking page ii of the index.

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
	Page Number	**Page Number**
Index	i through xii	i through xii
I General Provisions	Part I Index I-1 through I-22	Part I Index I-1 through I-22
II Licensing of Radioactive Materials	Part II Index II-45 through II-46 II-53 through II-54	Part II Index II-45 through II-46 II-53 through II-54
IV Radiation Safety Requirements for Industrial Radiographic Operations	Part IV Index IV-1 through IV-16	Part IV Index IV-1 through IV-24
VI Use of Radionuclides in the Healing Arts	Part VI Index VI-1 through VI-2 VI-5 through VI-6 VI-23 through VI-26	Part VI Index VI-1 through VI-2 VI-5 through VI-6 VI-23 through VI-26
Attachment Certificate – Disposition of Radioactive material	Attachment page not numbered	Attachment not numbered (mailing address change only)

PART	PAGES TO BE REMOVED	PAGES TO BE INSERTED
	Page Number	Page Number
Attachment Authorized Nuclear Pharmacy Training Requirements		New – place at end of attachments
Attachment Map – State Boundaries Florida Constitution		New – place at end of attachments

Below is a brief summary of the substantive changes. This list only identifies substantive changes. Please refer to the actual text for details.

Part I: Definitions for "authorized nuclear pharmacist," "baggage x-ray system," "cabinet x-ray system" added. Definition of "radiographer," "radiographer assistant," "radiographic exposure device," "shielded position" and "storage container" changed to reflect industrial radiography rule language specified in Part IV. Definition of "offshore" added to identify Florida boundaries as specified in the Florida Constitution.

Part II: The requirements to distribute radiopharmaceuticals have changed. Section 64E-5.210(10) identifies new requirements needed. These changes impact all radiopharmacy and radioactive drug manufacturers licensed by the department.

Part IV: All sections have been repealed and replaced with sections 64E-5.423 – 64E-5.441. Radiographer certification is required for both radioactive materials and x-ray industrial radiography. Training requirements specified. All radiography licensees and registrants are impacted by this revision. A 12-month grace period is provided to allow current radiographers to become certified.

Part VI: Allows "authorized nuclear pharmacists" to be added to the license to compound radiopharmaceuticals. Requires all radiopharmaceuticals to be received by licenses authorized by 64E-5.210(10) or prepared by an authorized nuclear pharmacist or authorized user named on the license. Deleted the requirement that radiopharmaceuticals must have an IND or NDA issued by the U.S. FDA.

Attachment: Certificate – Disposition Radioactive Materials (DOH Form DH – 1059); mailing address change

Authorized Nuclear Training Requirements as required by 64B16-28.903

State of Florida Boundaries (Map) showing approximate boundaries with exact boundaries described in Florida Constitution

No specific actions nor written response is required. If you have any questions or need additional information, please call the Radioactive Materials Section at (850) 245-4545.

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

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

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PARTS X and XII

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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 http://fac.dos.state.fl.us/.

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

PART III STANDARDS FOR PROTECTION

SUBPART A GENERAL PROVISIONS

SUBPART B RADIATION PROTECTION PROGRAMS

SUBPART C OCCUPATIONAL DOSE LIMITS

SUBPART D RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

SUBPART E SURVEYS AND MONITORING

SUBPART F CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

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

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

PART IV RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

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

PART V X-RAYS IN THE HEALING ARTS

PART VI USE OF RADIONUCLIDES IN THE HEALING ARTS

PART XV TRANSPORTATION OF RADIOACTIVE MATERIALS

ATTACHMENTS

PART I GENERAL PROVISIONS

PART I

GENERAL PROVISIONS

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

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

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

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

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

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

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

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

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

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

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

(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 acheivable 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.

(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.

R3 (177) “Authorized nuclear pharmacist” means a pharmacist who is actively licensed as a nuclear pharmacist by the Board of Pharmacy as specified in Rule 64B16-28.903, F.A.C., and is authorized on a radioactive materials license by the department.

(16) "Authorized user" means a physician, dentist or podiatrist who is identified as an authorized user on a department, U.S. Nuclear Regulatory Commission, agreement state, or licensing state license that authorizes the medical use of 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 environment from the testing of nuclear explosive devices. 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 less than 120 kVp that produces only fluoroscopic images and that is used for 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.

R4 (21) "Brachytherapy" means a method of radiation therapy in which sealed sources are used to deliver a radiation dose by surface, intracavitary, or interstitial application.

R4 (22) "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.

R4 (23) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an R4 enclosure or cabinet that, independently of existing architectural structures R4 except the floor on which it is placed, is intended to contain at least the portion of R4 the material being irradiated, to provide radiation attenuation, and to exclude R4 persons from its interior during generation of x-radiation. An x-ray tube used R4 within a shielded part of a building or x-ray equipment that temporarily or R4 occasionally incorporates portable shielding is not considered a cabinet x-ray R4 system.

R4 (24) "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.

R4 (25) "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.

R4 (26) "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.

R4 (27) "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.

R4 (28) "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.

R4 (29) "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.

R4 (30) "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 ($H_{E,50} = \Sigma W_T H_{T,50}$).

R4 (31) "Constraint" or "dose constraint" means a value above which specified licensee
R2 actions are required.

R4 (32) "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).

R4 (33) "Declared pregnant woman" means a woman who has voluntarily informed her employer in writing of her pregnancy and the estimated date of conception.
R2 The declaration remains in effect until the declared pregnant woman withdraws
R2 the declaration in writing or is no longer pregnant.

R4 (34) "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.

R4 (35) "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).

R4 (36) "Decommission" means to remove a facility safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

R4 (37) "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.

R4 (38) "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.

R4 (39) "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).

R4 (40) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method and other instructions and precautions by which the licensee shall perform diagnostic clinical procedures. Each diagnostic clinical procedure shall be approved by the authorized user and shall include the radiopharmaceutical, dosage, and route of administration.

R4 (41) "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.

R4 (42) "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.

R4 (43) "Dose limits" means the permissible upper bounds of radiation doses established as specified in these rules. For the purpose of these rules, "limits" is an equivalent term.

R4 (44) "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.

R4 (45) "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 ($H_E = \Sigma W_T H_T$).

R4 (46) "Embryo" or "fetus" means the developing human organism from conception until birth.

R4 (47) "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.

R4 (48) "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 64E-5.106 for the SI equivalent.

R4 (49) "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

R4 (50) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

R4 (51) "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

R4 (52) "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).

R4 (53) "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.

R4 (54) "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.

R4 (55) "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.

R4 (56) "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.

R4 (57) "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

R4 (58) "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.

R4 (59) "High radiation area" means an area, accessible to individuals, in which radiation
R2 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.

R4 (60) "Human use" means the internal or external administration of radiation or radioactive material to human beings.

R4 (61) "Individual" means any human being.

R4 (62) "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.

R4 (63) "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.

R4 (64) “Industrial radiography” means nondestructive testing using ionizing radiation to make radiographic images or radiographs to detect flaws in objects.

R4 (65) "Inhalation class" (see "Class").

R4 (66) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

R4 (67) "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.

R4 (68) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

R4 (69) "Large irradiator" means an irradiator where radiation dose rates exceeding 500 rem (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.

R4 (70) "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).

R4 (71) "License" means a license issued by the department in accordance with the rules adopted by the department.

R4 (72) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the department.

R4 (73) "Licensee" means any person who is licensed by the department in accordance with these rules and the Act.

R4 (74) "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.

R4 (75) "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.

R4 (76) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.

R4 (77) "Logging tool" means a device used subsurface to perform well-logging.

R4 (78) "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.

R4 (79) "Low specific activity material (LSA)" means any of the following:

(a) Uranium or thorium ores and physical or chemical concentrates of these ores;

(b) Unirradiated natural or depleted uranium or unirradiated natural thorium;

(c) Tritium oxide in aqueous solutions provided the concentration does not exceed 5.0 millicuries (185 MBq) per milliliter;

(d) Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration of contents does not exceed:

1. 0.0001 millicurie (3.7 kBq) per gram of radionuclides for which the A_2 quantity is not more than 0.05 curie (1.85 GBq);

2. 0.005 millicurie (185 kBq) per gram of radionuclides for which the A_2 quantity is more than 0.05 curie (1.85 GBq), but not more than 1 curie (37 GBq); or

3. 0.3 millicurie (11.1 MBq) per gram of radionuclides for which the A_2 quantity is more than 1 curie (37 GBq).

(e) Objects externally contaminated with radioactive material, provided that the radioactive material is not readily dispersible and the surface contamination, when averaged over an area of 1 square meter, does not exceed 0.0001 millicurie (3.7 kBq) per square centimeter for radionuclides of which the A_2 quantity in Appendix A is not more than 0.05 curie (1.85 GBq), or, for all other radionuclides, 0.001 millicurie (37 kBq) per square centimeter.

R4 (80) "Lung class" (see "Class").

R4 (81) "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.

R4 (82) "Management" means the chief executive officer or that individual's designee.

R4 (83) "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.

R4 (84) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to humans in the practice of the healing arts.

R4 (85) "Member of the public" means any individual except when that individual is receiving an occupational dose.

R4 (86) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

R4 (87) "Minor" means an individual less than 18 years of age.

R4 (88) "Misadministration" means the administration of:

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

R2 1. Involving the wrong individual or wrong radiopharmaceutical; or

2. When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and the prescribed dosage exceeds 30 microcuries.

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

R2 1. Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or

2. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(c) A gamma stereotactic radiosurgery radiation dose:

R2 1. Involving the wrong individual or wrong treatment site; or

2. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

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

R2 1. Involving the wrong individual, wrong mode of treatment, or wrong treatment;

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

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

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

(e) A brachytherapy radiation dose:

R2 1. Involving the wrong individual, wrong radioisotope, or wrong treatment site, excluding, for permanent implants, seeds that were implanted in the correct site but which migrated outside the treatment site;

2. Involving a sealed source that is leaking;

3. When, for a temporary implant, one or more seeds are not removed upon completion of the procedure; or

4. When the calculated administered dose differs from the prescribed dose by more than 20 percent from the prescribed dose.

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

R2 1. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

R2 2. When the dose to the individual exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

R4 (89) "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.

R4 (90) "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.

R4 (91) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

R4 (92) "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.

R4 (93) "Normal form" means radioactive material which has not been demonstrated to qualify as "special form"; also referred to as "nonspecial form."

R4 (94) "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.

R4 (95) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

R4 (96) "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.

R4 (97) “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.

R4 (98) “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.

R4 (99) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

R4 (100) "Package" means the packaging, together with its radioactive contents, as presented for transport.

R4 (101) "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.

R4 (102) "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.

R4 (103) "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.

R4 (104) "Permit" means the written authorization issued by the department for the transportation of radioactive waste as described in Rule 64E-5.1509.

R4 (105) "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.

R4 (106) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

R4 (107) "Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

(a) In a written directive; or

(b) Either in the diagnostic clinical procedures manual or in any appropriate record as specified in the directions of the authorized user for diagnostic procedures.

R4 (108) "Prescribed dose" means:

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

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

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

R4 (109) "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.

R2 (176) “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.

R4 (110) "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.

R4 (111) "Quality factor" (Q) means the modifying factor listed in the tables in 64E-5.106(3) and (4) used to derive dose equivalent from absorbed dose.

R4 (112) "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.

R4 (113) "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).

R4 (114) "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.

R4 (115) "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.

R4 (116) "Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

R4 (117) "Radiation Safety Officer or RSO" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules.

R4 (118) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

R4 (119) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

R4 (120) "Radiographer" means any individual who has completed successfully the
R4 training and testing requirements specified in Rule 64E-5.434(2), F.A.C., performs or personally supervises radiographic operations and is responsible to the licensee or registrant for assuring compliance with the requirements of these rules and all license or certificate of registration conditions.

R4 (121) "Radiographer's assistant or assistant radiographer " means any individual who
R4 has completed successfully the training and testing requirements specified in
R4 Rule 64E-5.434(1), F.A.C., and who, under the personal supervision of a
R4 radiographer, conducts radiographic operations.

R4 (122) "Radiographic exposure device" means any instrument containing a sealed
R4 source that is used to make a radiographic exposure. It also is known as a
R4 camera or a projector.

R4 (123) "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;

(c) Iodine 123, iodine 125 or iodine 131 as sodium iodide in quantitie s 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.

(d) A therapeutic administration of a radiopharmaceutical other than iodine 123, iodine 125 or iodine 131 as sodium iodide, when the administered dosage differs from the prescribed dosage by more than 10 percent from the prescribed dosage;

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

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

R4 (124) "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."

R4 (125) "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.

R4 (126) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR, Parts 100-189.

R4 (127) "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).

R4 (128) "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.

R4 (129) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

R4 (130) "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.

R4 (131) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air.

R4 (132) "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.

R4 (133) "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

R4 (134) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

R4 (135) "Shielded position" means the location within the radiographic exposure device
R4 or source changer where the sealed source is secured and restricted from
R4 movement by manufacturer's design.

R4 (136) "Shielded-room radiography" means industrial radiography conducted in a room so shielded that radiation levels at every location on the exterior meet the limitations specified in Part III.

R4 (137) "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.

R4 (138) "SI" means an abbreviation of the International System of Units.

R4 (139) "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).

R4 (140) “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.

R4 (141) "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.

R4 (142) "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.

R4 (143) "Source material milling" means any activity that results in the production of byproduct material as defined by 64E-5.101.

R4 (144) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

R4 (145) "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.

R4 (146) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

R4 (147) "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.

R4 (148) "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.

R4 (149) "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.

R4 (150) "Storage container" means a container in which sealed sources are secured and stored.

R4 (151) "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.

R4 (152) "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.

R4 (153) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

R4 (154) "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.

R4 (155) "Temporary job site" means a site, base or facility that is created and maintained to support a single job lasting for less than 2 years.

R4 (156) "Test" means the process of verifying compliance with an applicable rule.

R4 (157) "Total effective dose equivalent" means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

R4 (158) "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.

R4 (159) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating or refining.

R4 (160) "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.

R4 (161) "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.)

R4 R2 (162) "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.

R4 (163) "Visiting authorized user" means an authorized user who is not identified on the license.

R4 (164) "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

R4 (165) "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.

R4 (166) "Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed

R4 (167) "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.

R4 (168) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

R4 (169) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

R4 (170) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

R4 (171) "Worker" means an individual engaged in work in a restricted area under the authority of a license or registration issued by the department.

R4 (172) "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy. The short-lived radon daughters are:

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

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

R4 (173) "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.

R4 (174) "Written directive" means a written order for a specific patient, 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 other than iodine 123, iodine 125 or iodine 131 as sodium iodide, the radiopharmaceutical, dosage, and route of administration;

(b) For any administration of iodine 123, iodine 125 or iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels), the dosage;

(c) For gamma stereotactic radiosurgery, target coordinates, collimator size, plug pattern, and total dose;

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

(e) For high dose rate remote afterloading brachytherapy, the radioisotope, treatment site, and total dose; and

(f) For all other brachytherapy,

1. Prior to implantation, the radioisotope, 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.

R4 (175) "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.

R1 Editor's Note: Definitions have been alphabetized effective, May 15, 1996 . (Principal activity
R2 (176) added alphabetically May 18, 1998. Authorized Nuclear Pharmacist (177) added August 8, 2001)

Specific Authority: 404.051, 404.061, F.S.
Law Implemented: 404.031, 404.061(2), 404.20, 404.22, 404.30, F.S.
History: New July 17, 1985, Amended April 4, 1989, Amended May 12, 1993, Amended January 1, 1994,
R2 Amended May 15, 1996, Formerly 10D-91.102, Amended May 18, 1998, Amended October 8, 2000.,
R3, R4 Amended August 6, 2001, Amended September 11, 2001 .

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

PART II LICENSING OF RADIOACTIVE MATERIALS

SUBPART A LICENSE TYPES AND FEES

SUBPART B GENERAL LICENSES

SUBPART C SPECIFIC LICENSES

SUBPART D RECIPROCITY

SUBPART E BONDING

SUBPART F ..... INSPECTION AND ENFORCEMENT

SUBPART G REPORTING REQUIREMENTS FOR GENERAL AND SPECIFIC LICENSEES

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 64E-5.206(9) will be approved if:

(a) The applicant satisfies the general requirements of 64E-5.208; 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 64E-5.626, 64E-5.627, and 64E-5.630 will be approved if:

(a) The applicant satisfies the general requirements specified in 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.

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.

Specific 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), 404.081(1), 404.141, F.S.
History: New July 17, 1985, Amended August 25, 1991, Amended May 12, 1993, Amended January 1, 1994,
R3 Amended May 15, 1996, Formerly 10D-91.311, Amended August 6, 2001.

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.

PART IV

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Sections 64E-5.401- 64E-5.422 Repealed and Replaced with Sections 64E-5.423 – 64E-5.441

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

PART IV

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

R4 **64E-5.423 Definitions.** As used in this part, the following definitions apply:

R4 (1) "Associated equipment" means equipment, such as guide tubes, control tubes,
R4 control cables, removable source stops, J-tubes, and collimators, used in
R4 conjunction with a radiographic exposure device that drives, guides, or comes in
R4 contact with the sealed source.

R4 (2) "Certifying entity" means:

R4 (a) For radiographic operations using radioactive materials, an independent
R4 certifying organization that meets the requirements of Appendix A of 10
R4 CFR Part 34, which is herein incorporated by reference and which is
R4 available from the department, or an agreement state that meets the
R4 requirements of Appendix A, Parts II and III of 10 CFR Part 34.

R4 (b) For radiographic operations using radiation machines, any agreement
R4 state or organization approved by the Conference of Radiation Control
R4 Directors, Inc.

R4 (3) "Collimator" means a radiation shield that is placed on the end of the guide tube
R4 or directly onto a radiographic exposure device to restrict the size of the radiation
R4 beam when the sealed source is cranked into position to make a radiographic
R4 exposure.

R4 (4) "Control cable" means the cable that is connected to the source assembly and
R4 used to drive the source from and return it to the shielded position. It also is
R4 known as a drive cable.

R4 (5) "Control drive mechanism" means a device that enables the source assembly to
R4 be moved to and from the shielded position. It also is known as a crank
R4 assembly.

R4 (6) "Control tube" means a protective sheath for guiding the control cable. The
R4 control tube connects the control drive mechanism to the radiographic exposure
R4 device.

R4 (7) "Exposure head" means a device that locates the sealed source in the selected
R4 position. It also is known as a source stop.

R4 (8) "Guide tube" means a flexible or rigid tube for guiding the source assembly and
R4 the attached control cable from the radiographic exposure device to the exposure
R4 head and includes the connections to attach to the radiographic exposure device
R4 and to the exposure head. It also is known as a projection sheath or source
R4 tube.

R4 (9) “Industrial cabinet x-ray system” means a cabinet x-ray system used to perform
R4 industrial radiography excluding baggage x-ray systems.

R4 (10) "Lay-barge radiography" means industrial radiography performed on any water
R4 vessel used for laying pipe.

R4 (11) “Platform radiography” means industrial radiography performed on an offshore
R4 platform or other structure over a body of water.

R4 (12) "Radiographer certification" means a written document received from a certifying
R4 entity stating that an individual has met radiation safety training, testing, and
R4 experience criteria satisfactorily.

R4 (13) “Radiographic operations” means all activities including surveys that involve the
R4 use or transport of radiation machines, radiographic exposure devices, source
R4 changers, or industrial cabinet x-ray systems to conduct industrial radiography.

R4 (14) “Radiographic personnel” means radiographers and radiographer’s assistants.

R4 (15) “Reference survey” means a survey made with a radiation survey instrument
R4 within 6 inches (15 cm) of the surface of a radiographic exposure device or
R4 source changer at a location established by the licensee. The reference survey
R4 is used to verify that the sealed source is located properly in the shielded position
R4 and to establish a radiation level for reference before, during, and after
R4 radiographic operations.

R4 (16) “S-tube” means a tube through which the radioactive source travels inside a
R4 radiographic exposure device.

R4 (17) “Source assembly” means a set of assembled parts consisting of a sealed
R4 source and a connector that attaches the source to the control cable. The
R4 source assembly sometimes includes a stop ball used to secure the source in the
R4 shielded position. It also is known as a pigtail.

R4 (18) “Special training session” means training not conducted during production
R4 radiography.

R4 (19) “Transport container” means a package that is designed to provide radiation
R4 safety and security when sealed sources are transported and that meets all
R4 applicable requirements of the U.S. Department of Transportation (USDOT).

R4 (20) “Underwater radiography” means industrial radiography performed when the
R4 radiation machine, radiographic exposure device, or related equipment are
R4 beneath the surface of the water.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.031, 404.051(1), (4), (6), F.S.
R4 History: New September 11, 2001.

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SUBPART D
(Formerly Subpart A)
EQUIPMENT CONTROL

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

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

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

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

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

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

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

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

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

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

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

R4 CAUTION (or DANGER)
R4 RADIOACTIVE MATERIAL – DO NOT HANDLE
R4 NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)

R4 (c) Modification of radiographic exposure devices, source changers, source assemblies, and associated equipment is prohibited unless the design of any replacement component, including source holder, source assembly, controls, or guide tubes will not compromise design safety features.

R4 (3) Radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the radiographic exposure device for radiographic operations or to source changers must meet the requirements specified below.

R4 (a) The coupling between the source assembly and the control cable shall be designed so that the source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be designed so that it cannot be disconnected unintentionally under normal and reasonably foreseeable abnormal conditions.

R4 (b) The radiographic exposure device shall secure the source assembly automatically when it is cranked back into the fully shielded position within the device. This securing system shall be able to be released only by a deliberate operation on the exposure device.

R4 (c) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers that are installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter.

R4 (d) 1. Each sealed source or source assembly shall have attached to it or engraved on it a durable, legible, visible label with the words: "DANGER – RADIOACTIVE."

R4 2. The label cannot interfere with the safe operation of the radiographic exposure device, source changer, or associated equipment.

R4 (e) The guide tube shall be able to withstand a crushing test that approximates closely the crushing forces that are likely to be encountered during use and be able to withstand a kinking resistance test that approximates closely the kinking forces that are likely to be encountered during use.

R4 (f) Guide tubes shall be used when moving the source out of the device.

R4 (g) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.

R4 (h) The guide tube exposure head connection shall be able to withstand the
R4 tensile test for control units specified in ANSI N432-1980.

R4 (i) Source changers shall have a system to ensure that the source will not be
R4 withdrawn from the changer accidentally when connecting or
R4 disconnecting the drive cable to or from a source assembly.

R4 (4) The maximum exposure rate limits for storage containers and source changers
R4 are 200 millirem (2 mSv) per hour at any exterior surface and 10 millirem (0.1
R4 mSv) per hour at 1 meter from any exterior surface with the sealed source in the
R4 shielded position.

R4 (5) Each radiographic exposure device, source changer, and storage container shall
R4 have a lock or outer locked container designed to prevent unauthorized or
R4 accidental removal of the sealed source from its shielded position.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), (6), F.S.
R4 History: New September 11, 2001.

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

R4 (1) Each radiation machine, radiographic exposure device, source changer, and
R4 storage container shall be kept locked with the key removed from any keyed lock
R4 except when under the direct supervision of radiographic personnel or as
R4 specified in section (6), below.

R4 (2) Each radiation machine, radiographic exposure device, source changer, and
R4 storage container shall be locked and the key removed from any keyed lock
R4 before being moved or transported and before being stored at a given location,
R4 except at permanent radiographic installations as specified in 64E-5.431, F.A.C.
R4 Keys to radiation machines, radiographic exposure devices, source changers,
R4 storage containers, transport containers, and transport vehicles shall be
R4 maintained in the possession of the radiographer or radiographer's assistant
R4 responsible for the equipment in a manner that prevents access to sources of
R4 radiation by unauthorized personnel.

R4 (3) Locked radiographic exposure devices, source changers, storage containers,
R4 and radiation machines shall be secured physically except when under the direct
R4 surveillance of radiographic personnel or as specified in section (6), below, to
R4 prevent tampering or removal by unauthorized personnel. The licensee shall
R4 store licensed material in a manner that minimizes danger from explosion or fire.

R4 (4) Each sealed source shall be secured in its shielded position by locking the
R4 radiographic exposure device or source changer each time the sealed source is
R4 returned to the shielded position.

R4 (5) Transport containers containing licensed material shall be locked and secured in
R4 the transporting vehicle to prevent accidental loss, tampering, or unauthorized
R4 removal of the licensed material from the vehicle.

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

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

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), (6), F.S.
R4 History: New September 11, 2001.

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

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

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

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

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

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

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

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

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), F.S.
R4 History: New September 11, 2001.

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

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

R4 (2) Each sealed source shall be tested for radioactive contamination leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within the 6 months before the transfer, the sealed source shall not be used until tested. Sealed sources that are listed in a department license for storage only do not require leak testing during storage but shall be tested before use or transfer to another person if the interval of storage exceeds 6 months.

R4 (3) Each exposure device using depleted uranium (DU) shielding and an S-tube configuration shall be tested for DU contamination at intervals not to exceed 12 months. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. However, the DU devices shall be tested for DU contamination before use or transfer if the interval of storage exceeds 12 months. Licensees must comply with the DU leak testing requirements of this section within 6 months after the effective date of this rule.

R4 (4) Leak testing as specified in 64E-5.427(2) and (3), F.A.C., shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of removable contamination on the test sample. The wipe sample shall be taken from the nearest accessible point to the sealed source when contamination could accumulate.
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R4 (5) If any test conducted pursuant to this section reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee immediately shall withdraw the equipment from use and cause it to be decontaminated and repaired or disposed of in accordance with the applicable sections of rules contained in Parts III and XV of Chapter 64E-5, F.A.C. If DU leak testing reveals the presence of 0.005 microcurie (185 Bq) or more of removable DU contamination, the exposure device shall be removed from use until an evaluation of the wear on the S-tube has been made. If the evaluation reveals that the S-tube is worn through, the device shall not be used. The licensee shall file a report with the department describing the equipment involved, the test results, and the corrective action taken within 5 days after obtaining results of the test.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), (6), F.S.
R4 History: New September 11, 2001.

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

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.
R4 History: New September 11, 2001.

R4 **64E-5.429 Source Movement Logs, Daily Survey Reports, and Individual**
R4 **Dosimeter Logs.**

R4 (1) Each time a radiation source is removed from storage, the licensee or registrant
R4 shall complete and maintain source movement logs for each radiation source
R4 with the following information, as applicable:

R4 (a) The locations where used, the names of the jobs or clients, and the dates
R4 of use;

R4 (b) The manufacturer's name, model, and serial number of the radiographic
R4 exposure device, source changer, or radiation machine used;

R4 (c) The sealed source manufacturer's name, model, and serial number,
R4 activity in curies (becquerels) on the date of receipt and each date of use,
R4 and the due date of the next leak test;

R4 (d) The results of the reference survey of the radiographic exposure device or
R4 source changer performed upon removal and return to storage; and

R4 (e) The signature or initials of the radiographer to whom the radiation source
R4 has been assigned.

R4 (2) Before performing industrial radiography, leak tests, source exchanges, or
R4 quarterly inspection and maintenance of radiographic equipment, the licensee or
R4 registrant shall prepare and maintain a daily survey report for each radiation
R4 source with the information described below as it becomes available:

R4 (a) The location where used, the name of the job or client, and the date of
R4 use;

R4 (b) The manufacturer's name, model, and serial number of the radiographic
R4 exposure device, source changer, or radiation machine used;

R4 (c) The sealed source manufacturer's name, model, and serial number and
R4 activity in curies (becquerels) for the date of use;

R4 (d) The names and titles of the radiographic personnel working with the
R4 radiation source;

R4 (e) The serial number of the personnel monitoring badge, pocket dosimeter,
R4 and alarm ratemeter used by each of the radiography crew members;

R4 (f) The manufacturer's name, model, serial number, and date of calibration or
R4 calibration due date for each survey meter used;

R4 (g) The results of the reference survey performed when the radiographic
R4 exposure device or source changer is removed from or returned to
R4 storage;

R4 (h) Evidence of performance of the equipment checks described in 64E-
R4 5.430(1), F.A.C.;

R4 (i) The results of the survey of the posted perimeter in mR/hr (mSv/hr) and
R4 feet (meters);

R4 (j) The total exposure time; and

R4 (k) The start, end, and total pocket dosimeter readings for all radiographic
R4 personnel.

R4 (3) Radiographic personnel shall maintain an individual log of their daily dosimeter
R4 totals. Each individual shall record the doses measured by his or her dosimeter
R4 at the end of each day of radiographic operations and total the recorded doses at
R4 the end of each week and at the end of each month. Copies of the individual
R4 dosimeter logs shall be provided to the radiation safety officer (RSO) or the
R4 RSO's designee no later than 7 days after each month. The RSO or the RSO's
R4 designee shall review the logs within 7 days of receipt and shall date and sign or
R4 initial the logs at the time of the review. Each log shall include the following
R4 information:

R4 (a) The name of the individual;

R4 (b) The dates of the monitoring periods;

R4 (c) The daily, weekly, and monthly individual radiation dose totals as
R4 measured by the dosimeter; and

R4 (d) The date the log was reviewed by the RSO or the RSO's designee and the
R4 signature or initials of the RSO or the RSO's designee.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.
R4 History: New September 11, 2001.

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

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

R4 (2) Each licensee or registrant shall perform equipment inspection and maintenance
R4 as described below.

R4 (a) Inspection and maintenance of survey instruments, radiation machines,
R4 radiographic exposure devices, associated equipment, source changers,
R4 storage containers, and transport containers shall be performed quarterly
R4 to assure proper functioning of components important to safety. All
R4 appropriate parts shall be maintained in accordance with the
R4 manufacturer's specifications. Verification of compliance with radiation
R4 limits specified in 64E-5.424(4), F.A.C., shall be included in each quarterly
R4 inspection. If equipment problems are found, the equipment shall be
R4 labeled as defective and removed from service until repaired.
R4 Replacement components shall meet manufacturer's specifications.

R4 (b) Inspection and maintenance of Type B packages used to transport
R4 radioactive materials shall be performed quarterly in accordance with each
R4 package's certificate of compliance or other approval.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.
R4 History: New September 11, 2001.

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

R4 (1) Each entrance used for personnel access to a high radiation area in a permanent
R4 radiographic installation shall have either:

R4 (a) An entrance control that reduces the radiation level to below the level at
R4 which an individual might receive a deep dose equivalent of 0.1 rem (1
R4 millisievert) in 1 hour at 30 centimeters from the source of radiation from
R4 any surface the radiation penetrates, or

R4 (b) Conspicuous visible and audible signals to warn of the presence of
R4 radiation. The visible signal shall be actuated by radiation. The audible
R4 signal shall be actuated when an attempt is made to enter the installation
R4 while the source is exposed or the radiation machine is activated.

R4 (2) The alarm system shall be tested for proper operation with a radiation source
R4 each day before radiographic operations. The test shall include a check of both
R4 the visible and audible signals. Entrance control devices that reduce the
R4 radiation level upon entry shall be tested monthly. If an entrance control device
R4 or an alarm is operating improperly, it shall be labeled immediately as defective
R4 and repaired within 7 days. The installation can continue to be used by an
R4 unaccompanied radiographer during this 7-day period if the continuous
R4 surveillance requirements of 64E-5.425(6), F.A.C., are implemented and an
R4 alarming ratemeter is used.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), F.S..
R4 History: New September 11, 2001.

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SUBPART E
(Formerly Subpart B)
RADIATION SAFETY REQUIREMENTS

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

R4 (1) A description of the overall organizational structure pertaining to the licensee's or
R4 registrant's radiation protection program, including specific delegation of authority
R4 and responsibility, the name of the RSO, and the minimum qualifications of the
R4 RSO and the RSO's designees.

R4 (2) A radiation safety training program for radiographic personnel that meets the
R4 requirements of 64E-5.434, F.A.C., and includes the components described
R4 below.

R4 (a) Initial, periodic, and on-the-job training.

R4 (b) Written and practical examinations to determine knowledge,
R4 understanding of, and ability to comply with department and applicable
R4 USDOT rules, licensee or registrant requirements, operating and
R4 emergency procedures, and use of radiographic and related equipment.

R4 (3) Procedures to verify the certification of radiographers and to ensure that the
R4 certification remains valid.

R4 (4) A written policy to maintain radiation doses as low as reasona bly achievable as
R4 specified in 64E-5.303, F.A.C. The policy shall include:

R4 (a) A commitment by management to keep radiation doses as low as
R4 reasonably achievable and a description of the participation of
R4 management, the RSO, and radiographic personnel in the implementation
R4 of the policy;

R4 (b) Investigation within 30 days by the RSO of any exposure level that
R4 exceeds established monthly and quarterly levels and implementation of
R4 corrective actions to halt unnecessary exposures and p revent recurrence;
R4 and

R4 (c) An audit of the program to evaluate its effectiveness in minimizing
R4 exposures in conjunction with the annual review of the radiation protection
R4 program specified in 64E-5.303(3), F.A.C. A summary of the results of
R4 each audit, including a description of corrective actions taken, shall be
R4 prepared by the RSO and approved by the licensee or registrant.

R4 (5) An auditing program for internal inspections of the job performance of all
R4 radiographic personnel at intervals not to exceed 6 months as described in 64E-
R4 5.434, F.A.C.

R4 (6) Written operating and emergency procedures as described in 64E-5.436, F.A.C.
R4

R4 (7) Leak testing procedures, including a description of:

R4 (a) The method of taking wipes and preparing samples for analysis using only
R4 radiographers or radiographer's assistants working under the personal
R4 supervision of a radiographer or persons specifically licensed by the
R4 department, another agreement state, licensing state, or the NRC to
R4 perform such services; and

R4 (b) The method of performing leak test sample analyses, including
R4 instrumentation to be used and experience of the individuals who will
R4 perform the analyses or a commitment to use vendors specifically
R4 licensed to perform such analyses by the department, another agreement
R4 state, licensing state, or the NRC.

R4 (8) Procedures for the semiannual calibration of survey instruments and the annual
R4 calibration of alarm ratemeters, including a description of the calibration
R4 instrumentation and the experience of the person who will perform the
R4 calibrations or a commitment to use persons specifically licensed to perform such
R4 calibrations by the department, another agreement state, licensing state, or the
R4 NRC. All survey instrument calibrations shall be performed in accordance with
R4 64E-5.426(2), F.A.C.

R4 (9) Procedures for quarterly inspection and maintenance of survey instruments,
R4 radiation machines, radiographic exposure devices, associated equipment,
R4 source changers, storage containers, and transport containers to assure proper
R4 function of components important to safety, performed in accordance with 64E-
R4 5.430, F.A.C.

R4 (10) Procedures for annual calibration of pocket or electronic dosimeters, including a
R4 description of the calibration instrumentation and the experience of the person
R4 who will perform the calibrations or a commitment to use persons specifically
R4 licensed to perform such calibrations by the department, another agreement
R4 state, licensing state, or the NRC.

R4 (11) Procedures for lay-barge, offshore platform and underwater radiography if
R4 conducting such activities.

R4 Specific Authority: 404.051, 404.061, F.S.
R4 Law Implemented: Implemented 404.022; 404.051(1), (4), (6), (9), (10), 404.061(2); 404.081(1); 404.141, F.S.
R4 History: New September 11, 2001.

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

R4 (1) The licensee or registrant shall appoint an RSO and delegate the authority R4 needed to fulfill the duties of the position. Except as specified in 64E-5.433(2), R4 F.A.C., below, the minimum qualifications, training, and experience for the RSO R4 shall be:

R4 (a) One year of documented industrial radiography experience as a R4 radiographer; and

R4 (b) Sixteen hours of formal instruction in the establishment and maintenance R4 of a radiation protection program, including training to perform internal R4 audits and mitigation of radiological incidents. Individuals identified as an R4 RSO on an industrial radiography license or registration before the R4 effective date of this rule are not required to comply with the training R4 requirements of this paragraph.

R4 (2) Equivalent alternative radiation and safety training and experience in R4 radiographic operations and formal training in the establishment and R4 maintenance of a radiation protection program can substitute for the R4 requirements specified in 64E-5.433(1)(a) and (b), F.A.C., above.

R4 (3) In addition to other duties specified in this part, the RSO shall:

R4 (a) Ensure compliance with all components of the licensee's or registrant's R4 radiation protection program as specified in 64E-5.432, F.A.C., the terms R4 and conditions of the license, and this rule;

R4 (b) Investigate incidents and direct corrective actions, including halting R4 operations when necessary;

R4 (c) Serve as the licensee's or registrant's contact with the department; and

R4 (d) Ensure that radiation safety activities are performed using approved R4 procedures and requirements in Chapter 64E-5, F.A.C., in the daily R4 operation of the licensee's program.

R4 Specific Authority: 404.051, 404.061, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.061(2), F.S.
R4 History: New September 11, 2001.

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

R4 (1) The licensee or registrant shall not permit any individual to act as a R4 radiographer's assistant until such individual:

R4 (a) Receives a copy of the licensee's or registrant's operating and emergency R4 procedures;

R4 (b) Completes 8 hours of training, including instruction in the licensee's or R4 registrant's operating and emergency procedures and supervised R4 instruction in use of the licensee's or registrant's radiographic equipment, R4 related handling tools, radiation survey instruments, and personnel R4 monitoring devices during a special training session; and

R4 (c) Successfully completes a closed-book, written examination on the R4 licensee's or registrant's operating and emergency procedures and a R4 practical examination that is not conducted during production radiography R4 to demonstrate competence in the use of the licensee's or registrant's R4 radiographic equipment, related handling tools, radiation survey R4 instruments, and personnel monitoring devices.

R4 (2) Licensees and registrants can allow individuals who have completed the training R4 and testing specified in 64E-5.434(2)(a) – (d), F.A.C., below, to perform industrial R4 radiography for 12 months after the effective date of these rules. The licensee or R4 registrant shall not permit any individual to act as a radiographer until such R4 individual:

R4 (a) Receives copies of rules contained in Chapter 64E-5, Parts I – IV, IX and R4 XV, F.A.C., applicable USDOT regulations, the appropriate license or R4 certificate of registration, and the licensee's or registrant's operating and R4 emergency procedures;

R4 (b) 1. For radioactive material radiographic operations, completes 320 R4 hours of on-the-job training in industrial radiography, excluding R4 hours as specified in 64E-5.434(2)(b)2., F.A.C., below, as a R4 radiographer's assistant using radioactive material; or

R4 2. For machine produced radiographic operations, completes 200 R4 hours of on-the-job training using radiation machines;

R4 (c) Receives 40 hours of formal instruction in the subjects outlined in R4 64E-5.434(6), F.A.C., and supervised instruction during a special training R4 session in the inspection and use of the licensee's or registrant's R4 radiographic equipment, related handling tools, radiation survey R4 instruments, and personnel monitoring devices;

R4 (d) Successfully completes a closed-book, written examination on the R4 subjects outlined in 64E-5.434(4), F.A.C., and a practical examination to R4 demonstrate competence in the use of the licensee's or registrant's R4 radiographic and safety equipment; and

R4 (e) Is certified by a certifying entity.

R4 (3) Radiographers who work for an out-of-state radioactive materials license under reciprocal recognition are authorized to conduct radiographic operations within the state if they have a valid certification from a certifying entity for the activities being conducted before entering the state.

R4 (4) Any individual who has completed all requirements specified in 64E-5.434(2), F.A.C., above, and begins work for a different Florida licensee or registrant shall complete 4 hours of additional training and testing before conducting radiographic operations. The training shall consist of instructions in the licensee's or registrant's operating and emergency procedures and supervised instruction during a special training session in the use of the licensee's or registrant's radiographic and safety equipment. The testing shall consist of successful completion of the written and practical examinations described in 64E-5.434(1)(c), F.A.C. The RSO shall document how the prior radiation training and experience was verified.

R4 (5) Personnel using industrial cabinet x-ray systems for industrial radiography shall complete 16 hours of training and testing as described below:

R4 (a) Ten hours of training and testing as described in 64E-5.434(6), F.A.C.; and

R4 (b) Two hours of instruction in the registrant's operating and emergency procedures pertaining to industrial radiography using industrial cabinet x-ray systems, 2 hours of supervised instruction during a special training session in the use of the registrant's industrial cabinet x-ray system, related handling tools, radiation survey instruments, and personnel monitoring devices, and 2 hours of testing, which shall consist of a written examination covering operating and emergency procedures and equipment use and a practical examination to demonstrate competence in the use of the registrant's industrial cabinet x-ray system and related equipment.

R4 (6) The subjects to be covered during the instruction of radiographers shall include:

R4 (a) Fundamentals of radiation safety, including characteristics of radiation, units of radiation dose, quantities of radioactivity, hazards of radiation exposure, radiation protection standards, radiation levels from sources of radiation, and methods of minimizing radiation dose.
R4

R4 (b) Radiation detection instruments, including:

R4 1. Use, operation, calibration, and limitations of radiation survey instruments;

R4 2. Survey techniques; and

R4 3. Use of personnel monitoring equipment.

R4 (c) Equipment to be used, including, as applicable:

R4 1. Operation and control of radiation machines, radiographic exposure
R4 equipment, remote handling equipment, source changers, storage
R4 containers, and transport containers, including pictures or models
R4 of source assemblies;

R4 2. Storage, control, and disposal of licensed material; and

R4 3. Inspection and maintenance of equipment.

R4 (d) The applicable requirements of these rules and NRC and USDOT
R4 regulations.

R4 (e) The licensee's or registrant's operating and emergency procedures.

R4 (f) Case histories of industrial radiography accidents.

R4 (7) Each licensee or registrant shall provide 8 hours of annual radiation safety
R4 training to all radiographic personnel, which can be conducted in multiple
R4 sessions.

R4 (8) The RSO or the RSO’s designee shall audit the job performance of each
R4 radiographer and radiographer's assistant to ensure that the department’s
R4 regulations, license requirements, and the licensee's or registrant's operating and
R4 emergency procedures are followed. The audits shall include observation of the
R4 performance of each radiographer or radiographer's assistant during an actual
R4 radiographic operation at intervals not to exceed 6 months. Radiographers or
R4 radiographer's assistants who have not participated in a radiographic operation
R4 for more than 6 months since the last audit shall demonstrate knowledge of the
R4 licensee's or registrant's operating and emergency procedures and safe use of
R4 radiographic and related equipment by a practical examination before
R4 participating in a radiographic operation. Audits of the RSO are not required.

R4 (9) Individuals conducting internal radiation safety training or audits shall meet the
R4 minimum qualifications specified in 64E-5.433(1), F.A.C., for the RSO.

R4 Specific Authority: 404.051404.061, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.061(2), F.S.
R4 History: New September 11, 2001.

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

R4 (1) With the exception of industrial cabinet x-ray systems, the radiographer shall be R4 accompanied by at least one other radiographer or radiographer's assistant R4 whenever radiography is performed at a location other than a permanent R4 radiographic installation. The additional qualified individual shall observe the R4 radiographic operations and be capable of providing immediate assistance to R4 prevent unauthorized entry. Radiography is prohibited if only one qualified R4 individual is present. Radiography performed in an industrial cabinet x-ray R4 system by a single individual meeting the training and testing requirements R4 specified in 64E-5.434(5), F.A.C., is permitted.

R4 (2) The radiographer's assistant shall be under the personal supervision of a R4 radiographer when using a radiation machine, radiographic exposure device, R4 source changer, or related source handling tools or conducting radiation surveys R4 to determine that the sealed source has returned to the shielded position or that R4 the radiation machine is off after an exposure.

R4 (3) All radiographic operations conducted at a licensee's or registrant's permanent R4 facility shall be conducted in a permanent radiographic installation or an R4 industrial cabinet x-ray system or using equipment, facilities, and procedures that R4 are adequate to protect public health, safety, and property and included in the R4 radiation protection program specified in 64E-5.432, F.A.C.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), (11), 404.081(1), F.S.
R4 History: New September 11, 2001.

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

R4 (1) Handling and use of sources of radiation to be used so that exposures are R4 maintained as low as reasonably achievable and no individual is likely to be R4 exposed to radiation doses in excess of the limits established in rules contained R4 in Part III of Chapter 64E-5, F.A.C.;

R4 (2) Methods and occasions to conduct radiation surveys;

R4 (3) Methods to control access to radiographic areas;

R4 (4) Methods and occasions to lock and secure sources of radiation;

R4 (5) Personnel monitoring and the use of personnel monitoring equipment, including R4 steps to be taken immediately by radiography personnel when a pocket R4 dosimeter is found off-scale, an alarm ratemeter alarms unexpectedly, or a R4 personnel monitoring badge is damaged or lost;

R4 (6) Transportation of licensed material to field locations and preparation of packages R4 for shipment by common or contract carriers, including packaging, marking, R4 labeling, shipping papers, emergency response information, blocking and R4 bracing, security, surveys, and vehicle placarding in accordance with applicable R4 requirements of the USDOT;

R4 (7) Leak testing, quarterly inventories, and equipment inspection, maintenance and operability checks, and disposal of licensed material;

R4 (8) Source exchanges for licensees who perform source exchanges;

R4 (9) Calibration of survey instruments, dosimeters, and alarm ratemeters for licensees who perform calibrations;

R4 (10) Emergency response, including response to loss, damage, or theft of sources of radiation, unauthorized entries into restricted areas, notifications, exposure minimization, and source recovery;

R4 (11) Identifying and reporting equipment defects and noncompliance issues; and

R4 (12) Maintenance of records.

R4 Specific Authority: 404.051, 404.20, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), (6), 404.081, 404.20(1), F.S..
R4 History: New September 11, 2001.

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

R4 (1) The licensee or registrant shall not permit any individual to act as a radiographer or a radiographer's assistant unless the individual wears on the trunk of his or her body at all times during radiographic operations:

R4 (a) A NVLAP-approved personnel monitoring badge such as a film badge, thermoluminescent dosimeter (TLD) or optically stimulated luminescent device (OSLD);

R4 (b) A direct reading pocket dosimeter, which can be either an ion chamber or electronic personal dosimeter; and

R4 (c) An alarming ratemeter. Alarm ratemeters are not required for radiography performed in an approved permanent radiographic installation meeting the requirements of 64E-5.431, F.A.C.

R4 (2) Each personnel monitoring badge shall be assigned to and worn by only one individual and shall be exchanged monthly. After exchange each badge shall be processed as soon as possible. If a report is received from the badge processor that indicates an individual has received a radiation exposure in excess of 5 rem (0.05 Sv), the licensee or registrant shall notify the department within 24 hours as specified in 64E-5.344(2), F.A.C. If a personnel monitoring badge is lost or damaged, the worker shall cease work immediately until a replacement badge is provided and the exposure is calculated by the RSO or the RSO's designee for the time period from issuance to loss or damage of the badge. The results of the calculated exposure and the time period for which the personnel monitoring badge was lost or damaged shall be provided to the processor to adjust the individual's occupational exposure record.

R4 (3) Pocket dosimeters shall have a range from 0 to 200 millirem (2 mSv) and shall be recharged at the start of each shift and when 75% of the full scale of the dosimeter is exceeded. Initial, final, and total pocket dosimeter readings shall be recorded at the start and end of each shift.

R4 (4) If an individual's pocket dosimeter is found to be off-scale or if an individual's electronic personal dosimeter reads more than 200 millirem (2 mSv) and the possibility of radiation exposure cannot be ruled out as the cause, the ind ividual's personnel monitoring badge shall be sent for processing within 24 hours. In addition, the individual shall not resume radiographic operations until a determination of the individual's radiation exposure has been made by the RSO or the RSO’s designee. The results of this determination shall be reported in writing to the department within 30 days of the determination.

R4 (5) Each alarming ratemeter shall:

R4 (a) Have a function test without being exposed to radiation to ensure that the audible alarm is functioning properly before use at the start of each work shift;

R4 (b) Give an alarm at a preset dose rate of no more than 500 millirem (0.5 mSv) per hour; and

R4 (c) Require special means to change the preset alarm function.

R4 (6) Pocket dosimeters and alarm ratemeters shall be calibrated annually for correct response to radiation by a person licensed by the department, another agreement state, licensing state, or the NRC. Acceptable dosimeters shall read within 20% of the true radiation exposure. Ion chamber dosimeters also shall be checked for response to drift by setting the dosimeter at zero and storing it in a low background area for at least 24 hours and for electrical leakage, which shall be no more than 1% of full scale for each 24 hours. Acceptable ratemeters shall alarm within 20% of the true radiation dose rate.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), (2), F.S.
R4 History: New September 11, 2001.

R4 R4 # SUBPART F
(Formerly Subpart C)
PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

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

R4 R4 R4 R4 R4 R4 (1) No radiographic operations shall be conducted unless at least one calibrated and operable radiation survey instrument meeting the requirements of 64E-5.426, F.A.C., is available for each radiographic exposure device and radiation machine in use at each site where radiographic exposures are made. All radiation surveys shall be performed with a calibrated and operable radiation survey instrument meeting the requirements of 64E-5.426, F.A.C.

R4 R4 (2) The surveys described below shall be performed by the licensee or registrant where applicable.

R4 R4 R4 (a) A reference survey of each radiographic exposure device or source changer immediately following removal from a storage area, including removal from storage following transportation.

R4 R4 R4 R4 (b) An area survey during the first radiographic exposure to verify that the posting requirements specified in 64E-5.439(1), F.A.C., have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 64E-5.312(1)(c), F.A.C.

R4 R4 R4 R4 R4 R4 (c) A survey of the radiographic exposure device and the length of the guide tube after each exposure when approaching the device or guide tube, concluding with a reference survey of the radiographic exposure device at the location established by the licensee after each radiographic exposure. The surveys shall be performed before exchanging film, repositioning the exposure head, or dismantling equipment.

R4 R4 (d) A reference survey of the radiographic exposure device and source changer before and after source exchanges.

R4 R4 (e) A reference survey of the radiographic exposure device, source changer, or storage container after returning the sealed source to a storage area.

R4 R4 (f) A survey after each radiographic exposure using radiation machines to verify that the machine is off.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.
R4 History: New September 11, 2001.

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

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

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

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), 404.20, F.S.
R4 History: New September 11, 2001.

R4 **64E-5.440 Records.**

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

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

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

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

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

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

R4 (f) Operation tests on permanent radiographic installation entrance controls and audible and visual alarms specified in 64E-5.431, F.A.C.;

R4 (g) Records of internal audits specified in 64E-5.434(8), F.A.C., including lists of audit items checked and any violations observed;

R4 (h) Records showing receipts and transfers of sealed sources and devices using DU for shielding, including the date, the name of the individual making the record, radionuclide, number of curies (becquerels) or mass, manufacturer, model, and serial number of each sealed source and device, as appropriate.

R4 (2) Each licensee or registrant shall maintain the following records until the department terminates the license or registration requiring the record:

R4 (a) Individual dosimeter logs specified in 64E-5.429, F.A.C.;

R4 (b) Initial and refresher radiation safety training specified in 64E-5.434, F.A.C., including lists of the topics discussed, dates the training was conducted, names of the instructors and attendees, and written and practical examinations;

R4 (c) Verification of previous radiography experience;

R4 (d) Radiographer certification documents specified in 64E-5.434(2)(e) – (f), F.A.C., and verification of certification status;

R4 (e) Records of personnel exposure investigations specified in 64E-5.432(4)(b), F.A.C., including the names of the individuals involved, the exposures received, the dates the exposures were received, a description of the cause of the exposures, the corrective actions taken, and the signature of the RSO;

R4 (f) Records of estimates of exposures as a result of off-scale dosimeters or lost or damaged personnel monitoring badges, including records of surveys used to determine an individual's exposure and reports submitted to the department as specified in 64E-5.437(3), F.A.C.;

R4 (g) Records of annual ALARA audits specified in 64E-5.432(3)(c), F.A.C.; and

R4 (h) Operating and emergency procedures.

R4 (3) Each licensee or registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for inspection by the department:

R4 (a) Appropriate license or registration;

R4 (b) Certification by a certifying entity;

R4 (c) Operating and emergency procedures;

R4 (d) Rules contained in Chapter 64E-5, Parts I – IV, IX, and XV, F.A.C.;

R4 (e) Calibration records for the survey instruments, pocket dosimeters, and
R4 alarm ratemeters used at the site or calibration tags or labels that are
R4 affixed to the devices;

R4 (f) Records of the latest leak test results for the specific devices in use at the
R4 site or leak test tags or labels that are affixed to the devices; and

R4 (g) Source movement logs and daily survey reports for the period of operation
R4 at the site.

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), 404.20, F.S.
R4 History: New September 11, 2001.

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

R4 (1) In addition to the reporting requirements specified in rules contained in Chapter
R4 64E-5, Parts III, IX, F.A.C., and other sections of this part, each licensee shall
R4 provide a written report to the department within 30 days of the occurrence of
R4 any of the incidents involving radiographic equipment described below. Such
R4 reports shall be mailed to the Bureau of Radiation Control, Radioactive Materials
R4 Section, Bin C21, 4052 Bald Cypress Way, Tallahassee, Florida 32399 -1741 for
R4 incidents involving radioactive materials or to the Bureau of Radiation Control,
R4 Radiation Machine Section, P. O. Box 210, Jacksonville, Florida 32231 for
R4 incidents involving radiation machines.

R4 (a) Unintentional disconnection of the source assembly from the control
R4 cable.

R4 (b) Inability to retract and secure the source assembly to the fully shielded
R4 position.

R4 (c) Failure of any component critical to safe operation of the device to perform
R4 its intended function properly.

R4 (2) The licensee shall include the information described below in each report
R4 submitted as specified in this section.

R4 (a) A description of the equipment problem.

R4 (b) Cause of each incident if known.

R4 (c) Manufacturer name and model number of the equipment involved in the
R4 incident.

R4 (d) Place, time, and date of the incident.

R4 (e) Actions taken to establish normal operations.

R4 (f) Corrective actions taken or planned to prevent recurrence.

R4 (g) Qualifications of the personnel involved in the incident.

R4 (3) Reports of overexposures submitted as specified in rules contained in Part III of
R4 Chapter 64E-5, F.A.C., that involve failure of safety components of radiography
R4 equipment also must include the information specified in 64E-5.441(2), F.A.C.
R4

R4 Specific Authority: 404.051, F.S.
R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.
R4 History: New September 11, 2001.

PART VI USE OF RADIONUCLIDES IN THE HEALING ARTS

SUBPART A GENERAL ADMINISTRATIVE REQUIREMENTS

SUBPART B GENERAL TECHNICAL REQUIREMENTS

SUBPART C UPTAKE, DILUTION, AND EXCRETION

SUBPART D IMAGING AND LOCALIZATION

SUBPART E RADIOPHARMACEUTICALS FOR THERAPY

SUBPART F SEALED SOURCES FOR DIAGNOSIS

SUBPART G SOURCES FOR BRACHYTHERAPY

SUBPART H TELETHERAPY

SUBPART I TRAINING AND EXPERIENCE REQUIREMENTS

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, 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 64E-5.626, 64E-5.627, 64E-5.630, or 64E-5.632 also is authorized to use radioactive material under a general license in 64E-5.206(8) for specified in vitro uses without filing the certificate required by 64E-5.206(8)(b), but is subject to the other provisions of 64E-5.206(8).

(3) Unless prohibited by license condition, a physician, dentist, or podiatrist in training may receive, possess, use, or transfer radioactive materials as provided in these regulations under the supervision of an authorized user as provided in 64E-5.608.

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

(a) That individual is listed on the licensee's specific license as an authorized
R3 user or an authorized nuclear pharmacist;

(b) Authorized by 64E-5.609;

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

(d) Authorized by 64E-5.601(3) and Subpart I of Part VI.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
R3 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 August 25, 1991, Amended May 12, 1993, Formerly 10D-91.707, Amended August 6, 2001.

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;

(2) Before permitting anyone, except a visiting authorized user described in 64E-5.609, to work as an authorized user;

(3) Before changing a radiation safety officer or teletherapy physicist;

(4) Before ordering or receiving radioactive material in excess of the amount 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.

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 August 25, 1991, Formerly 10D-91.708.

64E-5.603 Notification. A licensee shall notify the department in writing within
R3 30 days when an authorized user, radiation safety officer, authorized nuclear pharmacist, or teletherapy physicist permanently discontinues performance of these duties for the licensee.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
R3 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 August 25, 1991, Formerly 10D-91.709, Amended August 6, 2001.

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 64E-5.303.

(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.

(3) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

(4) The ALARA program shall include an annual review by the radiation safety committee for medical institution licensees, or by management and the radiation safety officer for licensees that are not medical institutions. 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.

(3) 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 64E-5.604 and 64E-5.606.

(4) 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.

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

R3 (6) The committee shall review and approve any individual to be an authorized user,
R3 an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist based on safety and the training and experience standards of this part before sending a license application or request for amendment or renewal.

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

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

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

(10) The committee shall review the radioactive materials program at least every 12 months with the assistance of the radiation safety officer as described in 64E-5.604(4).

(11) The committee shall establish levels for occupational dose that will result in investigations and considerations of action by the radiation safety officer when exceeded.

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.
R3 History: New August 25, 1991, Formerly 10D-91.712, Amended August 6, 2001.

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:

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

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

(c) For therapy procedures or diagnostic procedures involving more than 30 microcuries (1.11 MBq) of iodine 123, iodine 125 or iodine 131 as sodium iodide, prepare a written directive;

(d) For all other diagnostic procedures, prepare a written directive or assure that the procedure is in accordance with a diagnostic clinical procedures manual;

(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.

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 August 25, 1991, Amended May 12, 1993, Formerly 10D-91.713.

64E-5.608 Supervision.

(1) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 64E-5.601 shall:

(c) 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 64E-5.312. 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.

(d) Provide the patient with radiation safety guidance before autho rizing release of the patient that will help to keep radiation dose to household members and the public as low as reasonably achievable.

(e) Notify the radiation safety officer or the authorized user immediately if the patient dies or has a medical emergency.

R2 (7) A licensee shall provide a private room with a private sanitary facility for a radiopharmaceutical therapy patient. The licensee shall not place a brachytherapy patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of 64E-5.312(1)(c), at a distance of 1 meter from the implant.

R2 (8) A licensee shall take these additional safety precautions for radiopharmaceutical therapy patients who are hospitaliz ed:

(a) Monitor material and items removed from the patient'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.

(c) Establish a bioassay program to measure the thyroid burden of each individual who helped prepare or administer a dosage of liquid iodine 131 within 3 days after administering the dosage, and retain for the period required by 64E-5.339(5) a record of each thyroid burden measurement, the date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. Action levels and corresponding actions will be in accordance with the U.S. Nuclear Regulatory Commission's Regulatory Guide 8.20, Revision 1, September, 1979.

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 May 15, 1996, Formerly 10D-91.721.

SUBPART C
UPTAKE, DILUTION, AND EXCRETION

64E-5.626 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies. A licensee is allowed to use any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for medical use that is either:

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

(2) Prepared by an authorized nuclear pharmacist as specified in Rule 64B16-28.903, F.A.C., or by a physician who is an authorized user.

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 August 25, 1991, Formerly 10D-91.733, Amended August 6, 2001.

SUBPART D
IMAGING AND LOCALIZATION

64E-5.627 Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.

(1) A licensee is allowed to use any radioactive material in a diagnostic radiopharmaceutical, except in an aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for medical use that is either:

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

(b) Prepared by an authorized nuclear pharmacist as specified in Rule 64B16-28.903, F.A.C., or by a physician who is an authorized user.

(2) A licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the department and the requirements of 64E-5.629 are met.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.08 1, 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 August 25, 1991, Amended May 12, 1993, Formerly 10D-91.735, Amended August 6, 2001.

64E-5.628 Permissible Molybdenum 99 Concentration.

(1) A licensee shall not administer a radiopharmaceutical containing more than 0.15 microcurie of molybdenum 99 per millicurie of technetium 99m (5.55 kilo-becquerel of molybdenum 99 per 37 megabecquerel of technetium 99m).

(2) A licensee preparing technetium 99m radiopharmaceuticals from molybdenum 99/technetium 99m generators shall measure the molybdenum 99 concentration in each eluate or extract.

(3) A licensee who is required to measure molybdenum concentrations shall retain a record of each measurement for 3 years. The record shall include for each elution or extraction of technetium 99m:

(a) The measured activity of the technetium expressed in millicuries (megabecquerels);

(b) The measured activity of molybdenum expressed in microcuries (kilobecquerels);

(c) The ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium);

(d) The date of the test; and

(e) The initials of the individual who performed the test.

(4) A licensee shall report immediately to the department each occurrence of molybdenum 99 concentration exceeding the limits specified in 64E-5.628(1).

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 August 25, 1991, Formerly 10D-91.736.

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 64E-5.629(4) at the area of use and require that individuals evacuate the room until the posted time has elapsed if a gas spill occurs.

(6) A licensee shall check the operation of collection systems monthly 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 64E-5.629(4) shall be recorded and retained for the duration of the license.

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 August 25, 1991, Amended January 1, 1994, Formerly 10D-91.737.

SUBPART E
RADIOPHARMACEUTICALS FOR THERAPY

64E-5.630 Use of Radiopharmaceuticals for Therapy. A licensee may use any
R3 radioactive material in a radiopharmaceutical and for a therapeutic medical use that is either:

R3 (1) Obtained from a manufacturer or pharmacy licensed as specified in
R3 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory Commission or
R3 Agreement State regulations; or

R3 (2) Prepared by an authorized nuclear pharmacist as specified in Rule
R3 64B16-28.903, F.A.C., or by a physician who is an authorized user.

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.
R3 History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.739, Amended August 6, 2001.

SUBPART F
SEALED SOURCES FOR DIAGNOSIS

64E-5.631 Use of Sealed Sources for Diagnosis. A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for diagnosis:

(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; and

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

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 August 25, 1991, Formerly 10D-91.743.

SUBPART G
SOURCES FOR BRACHYTHERAPY

64E-5.632 Use of Sources for Brachytherapy. A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for brachytherapy:

(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;

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL
Bin #C21 ? 4052 Bald Cypress Way ? TALLAHASSEE, FLORIDA 32399-1741

CERTIFICATE - DISPOSITION OF RADIOACTIVE MATERIALS

(All items MUST be completed, please print)

LICENSEE NAME AND ADDRESS	LICENSE NUMBER LICENSE EXPIRATION DATE

THE LICENSEE OR ANY INDIVIDUAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE LICENSEE CERTIFIES THAT:
(Check and complete the appropriate item(s) below.)

A. MATERIALS DATA (Check one and complete, as necessary)

☐ 1. NO MATERIALS HAVE EVER BEEN PROCESSED OR PROCURED BY THE LICENSEE UNDER THIS LICENSE

OR

☐ 2. ALL MATERIALS PROCURED OR PROCESSED BY THE LICENSEE UNDER THE LICENSE NUMBER CITED ABOVE HAVE BEEN TRANSFERRED ON

DATE:	TO: LICENSE NUMBER:

OR

☐ 3. ALL MATERIALS PROCURED OR PROCESSED BY THE LICENSEE UNDER THE LICENSE NUMBER CITED ABOVE HAVE BEEN TRANSFERRED ON

DATE:	TO:	
	WHICH HAS LICENSE NUMBER	ISSUED BY THE STATE OF

OR

☐ 4. MATERIALS HAVE BEEN DISPOSED OF IN THE FOLLOWING MANNER. (Describe specific disposal procedures- if additional space is needed, use the reverse of this form, of provide attachments)

B. OTHER DATA

☐ 1. OUR LICENSE HAS NOT YET EXPIRED, PLEASE TERMINATE IT.

☐ 2. WAS A RADIATION SURVEY CONDUCTED TO CONFIRM THE ABSENCE OF LICENSED RADIOACTIVE MATERIALS AND TO DETERMINE WHETHER ANY CONTAMINATION REMAINS ON THE PREMISES COVERED BY THE LICENSE? (Check one)

☐ NO

☐ YES, THE RESULTS (Check one)

☐ ARE ATTACHED, OR

☐ WERE FORWARDED TO DEPARTMENT OF HEALTH ON (Date)

3. THE PERSON TO BE CONTACTED REGARDING THIS INFORMATION PROVIDED ON THIS FORM

NAME	TELEPHONE NUMBER

4. MAIL ALL FUTURE CORRESPONDENCE REGARDING LICENSE TO

RETURN TO:
BUREAU OF RADIATION CONTROL
BIN #C21
4052 BALD CYPRESS WAY
TALLAHASSEE, FL 32399-1741

CERTIFYING OFFICIAL

SIGNATURE	DATE
PRINTED NAME AND TITLE	

DH-1059, Edition 05/1997 (Replaces HRS Form 1059, Jan 85 which may also be used)

Authorized Nuclear Pharmacist Training Requirements

64B16-28.903 Training Qualifications.

(1) A pharmacist licensed to practice pharmacy in this state who performs a radiopharmaceutical service shall, prior to engaging in such specialized practice, be actively licensed as a nuclear pharmacist from the Board of Pharmacy.

(2) A licensed pharmacist seeking licensure as a nuclear pharmacist in this state shall submit to the Board of Pharmacy a course outline from an accredited college of pharmacy or other program recognized by the Florida Department of Health and the Florida Board of Pharmacy (a program comparable to those offered by accredited colleges of pharmacy for the training of nuclear pharmacists), and a certificate of training which provides a minimum of 200 clock hours of formal didactic training, which includes:

(a) Radiation physics and instrumentation (85 hours);

(b) Radiation protection (45 hours);

(c) Mathematics pertaining to the use and measurement of radioactivity (20 hours);

(d) Radiation biology (20 hours);

(e) Radiopharmaceutical chemistry (30 hours).

(3) Such academic training programs will be submitted to the Board for approval by an accredited educational institution which operates under the auspices of or in conjunction with an accredited college of pharmacy.

(4) The minimum on-the-job training which shall be included in a radiopharmacy internship is five hundred (500) hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and experience shall include, but shall not be limited to the following:

(a) Ordering, receiving and unpackaging in a safe manner, radioactive material, including the performance of related radiation surveys;

(b) Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment;

(c) Calculating, preparing and verifying patient doses, including the proper use of radiation shields;

(d) Following appropriate internal control procedures to prevent mislabeling;

(e) Learning emergency procedures to safely handle and contain spilled materials, including related decontamination procedures and surveys;

(f) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals;

(g) Clinical practice concepts.

(5) Guidelines for such programs are in a publication entitled "Guidelines for Florida Board of Pharmacy Internship Training in Radiopharmacy" (1988). Governmental and private radiopharmacy internship programs shall not apply to the pharmacy internship required under Rule 64B16-26.401, F.A.C.

(6) If the didactic and experiential training required in this section have not been completed within the last seven years, the applicant must have been engaged in the lawful practice of nuclear pharmacy in another jurisdiction at least 1080 hours during the last seven years.

(7) The Board of Pharmacy shall, subsequent to its review of the certificates of training, inform each applicant in writing as to whether or not licensure has been granted.

Specific Authority 465.005 FS. Law Implemented 465.003(14), 465.0126 FS. History–New 4-17-76, Amended 4-8-80, 6-23-83, Formerly 21S-3.05, Amended 8-11-86, 4-4-88, Formerly 21S-3.005, Amended 7-31-91, Formerly 21S-28.903, 61F10-28.903, Amended 6-12-96, Formerly 59X-28.903.

State Boundaries

Approximate Boundaries Shown

See Florida Constitution for Exact Boundaries

N

0 40 80 120 Miles

1:4158925

FLORIDA DEPARTMENT OF HEALTH

Florida Department of Health

Bureau of Radiation Control

ARTICLE II GENERAL PROVISIONS

SECTION 1. State boundaries.

(a) The state boundaries are: Begin at the mouth of the Perdido River, which for the purposes of this description is defined as the point where latitude 30°16'53" north and longitude 87°31'06" west intersect; thence to the point where latitude 30°17'02" north and longitude 87°31'06" west intersect; thence to the point where latitude 30°18'00" north and longitude 87°27'08" west intersect; thence to the point where the center line of the Intracoastal Canal (as the same existed on June 12, 1953) and longitude 87°27'00" west intersect; the same being in the middle of the Perdido River; thence up the middle of the Perdido River to the point where it intersects the south boundary of the State of Alabama, being also the point of intersection of the middle of the Perdido River with latitude 31°00'00" north; thence east, along the south boundary line of the State of Alabama, the same being latitude 31°00'00" north to the middle of the Chattahoochee River; thence down the middle of said river to its confluence with the Flint River; thence in a straight line to the head of the St. Marys River; thence down the middle of said river to the Atlantic Ocean; thence due east to the edge of the Gulf Stream or a distance of three geographic miles whichever is the greater distance; thence in a southerly direction along the edge of the Gulf Stream or along a line three geographic miles from the Atlantic coastline and three leagues distant from the Gulf of Mexico coastline, whichever is greater, to and through the Straits of Florida and westerly, including the Florida reefs, to a point due south of and three leagues from the southernmost point of the Marquesas Keys; thence westerly along a straight line to a point due south of and three leagues from Loggerhead Key, the westernmost of the Dry Tortugas Islands; thence westerly, northerly and easterly along the arc of a curve three leagues distant from Loggerhead Key to a point due north of Loggerhead Key; thence northeast along a straight line to a point three leagues from the coastline of Florida; thence northerly and westerly three leagues distant from the coastline to a point west of the mouth of the Perdido River three leagues from the coastline as measured on a line bearing south 0°01'00" west from the point of beginning; thence northerly along said line to the point of beginning. The State of Florida shall also include any additional territory within the United States adjacent to the Peninsula of Florida lying south of the St. Marys River, east of the Perdido River, and south of the States of Alabama and Georgia.

(b) The coastal boundaries may be extended by statute to the limits permitted by the laws of the United States or international law.

(one league = three statute miles)