64E-5.101 Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(14) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by Reference Man that would result in a committed effective dose equivalent of 5 rem (0.05 sievert) or a committed dose equivalent of 50 rem (0.5 sievert) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, Table I, Columns 1 and 2.

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

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

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

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

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

1).

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

(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.

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

2. Any material that meets the following:

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

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

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

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

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

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

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

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

(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).

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

(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.

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

(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 or release of the property under restricted conditions and the termination of the license.

(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.

(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, June 2012, Table I, Column 3.

(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).

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

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

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

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

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

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

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

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

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

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

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

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

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

(52) “Field station” means a temporary or portable facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

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

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

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

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

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

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

(59) “Individual” means any human being.

(60) “Individual monitoring” means the assessment of:

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

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

(61) “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.

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

(63) “Inhalation class” (see “Class”).

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

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

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

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

(68) “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/cm^2).

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

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

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

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

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

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

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

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

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

(78) “Lung class” (see “Class”).

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

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

(81) “Medical institution” means any establishment that:

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

(b) Regularly makes available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment of similar extent.

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

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

(84) “Minor” means an individual less than 18 years of age.

(85) “Medical event” means the administration of:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(93) "Occupational dose" means the dose received by an individual in the course of employment in 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.

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

(95) "Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of

his body in the primary beam path during normal operation.

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

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

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

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

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

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

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

(103) “Prescribed Dosage” means the quantity of radiopharmaceutical activity as documented:

(a) In a written directive; or

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

(104) “Prescribed Dose” means:

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

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

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

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

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

(106) “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.

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

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

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

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

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

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

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

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

(115) “Radioactivity” means the transformation of unstable atomic nuclei by the emission of radiation.

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

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

(118) “Radiographic exposure device” means any instrument containing a sealed source, fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed from a shielded position to an unshielded position for the purpose of making a radiographic exposure. It also is known as a camera or a projector.

(119) “Recordable event” means the administration of:

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

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

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

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

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

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

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

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

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

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

(122) “Regulations of the U.S. Department of Transportation” means the regulations in 49 C.F.R. Parts 100-189.

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

(124) “Research and development” means:

(a) Theoretical analysis, exploration or experimentation; or

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

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

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

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

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

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

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

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

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

(133) “SI” means an abbreviation of the International System of Units.

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

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

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

(137) “Source material” means:

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

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

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

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

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

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

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

(c) It satisfies the test requirements of 49 C.F.R., Part 173.469. Special form encapsulations designed in accordance with the requirements of 49 C.F.R., 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.

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

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

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

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

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

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

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

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

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

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

(150) “Test” means the process of verifying compliance with an applicable rule.

(151) “Total effective dose equivalent” (TEDE) means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

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

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

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

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

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

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

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

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

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	W_T
Gonads	0.25
Breast	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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(170) “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.

(171) “Authorized nuclear pharmacist” means a pharmacist who satisfies the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(189) “Nationally tracked source” means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Rule 64E-5.351, F.A.C. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form, and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

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

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

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

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

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

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

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

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

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

Rulemaking Authority 404.051, 404.061 FS. Law Implemented 404.031, 404.051, 404.061, 404.20, 404.22 FS. History–New 7-17-85, Amended 4-4-89, 5-12-93, 1-1-94, 5-15-96, Formerly 10D-91.102, Amended 5-18-98, 10-8-00, 8-6-01, 9-11-01, 12-18-01, 9-28-06, 8-16-07, 2-28-08, 2-11-10, 5-8-13, 12-26-13.

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 material 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.

(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.

Rulemaking Authority 404.051(4), 404.061(2), 404.20 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), 404.061(2), 404.081(1), 404.091, 404.141, 404.161, 404.162, 404.20(1) FS. History–New 7-17-85, Amended 8-25-91, 5-12-93, 5-15-96, Formerly 10D-91.301, Amended 10-8-00.

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

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

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

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

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

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

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

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

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

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

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

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

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

64E-5.220 Radioactive Quantities.

(1) Listed below are the quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release as required in Rule 64E-5.219, F.A.C.:

Material	Release Fraction	Curies
Actinium 228	.001	4,000
Americium 241	.001	2
Americium 242	.001	2
Americium 243	.001	2
Antimony 124	.01	4,000
Antimony 126	.01	6,000
Barium 133	.01	10,000
Barium 140	.01	30,000
Bismuth 207	.01	5,000
Bismuth 210	.01	600
Cadmium 109	.01	1,000
Cadmium 113	.01	80
Calcium 45	.01	20,000
Californium 252	.001	9
Carbon 14	.01 (non CO_2)	50,000
Cerium 141	.01	10,000
Cerium 144	.01	300
Cesium 134	.01	2,000
Cesium 137	.01	3,000
Chlorine 36	.5	100
Chromium 51	.01	300,000
Cobalt 60	.001	5,000
Copper 64	.01	200,000
Curium 242	.001	60
Curium 243	.001	3
Curium 244	.001	4
Curium 245	.001	2
Europium 152	.01	500
Europium 154	.01	400
Europium 155	.01	3,000
Gadolinium 153	.01	5,000
Germanium 68	.01	2,000
Gold 198	.01	30,000
Hafnium 172	.01	400
Hafnium 181	.01	7,000
Holmium 166m	.01	100
Hydrogen 3	.5	20,000
Iodine 125	.5	10
Iodine 131	.5	10
Indium 114m	.01	1,000
Iridium 192	.001	40,000
Iron 55	.01	40,000
Iron 59	.01	7,000
Krypton 85	1.0	6,000,000
Lead 210	.01	8

Manganese 56	.01	60,000
Mercury 203	.01	10,000
Molybdenum 99	.01	30,000
Neptunium 237	.001	2
Nickel 63	.01	20,000
Niobium 94	.01	300
Phosphorus 32	.5	100
Phosphorus 33	.5	1,000
Polonium 210	.01	10
Potassium 42	.01	9,000
Promethium 145	.01	4,000
Promethium 147	.01	4,000
Radium 226	.001	100
Ruthenium 106	.01	200
Samarium 151	.01	4,000
Scandium 46	.01	3,000
Selenium 75	.01	10,000
Silver 110m	.01	1,000
Sodium 22	.01	9,000
Sodium 24	.01	10,000
Strontium 89	.01	3,000
Strontium 90	.01	90
Sulfur 35	.5	900
Technetium 99	.01	10,000
Technetium 99m	.01	400,000
Tellurium 127m	.01	5,000
Tellurium 129m	.01	5,000
Terbium 160	.01	4,000
Thulium 170	.01	4,000
Tin 113	.01	10,000
Tin 123	.01	3,000
Tin 126	.01	1,000
Titanium 44	.01	100
Vanadium 48	.01	7,000
Xenon 133	1.0	900,000
Yttrium 91	.01	2,000
Zinc 65	.01	5,000
Zirconium 93	.01	400
Zirconium 95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma	.001	10,000
Any other alpha emitter	.001	2

Contaminated equipment, alpha	.0001	20
Packaged waste, alpha	.0001	20

(2) For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in this section exceeds one.

(3) Waste packaged in Type B containers as specified in Rule 64E-5.101, F.A.C., does not require an emergency plan.

Rulemaking Authority 404.022, 404.042, 404.051, 404.061, 404.071, 404.081 FS. Law Implemented 404.022, 404.042, 404.051(1), (4), (6), (9), (10), 404.061(2), (3), 404.071(1), 404.081(1) FS. History–New 5-12-93, Formerly 10D-91.327.

64E-5.304 Occupational Dose Limits for Adults.

(1) The licensee or registrant shall control the occupational dose to individual adults, 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 of the whole body, and to the skin of the extremities which are:

1. A lens dose equivalent of 15 rem (0.15 sievert), and

2. A shallow dose equivalent of 50 rem (0.5 sievert) to the skin of the whole body or to skin of any extremity.

(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 paragraphs 64E-5.309(5)(a) and (b), F.A.C.

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

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, Table I, and can be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See Rule 64E-5.339, F.A.C.

(5) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012 (see 64E-5.101, F.A.C.).

(6) The licensee or registrant shall reduce the dose that an individual can be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See subsection 64E-5.308(5), F.A.C.

Rulemaking Authority 404.051 FS. Law Implemented 404.022, 404.051(1), (4) FS. History–New 1-1-94, Formerly 10D-91.435, Amended 10-8-00, 9-28-06, 12-26-13.

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, June 2012, (see 64E-5.101, F.A.C.) footnotes 1 and 2.

(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

Rulemaking Authority 404.051 FS. Law Implemented 404.022, 404.051(1), (4) FS. History–New 1-1-94, Formerly 10D-91.437, Amended 12-26-13.

64E-5.307 Determination of Internal Exposure.

(1) To assess dose used to determine compliance with occupational dose equivalent limits when required as specified in Rule 64E-5.315, F.A.C., the licensee shall take suitable and timely measurements of:

(a) Concentrations of radioactive materials in air in work areas;

(b) Quantities of radionuclides in the body;

(c) Quantities of radionuclides excreted from the body; or

(d) Combinations of these measurements.

(2) Unless respiratory protective equipment is used as specified in Rule 64E-5.319, F.A.C., or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee is permitted to:

(a) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record;

(b) Upon prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in paragraph 64E-5.307(1)(b) or (c), F.A.C., the licensee can delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by Rule 64E-5.344 or 64E-5.345, F.A.C. This delay permits the licensee to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(a) The sum of the ratios of the concentration to the appropriate DAC value, that is D, W, or Y, from State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, for each radionuclide in the mixture; or

(b) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, a licensee is permitted to disregard certain radionuclides in the mixture if:

(a) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in Rule 64E-5.304, F.A.C., and in complying with the monitoring requirements in subsection 64E-5.315(2), F.A.C.;

(b) The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

(c) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(8) When determining the committed effective dose equivalent, the following information can be considered:

(a) To calculate the committed effective dose equivalent, the licensee can assume that the inhalation of one ALI or an exposure of 2,000 DAC-hours results in a committed effective dose equivalent of 5 rem (0.05 sievert) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rem (0.5 sievert), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 sievert), that is, the stochastic ALI, as listed in parentheses in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) Table I. The licensee can use the stochastic ALI to determine committed effective dose equivalent as a simplifying assumption. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in subparagraph 64E-5.304(1)(a)2., F.A.C., is met.

Rulemaking Authority 404.051 FS. Law Implemented 404.022, 404.051(1), (4) FS. History–New 1-1-94, Formerly 10D-91.438, Amended 12-26-13.

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 Rule 64E-5.312, F.A.C.

(2) A licensee or registrant shall show compliance with the annual dose limit in Rule 64E-5.312, F.A.C., 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, June 2012, Table II; and

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

(3) Upon approval from the Department, the licensee can adjust the effluent concentration values in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) for members of the public to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

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

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

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

64E-5.315 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum:

(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

(a) Adults likely to receive in 1 year from sources external to the body a dose in excess of 10 percent of the limits in subsection 64E-5.304(1), F.A.C.;

(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);

(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

(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:

(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 June 2012, (see 64E-5.101, F.A.C.) Table I, Columns 1 and 2; and

(b) Minors likely to receive in 1 year a committed effective dose equivalent in excess of 0.1 rem (1.0 millisievert); and

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

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

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, June 2012, (see 64E-5.101, F.A.C.) Table III;

(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this part;

(4) Containers when they are in transport and packaged and labeled as specified by the rules of the U.S. Department of Transportation;

(5) Containers that are accessible only to individuals authorized to handle or use them or to work in the vicinity of the containers if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(6) Installed manufacturing or process equipment, such as piping and tanks.

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

64E-5.328 General Requirements.

(1) Unless otherwise exempted, a licensee shall transfer waste for disposal, discharge, or decay licensed material only:

(a) By transfer to an authorized recipient as specified in Rule 64E-5.332, F.A.C., or in Part II of these regulations or to the U.S. Department of Energy;

(b) By decay in storage;

(c) By release in effluents within the limits in Rule 64E-5.312, F.A.C.; or

(d) As authorized in this subpart.

(2) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

(a) Treatment prior to disposal;

(b) Treatment by incineration;

(c) Decay in storage;

(d) Disposal at a licensed land disposal facility; or

(e) Storage until transferred to a storage or disposal facility authorized to receive the waste.

Rulemaking Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1), (4), 404.081 FS. History–New 1-1-94, Formerly 10D-91.461.

64E-5.329 Method of Obtaining Approval of Proposed Disposal Procedures.

(1) A person can apply to the department for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this part. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and conditions of disposal. The application where appropriate should also include an analysis and evaluation of pertinent information of the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposure.

(2) The department will not approve any application for a licensee to receive radioactive material from other persons for disposal on land not owned by a state or the federal government.

Rulemaking Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1), (4), 404.081 FS. History–New 1-1-94, Formerly 10D-91.462.

64E-5.330 Discharge by Release into Sanitary Sewerage.

(1) A licensee can discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(a) The material is readily soluble or is readily dispersible biological material in water;

(b) The quantity of licensed radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, Table III;

(c) If more than one radionuclide is released, the following conditions must also be satisfied;

1. The licensee shall determine the fraction of the limit in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, Table III represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) Table III; and

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

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

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

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

64E-5.331 Disposal of Specific Wastes.

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

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

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

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

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

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

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

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

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

a. The date of the disposal;

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

c. The radionuclides disposed;

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

e. The background dose rate;

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

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

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

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

(3) The licensee shall maintain records as specified in Rule 64E-5.340, F.A.C.

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

64E-5.332 Transfer for Disposal and Manifests.

(1) The requirements of this section, Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997, hereafter referred to as "Requirements for Low-Level Radioactive Waste Disposal," which is herein incorporated by reference and which is available from the department, and Part XV are designed to control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Requirements for Low-Level Radioactive Waste Disposal, who ships low-level waste directly or indirectly through a waste collector or waste processor to a licensed low-level waste land disposal facility as defined in Requirements for Low-Level Radioactive Waste Disposal, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes. Requirements for Low-Level Radioactive Waste Disposal incoporates NRC Form 540 (3-95), Uniform Low-Level Radioactive Waste Manifest – Shipping Paper; NRC Form 541 (11-96), Uniform Low-Level Radioactive Waste Manifest – Container and Waste Description; and NRC Form 542 (3-95), Uniform Low-Level Radioactive Waste Manifest – Manifest Index and Regional Compact Tabulation.

(2) Prior to March 1, 1998, each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in subsection 64E-5.333(12), F.A.C. Beginning March 1, 1998, any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required on forms specified in Requirements for Low-Level Radioactive Waste Disposal and transfer this recorded information to the intended consignee as specified in Requirements for Low-Level Radioactive Waste Disposal.

(3) Prior to March 1, 1998, each shipment manifest shall include a certification by the waste generator as specified in subsection 64E-5.333(12), F.A.C. Beginning March 1, 1998, each shipment manifest shall include a certification by the waste generator as specified in Requirements for Low-Level Radioactive Waste Disposal.

(4) Prior to March 1, 1998, each person involved in the transfer of waste for disposal, including the waste generator, waste collector, waste processor and disposal facility operator, shall comply with the requirements specified in subsection 64E-5.333(12), F.A.C. Beginning March 1, 1998, each person participating in the transfer of waste for disposal, including the waste generator, waste collector, waste processor and disposal facility operator, shall comply with the requirements specified in Requirements for Low-Level Radioactive Waste Disposal.

Rulemaking Authority 404.051, 404.081, 404.20 FS. Law Implemented 404.051(1), (4), 404.081, 404.20 FS. History–New 1-1-94, Formerly 10D-91.466, Amended 5-18-98.

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.

(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 Rule 64E-5.344, F.A.C., so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

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

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

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

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

(a) An unplanned contamination event that:

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

2. Involves a quantity of material greater than five times the lowest annual limit on intake of materials as specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012 (see 64E-5.101, F.A.C.); and

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

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

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

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

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

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

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

1. The quantity of material involved is five times the lowest annual limit on intake for material specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012; and

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

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

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

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

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

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

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

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

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

3. The exact location of the event;

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

5. Any personnel radiation exposure data available.

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

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

2. The exact location of the event;

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

4. Date and time of the event;

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

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

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

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

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

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

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

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

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

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

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

5. Any applicable limit in the license or registration;

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

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

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

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

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

(2) Contents of Reports.

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

1. Estimates of each individual's dose;

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

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

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

(b) Each report filed as specified in subsection 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.

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

(4) Reports of Medical Events.

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

(b) Written Report. Within 15 days after the medical event report to the department, the licensee or registrant shall report in writing to the department and to the referring physician and furnish a copy of the report to the individual or the individual's responsible relative or guardian if either was previously notified by the licensee or registrant as specified in (4)(a), above, or a brief

description of both event and consequences as they affect the individual or the individual's responsible relative or guardian if a statement is included that the report submitted to the department can be obtained from the licensee or registrant. The written report shall include the licensee's or registrant's name; the prescribing physician's name; the referring physician's name; a brief description of the event; why the event occurred; the effect on the individual; the action taken to prevent recurrence; whether the licensee or registrant informed the individual or the individual's responsible relative or guardian and what information was provided to the individual or individual's responsible relative or guardian, and if not, a written medical justification. The report shall not include the individual's name or other information that could lead to identification of the individual.

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

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

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

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

(b) Written Report.

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

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

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

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

Rulemaking Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1), (4), 404.081 FS. History–New 1-1-94, Formerly 10D-91.482,

Amended 10-8-00, 2-11-10.

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.

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

Rulemaking Authority 404.051, 404.081 FS. Law Implemented 404.051(1), (4), 404.081 FS. History–New 1-1-94, Formerly 10D-91.484, Amended 5-18-98.

64E-5.601 License Required.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, 483.901 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.707, Amended 8-6-01, 2-11-10.

64E-5.605 Radiation Safety Officer.

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

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

(a) Overexposures;

(b) Accidents;

(c) Spills;

(d) Losses;

(e) Thefts;

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

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

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

(a) Authorize the purchase of radioactive material;

(b) Receive and open packages of radioactive material;

(c) Store radioactive material;

(d) Keep an inventory record of radioactive material;

(e) Use radioactive material safely;

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

(g) Perform periodic radiation surveys;

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

(i) Dispose of radioactive material;

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

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

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

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

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

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

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

64E-5.607 Authority and Responsibilities.

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

(a) Identify radiation safety problems;

(b) Initiate, recommend, or provide solutions;

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

(d) Stop unsafe operations.

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

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

(a) For written directives:

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

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

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

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

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

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

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

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

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

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

f. For all other brachytherapy;

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

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

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

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

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

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

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

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

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

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

(f) Interpret results of diagnostic procedures; and

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

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

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.713, Amended 2-11-10, 12-26-13.

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

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

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

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

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

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

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

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

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

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.715, Amended 2-11-10, 12-26-13.

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

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

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

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

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

(c) The date of the check;

(d) The activity measured;

(e) The percent error;

(f) The instrument settings; and

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

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

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

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

(c) The date of the test;

(d) The results of the test;

(e) The instrument settings; and

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

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

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

(b) The calculated activities;

(c) The measured activities;

(d) The date of the test; and

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

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

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

(b) The configuration of the source measured;

(c) The activity measured and the instrument setting for each volume measured;

(d) The date of the test; and

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

(6) A licensee shall correct mathematically dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(7) A licensee shall also perform checks and tests required by Rule 64E-5.614, F.A.C., following adjustment or repair of the dose calibrator.

(8) A licensee shall retain a record of each check and test required by Rule 64E-5.614, F.A.C., for 3 years.

(9) A licensee may calibrate instrumentation used in Rule 64E-5.614, F.A.C., using nationally recognized standards or the manufacturer's instructions. The standards or instructions used by the licensee must be available for inspection by the department.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.720, Amended 2-11-10, 12-26-13.

64E-5.616 Determination of Dosages of Unsealed Radioactive Material for Medical Use.

(1) The licensee shall determine by assay or direct measurement within 30 minutes before each radiopharmaceutical dosage and record the activity of each dosage before medical use. A record of the assay shall be made which shall include:

(a) The generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number; expiration date; and the radionuclide;

(b) The patient's or human research subject's name or identification number if one has been assigned;

(c) The prescribed dosage and activity of the dosage at the time of assay or a notation that the total activity assayed is less than 10 microcuries (370 kBq);

(d) The date and time of the assay and administration; and

(e) The name of the individual who performed the assay.

(2) Unless directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(3) A licensee shall retain a record of the assays listed in Rule 64E-5.616, F.A.C., for 3 years.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.722, Amended 2-11-10.

64E-5.628 Generators.

(1) Permissible Molybdenum/Technetium Concentration.

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

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

(c) 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:

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

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

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

4. The date of the test; and

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

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

(2) Permissible Strontium/Rubidium Concentration.

(a) A licensee shall not administer a radiopharmaceutical containing more than 0.02 microcurie of strontium 82 per millicurie of rubidium 82 (0.74 kilobecquerel of strontium 82 per 37 megabecquerel of rubidium 82) or more than 0.2 microcurie of strontium 85 per millicurie of rubidium 82 (7.4 kilobecquerel of strontium 85 per 37 megabecquerel of rubidium 82).

(b) A licensee preparing rubidium 82 radiopharmaceuticals from strontium 82/rubidium 82 generators shall measure and calculate the strontium 82 and strontium 85 concentration on each day of use prior to the use of rubidium chloride for injection.

(c) A licensee who is required to measure strontium 82 and strontium 85 concentrations shall retain a record of each measurement for 3 years. The record shall include for each day of use assay:

1. The measured activity of the rubidium 82 expressed in millicuries (megabecquerels);

2. The measured activity of strontium 82 expressed in microcuries (kilobecquerels);

3. The calculated activity of strontium 85 expressed in microcuries (kilobecquerels);

4. The ratio of the measures expressed as microcuries of strontium 82 per millicurie of rubidium 82 (kilobecquerels of strontium 82 per megabecquerel of rubidium 82) and the ratio of the measures expressed as microcuries of strontium 85 per millicurie of rubidium 82 (kilobecquerels of strontium 85 per megabecquerel of rubidium 82);

5. The date of the test; and

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

(d) A licensee shall report immediately to the department each occurrence of strontium 82 or strontium 85 concentrations exceeding the limits specified in subsection 64E-5.628(2), F.A.C.

(3) Other Permissible Parent/Daughter Concentration.

(a) If a licensee seeks to utilize a Parent/Daughter concentration other than those listed in subsection (1) or (2) above, the licensee must submit a license amendment to the department for review and approval of the maximum parent isotope or other contaminate concentrations breakthrough per daughter isotope concentration allowed for administration to patients or human research subjects, and the instrumentation and procedures used in determining parent isotope or other contaminate breakthrough concentrations;

(b) Each license must perform the determination listed in paragraph (3)(a), above, on each day of use prior to the administration to patients or human research subjects;

(c) Retain a record of each measurement for 3 years. The record shall include for each day of use assay:

1. The measured activity of the daughter isotope expressed in millicuries (megabecquerels);

2. The measured activity of parent isotope(s) and other contaminates expressed in microcuries (kilobecquerels);

3. The calculated activity of parent isotope(s) and other contaminates expressed in microcuries (kilobecquerels) as applicable;

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

5. The date of the test; and

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

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

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.736, Amended 2-11-10.

64E-5.629 Control of Aerosols and Gases.

(1) A licensee shall only administer radioactive aerosols or gases when airborne concentrations are within the limits prescribed by State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) Table I, Column 3, and Table II.

(2) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(3) A 1icensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(4) Before receiving, using, or storing radioactive gas, the licensee shall calculate the time needed after a release to reduce the concentration in the area of use to the occupational limit listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(5) A licensee shall post the time calculated in subsection 64E-5.629(4), F.A.C., at the area of use and require that individuals evacuate the room until the posted time has elapsed if a gas spill occurs.

(6) A licensee shall check the operation of collection systems prior to use each month of use and measure the ventilation rates in areas of use every 6 months. Records of these checks and measurements shall be maintained for 3 years.

(7) A copy of the calculations required in subsection 64E-5.629(4), F.A.C., shall be recorded and retained for the duration of the license.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.737, Amended 2-11-10, 12-26-13.

64E-5.632 Use of Sources for Manual Brachytherapy.

The licensee is allowed to use the brachytherapy sources listed below, provided they are approved by and used as specified in, the Sealed Source and Device Registry for medical uses, or in research in accordance with an active IDE application accepted by the FDA and the requirements of Rule 64E-5.612, F.A.C., are met.

(1) Cobalt 60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(2) Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions;

(3) Palladium 103 as a sealed source in seeds for interstitial treatment of cancer;

(4) Iodine 125 as a sealed source in seeds for interstitial treatment of cancer;

(5) Cesium 137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(6) Iridium 192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(7) Gold 198 as a sealed source in seeds for interstitial treatment of cancer;

(8) Radon 222 as seeds for interstitial treatment of cancer;

(9) Radium 226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(10) Cesium 131 as a sealed source in seeds for interstitial treatment of cancer; or

(11) For isotopes or uses not listed in subsections 64E-5.632(1) through (10), F.A.C., above, the licensee must amend their radioactive materials license.

In order to use isotopes in accordance with Rule 64E-5.632, F.A.C., an authorized user must satisfy the training and experience requirements specified in Rule 64E-5.652 or 64E-5.657, F.A.C. An authorized user of only Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions listed in subsection 64E-5.632(2), F.A.C., above must satisfy the training and experience specified in Rule 64E-5.652, 64E-5.653 or 64E-5.657, F.A.C.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.745, Amended 2-11-10, 12-26-13.

64E-5.633 Manual Brachytherapy Sources Inventory and Surveys.

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

(a) As soon as possible each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned; and

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

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

(a) For temporary implants;

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

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

(b) For permanent implants;

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

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

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

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

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

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.748, Amended 2-11-10, 12-26-13.

64E-5.643 Radiation Surveys for Teletherapy Facilities.

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

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

(b) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, radiation levels in restricted areas shall be unlikely to 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 paragraph 64E-5.312(1)(c), F.A.C.

(2) If the results of the surveys required in subsection 64E-5.643(1), F.A.C., indicate any radiation levels in excess of the limits specified, the licensee shall lock the control in the off position and shall not use the unit:

(a) Except to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

(b) Until the licensee has received a specific exemption from the department.

(3) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include:

(a) The date of the measurements;

(b) The reason the survey is required;

(c) The manufacturer’s name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels;

(d) Each dose rate measured around the teletherapy source while in the off position and the average of all measurements;

(e) A plan of the areas surrounding the treatment room that were surveyed;

(f) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;

(g) The calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and

(h) The signature of the RSO or the authorized medical physicist.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.762, Amended 10-8-00, 2-11-10, 12-26-13.

64E-5.644 Radiation Surveys for Remote Afterloader and Gamma Stereotactic Radiosurgery Facilities.

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

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

(3) A licensee shall retain a record of the radiation surveys required by subsection 64E-5.644(1), F.A.C., for the duration of the license. These records shall include:

(a) The date of the measurements;

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

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

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

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.763, Amended 2-11-10.

64E-5.645 Remote Afterloader, Gamma Stereotactic, and Teletherapy Therapy-Related Computer Systems.

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

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

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

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

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

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

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.764, Amended 10-8-00, 2-11-10, 12-26-13.

64E-5.654 Training for Use of Sealed Sources for Diagnosis.

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

(1) Be certified by a specialty board whose certification process includes all of the requirements in subsections 64E-5.654(2) and (3), F.A.C., of this section and whose certification has been recognized by the NRC or an agreement state. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

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

Rulemaking Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.774, Amended 2-11-10, 12-26-13.

64E-5.903 Notification and Reports to Individuals.

(1) Licensees or registrants for which personnel monitoring is required shall prepare a report as specified in this section of the radiation exposure data for each affected individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of the individual. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to Part III. Each notification and report shall:

(a) Be in writing;

(b) Include appropriate identifying data such as the name of the licensee or registrant and the name of the individual;

(c) Include the individual's exposure information; and

(d) Contain the following statement: "This report is furnished to you under the provisions of the Florida Department of Health regulation entitled Chapter 64E-5, F.A.C., Control of Radiation Hazards. You should preserve this report for future reference."

(2) Each licensee or registrant for which personnel monitoring is required shall furnish each worker annually a written copy of the report specified in (1), above, of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to Part III. The licensee or registrant shall maintain records that the report was furnished for 3 years.

(3) Each licensee or registrant shall furnish to the worker upon termination of employment a written report as specified in (1), above, of the worker's exposure to radiation received by that worker from operations of the licensee or registrant. Such report shall be furnished within 30 days from the time of termination of employment or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover each calendar quarter in which the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated. The licensee or registrant shall maintain records that the report was furnished for 3 years.

(4) When a licensee or registrant is required pursuant to Part III to report to the Department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Department.

(5) At the request of a worker who is terminating employment in a given calendar quarter with the licensee or registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's or registrant's facility in that calendar quarter, each licensee or registrant shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.

Rulemaking Authority 404.051, 404.061, 404.081 FS. Law Implemented 404.022, 404.051(1), (4), 404.061(2), 404.081 FS. History–New 7-17-85, Amended 5-12-93, Formerly 10D-91.1004.

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 Protection determine that such injection will not endanger the public health, safety and welfare.

(3) No licensee shall inject radioactive material into any well unless it can be demonstrated to the Department that the procedure will not result in any liquids or gases distributed to the public exceeding the following criteria:

(a) For gases, the air concentration in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) Table II, Column 1, shall apply.

(b) For liquids, the water concentration values in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, Table II, Column 2, shall apply.

Rulemaking Authority 404.051, 404.061 FS. Law Implemented 404.022, 404.031, 404.051(1), (4), 404.061(2) FS. History–New 7-17-85, Amended 1-1-94, Formerly 10D-91.1216, Amended 12-26-13.

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.

Rulemaking Authority 404.051, 404.061, 404.071, 404.081 FS. Law Implemented 404.022, 404.051(1), (4), (6), (9), (10), 404.061(2), (3), 404.071(1), 404.081(1) FS. History–New 5-12-93, Formerly 10D-91.1409.

64E-5.1419 Radiation Surveys.

(1) Before the facility starts operation, the following radiation surveys must be performed:

(a) A radiation survey of the area above the pool after the sources are loaded and in the shielded position; and

(b) A survey of the area outside the shielding of the radiation room of a panoramic irradiator with the sources in the exposed position.

(2) If the surveys indicate that radiation levels specified in Rule 64E-5.1407, F.A.C., are exceeded, the shielding must be repaired to comply with the dose rate requirement in Rule 64E-5.1407, F.A.C., before operation of the facility can start.

(3) Radiation surveys described in (1) above must be performed after new sources are loaded and after any modifications which might increase dose rates are made to the radiation room, shielding or structure and at intervals not to exceed 3 years.

(4) Portable radiation survey meters used to meet the requirements of subsections (1) and (3) of this section and the requirements of subsections 64E-5.1413(3) and 64E-5.1424(1), F.A.C., must be calibrated at least annually to an accuracy of 20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

(5) Water from the irradiator pool or other potentially contaminated liquids and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) Table II, Column 2, or Table III, as applicable. The lower limit of detection for the measurements must be below those concentrations.

(6) Resins to be released for unrestricted use must be monitored before release in an area with a background level less than 0.05 millirem (0.0005 millisievert) per hour. The resins can be released only if the survey does not detect radiation levels above background radiation levels. The survey meter must be capable of detecting radiation levels of 0.05 millirem (0.0005 millisievert) per hour.

Rulemaking Authority 404.051(4) FS. Law Implemented 404.051(1), (5), (6), 404.061, 404.081, 404.141 FS. History–New 8-14-96, Formerly 10D-91.1519, Amended 12-26-13.

64E-5.1420 Detection of Leaking or Contaminated Sources.

(1) Each dry-source-storage sealed source must be tested for leakage at least every 6 months using a leak test kit or a method approved by the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state. The analysis must be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material and must be performed by a person approved by the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state to perform the analysis.

(2) For pool irradiators, the pool water must be checked for contamination each day the irradiator operates. The check must be done by using an on-line radiation monitor on a pool water circulating system as described in subsection 64E-5.1410(2), F.A.C., or by analysis of pool water. If a check for contamination is done by analysis of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical but high enough to avoid false alarms. The licensee can reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(3) The licensee shall have written procedures and equipment available for the detection, isolation and removal of leaking sources.

(4) If a leaking source is detected, the licensee shall remove the leaking source from service and have it decontaminated, repaired, or disposed of by a licensee of the Department, NRC, Agreement State or Licensing State authorized to perform these functions. The licensee shall check its personnel, equipment, facilities, and irradiated product promptly for radioactive contamination. No product shall be shipped until the product has been checked and found free of contamination. If a product has been shipped that could have been contaminated inadvertently, the licensee shall arrange to locate and survey that product for contamination. If any personnel are contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall have them decontaminated or disposed of by a licensee of the Department, NRC, Agreement State or Licensing State authorized to perform these functions. If the pool water is contaminated, the licensee shall clean the pool water until the contamination levels do not exceed the appropriate concentration in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) Table II, Column 2.

Rulemaking Authority 404.051(4) FS. Law Implemented 404.051(1), (5), (6), 404.061, 404.081, 404.141 FS. History–New 8-14-96, Formerly 10D-91.1520, Amended 12-26-13.

64E-5.1501 Purpose and Scope.

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

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

(3) The regulations in this part apply to any licensee authorized by specific or general license issued by the department to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the license, or transports that material on public highways. No provision of this part authorizes possession of licensed material.

(4) Definition of terms used in this part are those listed in Rule 64E-5.1502, F.A.C., as described in 49 C.F.R. and 10 C.F.R. 71.4, except that whenever a definition refers to evaluation or approval by the U.S. Department of Transportation or NRC, and such evaluation or approval is within the jurisdiction of the State of Florida as an Agreement State, the Department shall perform the evaluation or approval.

Rulemaking Authority 404.051, 404.20 FS. Law Implemented 404.022, 404.051(1), (4), (6), (11), 404.20(1) FS. History–New 7-17-85, Amended 5-15-96, Formerly 10D-91.2001, Amended 2-28-08, 12-26-13.

64E-5.1502 Transportation of Radioactive Material.

(1) No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general license or specific license issued by the Department or as exempted in Rule 64E-5.1503, F.A.C.

(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 current applicable requirements, appropriate to the mode of transport, of 49 C.F.R. Parts 107, 171-180, 383, 390-397, published on 01/01/2012 which is herein incorporated by reference and can be obtained from the internet http://www.flrules.org/Gateway/reference.asp?No=Ref-03458, https://www.flrules.org/Gateway/reference.asp?No=Ref-03473, https://www.flrules.org/Gateway/reference.asp?No=Ref-03474, https://www.flrules.org/Gateway/reference.asp?No=Ref-03475, and https://www.flrules.org/Gateway/reference.asp?No=Ref-03476 or at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR&searchPath=Title+49%2FSubtitle+B&oldPath=Title+49&isCollapsed=true&selectedYearFrom=2012&ycord=1546 and 10 C.F.R. Part 71 published on 01/01/2012 which is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03459 or at http://www.gpo.gov/fdsys/pkg/CFR-2012-title10-vol2/pdf/CFR-2012-title10-vol2-part71.pdf, and 10 C.F.R. Parts 73.72 through 73.74 published on 01/01/2012 which is herein incorporated by reference and can be obtained from the internet at http://www.flrules.org/Gateway/reference.asp?No=Ref-03460 or at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR&searchPath=Title+10%2FChapter+I%2FPart+73%2FSubjgrp&oldPath=Title+10%2FChapter+I%2FPart+73%2FSubjgrp&isCollapsed=true&selectedYearFrom=2012&ycord=1772.

(b) Establish procedures for safely opening and closing packages in which radioactive material is transported and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(c) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

(d) The licensee shall comply with U.S. Department of Transportation and NRC regulations in the following areas:

1. Packaging, 49 C.F.R. part 173, subparts A, B, and I;
2. Marking and labeling, 49 C.F.R. part 172, subpart D, §§172.400 through 172.407, §§172.436 through 172.441 of subpart E;
3. Placarding, 49 C.F.R. part 172, subpart F, especially §§172.500 through 172.519 and 172.556, and appendices B and C;
4. Accident reporting, 49 C.F.R. part 171, §§171.15 and 171.16;
5. Shipping papers and emergency information, 49 C.F.R. part 172, subparts C and G;
6. Hazardous material employee training, 49 C.F.R. part 172, subpart H;
7. Security plans, 49 C.F.R. part 172, subpart I;
8. Hazardous material shipper/carrier registration, 49 C.F.R. part 107, subpart G;
9. Definitions, 10 C.F.R. 71.4;
10. Transportation of licensed material, 10 C.F.R. 71.5;
11. Exemptions for low level material, 10 C.F.R. 71.14(a);
12. General license, NRC-approved package, 10 C.F.R. 71.17;
13. Previously approved package, 10 C.F.R. 71.19(a) and (b);
14. General license, U.S. Department of Transportation specification container material, 10 C.F.R. 71.20;
15. General license, Use of foreign approved package, 10 C.F.R. 71.21;
16. General license, Fissile material, 10 C.F.R. 71.22;
17. External radiation standards for all packages, 10 C.F.R. 71.47;
18. Assumptions as to unknown properties, 10 C.F.R. 71.83;
19. Preliminary determinations, 10 C.F.R. 71.85;
20. Routine determinations, 10 C.F.R. 71.87;
21. Air transportation of plutonium, 10 C.F.R. 71.88;
22. Opening instructions, 10 C.F.R. 71.89;
23. Advance notification of shipment of irradiated reactor fuel and nuclear waste, 10 C.F.R. 71.97;
24. Quality assurance requirements, 10 C.F.R. 71.101(a), (b), (c), (f) and (g);
25. Quality assurance organization, 10 C.F.R. 71.103;
26. Quality assurance program, 10 C.F.R. 71.105;

27. Exemption of physicians, 10 C.F.R. 71.13;

28. Handling storage and shipping control, 10 C.F.R. 71.127;

29. Inspection tests and operating status, 10 C.F.R. 71.129;

30. Nonconforming materials parts or components, 10 C.F.R. 71.131;

31. Corrective action, 10 C.F.R. 71.13;

32. Quality assurances records, 10 C.F.R. 71.135;

33. Audits, 10 C.F.R. 71.137;

34. Appendix A to Part 71; and

35. General license plutonium beryllium special form material.

(e) The licensee shall also comply with U.S. Department of Transportation regulations pertaining to the following modes of transportation:

1. Rail, 49 C.F.R. part 174, subparts A through D and K;

2. Air, 49 C.F.R. part 175;

3. Vessel, 49 C.F.R. part 176, subparts A through F and M; and

4. Public Highway, 49 C.F.R. part 177 and parts 390 through 397.

(3) If U.S. Department of Transportation regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the U.S. Department of Transportation specified in subsection (2) of this section to the same extent as if the shipment or transportation were subject to U.S. Department of Transportation regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Department.

Rulemaking Authority 404.051, 404.061, 404.141, 404.20 FS. Law Implemented 404.022, 404.051(1), (4), (6), (11), 404.061(2), 404.141, 404.20(1) FS. History–New 7-17-85, Formerly 10D-91.2003, Amended 10-8-00, 9-28-06, 2-28-08, 12-26-13.

64E-5.6011 Definitions.

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

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

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

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

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

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

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

(2) “Authorized user” means:

(a) A physician, dentist, or podiatrist who meets the requirements in Rule 64E-5.658 and subsection 64E-5.649(1), 64E-5.660(1), 64E-5.661(1), 64E-5.662(1), 64E-5.652(1), 64E-5.654(1) or 64E-5.655(1), F.A.C.; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(15) “Radiation Safety Officer” or “RSO” means an individual who:

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

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

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

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

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

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

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

Rulemaking Authority 404.051, 404.061 FS. Law Implemented 404.031, 404.061(2), 404.20, 404.22, 404.30 FS. History–New 2-11-10, Amended 12-26-13.

64E-5.6251 Manual Brachytherapy Therapy Related Computer Systems.

The licensee shall perform acceptance testing on the treatment planning system of manual brachytherapy therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

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

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

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

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

The licensee shall maintain records of this acceptance testing and protocols used in performing these tests for inspection by the department.

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

64E-5.6412 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

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

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

(b)1. Before medical use whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

2. Before medical use following replacement of the source or following reinstallation of the gamma stereotactic radiosurgery unit in a new location;

3. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(c) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) Full calibration measurements of the gamma stereotactic radiosurgery unit shall include the determination of:

(a) The output within 3 percent;

(b) Relative helmet factors;

(c) Isocenter coincidence;

(d) Timer constancy and linearity over the range of use;

(e) On-off errors;

(f) Trunnion centricity;

(g) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(h) Helmet microswitches;

(i) Emergency timing circuits; and

(j) Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C., to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 64E-5.6412(2)(a), F.A.C., may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by subsection 64E-5.6412(1), F.A.C., in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall correct mathematically the outputs determined in paragraph 64E-5.6412(2)(a), F.A.C., at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(6) Full calibration measurements required by subsection 64E-5.6412(1), F.A.C., and physical decay corrections required by subsection 64E-5.6412(5), F.A.C., shall be performed by the authorized medical physicist.

(7) A licensee shall maintain a record of each gamma stereotactic radiosurgery unit calibration for three years. The record shall include:

(a) The date of the calibration;

(b) The manufacturer’s name, model number, and serial number for both the gamma stereotactic radiosurgery unit and the source;

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

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

(e) The signature of the authorized medical physicist.

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

64E-5.6422 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform the following spot-checks:

(a) Monthly:

(b) Before the first use of the unit on a given day; and

(c) After each source installation.

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

(a) Assure the proper operation of the:

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

2. Helmet microswitches;

3. Emergency timing circuits; and

4. Stereotactic frames and localizing devices (trunnions).

(b) Determine the following elements:

1. The output for one typical set of operating conditions measured with the dosimetry system described in subsection 64E-5.640(2), F.A.C.;

2. The difference between the measurement made in subparagraph 64E-5.6422(2)(b)1., F.A.C., and the anticipated output, expressed as a percentage of the anticipated output value obtained at last full calibration corrected mathematically for physical decay;

3. Source output against computer calculation;

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

5. On-off error; and

6. Trunnion centricity.

(3) A licensee shall perform spot-checks required by subsection 64E-5.6422(1), F.A.C., following procedures established by the authorized medical physicist.

(4) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days and promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for 3 years.

(5) To satisfy the requirements of paragraphs 64E-5.6422(1)(b) and (c), F.A.C., the licensee's spot-checks must assure proper operation of the following:

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

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

(c) Viewing and intercom systems;

(d) Timer termination;

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

(f) Emergency off buttons.

(6) If the results of the checks required in subsection 64E-5.6422(5), F.A.C., of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall arrange for the repair of any system identified in subsection 64E-5.6422(2), F.A.C., that is not operating properly as soon as possible.

(8) A licensee shall maintain a record of each spot-check required by subsections 64E-5.6422(2) and (5), F.A.C., for 3 years and a copy of the procedures required in subsections 64E-5.6422(2) and (3), F.A.C., until the licensee no longer possesses the gamma stereotactic radiosurgery unit. The record shall include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit;

(c) The manufacturer's name, model number and serial number of the instrument used to measure the output of the gamma stereotactic radiosurgery unit;

(d) The timer linearity and constancy;

(e) The calculated on-off error;

(f) A determination of trunnion centricity;

(g) The difference between the anticipated output and the measured output;

(h) An assessment of source output against computer calculations;

(i) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

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

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