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).

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