



Jeb Bush
Governor

Robert G. Brooks, M.D.
Secretary

January 10, 2001

Richard Woodruff
Regional State Agreements Officer
U.S. Nuclear Regulatory Commission
Sam Nunn Atlanta Federal Center, 23 T 85
61 Forscyth Street, SW
Atlanta, GA 30303-3415

Dear Mr. Woodruff:

Please find enclosed four copies of the latest revision to the state of Florida's Chapter 64E-5, Florida Administrative Code. Only minor changes were made to the draft version that was sent back in July 2000. Please feel free to contact us at (850) 245-4545, if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Michael N. Stephens".

Michael N. Stephens
Environmental Administrator

MNS/nm
Enclosures

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OSP

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R10S Cdr. SP06*



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October 2000

**Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2000-02**

***Revision 2 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 October 8, 2000. **These changes are denoted as Revision 2 or (R2) in the margin.** Enclosed are copies of the pages to be inserted.

These instructions apply to the complete version (brown cover) of Chapter 64E-5, F.A.C. Be sure that Revision 1 changes have been made before making these changes.

PAGES TO BE REMOVED		PAGES TO BE INSERTED
Part	Page Number	Page Number
Index	i-xii	i-xii
I General Provisions	Part I Index I-3 through I-22	Part I Index I-3 through I-22
II Licensing of Radioactive Materials	Part II Index II-1 through II-2 II-9 through II-10, ---- II-11 through II-12 II-60a through II-60b II-63 through II-66	Part II Index II-1 through II-2 II-9 through II-9a, II-9b through II-10 II-11 through II-12 II-60a through II-60b II-63 through II-66
III Standards for Protection Against Radiation	Part III Index III-1 through III-4 III-7 through III-14 III-19 through III-22 III-35 through III-36 III-37 through III-46	Part III Index III-1 through III-4 III-7 through III-14 III-19 through III-22 III-35 through III-36 III-37 through III-46

PAGES TO BE REMOVED		PAGES TO BE INSERTED
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V X-Rays in the Healing Arts	Part V Index V-31 through V-32	Part V Index V-31 through V-32
VI Use of Radionuclides in the Healing Arts	Part VI Index VI-19 through VI-20 -- -- VI-21 through VI-24 VI-35 through VI-36	Part VI Index VI-19 through VI-20 VI-20a through VI-20b VI-21 through VI-24 VI-35 through VI-36
XI Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies	Part XI Index XI-1 through XI-2 XI-7 through XI-8	Part XI Index XI-1 through XI-2 XI-7 through XI-8
XIII Radiation Safety Requirements for Possession and Use of Sealed or Unsealed Sources of Radioactive Materials	Part XIII Index XIII-5 through XIII-8	Part XIII Index XIII-5 through XIII-8
XIV Licensing and Radiation Safety Requirements for Irradiators	Part XIV Index XIV-7 through XIV-8 XIV-17 through XIV-18	Part XIV Index XIV-7 through XIV-8 XIV-17 through XIV-18

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XV Transportation of Radioactive Materials	Part XV Index XV-1 through XV-2 XV-9 through XV-10	Part XV Index XV-1 through XV-2 XV-9 through XV-10
Attachment Radioactive Material Requiring Labeling	Attachment page 68 Attachment pages 69-70	Attachment page 68 Attachment pages 69-70

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

- PART I: Definition of "Dose constraint" added. Definition of "Individual monitoring devices" changed to include optically stimulated luminescent devices (OSLD). Minor clarifying wording changes were made to the definition of "Declared pregnant woman, High radiation area, Misadministration, Occupational dose, Public dose, Very high radiation area."
- PART II: Added exemption for 1 microcurie C-14 urea capsules for medical use. Mailing address changed.
- PART III: ALARA dose constraints for air emissions not to exceed a dose of 10 millirem per year along with reporting requirements if the dose is exceeded. Most licensee are not impacted by this change. Clarified that a declared pregnant woman must monitor her radiation dose if she is likely to receive more than 100 millirem during the entire pregnancy.
- PARTS IV, XI, XIII, XIX: Optically stimulated luminescent devices are added as a personnel monitoring option.
- PART VI: Adds a third option for the release of patients containing radioactive materials from medical confinement. This option requires a license amendment prior to being used and is dose (< 500 millirem) based with record keeping requirements.
- PART XV: Mailing address change.

No specific actions nor written response is required. If you have any questions or need additional information, please contact us.

**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 a particular part not herein contained.

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

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This is an "unofficial" copy that has been re-formatted for ease of use and to provide attachments. Chapter 64 along with the other Florida Administrative Codes may be viewed at <http://fac.dos.state.fl.us/>.

Chronology of Rule Revisions

Revision Number	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

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- (19) "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.
- (20) "Brachytherapy" means a method of radiation therapy in which sealed sources are used to deliver a radiation dose by surface, intracavitary, or interstitial application.
- (21) "Byproduct material" means:
- (a) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and
 - (b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface waste resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute byproduct material within this definition.
- (22) "Cabinet x-ray system" means industrial radiography using a radiation machine, which is conducted in an enclosed and interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed, and which cabinet is so shielded that every location on the exterior meets conditions for an unrestricted area as specified in 64E-5.312.
- (23) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin on January 1 and subsequent calendar quarters shall be arranged so that no day is included in more than 1 calendar quarter, no calendar quarter, or part thereof, is included in more than 1 calendar year, and no day in any 1 year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him to determine calendar quarters for purposes of these rules except at the beginning of a calendar year.
- (24) "Calibration" means:
- (a) The determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
 - (b) The determination of the strength of a source of radiation relative to a standard.
- (25) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier or by civil aircraft.

- (26) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.
- (27) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.
- (28) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.
- (29) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum W_T H_{T,50}$).
- R2 (30) "Constraint" or "dose constraint" means a value above which specified licensee
R2 actions are required.
- R2 (31) "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of
radioactive material which decays at the rate of 3.7×10^{10} transformations per
second (tps).
- R2 (32) "Declared pregnant woman" means a woman who has voluntarily informed her
R2 employer in writing of her pregnancy and the estimated date of conception.
R2 The declaration remains in effect until the declared pregnant woman withdraws
the declaration in writing or is no longer pregnant.
- R2 (33) "Dedicated check source" means a radioactive source that is used to assure the
consistent operation of a radiation detection or measurement device over several
months or years. This source may also be used for other purposes.
- R2 (34) "Deep dose equivalent" (H_d), which applies to external whole body exposure,
means the dose equivalent at a tissue depth of 1 centimeter ($1,000 \text{ mg/cm}^2$).
- R2 (35) "Decommission" means to remove a facility safely from service and reduce
residual radioactivity to a level that permits release of the property for
unrestricted use and termination of license.
- R2 (36) "Depleted uranium" means the source material uranium in which the isotope
uranium 235 is less than 0.711 weight percent of the total uranium present.
Depleted uranium does not include special nuclear material.

- R2 (37) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3.
- R2 (38) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee can take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rem (0.05 sievert).
- R2 (39) "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.
- R2 (40) "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.
- R2 (41) "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.
- R2 (42) "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.
- R2 (43) "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.
- R2 (44) "Effective dose equivalent" (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$).
- R2 (45) "Embryo" or "fetus" means the developing human organism from conception until birth.

- R2 (46) "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.
- R2 (47) "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.
- R2 (48) "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.
- R2 (49) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.
- R2 (50) "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.
- R2 (51) "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).
- R2 (52) "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.
- R2 (53) "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.
- R2 (54) "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.
- R2 (55) "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.

- R2 (56) "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
- R2 (57) "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.
- R2 (58) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates. For purposes of these rules, rooms or areas in which diagnostic x-ray systems are used for healing arts purposes are not considered high radiation areas.
- R2 (59) "Human use" means the internal or external administration of radiation or radioactive material to human beings.
- R2 (60) "Individual" means any human being.
- R2 (61) "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.
- R2 (62) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters, pocket ionization chambers, and personal or lapel air sampling devices. For purposes of these rules, individual monitoring equipment and personnel monitoring equipment are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), optically stimulated luminescent devices (OSLDs), pocket ionization chambers, and personal air sampling devices.
- R2 (63) "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods using sources of radiation.
- R2 (64) "Inhalation class" (see "Class").
- R2 (65) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.
- R2 (66) "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.

- R2 (67) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.
- R2 (68) "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.
- R2 (69) "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at the tissue depth of 0.3 centimeter (300 mg/cm²).
- R2 (70) "License" means a license issued by the department in accordance with the rules adopted by the department.
- R2 (71) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the department.
- R2 (72) "Licensee" means any person who is licensed by the department in accordance with these rules and the Act.
- R2 (73) "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.
- R2 (74) "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.
- R2 (75) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.
- R2 (76) "Logging tool" means a device used subsurface to perform well-logging.
- R2 (77) "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.

- R2 (78) "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.
- R2 (79) "Lung class" (see "Class").
- R2 (80) "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.
- R2 (81) "Management" means the chief executive officer or that individual's designee.

- R2 (82) "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.
- R2 (83) "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.
- R2 (84) "Member of the public" means any individual except when that individual is receiving an occupational dose.
- R2 (85) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.
- R2 (86) "Minor" means an individual less than 18 years of age.
- R2 (87) "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):
 - 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:
 - 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.
- R2 (88) "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.
- R2 (89) "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.
- R2 (90) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
- R2 (91) "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.
- R2 (92) "Normal form" means radioactive material which has not been demonstrated to qualify as "special form"; also referred to as "nonspecial form."
- R2 (93) "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.
- R2 (94) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.
- R2 (95) "Occupational dose" means the dose received by an individual in the course of employment which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, **from any medical administration the individual has received, from exposure to individuals administered radioactive material and released as specified in Rule 64E-5.622, F.A.C., from voluntary participation in medical research programs, or as a member of the public.**
- R2
- R2
- R2

- R2 (96) "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.
- R2 (97) "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.
- R2 (98) "Package" means the packaging, together with its radioactive contents, as presented for transport.
- R2 (99) "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.
- R2 (100) "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.
- R2 (101) "Permanent radiographic installation" means an installation or structure designed or intended for radiography and in which radiography is regularly performed, but not meeting the requirements of shielded room radiography.
- R2 (102) "Permit" means the written authorization issued by the department for the transportation of radioactive waste as described in section 64E-5.1509.
- R2 (103) "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.
- R2 (104) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.
- R2 (105) "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.

- R2 (106) "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.
- R2 (107) "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 (174) "Principal activities" means activities authorized by the license that are essential to achieve the purpose for which the department issued or amended the license. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.
- R1
R1
R1
R1
- R2 (108) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive materials released by a licensee or registrant, or to any other sources of radiation under the control of the licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released as specified in Rule 64E-5.622, F.A.C., or from voluntary participation in medical research programs.
- R2
R2
R2
R2
R2
R2
- R2 (109) "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.
- R2 (110) "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.
- R2 (111) "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).
- R2 (112) "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.
- R2 (113) "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.
- R2 (114) "Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

- R2 (115) "Radiation Safety Officer or RSO" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules.
- R2 (116) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.
- R2 (117) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.
- R2 (118) "Radiographer" means any individual who performs or personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these rules and all license or certificate of registration conditions.
- R2 (119) "Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools or radiation survey instruments in industrial radiography.
- R2 (120) "Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position, for purposes of making a radiographic exposure.
- R2 (121) "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 quantities greater than 30 microcuries (1.11 megabecquerels) when:
 1. The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage; and
 2. The difference between the administered dosage and the prescribed dosage exceeds 15 microcuries.
 - (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.
- R2 (122) "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."
- R2 (123) "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.
- R2 (124) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR, Parts 100-189.
- R2 (125) "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).
- R2 (126) "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.
- R2 (127) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.
- R2 (128) "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.
- R2 (129) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air.

- R2 (130) "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.
- R2 (131) "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.
- R2 (132) "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.
- R2 (133) "Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.
- R2 (134) "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.
- R2 (135) "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.
- R2 (136) "SI" means an abbreviation of the International System of Units.
- R2 (137) "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 ($1 \text{ Sv} = 100 \text{ rem}$).
- R2 (138) "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.
- R2 (139) "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.
- R2 (140) "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.

- R2 (141) "Source material milling" means any activity that results in the production of byproduct material as defined by 64E-5.101.
- R2 (142) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.
- R2 (143) "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.
- R2 (144) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:
- $$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$
- R1
- R2 (145) "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.
- R2 (146) "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.

- R2 (147) "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.
- R2 (148) "Storage container" means a device in which sealed sources are transported or stored.
- R2 (149) "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.
- R2 (150) "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.
- R2 (151) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
- R2 (152) "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.
- R2 (153) "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.
- R2 (154) "Test" means the process of verifying compliance with an applicable rule.
- R2 (155) "Total effective dose equivalent" means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.
- R2 (156) "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.
- R2 (157) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating or refining.
- R2 (158) "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.

- R2 (159) "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.)
- R2 (160) "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.
- R2 (161) "Visiting authorized user" means an authorized user who is not identified on the license.
- R2 (162) "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.
- R2 (163) "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.

- R2 (164) "Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed
- R2 (165) "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.
- R2 (166) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.
- R2 (167) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.
- R2 (168) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.
- R2 (169) "Worker" means an individual engaged in work in a restricted area under the authority of a license or registration issued by the department.
- R2 (170) "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.
- R2 (171) "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.
- R2 (172) "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.

R2 (173) "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 (174) added alphabetically May 18, 1998.

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.

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

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PART II

LICENSING OF RADIOACTIVE MATERIALS

64E-5.201 Licensing of Radioactive Material.

- (1) This part provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this part or as otherwise provided in this part. Unless otherwise specified in the license or these rules, no licensee shall use radioactive materials:
 - (a) In or on human beings;
 - (b) In field applications where radioactive materials is released to the environment;
 - (c) In products distributed to the public;
 - (d) In animals, plants, or their products which will be used for human consumption; or
 - (e) In plants or animals where their products are released to the environment
- (2) In addition to the requirements of this part, all licensees are subject to the requirements of Parts I, III, IX and XV. Licensees engaged in industrial radiographic operations are also subject to the requirements of Part IV, licensees using radionuclides in the healing arts are subject to the requirements of Part VI and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part XI.
- R2 (3) The **Procedures for Radioactive Materials Enforcement Actions, May 2000**, which is available from the department and which is herein incorporated by reference, will be used to determine enforcement actions to be taken.
- (4) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the law, or because of conditions revealed by such application or statement of fact on any report, record or inspection or other means which would warrant the department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the law or of the license, a rule, or an order of the department.

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

R1 Law Implemented: 404.022, 404.051(1),(4),(6), 404.061(2), 404.081(1), 404.091, 404.141, 404.161, 401.162, 404.20(1)F.S.

R1 History: New July 17, 1985, Amended August 25, 1991, Amended May 12, 1993,
Amended, May 15, 1996, Formerly 10D-91.301, Amended October 8, 2000.

64E-5.202 Source Material - Exemptions

- (1) Any person is exempt from this part to the extent that such person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of 1 percent of the mixture, compound, solution or alloy.
- (2) Any person is exempt from this part to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.
- (3) Any person is exempt from this part to the extent that such person receives, possesses, uses or transfers:
 - (a) Any quantities of thorium contained in:
 1. Incandescent gas mantles;
 2. Vacuum tubes;
 3. Welding rods;
 4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium;
 5. Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium;
 6. Rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these; or
 7. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
 - (b) Source material contained in the following products:
 1. Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material;
 2. Glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, ceramic tile or other glass, or ceramic used in construction;

by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR, Part 32; or a Licensing State pursuant to 64E-5.210(3), which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements. Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing by-product material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

2. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under (3)(c)1., above, provided that the device is labeled in accordance with the specific license authorizing distribution of devices under a general license, and provided further that they meet the requirements of 64E-5.210 (3).
3. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under (3)(c)1., above, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 64E-5.210 (3).

- (d) Resins Containing Scandium 46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium 46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR, Part 32. This exemption does not authorize the manufacture of any resins containing scandium 46.

- R2 (4) Radioactive drug: capsules containing carbon 14 urea for in vivo diagnostic use
R2 for humans.
- R2 (a) Except as provided in paragraphs (b) and (c) of this section, any person is
R2 exempt from the requirements for a license set forth in these regulations if
R2 such person receives, possesses, uses, transfers, owns, or acquires
R2 capsules containing 1 microcurie (37 kBq) carbon 14 urea each, allowing
R2 for nominal variation that can occur during the manufacturing process, for
R2 in vivo diagnostic use for humans.

- R2 (b) Any person who desires to use the capsules for research involving human
R2 subjects shall apply for and receive a specific license as specified in these
R2 regulations.
- R2 (c) Any person who desires to manufacture, prepare, process, produce,
R2 package, repackage, or transfer for commercial distribution such capsules
R2 shall apply for and receive a specific license as specified in 10 CFR Part
R2 32, Sec. 32.21.
- R2 (d) Nothing in this section relieves a person from complying with applicable
R2 FDA, other Federal, and State requirements governing receipt,
R2 administration, and use of drugs

Specific Authority: 404.051, 404.061, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(10), 404.141, F.S.

R2 History: New July 17, 1985, Amended April 4, 1989, May 15, 1996, Formerly 10D-91.303, Amended October 8, 2000.

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**SUBPART A
LICENSE TYPES AND FEES**

64E-5.204 Types of Licenses. Licenses for radioactive materials are of two types: general and specific.

- (1) Some general licenses provided in this part may be effective without the filing of applications with the department or the issuance of licensing documents to the particular persons, although the filing of a certificate with the department for general licenses pursuant to 64E-5.206(7) or (8) shall be required of the particular general licensee prior to the receipt of radioactive material. The payment of a fee is also required by all persons possessing general licensed material described in (1)(c), below. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.
- (a) The annual registration fee set forth in this section for general licenses shall be payable every July 1, for as long as the license remains in effect.
- (b) The annual fee for a general license set forth in 64E-5.216 under reciprocal agreement shall be paid before the first entrance into the State and on each anniversary date thereafter, if applicable. Manufacturers, manufacturer's representatives, distributors, and waste treatment, storage or disposal companies servicing Florida radioactive materials license applicants or licensees are exempt from this fee.
- (c) Payment of the indicated annual fee pursuant to (1)(a), above, is required for the following types of devices held or activities performed under a general license:
1. Static elimination devices
as described in 64E-5.206(1)(a).....\$25.00 per unit.
 2. Measuring, gauging, and control devices
as described in 64E-5.206(4).....\$25.00 per unit.
 3. *In Vivo* testing
as described in 64E-5.206(7)..... \$125.00 per license.
 4. *In Vitro* testing
as described in 64E-5.206(8)..... \$125.00 per license.
 5. Depleted uranium
as described in 64E-5.206(4)..... \$125.00 per license.

- (d) Those persons who hold a specific license from the U.S. Nuclear Regulatory Commission, an agreement state or licensing state and conduct activities under a reciprocal agreement with this State shall meet the requirements of 64E-5.216(1), and pay the annual fee as specified in (2)(e), below.
- (2) Specific licenses require the submission of an application to the department and the issuance of a licensing document by the department. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document. The licensee is subject to the payment of fees as authorized under section 404.131, Florida Statutes and as outlined below:
- (a) The requirements of this part apply to a person who is an applicant for, or holder of a specific radioactive materials license issued pursuant to Subpart III C, and for a special review of safety designs of sealed sources and devices, whether or not in conjunction with a license application on file or which may be filed.
- (b) All communications concerning the requirements of this part should be addressed to or delivered in person to the Department of Health, Bureau of Radiation Control, Bin #C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741.
- (c) No additional fees shall be required for amendments to licenses.
- (d) Payment of fees.
1. **Application fees.** Each application for a specific license for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. No application will be processed prior to payment of the fee specified herein. The application fee is not refundable except in those cases where the department has determined that a license is not required. The department will consider any application abandoned if the department does not receive a reply within 90 days to its most recent request for additional information. In such cases, the applicant must submit a new application with the application fee specified herein.
 2. **Annual fees.** All current specific licenses that were in effect on January 1, 1979, are subject to payment of the annual fee prescribed herein and on every January 1, thereafter, as long as the license remains in effect. All specific licenses issued after January 1, 1979, are subject to payment of the annual fee specified in this section within 60 days of issuance of the license and on each anniversary date thereafter. The annual fee is not refundable except in those cases where the department has determined that the fee is not required.

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3. Method of payment. Checks, drafts or money orders for payment of fees shall be payable to DOH, Bureau of Radiation Control; and sent to: Department of Health, Bureau of Radiation Control, Bin #C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741.

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

		APPLICATION FEE	ANNUAL FEE
	1. SOURCE MATERIAL.		
R1	a. Licenses for concentration of uranium from phosphate ores for the production of uranium as "yellow cake" or powdered solid;	\$6,907	\$11,942
R1	b. License for concentration of uranium from phosphate ores for the production of "green cake" or equivalent, moist or solid;	\$3,768	\$7,439
R1	c. All other specific source material licenses excluding depleted uranium used as shielding and counterweights.	\$544	\$229
	2. SPECIAL NUCLEAR MATERIAL (SNM).		
R1	a. Licenses for use of SNM in sealed sources contained in devices used in measuring systems;	\$653	\$518
R1	b. Licenses for use of SNM not sufficient to form a critical mass, except as in 2.a., above, and 2.c. and 5.e., below	\$1,340	\$1,944
R1	c. Licensed for use of SNM to be used as calibration and reference sources	\$205	\$109
	3. BY-PRODUCT, NATURALLY OCCURRING OR ACCELERATOR PRODUCED MATERIAL		
R1	a. Licenses for processing or manufacturing for commercial distribution or industrial uses;	\$2,923	\$2,802
R1	b. Licenses for processing or manufacturing and distribution of radiopharmaceuticals. This category includes radiopharmacies;	\$2,560	\$3,840
R1	c. Licenses industrial radiography performed only in an approved shielded radiography installation;	\$1,558	\$2,161
R1	d. Licenses for industrial radiography performed only at the address indicated in the license, or at temporary job sites of the licensee;	\$1,643	\$2,657

1. Terminate the use of radioactive material;
 2. Remove radioactive contamination to the extent acceptable to the department;
 3. Properly dispose of the radioactive material;
 4. Submit a properly completed DH Form 1059, which is herein incorporated by reference effective July 17, 1985; and
 5. Submit a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual contamination in some other manner. The licensee shall, as appropriate:
 - a. For gamma radiation, report levels of radiation in units of microrentgens per hour at 10 centimeters and at 1 meter from surfaces.
 - b. For alpha and beta radiation, report levels of radioactivity in units of transformations per minute or microcuries per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and
 - c. Specify the instruments used and certify that each instrument is properly calibrated or tested.
- (b)
1. If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. The department will notify the licensee, in writing, of the termination of the license.
 2. Specific licenses will be terminated by written notice to the licensee when the department determines that:
 - a. Radioactive material has been properly disposed; and
 - b. A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or
 - c. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.
 - d. Department has received the following records, if

- R2 requested:
- R2 (I) Disposal records specified in Rules 64E-5.330,
R2 64E-5.331(1)(a)(c), (2), (3), or 64E-5.336(2)(d),
R2 F.A.C.; and
- R2 (II) Records specified in Rule 64E-5.214(6), F.A.C.

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- (c) Except for areas containing only radioactive materials having half-lives of less than 65 days or sealed sources that either have not leaked or no contamination remains after any leak, a list contained in a single document and updated every 2 years, of the following:
1. All areas designated and formerly designated restricted areas as defined in 64E-5.101;
 2. All areas outside of restricted areas that require documentation under 64E-5.214(6)(a);
 3. All areas outside of restricted areas where current and previous wastes have been buried as documented under 64E-5.340; and
 4. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 64E-5.329; and
- (d) Records of the cost estimate performed for the performance bond required in 64E-5.217 and records of the funding method used.
- (7) Confirmatory or closeout surveys will be performed by the department according to the Closeout Inspection and Survey Procedures, November 1991, which are herein incorporated by reference and which are available from the department.

R1 Specific Authority: 404.051, 404.061, 404.081, 404.141, F.S.

R1 Law Implemented: 404.051(1),(4),(9), 404.061(2), 404.081(1), 404.141, F.S.

R1 History: New July 17, 1985, Amended May 12, 1993, Amended August 14, 1996, Formerly 10D-91.315,

R2 Amended May 18, 1998, Amended October 8, 2000.

64E-5.215 Transfer of Material.

- (1) No licensee shall transfer radioactive material except as authorized pursuant to this section.
- (2) Except as otherwise provided in his license and subject to the provisions of (3) and (4), below, a licensee may transfer radioactive material:
 - (a) To the department after receiving approval from the department;
 - (b) To the U.S. Department of Energy;
 - (c) To any person exempt from these regulations to the extent permitted under such exemption;

- (d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the U.S. Nuclear Regulatory Commission, an agreement state, a licensing state, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the department, an agreement state or a Licensing State.
- (3) Before transferring radioactive material to a specific licensee of the department, the U.S. Nuclear Regulatory Commission, an agreement state, a licensing state or to a general licensee who is required to register with the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.
- (4) Any of the following methods for the verification required by (3), above, are applicable:
- (a) The transferor may possess and read a current copy of the transferee's specific or general license.
 - (b) The transferor may possess a written certification by the transferee that the transferee is authorized by license to receive the type, form and quantity of radioactive material to be transferred, specifying the license number, issuing agency and expiration date.
 - (c) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license to receive the type, form and quantity of radioactive material to be transferred, specifying the license number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.
 - (d) The transferor may obtain other information compiled by a reporting service from official records of the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state regarding the identity of licensees and the scope and expiration dates of the licenses.
 - (e) When none of the methods of verification described in (4)(a) through (d), above, are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation for the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state that the transferee is licensed to receive the radioactive material.

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

Specific Authority: 404.051, 404.061, 404.081, 404.141, 404.20, F.S.

Law Implemented: 404.022, 404.051(1),(2),(4),(11), 404.061(2), 404.081(1), 404.20(1), F.S.

History: New July 17, 1985, Formerly 10D-91.319.

SUBPART D RECIPROCITY

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

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- (1) Subject to these regulations, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, **will** be granted a general license by the department to conduct the activities authorized in such licensing document within the State, **except for areas of exclusive Federal jurisdiction**, for a period not in excess of 365 consecutive days provided that:
- (a) The out-of-state license document does not limit the performance of the function authorized by such document to specified installations or locations;
- (b) The out-of-state licensee notifies the department in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner.
- R2 (c) The out-of-state licensee complies with these applicable regulations and with all the terms and conditions of the licensing document, except any such terms and conditions **that are** inconsistent with these applicable regulations; and
- (d) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person:
1. Specifically licensed by the department, by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State to receive such material, or
 - R2 2. Exempt from the requirements for a license for such material under **Rule 64E-5.203(1)(a), F.A.C.**

- (2) Notwithstanding the provisions of (1), above, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a Licensing State authorizing the holder to manufacture, transfer, install or service a device described in 64E-5.206(4)(a) within areas subject to the jurisdiction of the licensing body may be granted a general license by the department to install, transfer, demonstrate or service such a device in this State provided that:
- (a) Such person shall file a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of radioactive material contained in the device;
 - (b) The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, an agreement state or a Licensing State;
 - (c) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
 - (d) The holder of the specific license shall furnish to each general licensee to whom he transfers such device, or on whose premises he installs such device, a copy of the general license contained in 64E-5.206(4) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.
- (3) The department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health, safety or property.

Specific Authority: 404.051(4),(11) 404.061(2), 404.081(1), 404.141, F.S.

Law Implemented: 404.051(1),(2),(4),(6),(11), 404.061(2), 404.081(1), F.S.

R2 History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.321, Amended October 8, 2000.

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PART III
STANDARDS FOR PROTECTION AGAINST RADIATION

SUBPART A
GENERAL PROVISIONS

64E-5.301 Standards for Protection Against Radiation.

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

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

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

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

64E-5.302 Implementation.

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

Specific Authority: 404.051, 404.081, F.S.

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

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

SUBPART B-- RADIATION PROTECTION PROGRAMS

64E-5.303 Radiation Protection Programs.

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

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

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

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

SUBPART C -- OCCUPATIONAL DOSE LIMITS

64E-5.304 Occupational Dose Limits for Adults.

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

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

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

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

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

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

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

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

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.436.

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

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

Specific Authority: 404.051, 404.081, F.S.

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

History: New January 1, 1994, Formerly 10D-91.437.

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.309 Planned Special Exposures. A licensee or registrant can authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in **Rule 64E-5.304, F.A.C.**, if each of the following conditions is satisfied:

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.311 Dose to an Embryo or Fetus.

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

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

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

SUBPART D
RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

64E-5.312 Dose Limits for Individual Members of the Public.

- (1) Each licensee or registrant shall conduct operations so that:
 - (a) Except as specified in Rule 64E-5.312(1)(b), F.A.C., the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released as specified in Rule 64E-5.622, F.A.C., from voluntary participation in medical research programs and from the licensee's disposal of radioactive material into sanitary sewerage as specified in Rule 64E-5.330, F.A.C.;
 - (b) In facilities in operation before January 1, 1994, the total effective dose equivalent to individual members of the public from infrequent exposure to radiation from diagnostic and therapeutic radiation machines does not exceed 0.5 rem (5 millisievert) in a year; and
 - (c) The dose in any unrestricted area from external sources, exclusive of the dose contribution from patients administered radioactive material and released as specified in Rule 64E-5.622, F.A.C., does not exceed 0.002 rem (0.02 millisievert) in any one hour.

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- (2) If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.
 - (3) A licensee, registrant, or an applicant for a license or registration can apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 millisievert). This application shall include the following information:
 - (a) Demonstration of the need for and the expected duration of operations in excess of the limit in 64E-5.304(1);
 - (b) The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 millisievert) annual limit; and
 - (c) The procedures to be followed to maintain the dose ALARA.
 - (4) In addition to the requirements of this part, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New January 1, 1994, Amended May 15, 1996, Formerly 10D-91.443, Amended October 8, 2000.

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

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

SUBPART E SURVEYS AND MONITORING

64E-5.314 General.

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.315 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum:

- (1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
 - R2 (a) Adults likely to receive in 1 year from sources external to the body a dose in excess of 10 percent of the limits in Rule 64E-5.304(1), F.A.C.;
 - R2 (b) Minors likely to receive in 1 year from radiation sources external to the body a **deep dose equivalent** in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv) or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);
 - R2 (c) Declared pregnant women likely to receive during the entire pregnancy from radiation sources external to the body a deep dose equivalent in excess of 0.1 rem (1 mSv); and
 - R2 (d) Individuals entering a high or very high radiation area.
- (2) Each licensee shall monitor to determine compliance with Rule 64E-5.307, F.A.C., the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
 - R2 (a) Adults likely to receive in 1 year an intake in excess of 10 percent of the applicable ALI in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations July 1993, Table I, Columns 1 and 2; and
 - R2 (b) Minors likely to receive in 1 year a committed effective dose equivalent in excess of 0.10 rem (1.0 millisievert); and
 - R2 (c) Declared pregnant women likely to receive during the entire pregnancy a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

Specific Authority: 404.051, 404.081, F.S.

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

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

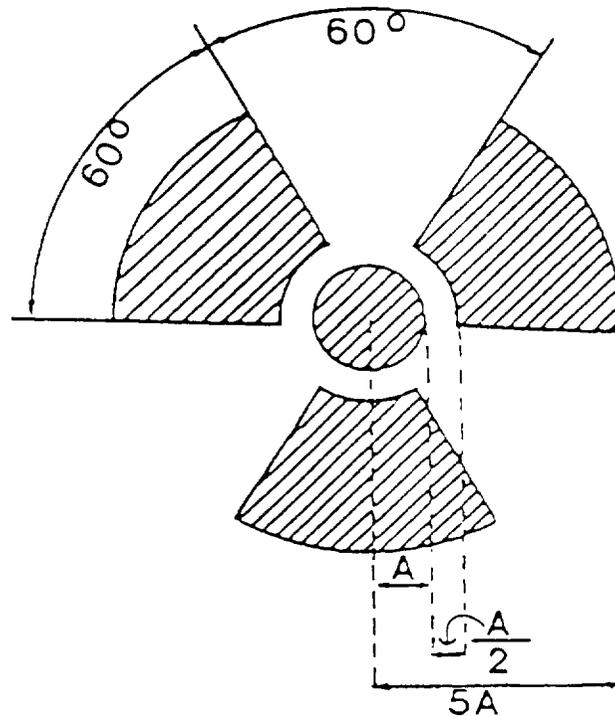
SUBPART F
CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

64E-5.316 Control of Access to High Radiation Areas.

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

64E-5.322 Caution Signs.

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



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

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

64E-5.323 Posting Requirements.

- (1) Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."
- (2) Posting of High Radiation Areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."
- (3) Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."
- (4) Posting of Airborne Radioactivity Areas. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."
- (5) Posting of Areas or Rooms in which Licensed Material is Used or Stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling, May 2000, which is herein incorporated by reference and which is available from the department, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

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Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.324 Exceptions to Posting Requirements.

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.325 Labeling Containers and Radiation Machines.

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

Specific Authority: 404.051, 404.081, F.S.

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

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

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

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.327 Procedures for Receiving and Opening Packages.

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

- (g) The land disposal facility operator shall:
1. Acknowledge receipt of the waste within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;
 2. Maintain copies of all completed manifests or equivalent documentation until the department authorizes their disposition; and
 3. Notify the shipper and the department when any shipment or portion of a shipment has not arrived within 60 days after the advance manifest was received.
- (h) Any low level radioactive waste shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:
1. Be investigated by the shipper if the shipper has not received notification of receipt within 20 days after transfer; and
 2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the department. Each licensee who conducts a trace investigation shall file a written report with the department within 2 weeks of completion of the investigation.
- R1 (13) Beginning March 1, 1998, all licensees shall comply with Requirements for Low-
R1 Level Radioactive Waste Disposal. Prior to March 1, 1998, a low-level waste
R1 disposal facility operator or its regulatory authority can require the shipper to use
R1 requirements specified in (12), above.

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

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

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

SUBPART K RECORDS

64E-5.334 General Provisions.

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.335 Records of Radiation Protection Programs.

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.338 Records of Planned Special Exposures.

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.339 Records of Individual Monitoring Results.

- R2 (1) Each licensee or registrant shall maintain records of doses received by all
R2 individuals for whom monitoring is required as specified in Rule 64E-5.315,
F.A.C., and records of doses received during planned special exposures,
accidents, and emergency conditions. Assessments of dose equivalent and
records made using units in effect before the effective date of the rule need not
be changed. These records shall include when applicable:
 - R2 (a) The deep dose equivalent to the whole body, lens dose equivalent,
shallow dose equivalent to the skin, and shallow dose equivalent to the
extremities;
 - R2 (b) The estimated intake of radionuclides as specified in Rule 64E-5.305,
R2 F.A.C.;
 - (c) The committed effective dose equivalent assigned to the intake of
radionuclides;
 - R2 (d) The specific information used to calculate the committed effective dose
equivalent as specified in Rule 64E-5.307(3), F.A.C.;
 - R2 (e) The total effective dose equivalent when required by Rule 64E-5.305,
R2 F.A.C.; and

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.340 Records of Waste Disposal or Transfers.

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

Specific Authority: 404.051, 404.081, F.S.

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

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

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

SUBPART L REPORTS

64E-5.343 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

- (1) Telephone Reports. Each licensee or registrant shall report to the department by telephone the following:
 - (a) Stolen, lost or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling, **May 2000**, immediately after its occurrence becomes known to the licensee if it appears to the licensee that an exposure could result to individuals in unrestricted areas; or
 - (b) Lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling **May 2000**, that is still missing within 30 days after its occurrence becomes known.
 - (c) A stolen, lost, or missing radiation machine immediately after its occurrence becomes known.
- (2) Written Reports. Each licensee or registrant required to make a report as specified in 64E-5.343(1) shall make a written report to the department setting forth the following information within 30 days after making the telephone report:
 - (a) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;
 - (b) A description of the circumstances under which the loss or theft occurred;

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.344 Notification of Incidents.

- (1) Immediate Notification. Regardless of other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that might have caused or threatens to cause any of the following conditions:
- (a) An individual to receive:
 - 1. A total effective dose equivalent of 25 rem (0.25 sievert) or more;
 - 2. A lens dose equivalent of 75 rem (0.75 sievert) or more; or
 - 3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 gray) or more; or
 - (b) The release of radioactive material inside or outside of a restricted area so that if an individual had been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

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- (2) Twenty-Four Hour Notification. Each licensee or registrant shall report to the department within 24 hours of discovery of the event each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that might have caused or threatens to cause any of the following conditions:
 - (a) An individual to receive in a period of 24 hours:
 1. A total effective dose equivalent exceeding 5 rem (0.05 sievert);
 2. A lens dose equivalent exceeding 15 rem (0.15 sievert); or
 3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 sievert); or
 - (b) The release of radioactive material inside or outside of a restricted area so that if an individual had been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations such as hot-cells or process enclosures.
 - (3) The licensee or registrant shall prepare each report filed with the department as specified in 64E-5.344 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.
 - (4) Licensees or registrants shall make the reports required by 64E-5.344(1) and (2) to the department by telephone, telegram, mailgram, or facsimile to the department.
 - (5) The provisions of 64E-5.344 do not apply to doses that result from planned special exposures if such doses are within the limits for planned special exposures and are reported as specified in 64E-5.346.
 - (6) Immediate notification. In addition to the other reporting requirements in these regulations, each licensee shall notify the department as soon as possible but not later than 4 hours after the discovery of an event, such as a fire, explosion, or toxic gas release, that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or to avoid releases of licensed material that could exceed regulatory limits.
 - (7) Twenty-four hour report. Each licensee shall notify the department within 24 hours after the discovery of any of the following events involving licensed material:
 - (a) An unplanned contamination event that:
 1. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

2. Involves a quantity of material greater than five times the lowest annual limit on intake of materials as specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993; and
 3. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
- (b) An event in which equipment is disabled or fails to function as designed when:
1. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposure to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
 2. The equipment is required to be available and operable when it is disabled or fails to function; and
 3. No redundant equipment is available and operable to perform the required safety function.
- (c) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body;
- (d) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed materials when:
1. The quantity of material involved is five times the lowest annual limit on intake for material specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993; and
 2. The damage affects the integrity of the licensed material or its container.
- (8) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:
- (a) Licensees shall make reports required by 64E-5.344(6) and (7) by telephone to the department. If the information is available at the time of notification, the information provided in these reports must include:
1. The caller's name and call back telephone number;

2. A description of the event, including date and time;
3. The exact location of the event;
4. The isotopes, quantities, and chemical and physical forms of the licensed material involved; and
5. Any personnel radiation exposure data available.

(b) Written report. Each licensee who makes a report required by 64E-5.344(1) and (2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared as required by other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information. The reports must include the following:

1. A description of the event, including the probable cause and the manufacturer and model number of any equipment that failed or malfunctioned;
2. The exact location of the event;
3. The isotopes, quantities, and chemical and physical form of the licensed material involved;
4. Date and time of the event;
5. Corrective actions taken or planned and the results of any evaluations or assessments; and
6. The extent of exposure of individuals to radiation or to radioactive materials without identification of the individuals by name.

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New January 1, 1994, Amended , May 15, 1998, Formerly 10D-91.481, Amended October 8, 2000.

**64E-5.345 Reports of Exposures, Radiation Levels, Concentrations of
R2 Radioactive Material Exceeding the Constraints or Limits, and Misadministrations.**

- R2 (1) Reportable Events. In addition to the notification required by Rule 64E-5.344,
R2 F.A.C., each licensee or registrant shall submit a written report within 30 days
after learning of any of the following occurrences:
- R2 (a) Incidents for which notification is required by Rule 64E-5.344, F.A.C.; or
- R2 (b) Doses in excess of any of the following:
- R2 1. The occupational dose limits for adults in Rule 64E-5.304, F.A.C.;
 - R2 2. The occupational dose limits for a minor in Rule 64E-5.310, F.A.C.;
 3. The limits for an embryo or fetus of a declared pregnant woman in

- R2 Rule 64E-5.311, F.A.C.;
- R2 4. The limits for an individual member of the public in Rule 64E-5.312,
R2 F.A.C.; or
- R2 5. Any applicable limit in the license or registration;
- R2 6. The ALARA constraints for air emissions specified in Rule
R2 64E-5.303(5), F.A.C.; or
- (c) Levels of radiation or concentrations of radioactive material in:
1. A restricted area in excess of applicable limits in the license or registration; or
2. An unrestricted area in excess of 10 times the applicable limit set forth in this part or in the license or registration, whether or not involving exposure of any individual in excess of the limits in Rule 64E-5.312, F.A.C.; or
- R2
- (d) For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.
- (2) Contents of Reports.
- R2 (a) Each report required by Rule 64E-5.345(1), F.A.C., shall describe the extent of exposure of individuals to radiation and radioactive material, including as appropriate:
1. Estimates of each individual's dose;
2. The levels of radiation and concentrations of radioactive material involved;
3. The cause of the elevated exposures, dose rates, or concentrations; and
4. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.
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- R2 (b) Each report filed as specified in Rule 64E-5.345(1), F.A.C., shall include for each occupationally overexposed individual: the name, social security account number, and date of birth. With respect to the limit for the embryo or fetus in Rule 64E-5.311, F.A.C., the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.
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- (3) All licensees or registrants who make reports as specified in 64E-5.345(1) shall submit the report in writing to the department.

(4) Reports of Misadministrations.

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

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

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

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

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New January 1, 1994, Formerly 10D-91.482, Amended October 8, 2000.

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

Specific Authority: 404.051, 404.081, F.S.

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

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

64E-5.347 Notifications and Reports to Individuals.

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

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

Specific Authority: 404.051, 404.081, F.S.

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

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

PART IV RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

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64E-5.414 Personnel Monitoring Control.

- R2 (1) The licensee or registrant shall not permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter, an alarming ratemeter, and either a film badge , **optically stimulated luminescent device (OSLD)**, or a thermoluminescent dosimeter (TLD). Use of alarm ratemeters is not required for radiography performed in an approved permanent radiographic installation meeting the requirements of **Rule 64E-5.410, F.A.C.** Pocket dosimeters shall have a range from 0 to 200 milliroentgens (2 mSv) and shall be recharged daily or at the start of each shift. Each film badge, OSLD, or TLD shall be assigned to and worn by only one individual.
- R2 (2) Pocket dosimeters shall be read and exposures recorded at least once daily.
- R2 (3) Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure.
- R2 (4) If an individual's pocket dosimeter is discharged beyond its range, the individual's film badge, OSLD, or TLD shall immediately be sent for processing.
- R2 (5) Reports received from the film badge, OSLD, or TLD processor and records of daily pocket dosimeter readings shall be kept for inspection by the department for 5 years after the death of the individual. If a report is received from the film badge, OSLD, or TLD processor that indicates an individual has received a radiation exposure in excess of the amounts specified in **Rule 64E-5.304(1), F.A.C.**, the licensee or registrant shall notify the department pursuant to Part III, Subpart L.
- R2 (6) Each alarming ratemeter shall:
- (a) Have a function test to ensure that the audible alarm is functioning properly prior to use at the start of each work shift without being exposed to radiation;
 - (b) Give an alarm at a preset dose rate of 500 milliroentgens per hour;
 - (c) Require special means to change the preset alarm function; and
 - (d) Be calibrated at intervals not to exceed 1 year for correct response to radiation. Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of alarming ratemeter calibrations shall be maintained for 2 years from the date of calibration by the licensee or registrant.

Specific Authority: 404.051, 404.081, F.S.

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

R2 History: New July 17, 1985 Amended January 1, 1994, Formerly 10D-91.515, Amended October 8, 2000.

SUBPART C

PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

64E-5.415 Security. During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part I, except:

- (1) Where the high radiation area is equipped with a control device or alarm system as described in 64E-5.316(1); or
- (2) Where the high radiation area is locked to protect against unauthorized or accidental entry.

Specific Authority: 404.051, F.S.

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

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.516.

64E-5.416 Posting. Notwithstanding any exceptions in 64E-5.324(1), areas in which radiography is being performed shall be conspicuously posted as described in 64E-5.323(1) and 64E-5.323(2).

Specific Authority: 404.051, F.S.

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

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.517.

64E-5.417 Radiation Surveys and Survey Records.

- (1) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in Subpart IV A, is available and used at each site where radiographic exposures are made.
- (2) A survey with a radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the guide tube.
- (3) A physical radiation survey as specified in Subpart IV A shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device, storage container, or source changer in a storage area as defined in 64E-5.101.
- (4) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is off.
- (5) Records shall be kept of the surveys required by (3), above. Such records shall be maintained for inspection by the department for 3 years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the department authorizes their disposition.

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- (2) Radiation detection instrumentation to be used, including:
 - (a) Use of radiation survey instruments, including operation, calibration and limitations;
 - (b) Survey techniques;
 - (c) Use of personnel monitoring equipment, including film badges, OSLDs, thermoluminescent dosimeters (TLDs), pocket dosimeters, and alarm ratemeters;
 - (3) Radiographic equipment to be used, including remote handling equipment, radiographic exposure devices and sealed sources, source changers, storage containers, and operation and control of x-ray equipment;
 - (4) The requirements of these rules;
 - (5) The licensee's or registrant's written operating and emergency procedures; and
 - (6) Case histories of industrial radiography accidents.

Specific Authority: 404.051, 404.071, F.S.

Law Implemented: 404.071, F.S.

History: New July 17, 1985, Amended January 1, 1994, Amended May 15, 1996, Formerly 10D-91.521,

R2 Amended October 8, 2000.

64E-5.421 Use of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in 64E-5.208, a specific license for use of sealed sources industrial radiography will be issued if:

- (1) The applicant has a program training radiographers and radiographer's assistants and submits to the department a schedule or description of such program which specifies the:
 - (a) Initial training,
 - (b) Periodic training,
 - (c) On-the-job training,
 - (d) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with department rules and licensing requirements, and the operating and emergency procedures of the applicant, and
 - (e) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of, and ability to comply with, the operating and emergency procedures of the applicant;
- (2) The applicant has established and submits to the department satisfactory written operating and emergency procedures described in 64E-5.413;

- (3) The applicant has an internal inspection system adequate to assure that these rules, license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants; the inspection system shall include the performance of internal inspection at intervals not to exceed 3 months and the retention of records of such inspection for 2 years;
- (4) The applicant submits to the department a description of the overall organizational structure pertaining to the industrial radiography program, including specific delegations of authority and responsibility for operation of the program;
- (5) The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the department a description of such procedures, including:
 - (a) Instrumentation to be used;
 - (b) Method of performing tests; and
 - (c) Pertinent experience of the individual who will perform the test; and
- (6) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper function of components important to safety.

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); 404.071(1), (3); 404.081(1); 404.141, F.S.

History: New August 25, 1991, Amended May 15, 1996, Formerly 10D-91.522.

64E-5.422 Reporting Requirements.

- (1) In addition to the reporting requirements specified in Part III and in other sections of this part, each licensee shall provide a written report to the department within 30 days of the occurrence of any of the incidents involving radiographic equipment described below. Such reports shall be mailed to the **Department of Health, Bureau of Radiation Control, Bin #C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741.**
 - (a) Unintentional disconnection of the source assembly from the control cable.
 - (b) Inability to retract the source assembly to its fully shielded position and secure it in this position.
 - (c) Failure of any component critical to safe operation of the device to properly perform its intended function.

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PART V X-RAYS IN THE HEALING ARTS

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- (d) Special Purpose x-ray Systems.
1. For x-ray systems with more than one image receptor size,
 - a. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
 - b. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
 2. The requirements in this paragraph are met by a system that meets the requirements for a general purpose x-ray system as specified in (1)(a), above, or, when positive alignment means are also provided, may be met with either:
 - a. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed; each such device shall have clear markings to indicate the image receptor size and SID for which it is designed; or
 - b. A beam-limiting device having multiple fixed apertures sufficient to meet the requirements for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.
- (2) Radiation Exposure Control Devices.
- (a) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor.
 1. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to 0.
 2. It shall not be possible to make an exposure when the timer is set to a zero or off position, if either position is provided.

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

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64E-5.621 Surveys for Contamination and Ambient Radiation Dose Rate.

- (1) A licensee shall survey with a radiation survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.
- (2) A licensee shall survey all areas where radiopharmaceuticals or radioactive wastes are stored with a radiation survey instrument at least once each week.
- (3) A licensee shall conduct the surveys required by 64E-5.621(1) and (2) with an instrument capable of measuring dose rates as low as 0.1 millirem (1 μ Sv) per hour.
- (4) A licensee shall establish dose rate action levels for the surveys required by 64E-5.621(1) and (2) and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.
- (5) A licensee shall perform a wipe survey for removable contamination weekly of all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.
- (6) A licensee shall analyze the wipe surveys required by 64E-5.621(5) with an instrument capable of detecting contamination of 2,000 disintegrations per minute (33.3 Bq) or shall monitor each wipe sample in a low background area with a radiation survey instrument using a probe with a maximum window thickness of 2.0 mg/cm² and a minimum probe diameter of 1.5 inches.
- (7) A licensee shall establish removable contamination action levels for the wipe surveys required by 64E-5.621(5) and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.
- (8) A licensee shall retain a record of each survey required by 64E-5.621(1), (2), and (5) for 3 years. The record shall include:
 - (a) The date of the survey;
 - (b) A sketch of each area surveyed;
 - (c) Action levels established for each area;
 - (d) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, or counts per minute if performed with a radiation survey instrument as described in 64E-5.621(6);
 - (e) The serial number and the model number of the instrument used to make the survey or analyze the samples; and
 - (f) The initials of the person who performed the survey.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 04.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.729.

64E-5.622 Release of Patients Containing Radiopharmaceuticals or Permanent Implants.

- R2 (1) Except as authorized by 64E-Rule 5.622(4), F.A.C., a licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:
- (a) The dose rate from the patient is less than 5 millirems (50 μ Sv) per hour at a distance of 1 meter; or
- (b) The activity in the patient is less than 30 millicuries (1.11 GBq).
- R2 (2) Except as authorized by Rule 64E-5.622(4), F.A.C., a licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 5 millirems (50 μ Sv) per hour at a distance of 1 meter.
- (3) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation survey instrument to confirm that all sources have been removed. The licensee shall not release a patient treated by temporary implant from confinement for medical care until all sources have been removed.
- R2 (4) Licensees and license applicants whose proposed procedures to release
R2 individuals who have been administered radiopharmaceuticals or permanent
R2 implants containing radioactive material from the control of licensees differ from
R2 those specified in (1) and (2), above, must submit their proposed procedures to
R2 the department for approval. The procedures must:
- R2 (a) Demonstrate that the total effective dose equivalent to any other individual
R2 from exposure to the released individual is not likely to exceed 500
R2 millirem (5 μ Sv);
- R2 (b) Contain a copy of the instructions including written instructions to be given
R2 to the released individual on actions recommended to maintain doses to
R2 other individuals as low as is reasonably achievable if the total effective
R2 dose equivalent to another individual is likely to exceed 100 millirem (1
R2 μ Sv). If the dose to a breast-feeding infant or child could exceed 100
R2 millirem (1 μ Sv) if there were no interruption of breast-feeding, the
R2 instructions also shall include:
- R2 1. Guidance on the interruption or discontinuance of breast-feeding
R2 and
- R2 2. Information on the consequences of failing to follow the guidance.

R2 (c) Specify that the licensee shall maintain a record of the basis for
 R2 authorizing the release of an individual from their control who has been
 R2 administered radiopharmaceuticals or permanent implants containing
 R2 radioactive material for 3 years after the date of release.

R2 (5) A licensee shall maintain a record of patient surveys which demonstrates
 R2 compliance with Rule 64E-5.622(3), F.A.C., for 3 years. Each record shall
 include the date of the survey, the name of the patient, the dose rate from the
 patient expressed as millirems (microsieverts) per hour and measured within 1
 meter from the patient, and the initials of the individual who made the survey.

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.

R2 History: New August 25, 1991, Amended May 15, 1996, Formerly 10D-91.730, Amended October 8, 2000.

64E-5.623 Storage of Volatiles and Gases. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container or an equivalent shield and container. A licensee shall store and use a multidose container in a properly functioning fume hood.

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

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.731.

64E-5.624 Decay In Storage.

(1) A licensee shall hold radioactive material with a physical half life of less than 90 days for decay in storage before disposal as ordinary trash. A licensee is exempt from the requirements of 64E-5.328 of these regulations if:

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- (a) The radioactive material is held for decay a minimum of 10 half-lives;
 - (b) The radioactive material is monitored at the container surface before disposal as ordinary trash and its radioactivity cannot be distinguished from the background radiation level in a low background radiation area with a radiation survey instrument set on its most sensitive scale and with no interposed shielding;
 - (c) All radiation labels are removed or obliterated; and
 - (d) Each generator column is separated and monitored individually with all radiation shielding removed to ensure that its contents have decayed to background radiation levels before disposal.
- (2) The licensee shall retain a record of each disposal for 3 years. The record shall include:
- (a) The date of the disposal;
 - (b) The date on which the radioactive material was placed in storage;
 - (c) The radionuclides disposed;
 - (d) The model and serial number of the radiation survey instrument used;
 - (e) The background dose rate;
 - (f) The radiation dose rate measured at the surface of each waste container; and
 - (g) The name of the individual who performed the disposal.

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-91.732.

64E-5.625 Safety Instruction and Precautions for Radiopharmaceutical Therapy, Brachytherapy, and Teletherapy.

- (1) A licensee shall provide oral and written radiation safety instructions to all personnel caring for patients undergoing radiopharmaceutical therapy or brachytherapy and to personnel who operate a teletherapy unit. Refresher training shall be provided at least every 12 months. The instruction shall describe the licensee's procedures for notification of the radiation safety officer or authorized user in case of the patient's death or medical emergency.
- (2) The instruction for radiopharmaceutical therapy shall describe the procedures for:
 - (a) Patient control;
 - (b) Visitor control;

- (c) Contamination control; and
 - (d) Waste control.
- R2 (3) The instruction for brachytherapy shall describe:
 - (a) Size and appearance of the brachytherapy sources;
 - (b) Safe handling and shielding instructions in case of a dislodged source;
 - (c) Procedures for patient control; and
 - (d) Procedures for visitor control.
- R2 (4) A licensee shall provide instruction and post conspicuously written instructions at the teletherapy unit console. These instructions shall inform the operator of:
 - (a) The procedure to be followed to ensure that only the patient is in the treatment room before turning on the primary beam of radiation or after a door interlock interruption;
 - (b) The procedure to be followed if the operator is unable to turn off the primary beam of radiation with controls outside the treatment room or any other abnormal operation occurs; and
 - (c) The names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.
- R2 (5) A licensee shall keep a record of individuals receiving instruction required by (1), (2), and (3), above, which includes a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the department for 3 years.
- R2 (6) A licensee shall take the following safety precautions for each patient receiving brachytherapy or radiopharmaceutical therapy and hospitalized:
 - (a) Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room.
 - (b) Authorize visits by individuals under 18 years of age only with the approval of the authorized user after consultation with the radiation safety officer.

- (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 authorizing 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 hospitalized:
- (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/cm² 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-91.7321.

SUBPART C

UPTAKE, DILUTION, AND EXCRETION

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

Studies. A licensee may use any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration has accepted an Investigational New Drug Application or approved a New Drug Application.

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.

SUBPART D

IMAGING AND LOCALIZATION

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

- (1) A licensee may 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 which the Food and Drug Administration has accepted an Investigational New Drug Application or approved a New Drug Application.
- (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, 404.081, 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-91.735.

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 kilobecquerel 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:

64E-5.643 Radiation Surveys for Teletherapy Facilities.

- R2 (1) The licensee shall perform radiation surveys with an operable radiation survey instrument calibrated as provided in Rule 64E-5.615, F.A.C., before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by Rule 64E-5.636, F.A.C.
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- (a) The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field shall not exceed 10 millirems (100 μ Sv) per hour and 2 millirems (20 μ Sv) per hour.
- (b) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, radiation levels in restricted areas shall be unlikely to cause any occupationally exposed individuals to receive a dose in excess of the limits specified in Rule 64E-5.304, F.A.C.; and radiation dose rates of any individual member of the public in unrestricted areas shall not exceed the limits specified in Rule 64E-5.312(1)(c), F.A.C.
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- (2) If the results of the surveys required in 64E-5.643(1) indicate any radiation levels in excess of the limits specified, the licensee shall lock the control in the off position and shall not use the unit:
- (a) Except to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or
- (b) Until the licensee has received a specific exemption from the department.
- (3) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include:
- (a) The date of the measurements;
- (b) The reason the survey is required;
- (c) The manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels;
- (d) Each dose rate measured around the teletherapy source while in the off position and the average of all measurements;
- (e) A plan of the areas surrounding the treatment room that were surveyed;
- (f) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;
- (g) The calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and

(h) The signature of the radiation safety officer or the teletherapy physicist.

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.

R2 History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.762, Amended October 8, 2000.

64E-5.644 Safety Spot-Checks for Teletherapy Facilities.

- (1) A licensee shall promptly spot-check all systems listed in 64E-5.642(7) for proper functioning after each installation of a teletherapy source and after making any change for which an amendment is required by 64E-5.636.
- (2) If the results of the safety spot-checks required in 64E-5.644(1) indicate the malfunction of any system specified in 64E-5.642, the licensee shall lock the control console in the off position and not use the unit except to repair, replace, or check the malfunctioning system.
- (3) A licensee shall maintain a record of the facility spot-checks following installation of a source for 3 years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer or the teletherapy physicist.

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-91.763.

64E-5.645 Modification of Teletherapy Unit or Room Before Beginning a

R2 **Treatment Program.** If the survey required by Rule 64E-5.643, F.A.C., indicates that any
R2 individual member of the public is likely to receive a dose in excess of those specified in Rule
64E-5.312(1)(c), F.A.C., before beginning the treatment program the licensee shall comply
with (1) or (2) below:

- R2 (1) Equip the unit with stops or add additional radiation shielding to ensure
R2 compliance with Rule 64E-5.312(1)(c), F.A.C.; perform the survey required by
R2 Rule 64E-5.643, F.A.C., again; and include in the report required by Rule
R2 64E-5.646, F.A.C., the results of the initial survey, a description of the
R2 modification made to comply with Rule 64E-5.645(1), F.A.C., and the results of
the second survey.
- (2) Request and receive a license amendment as provided in 64E-5.312(3) that
authorizes radiation levels in unrestricted areas greater than those permitted by
64E-5.312(1)(c).

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.

R2 History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.764, Amended October 8, 2000.

64E-5.646 Reports of Teletherapy Surveys, Checks, Tests, and Measurements.

A licensee shall furnish a copy of the records required in 64E-5.643, 64E-5.644, and 64E-5.645 and the output from the teletherapy source expressed as rads (grays) per hour at 1 meter from the source as determined during the full calibration required in 64E-5.641 to the department within 30 days following completion of the action that initiated the record requirement.

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PART XI

RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

64E-5.1101 Prohibitions.

- (1) No licensee shall perform wireline service operations with a sealed source unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor or land owner that:
 - (a) In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and
 - (b) In the event a decision is made to abandon the sealed source downhole, the requirements of 64E-5.1119 shall be met.
- (2) No registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of Part III, as applicable, are met.

Specific Authority: 404.051, 404.061, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(2), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1203.

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SUBPART A EQUIPMENT CONTROL

64E-5.1102 Storage and Transportation Precautions.

- (1) Each sealed source of radioactive material shall be provided with a storage or transport container. The container shall be provided with a lock or tamper seal to prevent unauthorized removal of, or exposure to, the source of radiation.
- (2) Sealed sources of radioactive material shall be stored in a manner which will minimize danger from explosion and fire.
- (3) Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

Specific Authority: 404.051, 404.061, F.S.

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

History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.1204.

64E-5.1103 Radiation Survey Instruments.

R2

- (1) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station **and temporary jobsite** to make physical radiation surveys as required by this part and by Part III.
Instrumentation shall be capable of measuring 0.1 milliroentgen (0.001 mSv) per hour through at least 50 milliroentgens (0.5 mSv) per hour.

R2

R2

- (2) Radiation survey instruments used to establish dose rates shall be calibrated:
 - (a) At energies and geometries appropriate for use;
 - (b) At intervals not to exceed 6 months, and after each instrument servicing;
 - (c) Such that accuracy within plus or minus 20 percent can be demonstrated; and
 - (d) For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points.
- (3) Records of survey instrument calibrations shall be maintained for 3 years after the calibration date for inspection by the department.

Specific Authority: 404.051, 404.061, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.081(1), 404.22, F.S.

History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.1205, Amended October 8, 2000.

R2

- (b) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools and radiation survey instruments which will be used on the job.
- (3) The licensee or registrant shall maintain employee training records for inspection by the department for 2 years following termination of employment.

Specific Authority: 404.051, 404.061, 404.071, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.071(1), 404.081(1), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.1211.

64E-5.1111 Operating and Emergency Procedures. The licensee's or registrant's operating and emergency procedures shall include appropriate instructions in at least the following:

- (1) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Part III;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods and occasions for locking and securing sources of radiation;
- (4) Personnel monitoring and the use of personnel monitoring equipment;
- (5) As applicable, the transportation of radioactive sources to temporary job sites and field stations, including the packaging and placing of such sources in vehicles, placarding of vehicles and securing the sources during transportation;
- (6) Minimizing exposure of individuals in the event of an accident;
- (7) Procedure for notifying proper personnel in the event of an accident;
- (8) Maintenance of records;
- (9) As applicable, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers and injection tools;
- (10) As applicable, procedures to be followed in the event a sealed source is lodged downhole; and
- (11) As applicable, procedures to be used for picking up, receiving and opening packages containing radioactive material.

Specific Authority: 404.051, 404.061, 404.081, 404.20, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.081(1), 404.20(1), 404.22, F.S.

History: New July 17, 1985, Formerly 10D-91.1212.

64E-5.1112 Personnel Monitoring. No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the use of sources of radiation unless such individual wears a film badge, optically stimulated luminescent device (OSLD), or a thermoluminescent dosimeter (TLD). Each film badge, OSLD or TLD shall be assigned to and worn by only one individual.

Specific Authority: 404.051, 404.061, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.061(2), 404.081(1)(2), F.S.

R2 History: New July 17, 1985, Amended May 15, 1996, Formerly 10D-91.1213, Amended October 8, 2000.

SUBPART C PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER OPERATIONS

64E-5.1113 Security. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in 64E-5.101.

Specific Authority: 404.051, 404.061, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4), 404.061(2), F.S.

History: New July 17, 1985, Amended August 29, 1994, Formerly 10D-91.1214.

64E-5.1114 Handling Tools. The licensee shall provide and require the use of tools that will assure remote handling of sealed sources except for low-activity calibration sources that result in a gamma exposure rate at contact of less than 100 milliroentgens (2.58×10^{-5} μC per kg) per hour.

Specific Authority: 404.051, 404.061, F.S.

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

History: New July 17, 1985, Formerly 10D-91.1215.

64E-5.1115 Subsurface Tracer Studies.

- (1) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.
- (2) No licensee shall intentionally inject radioactive material into any fresh water aquifers unless the Department of Health and the Department of Environmental Regulation determine that such injection will not endanger the public health, safety and welfare.
- (3) No licensee shall inject radioactive material into any well unless it can be demonstrated to the department that the procedure will not result in any liquids or gases distributed to the public exceeding the following criteria:

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

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- (f) Serve as a contact with the department for events such as the loss, theft or damage of radioactive material; and
- (g) Ensure that all users read and understand the licensee's emergency, operating and radiation safety procedures.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.
Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.
History: New May 12, 1993, Formerly 10D-91.1406.

64E-5.1306 Opening Sealed Sources. Unless otherwise specifically licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such services, the licensee shall not open sealed sources.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.
Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.
History: New May 12, 1993, Formerly 10D-91.1407.

64E-5.1307 Training Requirements for Authorized Users.

- (1) Radioactive materials shall be used by individuals who are qualified by training and experience to protect public health, safety and the environment. A description of this training must be submitted and approved by the department and include the following:
 - (a) Principles and fundamentals of radiation protection and safety practices related to the use of radioactive materials, including ALARA principles;
 - (b) Radioactivity measurements;
 - (c) Use of radiation detection instruments and monitoring techniques;
 - (d) Biological effects of radiation;
 - (e) Transportation of radioactive materials;
 - (f) Practical experience with the use of radioactive materials; and
 - (g) Licensee's operating and emergency procedures.
- (2) For licensees who propose to train their own personnel to be authorized users, the following must be provided to and approved by the department:
 - (a) Instructor qualifications, including training and experience with radioactive materials specifically relating to the topics of instruction;
 - (b) A detailed training program, including duration of training for each of the topics listed in (1) of this section;
 - (c) The method of testing the knowledge of students, such as a written and practical examination, and whether the examination is open or closed book; and

- (d) If an examination is used, the passing score, method of retesting students who do not pass and an example of the examination with the correct answers indicated.
- (3) Records of training shall be maintained during the employment of the individual or 5 years, whichever is greater.
- (4) Unless otherwise specified in the license, a licensee's authorized user training program is not transferable to another licensee.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1409.

64E-5.1308 Additional Requirements for General Licenses. Specific licensees authorized for a general license described in 64E-5.205(4), 64E-5.206(1), 64E-5.206(4) or 64E-5.206(6), shall comply with the regulations that are applicable to that general license and 64E-5.1304 and 64E-5.1305. Specific licensees authorized for the general license in 64E-5.205(4), or possess generally licensed devices described in 64E-5.206(1) or (4) are not required to remit the annual fees specified in 64E-5.204(1)(c)1., 2., or 5.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1410.

64E-5.1309 Training for Current Authorized Users. Individuals who are authorized users on a department, U.S. Nuclear Regulatory Commission, agreement state or licensing state license on May 12, 1993 who perform only those procedures for which they are authorized on that date need not comply with the training requirements in 64E-5.1307, 64E-5.1312 and 64E-5.1313.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1411.

64E-5.1310 Personnel Monitoring.

- R2 (1) Unless otherwise specified in the license, no licensee shall permit any individual to use or to assist in the use of sealed sources of radiation in portable devices unless such individual wears a film badge, OSLD, or a TLD.
- R2 (2) Unless otherwise specified in the license, no license shall permit any individual to perform installations, maintenance or service, initial radiation surveys, relocations or removal from service of sealed sources in fixed devices unless such individual wears a film badge, OSLD, or a TLD.
- (3) Licensees who use iodine 125, iodine 131, hydrogen 3, uranium 234, uranium 235 or uranium 238 and are required to have a bioassay program must submit a description of their bioassay program for approval by the department.

- R2 (4) A whole body film badge , **OSLD**, or TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of any gamma-emitting isotope with a gamma ray energy greater than 50 kiloelectron volts or the use of any beta-emitting isotope with a maximum beta energy of 300 kiloelectron volts or more.
- R2 (5) An extremity film badge or, **OSLD**, TLD is required to be worn by any individual using or assisting in the use of unsealed sources of radioactive materials of 1,000 microcuries (37 MBq) or more of beta-emitting isotopes with a maximum beta energy of 1,000 kiloelectron volts or more in any month or by any individual who receives a dose of 40 millirem (400 μ Sv) or more on a whole body film badge, **OSLD**, or TLD for 2 consecutive months.
- R2 (6) Each film, **OSLD**, and TLD badge shall be assigned to and worn by only one individual. Film badges and extremity **OSLDs** and TLDs must be replaced monthly. Whole body **OSLDs** and TLDs must be replaced quarterly. After replacement, each film badge, **OSLD**, and TLD must be promptly processed.

Specific Authority 404.051, 404.061, 404.081, F.S.

Law Implemented 404.022, 404.051(1), (4), (6), (10), 404.061(2), 404.081(1)(2), F.S.

R2 History--New May 15, 1996, Formerly 10D-91.1411, Amended October 8, 2000.

SUBPART B

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

64E-5.1311 Storage, Security and Transportation Precautions

- (1) Each sealed source of radioactive material shall be provided with a storage or transport container. The container shall be equipped with a lock or tamper seal to prevent unauthorized removal of or exposure to the source of radiation.
- (2) Sealed sources must have a minimum of two locks between the device and the public when being transported or stored.
- (3) Transport containers shall be physically secured in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal. The sealed source shall be transported as far away from occupied areas of the vehicle as possible.
- (4) Sealed sources not in storage or being transported must be under the constant surveillance and immediate control of the licensee.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1412.

64E-5.1312 Training and User Requirements.

- (1) Users of sealed sources in portable devices must have completed a minimum of 8 hours of training from individuals approved by the department. This training must include the areas described in 64E-5.1307.
- (2) Documentation of training for each user must be maintained for the duration of employment or 5 years, whichever is greater.
- (3) Sealed sources in portable devices may be used by individuals who are under the direct supervision and in the physical presence of an authorized user.

Specific Authority: 404.022, 404.042, 404.051, 404.061, 404.071, 404.081, F.S.

Law Implemented: 404.022, 404.042, 404.051(1)(4)(6)(9)(10), 404.061(2)(3), 404.071(1), 404.081(1), F.S.

History: New May 12, 1993, Formerly 10D-91.1415.

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

64E-5.1313 Training and User Requirements. Unless otherwise specifically licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such services, the licensee shall not remove sealed sources from source holders; remove source holders containing sealed sources from devices; perform maintenance or repair of devices or source holders containing sealed sources, including repair or maintenance of the shutter; perform installations, replacement, removal from service, relocations, or disposal of sealed sources, source holders or devices containing sealed sources; or perform initial radiation surveys of devices or source holders.

- (1) Users of sealed sources in fixed devices must have completed a minimum of 8 hours of training from individuals approved by the department. This training must include the areas described in 64E-5.1307.
- (2) Individuals who perform installations, maintenance or service, initial radiation surveys, relocations, or removal from service must have completed a minimum of 40 hours of training from individuals approved by the department. This training must include the following:
 - (a) The principles and fundamentals of radiation protection and safety practices related to the use of radioactive material;
 - (b) Radiation measurements, use of radiation detection instruments and monitoring techniques;
 - (c) Biological effects of radiation;
 - (d) Procedures for performing services; and
 - (e) Actual practice in performing the services.

PART XIV LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

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- (c) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when the monitor detects high radiation levels. The monitor must generate audible and visible alarms if high radiation levels are detected when personnel entry is attempted. The monitor can be located in the entrance or maze but not in the direct radiation beam.
- (d) Before sources move from their shielded position, the source control automatically must activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.
- (e) Each radiation room must have a clearly visible and readily accessible control which will allow an individual in the room to return the sources to their fully shielded position.
- (f) Each radiation room must contain a control which allows the sources to move from the shielded position only if the control has been activated and the door or barrier to the radiation room subsequently has been closed within a preset time.
- (g) Each entrance to the radiation room and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by Rule 64E-5.323, F.A.C. Panoramic irradiators also must be posted as required by Rule 64E-5.323, F.A.C. The sign can be removed, covered, or otherwise made inoperative when the sources are shielded fully.
- (h) If the radiation room has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement can be met by interlocks which prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

R2
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R2

- (2) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management shall have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual, not necessarily on site, who is prepared to respond or summon assistance.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

R2 History: New August 14, 1996, Formerly 10D-91.1506, Amended October 8, 2000.

64E-5.1407

Shielding.

- (1) The radiation dose rate in areas which normally are occupied during operation of a panoramic irradiator must not exceed 2 millirem (0.02 millisievert) per hour at 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Areas where the radiation dose rates exceed 2 millirem (0.02 millisievert) per hour must be locked, roped off, or posted to prevent access and not entered without written approval or in the physical presence of the radiation safety officer or his designee.
- (2) The radiation dose at 30 centimeters over the pool of a pool irradiator when the source is in the fully shielded position must not exceed 2 millirem (0.02 millisievert) per hour.
- (3) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator must not exceed 2 millirem (0.02 millisievert) per hour and at 5 centimeters from the shield must not exceed 20 millirem (0.02 millisievert) per hour.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1507.

64E-5.1408

Fire Protection.

- (1) The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must become fully shielded automatically and the air handling systems within the radiation room must be disabled automatically if a fire is detected.
- (2) The radiation room at a panoramic irradiator must be equipped with a fire suppression or extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1508.

- (6) Individuals who will be permitted unescorted access to the irradiators but who have not received the training required for operators and the radiation safety officer shall be trained and tested in precautions they should take to avoid radiation exposure, procedures or parts of procedures in 64E-5.1418 which they are expected to perform or comply with, and the proper response to alarms required in this part. Tests can be oral.
- (7) Individuals who must be prepared to respond to alarms required by 64E-5.1406, 64E-5.1408, 64E-5.1409, 64E-5.1411, and 64E-5.1412 shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests can be oral.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1516.

64E-5.1417 Operating and Emergency Procedures.

- (1) The licensee shall have and follow written operating procedures for the following:
 - (a) Operation of the irradiator, including entering and leaving the radiation room;
 - (b) Use of personnel dosimeters;
 - (c) Surveying the shielding of panoramic irradiators;
 - (d) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
 - (e) Leak testing of sources;
 - (f) Inspection and maintenance checks required by 64E-5.1422;
 - (g) Loading, unloading, and repositioning sources, if to be performed by the licensee;
 - (h) Inspection of movable shielding required by 64E-5.1406(1)(h), if applicable; and
 - (i) Security precautions while sources are stored outside the radiation room. Sealed sources must be moved into the radiation room within 48 hours of receipt unless the department is notified in writing that extenuating circumstances do not allow for source loading within the prescribed 48 hour period.
- (2) The licensee shall have and follow emergency or abnormal event procedures for the following:
 - (a) Sources stuck in the unshielded position;
 - (b) Personnel overexposures;

- (c) A radiation alarm from the product exit portal monitor or pool monitor;
 - (d) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
 - (e) A low water level alarm, a high water level alarm, an abnormal water loss, or leakage from the source storage pool;
 - (f) A prolonged loss of electrical power;
 - (g) A fire alarm or explosion in the radiation room;
 - (h) An alarm indicating unauthorized entry into the radiation room, the area around the pool, or another alarmed area;
 - (i) Natural phenomena, including an earthquake, a hurricane, a tornado, flooding, sinkhole formation, or other phenomena; and
 - (j) The jamming of automatic conveyor systems or an alarm indicating a collision between the barrier and product conveyor.
- (3) The licensee can revise operating and emergency procedures only with departmental approval.
- (4) The licensee shall provide and coordinate current emergency procedures annually with the local police, fire department, and civil authorities, including notification of responsible individuals and places of emergency treatment.

Specific Authority: 404.051(4), F.S.
 Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
 History: New August 14, 1996, Formerly 10D-91.1517.

64E-5.1418 Personnel Monitoring.

- R2 (1) Irradiator operators shall wear either a film badge, **OSLD** or a TLD while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge, **OSLD**, and TLD processor must be accredited by NVLAP for high energy photons in the normal and accident dose ranges. Each film badge, **OSLD**, and TLD must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and **OSLDs and TLDs** must be replaced at least quarterly. After replacement, each film badge **OSLD**, and TLD must be processed promptly.
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- R2 (2) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which can be a pocket dosimeter. For groups of visitors, only two people are required to wear dosimeters. Date of entry, all names and total dose must be recorded. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response must be done at least annually. Acceptable dosimeters must read within 30 percent of the true radiation dose.

Specific Authority: 404.051(4), F.S.
 Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
 R2 History: New August 14, 1996, Formerly 10D-91.1518, Amended October 8, 2000.

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PART XV

TRANSPORTATION OF RADIOACTIVE MATERIALS

64E-5.1501 Transportation of Radioactive Material.

- (1) The packaging and transportation of radioactive material are also subject to the requirements of other agencies such as the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission and the U.S. Postal Service. The requirements of this part are in addition to, and not in substitution for, other requirements.
- (2) Determinations and listings of A_1 and A_2 values are found in 10 CFR Part 71, Appendix A, which is herein incorporated by reference and which is available from the department.

Specific Authority: 404.051, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.20(1), F.S.

History: New July 17, 1985, Amended May 15, 1996, Formerly 10D-91.2001.

64E-5.1502 Transportation of Radioactive Material.

- (1) No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general license or specific license issued by the department or as exempted in 64E-5.1503.
- (2) Each licensee who transports radioactive material outside of the confines of his facility or other place of use, or who offers radioactive material to a carrier for transport shall:
 - (a) Comply with the applicable requirements, appropriate to the mode of transport, of **49 CFR Parts 171-173, 177, 383, and 390-397, dated 10-1-97, which are herein incorporated by reference and which are available from the department;**
 - (b) Establish procedures for safely opening and closing packages in which radioactive material is transported and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and
 - (c) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

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Specific Authority: 404.051, 404.061, 404.141, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.061(2), 404.141, 404.20(1), F.S.

R2 History: New July 17, 1985, Formerly 10D-91.2003, Amended October 8, 2000.

64E-5.1503 Exemptions.

- (1) Common and contract carriers, freight forwarders, and warehousemen who are subject to the requirements of the U.S. Department of Transportation in 49 CFR Parts 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR Part 111.1 (1974), are exempt from these regulations to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 64E-5.1501 and other applicable sections of these regulations.
- (2) Any licensee is exempt from the requirements of this part to the extent that he delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 0.002 microcurie (74 Bq) per gram.

Specific Authority: 404.051, 404.061, 404.141, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.061(2), 404.141, 404.20(1), F.S.

History: New July 17, 1985, Formerly 10D-91.2004.

64E-5.1504 General Licenses for Carriers.

- (1) A general license is hereby issued to any common or contract carrier not exempt under 64E-5.1503 to receive, possess, transport and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in these U.S. Department of Transportation requirements shall also be filed with, or made to, the department.
- (2) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in these U.S. Department of Transportation requirements shall be filed with, or made to, the department.
- (3) Persons who transport radioactive material pursuant to the general license in 64E-5.1504(1) or (2) are exempt from the requirements of Parts III and IX to the extent that they transport radioactive material.

Specific Authority: 404.051, 404.061, 404.141, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.061(2), 404.141, 404.20(1), F.S.

History: New July 17, 1985, Formerly 10D-91.2005.

- (4) All applications for permits and prior notifications of impending shipments shall be addressed to the department as outlined in 64E-5.1513(2).

Specific Authority: 404.051, 404.061, 404.131, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.131(2)(3), 404.20(6)(7)(8), F.S.

History: New July 17, 1985, Formerly 10D-91.2010.

64E-5.1510 Air Transport of Plutonium. Notwithstanding the provisions of any general license and notwithstanding any exemptions stated directly in this part or included indirectly by citation of the U.S. Department of Transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air or offered to a carrier for air transport unless:

- (1) The plutonium is contained in a medical device designed for individual human application; or
- (2) The plutonium is contained in a material in which the specific activity is not greater than 0.002 microcuries (74 Bq) per gram of material and in which the radioactivity is essentially uniformly distributed; or
- (3) The plutonium is shipped in a single package containing no more than an A₂ quantity of plutonium in any isotope or form and is shipped in accordance with 64E-5.1502; or
- (4) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the U.S. Nuclear Regulatory Commission.

Specific Authority: 404.051, 404.061, 404.141, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.061(2), 404.141, 404.20(1), F.S.

History: New July 17, 1985, Formerly 10D-91.2011.

64E-5.1511 Notification in the Event of Suspected or Real Breach of Containment. In addition to the reporting requirements of the U.S. Department of Transportation, any carrier transporting radioactive material in the state shall notify the department immediately in the event the carrier suspects or knows of a breach in the containment of the radioactive material being transported. Notification shall be made as described in 64E-5.1513(2).

Specific Authority: 404.051, 404.20, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(11), 404.20(1), F.S.

History: New July 17, 1985, Formerly 10D-91.2012.

64E-5.1512 Inspections.

- (1) A department representative is authorized to inspect any record of persons engaged in the transportation of a radioactive material where such records reasonably relate to packaging, preparing for shipment and transporting radioactive material.
- (2) A department representative is authorized to enter upon and inspect the premises and transport vehicles of any person engaged in the transportation of radioactive material for the purpose of determining compliance with or violation of the provisions of section 404.20, Florida Statutes, and these regulations.
- (3) The department may investigate the cause and circumstances of every event in which notification was made pursuant to 64E-5.1511.

Specific Authority: 404.051, 404.061, 404.071, F.S.

Law Implemented: 404.022, 404.051(1)(4)(12), 404.061(2), 404.071(1), 404.20(1)(2)(7)(8), F.S.

History: New July 17, 1985, Formerly 10D-91.2013.

64E-5.1513 Communications.

- (1) All communications concerning this part should be addressed to:
Department of Health, Bureau of Radiation Control, Bin #C21,
4052 Bald Cypress Way, Tallahassee, FL 32399-1741.
- (2) All notifications required to be made pursuant to 64E-5.1506, 64E-5.1508, 64E-5.1509 and 64E-5.1511 shall be addressed to:
Department of Health, Bureau of Radiation Control, Post Office Box 680069,
Orlando, Florida 32868-0069; telephone (407) 297-2095.
- (3) Immediate notification as required by 64E-5.1511 shall be made by telephone or telegraph.

Specific Authority: 404.042, 404.051, 404.20, F.S.

Law Implemented: 404.042, 404.051(1)(4)(6)(11), 404.061(2), 404.081(1), 404.141, 404.20(1), F.S.

History: New July 17, 1985, Amended April 4, 1989, Formerly 10D-91.2014.

R1
R2

STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
**RADIOACTIVE MATERIAL
REQUIRING LABELING**

May 2000

64E-5 Florida Administrative Code ATT 3 – Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Actinium-224	1	Antimony-125	100
Actinium-225	0.01	Antimony-126	100
Actinium-226	0.1	Antimony-126m	1000
Actinium-227	0.001	Antimony-127	100
Actinium-228	1	Antimony-128 (10.4m)	1000
Aluminum-26	10	Antimony-128 (9.01h)	100
Americium-237	1000	Antimony-129	100
Americium-238	100	Antimony-130	1000
Americium-239	1000	Antimony-131	1000
Americium-240	100	Argon-41	1000
Americium-241	0.001	Arsenic-72	100
Americium-242	10	Arsenic-73	100
Americium-242m	0.001	Arsenic-74	100
Americium-243	0.001	Arsenic-76	100
Americium-244	10	Astatine-207	100
Americium-244m	100	Astatine-211	10
Americium-245	1000	Barium-126	1000
Americium-246	1000	Barium-128	100
Americium-246m	1000	Barium-131	100
Antimony-115	1000	Barium-131m	1000
Antimony-116	1000	Barium-133	100
Antimony-116m	1000	Barium-133m	100
Antimony-117	1000	Barium-135m	100
Antimony-118m	1000	Barium-139	1000
Antimony-119	1000	Barium-140	100
Antimony-120 (16m)	1000	Barium-141	1000
Antimony-120 (5.76d)	100	Barium-142	1000
Antimony-122	100	Berkelium-245	100
Antimony-124	10	Berkelium-246	100
Antimony-124m	1000	Berkelium-247	0.001

64E-5 Florida Administrative Code ATT 3 – Radioactive Materials Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Berkelium-249	0.1	Cadmium-117	1000
Berkelium-250	10	Cadmium-117m	1000
Beryllium-10	1	Calcium-41	100
Beryllium-7	1000	Calcium-45	100
Bismuth-200	1000	Calcium-47	100
Bismuth-201	1000	Californium-244	100
Bismuth-202	1000	Californium-246	1
Bismuth-203	100	Californium-248	0.01
Bismuth-205	100	Californium-249	0.001
Bismuth-206	100	Californium-250	0.001
Bismuth-207	10	Californium-251	0.001
Bismuth-210	1	Californium-252	0.001
Bismuth-210m	0.1	Californium-253	0.1
Bismuth-212	10	Californium-254	0.001
Bismuth-213	10	Carbon-11	1000
Bismuth-214	100	Carbon-14	100
Bromine-74	1000	Cerium-134	100
Bromine-74m	1000	Cerium-135	100
Bromine-75	1000	Cerium-137	1000
Bromine-76	100	Cerium-137m	100
Bromine-77	1000	Cerium-139	100
Bromine-80	1000	Cerium-141	100
Bromine-80m	1000	Cerium-143	100
Bromine-82	100	Cerium-144	1
Bromine-83	1000	Cesium-125	1000
Bromine-84	1000	Cesium-127	1000
Cadmium-104	1000	Cesium-129	1000
Cadmium-107	1000	Cesium-130	1000
Cadmium-109	1	Cesium-131	1000
Cadmium-113	100	Cesium-132	100
Cadmium-113m	0.1	Cesium-134	10
Cadmium-115	100	Cesium-134m	1000
Cadmium-115m	10	Cesium-135	100