15A NCAC 11 .0104 is amended with changes as published in NCR 27:22, pp. 2031-2073, as follows:

15A NCAC 11 .0104 DEFINITIONS

As used in these Rules, the following definitions ~~shall~~ apply.

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

(2) "Accelerator produced material" means any material made radioactive by use of a particle accelerator.

(3) "Act" means North Carolina Radiation Protection Act as defined in G.S. 104E-1.

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

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

(6) "Agency" means the ~~North Carolina Department of Environment and Natural Resources, Division of Environmental Health~~, North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.

(7) "Agreement state" has the meaning as defined in G.S. 104E-5(2).

(8) "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(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 area in which airborne radioactive materials, composed wholly or partly of licensed radioactive material, exist in concentrations:

(a) in excess of the derived air concentrations ~~(DACs)~~ specified in Appendix B to 10 CFR 20.1001 - 20.2401; 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" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in the rules of this Chapter as is 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 benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

(12) "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 an effective dose equivalent of five rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. The ALI values

and 2, of Appendix B to 10 CFR 20.1001 - 20.2401. ~~(ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix B to 10 CFR 20.1001 - 20.2401).~~

(13) "Annually" means either:

(a) at intervals not to exceed 12 consecutive months; or

(b) once per year at the same time each year (completed during the same month each year over a period of multiple years).

(14) "Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. APF can be divided into the ambient airborne concentrations to estimate inhaled air concentrations.

(15) "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 ~~(SARs)~~ and self-contained breathing apparatus ~~(SCBA)~~ units.

(16) "Authorized representative" means an employee of the agency, or an individual outside the agency when the individual is ~~specifically~~ so designated by the agency under Rule .0112 of this Section.

(17) "Authorized user" means an individual who is authorized by license or registration condition to use a source of radiation.

(18) "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 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 and~~ are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation regulated by the agency.

(19) "Becquerel" is the SI unit of radioactivity. One becquerel is equal to one disintegration per second (s-1).

(20) "Bioassay" or "radiobioassay" 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~~ *in vivo* counting) or by analysis and evaluation of materials excreted or removed from the human body.

(21) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal or interstitial application.

(22) "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.

~~(21)~~ (23) "Byproduct material" has the meaning as defined in G.S. 104E-5(4), and in addition includes:

{~~(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 using special nuclear material;~~}

{~~(b)~~} (a) 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 wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

{~~(c)~~} (b) Any discrete source of Radium-226 that is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity; {activity, or {~~any material that:~~

~~(i) has been made radioactive by use of a particle accelerator; and~~

~~(ii) is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity; and~~}

(c) Any material that:

(i) has been made radioactive by use of a particle accelerator; or

(ii) 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~~} that:

(i) the US Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection, the Secretary of Energy, the Secretary of Homeland Security, and the head of {~~an~~} any other appropriate federal agency, determines would poses 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

(ii) is extracted or converted after extraction for use in a commercial, medical, or research activity.

~~(22)~~ (24) "Class", "lung class" or "inhalation 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 as follows:

CLASSIFICATION OF INHALED MATERIAL

Class	Clearance half-time
Class D (Day)	less than 10 days

Class W (Weeks) 10 days to 100 days

Class Y (Years) greater than 100 days

{~~(23)~~} (25) "Clinical procedures manual" means a collection of procedures governing the medical use of radioactive material not requiring a written directive that describes each method by which the licensee performs clinical procedures and includes other instructions and precautions. Each clinical {~~procedure~~} procedure, including the {~~radiopharmaceutical,~~} radiopharmaceutical dosage and route of administration, shall be approved in writing by an authorized user prior to inclusion in the manual. The radiation safety officer shall ensure that the manual includes the approved procedure(s) for all clinical procedures using radioactive material not requiring a written directive performed at the facility.

~~(23)~~{~~(24)~~} (26) "Collective dose" is 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.

~~(24)~~{~~(25)~~} (27) "Commission" has the meaning as defined in G.S. 104E-5(5).

~~(25)~~{~~(26)~~} (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.

~~(26)~~{~~(27)~~} (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 these organs or tissues ($H_{E,50} = \Sigma w_T H_{T,50}$).

{~~(28)~~} (30) "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~~}costs 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.~~} The consortium's PET radionuclide production facility must be located at an educational institution, federal or medical facility.

~~(27)~~{~~(29)~~} (31) ~~"Constraint (dose constraint)"~~ "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

~~(28)~~{~~(30)~~} (32) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

~~(29)~~{~~(31)~~} (33) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

~~(30)~~{~~(32)~~} (34) "Curie" is the special unit of radioactivity. One curie is equal to 3.7×10^{10} disintegrations per second = 3.7×10^{10} becquerels = 2.22×10^{12} disintegrations per minute.

~~(31)~~{~~(33)~~} (35) "Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant, 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.

~~(32)~~{~~(34)~~} (36) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for either unrestricted use and termination of the license or for restricted use and termination of the license.

~~(33)~~{~~(35)~~} (37) "Deep-dose equivalent" (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm^2).

~~(34)~~{~~(36)~~} (38) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

~~(35)~~{~~(37)~~} (39) "Department" has the meaning as defined in G.S. 104E-5(6).

~~(36)~~{~~(38)~~} (40) "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)~~{~~(39)~~} (41) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of ALI. DAC values are given in Table 1, Column 3, of Appendix B to 10 CFR 20.1001 - 20.2401).

~~(38)~~{~~(40)~~} (42) "Derived air concentration-hour" (DAC-hour) is 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 may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of five rems (0.05 Sv).

~~(39) "Diagnostic clinical procedures manual" means a collection of written procedures governing the use of radioactive material that describes each method by which the licensee performs diagnostic clinical procedures and includes other instructions and precautions. Each diagnostic clinical procedure including the radiopharmaceutical, dosage and route of administration, shall be approved by an authorized user prior to inclusion in the manual. The radiation safety officer shall ensure that the manual includes the approved written procedure for all diagnostic clinical procedures performed at the facility.~~

{~~(41)~~} (43) "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.

~~(40)~~{~~(42)~~} (44) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this

type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

~~(41)~~{~~(43)~~} (45) ~~"Distinguishable from Background"~~ "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using measurement technology, survey and statistical techniques as defined in 10 CFR 20.1003.

~~(42)~~{~~(44)~~} (46) "Dose" ~~(or radiation dose)~~ or "radiation 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, as defined in other Items of this Rule.

~~(43)~~{~~(45)~~} (47) "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 rem and sievert (Sv).

~~(44)~~{~~(46)~~} (48) "Dose limits" (see "Limits" defined in this Rule).

~~(45)~~{~~(47)~~} (49) "Dosimetry processor" means an individual or ~~an~~ organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

~~(46)~~{~~(48)~~} (50) "Effective dose equivalent" (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma w_T H_T$).

~~(47)~~{~~(49)~~} (51) "Embryo/fetus" means the developing human organism from conception until the time of birth.

~~(48)~~{~~(50)~~} (52) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

~~(49)~~{~~(51)~~} (53) "Equipment services" means the selling, installation, rebuilding, conversion, repair, inspection, testing, survey or calibration of equipment which can affect compliance with these Rules by a licensee or registrant.

~~(50)~~{~~(52)~~} (54) "Exposure" means being exposed to ionizing radiation or to radioactive material.

~~(51)~~{~~(53)~~} (55) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

~~(52)~~{~~(54)~~} (56) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

~~(53)~~{~~(55)~~} (57) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

~~(54)~~{~~(56)~~} (58) "Eye dose equivalent" (See "Lens dose equivalent" as defined in this Rule).

~~(55)~~{~~(57)~~} (59) ~~"Filtering facepiece (dust mask)"~~ "Filtering facepiece" or "dust mask" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the

entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

~~(56)~~{~~(58)~~} (60) "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.

~~(57)~~{~~(59)~~} (61) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

~~(58)~~{~~(60)~~} (62) "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 ~~(42 U.S.C. 2D11 et seq;),~~ (42 U.S.C. 2011 *et seq.*), 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 sources of radiation.

~~(59)~~{~~(61)~~} (63) "Gray" (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule/kilogram (100 rads).

~~(60)~~{~~(62)~~} (64) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(65) "High dose-rate remote afterloader" (HDR) 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.

~~(61)~~{~~(63)~~} (66) "High radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

~~(62)~~{~~(64)~~} (67) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

~~(63)~~{~~(65)~~} (68) "Hospital" means a facility that provides as its primary functions diagnostic services and intensive medical and nursing care in the treatment of acute stages of illness.

~~(64)~~{~~(66)~~} (69) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

~~(65)~~{~~(67)~~} (70) "Individual" means any human being.

~~(66)~~{~~(68)~~} (71) "Individual monitoring" means:

(a) the assessment of dose equivalent by the use of devices designed to be worn by an individual;

(b) the assessment of committed effective dose equivalent by bioassay ~~(see Bioassay)~~ or by determination of the time-weighted air concentrations to which an individual has been exposed, ~~i.e.,~~ *i.e.,* DAC-hours; or

(c) the assessment of dose equivalent by the use of survey data.

~~(67)~~{~~(69)~~} (72) "Individual monitoring devices" or "individual monitoring equipment" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

~~(68)~~{~~(70)~~} (73) "Inhalation class" (see "Class" defined in this Rule).

~~(69)~~{~~(71)~~} (74) "Inspection" means an ~~official~~ examination or observation by the agency to determine compliance with rules, orders, requirements and conditions of the agency or the Commission.

~~(70)~~{~~(72)~~} (75) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

~~(71)~~{~~(73)~~} (76) "Lens dose equivalent" (LDE) ~~or "LDE"~~ applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm (300 mg/cm^2).

~~(72)~~{~~(74)~~} (77) ~~"License",~~ "License," except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.

~~(73)~~{~~(75)~~} (78) "Licensee" means any person who is licensed by the agency pursuant to Section .0300 of this Chapter.

~~(74)~~{~~(76)~~} (79) "Licensing state" means any state designated as such by the Conference of Radiation Control Program Directors, Inc. Unless the context indicates otherwise, use of the term Agreement State in this Chapter ~~shall be deemed to include~~ includes licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).

~~(75)~~{~~(77)~~} (80) "Limits" or "dose limits" means the permissible upper bounds of radiation doses.

~~(76)~~{~~(78)~~} (81) "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

~~(77)~~{~~(79)~~} (82) "Lost or missing licensed radioactive material" means licensed radioactive material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

(83) "Low dose-rate remote afterloader" (LDR) 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.

~~(78)~~{~~(80)~~} (84) "Lung class" (see "Class" as defined in this Rule).

(85) "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

~~(79)~~{~~(81)~~} (86) "Medical event" means an event that meets the criteria in Rule .0364 of this Chapter.

~~(80)~~{~~(82)~~} (87) "Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

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

~~(81)~~{~~(83)~~} (89) "Member of the public" means any individual except when that individual is receiving an occupational dose.

~~(82)~~{~~(84)~~} (90) "Minor" means an individual less than 18 years of age.

~~(83)~~{~~(85)~~} (91) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

~~(84)~~{~~(86)~~} (92) ~~"Monitoring",~~ "Monitoring," "radiation monitoring" or "radiation protection monitoring" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

~~(85)~~{~~(87)~~} (93) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

~~(86)~~{~~(88)~~} (94) "Negative pressure respirator" means a tight-fitting respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside of the respirator.

~~(87)~~{~~(89)~~} (95) "Nonstochastic effect" or "deterministic effect" means health effects, the severity of which ~~varies~~ vary with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. ~~effect (also called a deterministic effect).~~

~~(88)~~{~~(90)~~} (96) "NRC" means the United States Nuclear Regulatory Commission or its authorized representatives.

~~(89)~~{~~(91)~~} (97) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or registrant or other person. Occupational dose does not include ~~dose~~ doses received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, from voluntary participation in medical research programs, or as a member of the ~~general~~ public.

~~(90)~~{~~(93)~~} (98) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged ~~particles.~~ particles, in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of

{~~1~~}one megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

(99) "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

~~(91)~~{~~(93)~~} (100) "Person" has the meaning as defined in G.S. 104E-5(11).

~~(92)~~{~~(94)~~} (101) "Personnel monitoring equipment" means devices, such as film badges, pocket dosimeters, and thermoluminescent dosimeters, designed to be worn or carried by an individual for the purpose of estimating the dose of radiation received by the individual.

~~(93)~~{~~(95)~~} (102) "Pharmacist" means a person licensed ~~by this state~~ {~~North Carolina~~} ~~to practice pharmacy.~~ {~~(21 NCAC 46.1500).~~} to practice pharmacy in North Carolina pursuant to G.S. Chapter 90, Article 4A.

~~(94)~~{~~(96)~~} (103) "Physician" means ~~an individual~~ a person licensed to practice medicine in ~~this state.~~ North Carolina {~~(NC G.S. Chapter 90, Article 1).~~} pursuant to G.S. Chapter 90, Article 1.

~~(95)~~{~~(97)~~} (104) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose ~~limits.~~ limits as defined in Rule .1608 of this Chapter.{~~.~~}

~~(96)~~{~~(98)~~} (105) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

{~~(99)~~} (106) "Positron Emission Tomography (PET) radionuclide production facility" means a facility operating an accelerator or a cyclotron for the purpose of producing PET radionuclides.

~~(97)~~{~~(100)~~} (107) "Powered air-purifying respirator (PAPR)" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

(101) {~~(101)~~} (108) "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

(a) In a written directive; or

(b) In accordance with the directions of an authorized user.

~~(99)~~{~~(102)~~} (109) "Prescribed dose" means:

(a) for teletherapy or accelerator radiation:

(i) the total dose; and

(ii) the dose per fraction as documented in the written directive;

(b) for brachytherapy:

(i) the total source strength and exposure time; or

(ii) the total dose, as documented in the written directive;

(c) for gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

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

~~(100)~~{~~(103)~~} (110) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

~~(101)~~{~~(104)~~} (111) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee or registrant, or ~~to~~ another source of radiation within a licensee's or registrant's control. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, or from voluntary participation in medical research programs.

(112) "Pulsed dose-rate remote afterloader" means a type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

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

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

~~(102)~~{~~(105)~~} (113) ~~"Qualitative fit test (QLFT)"~~ "Qualitative fit test" (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

~~(103)~~{~~(106)~~} (114) "Quality factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem in this Rule.

~~(104)~~{~~(107)~~} (115) ~~"Quantitative fit test (QNFT)"~~ "Quantitative fit test" (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

~~(105)~~{~~(108)~~} (116) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee or registrant (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

~~(106)~~{~~(109)~~} (117) ~~Quarterly"~~ "Quarterly" means either:

(a) at intervals not to exceed 13 weeks; or

(b) once per 13 weeks at about the same time during each 13 week period (completed during the same month of the quarter (first month, second month or third month) each quarter over a time period of several quarters.

~~(107)~~{~~(110)~~} (118) "Rad" is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

~~(108)~~{~~(111)~~} (119) "Radiation" ~~(ionizing radiation)~~, except as otherwise defined in Section .1400 of this Chapter, has the meaning as defined in G.S. 104E-5(12).

~~(109)~~{~~(112)~~} (120) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

~~(110)~~{~~(113)~~} (121) "Radiation dose" means dose.

~~(111)~~{~~(114)~~} (122) "Radiation machine" has the meaning as defined in G.S. 104E-5(13).

~~(112)~~{~~(115)~~} (123) "Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection rules.

~~(113)~~{~~(116)~~} (124) "Radioactive material" has the meaning as defined in G.S. 104E-5(14).

~~(114)~~{~~(117)~~} (125) "Radioactive waste disposal facility" means any low-level radioactive waste disposal facility, as defined in G.S. 104E-5(9c), established for the purpose of receiving low-level radioactive waste, as defined in Rule .1202 of this Chapter, generated by another licensee for the purpose of disposal.

~~(115)~~{~~(118)~~} (126) "Radioactive waste processing facility" means any low-level radioactive waste facility, as defined in G.S. 104E-5(9b), established for the purpose of receiving waste, as defined in this Rule, generated by another licensee to be stored, compacted, incinerated or treated.

~~(116)~~{~~(119)~~} (127) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.

~~(117)~~{~~(120)~~} (128) "Radiobioassay" means bioassay.

~~(118)~~{~~(121)~~} (129) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus as published by the International Commission on Radiological Protection. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

~~(119)~~{~~(122)~~} (130) "Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.

~~(120)~~{~~(123)~~} (131) "Registration" means registration with the agency in accordance with these Rules.

~~(121)~~{~~(124)~~} (132) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

~~(122)~~{~~(125)~~} (133) "Rem" is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the

quality factor (1 rem = 0.01 sievert). As used in this Chapter, the quality factors for converting absorbed dose to dose equivalent are as follows:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

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

[a] Absorbed dose in rad equal to one rem or the absorbed dose in gray equal to one sievert.

If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, one rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the rules of this Chapter, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body.

If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from the following table to convert a measured tissue dose in rads to dose equivalent in rems:

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

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})
(thermal)	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}

1×10^{-6}	2	810×10^{6}
1×10^{-5}	2	810×10^{6}
1×10^{-4}	2	840×10^{6}
1×10^{-3}	2	980×10^{6}
1×10^{-2}	2.5	1010×10^{6}
1×10^{-1}	7.5	170×10^{6}
5×10^{-1}	11	39×10^{6}
1	11	27×10^{6}
2.5	9	29×10^{6}
5	8	23×10^{6}
7	7	24×10^{6}
10	6.5	24×10^{6}
14	7.5	17×10^{6}
20	8	16×10^{6}
40	7	14×10^{6}
60	5.5	16×10^{6}
1×10^{2}	4	20×10^{6}
2×10^{2}	3.5	19×10^{6}
3×10^{2}	3.5	16×10^{6}
4×10^{2}	3.5	14×10^{6}

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

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

~~(123)~~{~~(126)~~} (134) ~~Research and development"~~ "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.

~~(124)~~{~~(127)~~} (135) "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 materials

remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials of radioactive materials at the site, even if the burials were made in accordance with the provisions of Section .1600 of this Chapter.

~~(125)~~{~~(128)~~} (136) "Respiratory protective device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

~~(126)~~{~~(129)~~} (137) "Restricted area" means an area, access to which is controlled by the licensee or registrant for purposes of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

~~(127)~~{~~(130)~~} (138) "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58 x 10^{-4} coulombs/kilogram of air.

~~(128)~~{~~(131)~~} (139) "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.

~~(129)~~{~~(132)~~} (140) "Sealed source" means radioactive material that is ~~permanently bonded, fixed or encapsulated so as to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.~~ encased in a capsule designed to prevent leakage or escape of the radioactive material.

~~(130)~~{~~(133)~~} (141) "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.

~~(131)~~{~~(134)~~} (142) "Self-contained breathing apparatus (SCBA)" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

~~(132)~~{~~(135)~~} (143) "Semiannually" means either:

(a) at intervals not to exceed six months; or

(b) once per six months at about the same time during each six month period (completed during the sixth month of each six month period over multiple six month periods).

~~(133)~~{~~(136)~~} (144) "Shallow-dose equivalent" (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

~~(134)~~{~~(137)~~} (145) "SI unit" means a unit of measure from the International System of Units as established by the General Conference of Weights and Measures.

~~(135)~~{~~(138)~~} (146) "Sievert" is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

~~(136)~~{~~(139)~~} (147) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

~~(137)~~{~~(140)~~} (148) "Source material" has the meaning as defined in G.S. 104E-5(15).

~~(138)~~{~~(141)~~} (149) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

~~(139)~~{~~(142)~~} (150) "Special form radioactive material" means radioactive material which satisfies 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 five millimeters (0.197 inch); and

(c) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission, Subpart F of 10 CFR Part 71, and the tests prescribed in Rule .0114 of this Section. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements, Subpart F of 10 CFR Part 71, in effect on June 30, 1984, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

~~(140)~~{~~(143)~~} (151) "Special nuclear material" has the meaning as defined in G.S. 104E-5(16).

~~(141)~~{~~(144)~~} (152) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope uranium-235 in quantities not exceeding 350 grams of contained uranium-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of uranium-235, uranium enriched in uranium-235 and plutonium 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 in this Rule for the same kind of special nuclear material. The sum of these ratios for all the kinds of special nuclear material in combination shall not exceed ~~unity.~~ one. For example, the following quantities in combination would not exceed the limitations and are within the formula, as follows:

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

~~(142)~~{~~(145)~~} (153) "State" means the State of North Carolina.

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

~~(143)~~{~~(146)~~} (155) "Stochastic effects" means health effects that occur 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.

~~(144)~~{~~(147)~~} (156) ~~"Supplied air respirator (SAR or airline respirator)"~~ "Supplied-air respirator" (SAR) or "airline respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

~~(145)~~{~~(148)~~} (157) "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 an evaluation includes a physical survey of the location of sources of radiation and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

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

~~(146)~~{~~(149)~~} (159) "These Rules" means Chapter 11 of this Title.

~~(147)~~{~~(150)~~} (160) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

~~(148)~~{~~(151)~~} (161) "To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable ~~effort.~~ effort, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

~~(149)~~{~~(152)~~} (162) "Total effective dose equivalent" (TEDE) means the sum of the ~~deep dose~~ effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

~~(150)~~{~~(153)~~} (163) "Toxic or hazardous constituent of the waste" means the nonradioactive content of waste which, notwithstanding the radioactive content, would be classified as "hazardous waste" as defined in G.S. 130A-290(8).

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

~~(151)~~{~~(154)~~} (165) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Rule .0113 of this Section or may be determined by procedures described in that Rule. ~~in Rule .0113 of this Section.~~ All quantities of radioactive material greater than a Type A quantity are Type B.

~~(152)~~{~~(155)~~} (166) "Unit dosage" means a dosage intended for medical use in an individual that has been obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent agreement state requirements.

~~(153)~~{~~(156)~~} (167) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

~~(154)~~{~~(157)~~} (168) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.

~~(155)~~{~~(158)~~} (169) ~~"User seal check (fit check)"~~ "User seal check" or "fit check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

~~(156)~~{~~(159)~~} (170) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at one meter from a radiation source or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose ~~(e.g., rads and grays)~~ (*e.g.*, rads and grays) are appropriate, rather than units of dose equivalent ~~(e.g., rems and sieverts).~~ (*e.g.*, rems and sieverts).

~~(157)~~{~~(160)~~} (171) "Waste" means low-level radioactive waste as defined in G.S. 104E-5(9a) and includes those low-level radioactive wastes containing source, special nuclear, or radioactive material that are acceptable for disposal in a land disposal facility. For purposes of this definition, low-level waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined {~~in paragraphs (b), (c), and (d) of the definition of "Byproduct Material" set forth in rule .0104 of this Section,~~}in this Rule, and licensed naturally occurring and accelerator produced radioactive material which is not subject to regulation by the U.S. Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended, except as defined differently in Rule .1202 of this Chapter.

~~(158)~~ {~~(161)~~} ~~"Waste, Class A" is defined in Rule .1650 of this Chapter.~~

~~(159)~~ {~~(162)~~} ~~"Waste, Class B" is defined in Rule .1650 of this Chapter.~~

~~(160)~~ {~~(163)~~} ~~"Waste, Class C" is defined in Rule .1650 of this Chapter.~~

~~(161)~~ {~~(164)~~} (172) "Week" means seven consecutive days. ~~days starting on Sunday.~~

~~(162)~~ {~~(165)~~} (173) "Weighting factor", w_T, for an organ or tissue (T) is 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[a]
Whole body	1.00[b]

[a] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[b] For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $w_T = 1.0$, has been specified.

~~(163)~~ {~~(166)~~} (174) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

~~(164)~~ {~~(167)~~} (175) "Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

~~(165)~~ {~~(168)~~} (176) "Working level" (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy.

~~(166)~~ {~~(169)~~} (177) "Working level month" (WLM) means an exposure to one working level for 170 hours.

~~(167)~~ {~~(170)~~} (178) "Written directive" means an order in writing for a specific patient or human research subject dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation from a licensed source, except as specified in Sub-item (e) of this definition, containing the patient or human research subject's name and the following information:

(a) for the administration of greater than 30 microcuries (1.11 Megabecquerels (MBq)) of sodium iodide I-131, the dosage;

(b) for the therapeutic administration of a radiopharmaceutical other than sodium iodide I-131:

(i) radionuclide;

(ii) dosage; and

(iii) route of administration;

(c) for teletherapy or accelerator radiation therapy:

(i) total dose;

(ii) dose per fraction;

(iii) treatment site; and

(iv) number of fractions;

(d) for high-dose-rate remote afterloading brachytherapy:

(i) radionuclide;

(ii) treatment site;

(iii) dose per fraction

(iv) number of fractions; and

(v) total dose;

(e) for all other brachytherapy:

(i) prior to implantation:

(A) radionuclide;

(B) treatment site; and

(C) dose; and

(ii) after implantation:

(A) radionuclide;

(B) treatment site;

(C) number of sources;

(D) total source strength and exposure time; and

(E) total dose; and

(f) for gamma stereotactic radiosurgery:

(i) the total dose;

(ii) treatment site; and

(iii) values for the target coordinate settings per treatment for each anatomically distinct treatment site.

~~(168)~~ {~~(171)~~} (179) "Year" means the period of time beginning in January used to determine compliance with the provisions of Section .1600 of this Chapter. The licensee or registrant may change the starting date of the year used to determine compliance

by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

History Note: *Authority G.S. 104E-7(a)(2);10 CFR 20. 1003;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989; June 1, 1989; October 1, 1984;
Transferred and Recodified from 10 NCAC 3G .2204 Eff. January 4, 1990;
Amended Eff. January 1, 1994; May 1, 1992;
Temporary Amendment Eff. August 20, 1994, for a Period of 180 Days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. October 1, 2013; November 1, 2007; May 1, 2006; January 1, 2005; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.