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Division of Health Service Regulation
Radiation Protection Section
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August 3, 2011

Terrence Reis, Acting Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
USNRC
MS:T8-E24
11555 Rockville Pike
Rockville, MD 20852

Dear Mr. Reis:

Enclosed is a copy of the revisions to the proposed North Carolina Regulations for Protection Against Radiation, 15A NCAC 11. The proposed revisions include changes requested in NRC comments letters dated August 15, 2006 and June 30, 2008, and RATS ID 2006-1, 2007-1, 2007-2, 2007-3, 2008-1, and 2009-1. The proposed revisions are being submitted for your review in accordance with FSME Procedure SA-201. In addition to the proposed rules revisions, tables have been included that link the NRC comments and/or RATS changes with the revised North Carolina rule. In cases where existing rules appear compatible with the NRC rules, we have also included those rules in their current form. We request NRC's comments by October 1, 2011 so that we can meet our strict timeline to get final approval by the North Carolina Rules Review Commission. The proposed regulations are identified by line-in/line-out text and correspond to the following equivalent amendments to NRC's regulations.

Rats ID	Title	State Section
2006-1	Minor Amendments Part 20, 30 32, 35, 40, and 70	See attached RATS 2006-1 Table in "State Section."
2007-1	Medical Use of By-Product Material Minor Corrections and Clarifications Parts 32 and 35	See attached RATS 2007-1 Table in "State Section."
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material	See attached RATS 2007-2 Table in "State Section."
2007-3	Requirements for Expanded Definition Of Byproduct Material	See attached RATS 2007-3 Table in "State Section."

Rats ID	Title	State Section
2008-1	Occupational Dose Records, Labeling Containers, and The Total Effective Dose Equivalent	See attached RATS 2008-1 Table in "State Section."
2009-1	Medical Use of Byproduct Material, Authorized User Clarification	See attached RATS 2009-1 Table in "State Section."
NRC Comments Letter Dated 8/15/2006		See attached Table 1
NRC Comments Letter Dated June 30, 2008		See attached Table 2

We believe that adoption of these revisions, or existing rules that are also included, satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at 919-571-4141, ext. 201 or Gerald Speight of my staff at 919-571-4141, ext 237, or gerald.speight@ncdenr.gov.

Sincerely,

W. Lee Cox, III, Section Chief
North Carolina Radiation Protection Section

WLC/gas

Enclosures:
As stated.

cc: Kathleen Schneider

Table 1. Actions Taken in Response to Comments in August 15, 2006 Letter

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	ACTION TAKEN
15A NCAC 11.0309(c)(4)	31.5(c)(4)	2001-1	B	North Carolina's regulations require records of tests for leakage of radioactive material and tests for on-off mechanism to be maintained for 1 year; records for other testing to be maintained for 2 years before transferring or disposing the device. However, the NRC's regulations require all the records to be retained for 3 years. North Carolina needs to revise the record retention period in 15A NCAC11.0309(c)(4) to meet the Compatibility Category B designation assigned to 10 CFR 31.5(c)(4).	**NRC's recommendation has been incorporated into the proposed revision of 15A NCAC 11 .0309.**

Table 1. Actions Taken in Response to Comments in August 15, 2006 Letter

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	ACTION TAKEN
15A NCAC 11.0309(c)(7)	31.5(c)(7)	2001-1	B	North Carolina has omitted the provision of 10 CFR 31.5(c)(7) regarding the export of the device containing byproduct material. Omitting this provision also caused a missing reference to 10 CFR 31.5(c)(7) and the phrase "or export" in 15A NCAC11.0309(c)(7). North Carolina needs to adopt the provision and add the equivalent phrase and reference to 15A NCAC11.0309(c)(7) to meet the Compatibility Category B designation assigned to 10 CFR 31.5(c)(7)	**NRC's recommendation has been incorporated into the proposed revision of 15A NCAC 11 .0309.**

Table 1. Actions Taken in Response to Comments in August 15, 2006 Letter

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	ACTION TAKEN
15A NCAC 11.0309(c)(7)(B)	31.5(c)(8)(ii)(B)	2001-1	B	North Carolina has omitted the phrase "(license number not applicable if exported)" in 15A NCAC11.0309(c)(7)(B) that appears in 10 CFR 31.5(c)(8)(ii)(B). This phrase provides a mechanism for tracking this material into and out of North Carolina jurisdiction. North Carolina needs to add the phrase "(license number not applicable if exported)" to NCAC11.0309(c)(7)(B) to meet the Compatibility Category B designation assigned to 10 CFR 31.5(c)(8)(ii)(B).	**NRC's recommendation has been incorporated into the proposed revision of 15A NCAC 11 .0309.**

Table 1. Actions Taken in Response to Comments in August 15, 2006 Letter

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	ACTION TAKEN
15A NCAC 11.0309(c)	31.5(c)(11)	2001-1	B	North Carolina has omitted the requirement of 10 CFR 31.5(c)(11), regarding general license response to information requests within 30 calendar days. North Carolina needs to add the requirement to 15A NCAC11.0309(c), to meet the Compatibility Category B designation assigned to 10 CFR 31.5(c)(11)	**NRC's recommendation has been incorporated into the proposed revision of 15A NCAC 11 .0309.**
15A NCAC 11.0309(d)	31.5(d)	2001-1	B	North Carolina uses the word "distribution" instead of "import" after "does not authorize" in 15A NCAC11.0309(d). North Carolina needs to replace the word "distribution" by the word "import" to meet the Compatibility Category B designation assigned to 10 CFR 31.5(d).	**NRC's recommendation has been incorporated into the proposed revision of 15A NCAC 11 .0309.**

Table 2. Actions Taken in Response to Comments in June 30, 2008 Letter

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	ACTION TAKEN
15 A NCAC 11 .0104(129)	35.2	2002-2	B	North Carolina's definition of Sealed source is not essentially identical to NRC's definition in 35.2. North Carolina needs to change their definition of Sealed source to be essentially identical to NRC's definition in order to meet the Compatibility Category [B] designation assigned to 10 CFR 35.2 Definition Sealed Source.	**NRC's recommendations have been incorporated into the proposed revision of 15A NCAC 11.0104.**
15A NCAC 11 .0322(c) (1-4)	10 CFR 35.49	2002-2	C	North Carolina omits the essential objectives of 10 CFR 35.49 from its regulations. North Carolina needs to add the essential objective of 10 CFR 35.49 in order to meet the Compatibility Category [C] designation assigned to 10 CFR 35.49.	**Essential objectives of 10 CFR 35.49 are in 15A NCAC 11. 0322 (c) (1-4)**

Table 2. Actions Taken in Response to Comments in June 30, 2008 Letter

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	ACTION TAKEN
15A NCAC 11.1626	10 CFR 35.69	2002-2	H&S	**Labeling of vials and syringes** North Carolina omits the essential objectives of 10 CFR 35.69 from its regulations. North Carolina needs to add the essential objectives of 10 CFR 35.69 in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.69	**NRC's recommendations have been incorporated into the proposed revision of 15A NCAC 11.1626.**
15A NCAC 11 .0322(c) (1-4)	10 CFR 35.400	2002-2	C	**Use of sealed sources for manual brachytherapy** North Carolina omits the essential objectives of 10 CFR 35.400 from its regulations. North Carolina needs to add the essential objectives of 10 CFR 35.400 to its regulations in order to meet the Compatibility Category [C] designation assigned to 10 CFR 35.400.	**Essential objectives of 10 CFR 35.49 are in 15A NCAC 11. 0322 (c) (1-4)**

Table 2. Actions Taken in Response to Comments in June 30, 2008 Letter

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	ACTION TAKEN
15 A NCAC 11.0318 (cc)	10 CFR 35.410	2002-2	H&S	**Safety instruction** North Carolina omits 10 CFR 35.410 (a)(1) and (a)(2) from its regulation. North Carolina needs to add the above in order to meet the Compatibility category H&S designation assigned to 10 CFR 35.410.	**Requirements in 10 CFR 35.410 are contained in 15A NCAC .0322(d).**

Table 2. Actions Taken in Response to Comments in June 30, 2008 Letter

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	ACTION TAKEN
15 A NCAC 11.0117	10 CFR 71	2004-1	NRC	North Carolina adopted 10 CFR 71 in its entirety in 11.0117, including all sections reserved to NRC jurisdiction. North Carolina's regulations should not include sections designated Compatibility Category NRC as incorporated by reference North Carolina needs to add 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.101(c)(2), (d), and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125 to a list of items not incorporated by reference in 11.0117 in order to meet the Compatibility Category NRC designation assigned to the above listed sections.	**NRC's recommendations have been incorporated into the proposed revision of 15A NCAC 11.0117.**

Table 2. Actions Taken in Response to Comments in June 30, 2008 Letter

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS	ACTION TAKEN
15A NCAC 11.0117	Multiple	Multiple	NRC	**Incorporation by reference** North Carolina incorporates many sections of the 10 CFR which have regulation authority delegated to the NRC and not North Carolina. North Carolina needs to either remove these sections or list specific provisions which are not incorporated by reference in order to meet the Compatibility Category NRC designation assigned to sections of the 10 CFR that are delegated NRC authority.	**NRC's recommendations have been incorporated into the proposed revision of 15A NCAC 11.0117.**

15A NCAC 11 .0104 IS PROPOSED FOR AMENDMENT 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, 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. (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 counting) or by analysis and evaluation of materials excreted or removed from the human body.

(21) "Byproduct material" has the meaning as defined in G.S. 104E-5(4).

(22) "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) "Clinical procedures manual" means a collection of documented 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 including the 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 documented procedure(s) for all clinical procedures using radioactive material not requiring a written directive performed at the facility.

~~(23)~~(24) "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) "Commission" has the meaning as defined in G.S. 104E-5(5).

~~(25)~~(26) "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) "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) 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.

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

~~(28)~~(30) "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) "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) "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) "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) "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) "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) "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) "Department" has the meaning as defined in G.S. 104E-5(6).

~~(36)~~(38) "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) "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) "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) 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) "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) "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) "Dose" (or radiation dose) is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, effective dose equivalent, or total effective dose equivalent, as defined in other Items of this Rule.

~~(43)~~(45) "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) "Dose limits" (see "Limits" defined in this Rule).

~~(45)~~(47) "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) "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) "Embryo/fetus" means the developing human organism from conception until the time of birth.

~~(48)~~(50) "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) "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) "Exposure" means being exposed to ionizing radiation or to radioactive material.

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

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

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

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

~~(55)~~(57) "Filtering facepiece (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) "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) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

~~(58)~~(60) "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;), 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) "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) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

~~(61)~~(63) "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) "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) "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) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

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

~~(66)~~(68) "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., DAC-hours; or

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

~~(67)~~(69) "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) "Inhalation class" (see "Class" defined in this Rule).

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

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

~~(71)~~(73) "Lens dose equivalent" 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) "License", except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.

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

~~(74)~~(76) "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 licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).

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

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

~~(77)~~(79) "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.

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

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

~~(80)~~(82) "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.

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

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

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

~~(84)~~(86) "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) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

~~(86)~~(88) "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) "Nonstochastic effect" means health effects, 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 (also called a deterministic effect).

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

~~(89)~~(91) "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 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)~~(92) "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 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

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

~~(92)~~(94) "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 received by the individual.

~~(93)~~(95) "Pharmacist" means a person licensed by this state to practice pharmacy.

~~(94)~~(96) "Physician" means an individual licensed to practice medicine in this state.

~~(95)~~(97) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

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

99 "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) "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.

~~(98)~~

(101) "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) "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) "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) "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.

~~(102)~~

(105) "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) "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) "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) "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) 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) "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) "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) "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) "Radiation dose" means dose.

~~(111)~~

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

~~(112)~~

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

~~(113)~~

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

~~(114)~~

(117) "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) "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) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.

~~(117)~~

(120) "Radiobioassay" means bioassay.

~~(118)~~

(121) "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) "Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.

~~(120)~~

(123) "Registration" means registration with the agency in accordance with these Rules.

~~(121)~~

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

~~(122)~~

(125) "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) 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) "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 at the site, even if the burials were made in accordance with the provisions of Section .1600 of this Chapter.

~~(125)~~

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

~~(126)~~

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

~~(128)~~

(131) "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) "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) "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) "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) "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) "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) "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) "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) "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) "Source material" has the meaning as defined in G.S. 104E-5(15).

~~(138)~~

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

~~(139)~~

(142) "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) "Special nuclear material" has the meaning as defined in G.S. 104E-5(16).

~~(141)~~

(144) "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. For example, the following quantities in combination would not exceed the limitations and are within the formula, as follows:

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

~~(142)~~

(145) "State" means the State of North Carolina.

~~(143)~~

(146) "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) "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) "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.

~~(146)~~

(149) "These Rules" means Chapter 11 of this Title.

~~(147)~~

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

~~(148)~~

(151) "To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable effort.

~~(149)~~

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

~~(150)~~

(153) "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).

~~(151)~~

(154) "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 Rule .0113 of this Section. All quantities of radioactive material greater than a Type A quantity are Type B.

~~(152)~~

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

~~(154)~~

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

~~(155)~~

(158) "User seal check (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) "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) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

~~(157)~~

(160) "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 .0104 (21), 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) "Week" means seven consecutive days starting on Sunday.

~~(162)~~

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

~~(164)~~

(167) "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) "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) "Working level month" (WLM) means an exposure to one working level for 170 hours.

~~(167)~~

(170) "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;

(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) "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);
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. August 1, 2011; November 1, 2007; May 1, 2006; January 1, 2005; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.

15A NCAC 11 .0117 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0117 INCORPORATION BY REFERENCE

(a) For the purpose of the rules in this Chapter, the following rules, standards and other requirements are hereby incorporated by reference including any subsequent amendments and editions:

(1) Appendix A, Appendix B, Appendix C, and Appendix G to 10 CFR Parts 20.1001 - 20.2401;

(2) 10 CFR Part 21, 10 CFR Part 30.1, 30.4, 30.10, 10 CFR Part 31, 10 CFR Part 32, Subpart J of 10 CFR Part 35, 10 CFR 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, Subpart H of 10 CFR Part 35, 35.1000, 10 CFR Part 36, 10 CFR Part 40~~ and 10 CFR Part 50~~;

~~(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71, 10 CFR Part 73, 10 CFR Part 110, 10 CFR Part 140 and 10 CFR Part 150;~~

(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71.0, 71.1, 71.2, 71.3, 71.4, 71.5, 71.8, 71.14(a), 71.15, 71.17(a) – (d), 71.20, 71.21, 71.22, 71.23, 71.47, Subpart G of 10 CFR Part 71, 10 CFR 71.101(a) – (c)(1), 71.101(f), 71.101(g), 71.103, 71.105, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, Appendix A to 10 CFR Part 71, and 10 CFR Part 150;

(4) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040;

(5) 39 CFR Part 14 and 39 CFR Part 15;

(6) Postal Service Manual (Domestic Mail Manual) Section 124.3 [incorporated by reference in 39 CFR Section 111.11];

(7) 40 CFR Part 261;

(8) 49 CFR Parts 100-189;

(9) "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended", signed July 21, 1964;

(10) "Standards and Specifications for Geodetic Control Networks (September 1984);

(11) "Geometric Geodetic Survey Accuracy Standards and Specifications for Geodetic Surveys Using GPS Relative Positioning Techniques";

(12) "Reference Man: Anatomical, Physiological and Metabolic Characteristics" (ICRP Publication No. 23) of the International Commission on Radiological Protection;

(13) "10 CFR, Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 FR 7540"; and

(14) American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography".

(b) The rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule are available for inspection at the ~~Department of Environment and Natural Resources, Division of Radiation Protection~~ Agency at the address listed in Rule .0111 of this Section. Except as noted in the Subparagraphs of this Paragraph, copies of the rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 at a cost as follows:

(1) Three dollars ($3.00) for the appendixes listed in Subparagraph (a)(1) of this Rule, available from the ~~Division of Radiation Protection~~ Agency;

(2) Twenty-five dollars ($25.00) for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts 0-50;

(3) Eighteen dollars ($18.00) for the regulations listed in Subparagraph (a)(3) of this Rule in a volume containing 10 CFR Parts 51-199;

(4) Eighteen dollars ($18.00) for the regulations listed in Subparagraph (a)(4) of this Rule in a volume containing 21 CFR Parts 800-1299;

(5) Sixteen dollars ($16.00) for the regulations listed in Subparagraph (a)(5) of this Rule in a volume containing 39 CFR;

(6) Thirty-six dollars ($36.00) for the manual listed in Subparagraph (a)(6) of this Rule;

(7) Thirty-one dollars ($31.00) for the regulations listed in Subparagraph (a)(7) of this Rule in a volume containing 40 CFR Parts 260-299;

(8) For the regulations listed in Subparagraph (a)(8) of this Rule:

(A) Twenty-three dollars ($23.00) for a volume containing 49 CFR Parts 100-177; and

(B) Seventeen dollars ($17.00) for a volume containing 49 CFR Parts 178-199;

(9) One dollar ($1.00) for the agreement in Subparagraph (a)(9) of this Rule, available from the ~~Division of Radiation Protection~~ Agency;

(10) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(10) of this Rule, available from the National Geodetic Information Center, N/CG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(11) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(11) of this Rule, available from the National Geodetic Information Center, NCG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(12) One hundred and five dollars ($105.00) for the ICRP Publication No. 23 in Subparagraph (a)(12) of this Rule, available from Pergamon Press, Inc., Maxwell House, Fairview Park, Elmsford, NY 10523;

(13) Two dollars ($2.00) for the document in Subparagraph (a)(13) of this Rule, available from the ~~Division of Radiation Protection~~ Agency; and

(14) Thirty-eight dollars plus five dollars shipping and handling ($43.00) for the American National Standard N432-1980 in Subparagraph (a)(14) of this Rule, available from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, telephone number (212) 642-4900.

(c) Nothing in this incorporation by reference of 10 CFR Part 61 in Subparagraph (a)(3) of this Rule shall limit or affect the continued applicability of G.S. 104E-25(a) and (b).

History Note: *Authority G.S. 104E-7; 104E-15(a); 150B-21.6;*
Eff. June 1, 1993;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff., *August 1, 2011;* *November 1, 2007; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.*

15A NCAC 11 .0309 IS PROPOSED FOR AMENDMENT AS FOLLOWS:

15A NCAC 11 .0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES

(a) A general license shall be issued to commercial and industrial firms; research, educational and medical institutions; individuals in the conduct of their business; and federal, state, or local government agencies to acquire, receive, possess, use, or transfer in accordance with Paragraphs (b), (c), and (d) of this Rule, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license in Paragraph (a) of this Rule applies only to radioactive material contained in devices which have been:

(1) manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to Rule .0328 of this Section or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes distribution of the devices to persons generally licensed pursuant to equivalent regulations; and

(2) received from one of the specific licensees referenced in Subparagraph (b)(1) of this Rule or through a transfer completed in accordance with Subparagraph (c)(8) of this Rule.

(c) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license issued under Paragraph (a) of this Rule:

(1) shall assure that all labels, affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by the labels;

(2) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, except as follows:

(A) Devices containing only krypton need not be tested for leakage of radioactive material;

(B) Devices containing only tritium or not more than 100 microcuries of other beta, gamma, or beta and gamma emitting material or ten microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) shall assure that the tests required by Subparagraph (c)(2) of this Rule and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment are performed:

(A) in accordance with the instructions provided on labels affixed to the device, except that tests for leakage or contamination may be performed by the general licensee using leak test kits provided and analyzed by a specific licensee who is authorized to provide leak test kit services; or

(B) by a person holding a specific license or registration which authorizes the providing of services required by this Rule and which is issued pursuant to Rules .0205 and .0306 of this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.

(4) shall maintain records, showing compliance with the requirements in Subparagraphs (c)(2) and (3) of this Rule, to include:

(A) the name of the person(s) performing the test(s) and the date(s) of the test(s);

(B) the name of the person(s) performing installation, servicing and removal of any radioactive material, shielding or containment;

(C) retention of leakage or contamination, on-off mechanism and on-off indicator test records for ~~one year~~ three years after the next required test is performed or until the sealed source is disposed of or transferred~~, whichever is shorter~~;

(D) retention of other records of tests required in Subparagraph (c)(3) of this Rule for ~~two~~ three years from the date of the recorded test or until the device is disposed of or transferred.

(5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been:

(A) repaired by the manufacturer or other person authorized to repair the device(s) by a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state; or

(B) disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device; and within 30 days, furnish to the agency at the address in Rule .0111 of this Chapter a report containing a brief description of the event and the remedial action taken. In the event that 0.005 microcurie or more of removable radioactive contamination is detected, or if the failure of or damage to a source of radiation is likely to result in the contamination of the facility or the environment, a plan for ensuring that the facility and the environment are acceptable for unrestricted use shall be submitted to the agency at the address in Rule .0111 of this Chapter.

(6) shall not abandon the device containing radioactive material;

(7) except as provided in Subparagraph (c)(8) of this Rule, shall transfer or dispose of the device containing radioactive material only by export in accordance with 10 CFR Part 110 or by transfer to a person holding a specific license authorizing receipt of the device; and, ~~prior to~~ within 30 days ~~of~~ after transfer of a device to a specific licesnee or export ~~the transfer~~ of a device ~~to a specific licensee~~, shall furnish to the agency at the address in Rule .0111 of this Chapter, a report that contains:

(A) the identification of the device by manufacturer's or initial transferor's name, model number, and serial number;

(B) the name, address and specific license number of the person receiving the device (license number not applicable if exported); ~~and~~

(C) the date of the transfer~~.~~; and

(D) shall obtain written approval by the agency before transferring the device to any other specific licensee not specifically identified in this Rule; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(i) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(ii) Removes, alters, covers, or clearly and unambiguously augments the existing label otherwise required by paragraph (c)(1) of this section so that the device is labeled in compliance with § .0328(a)(3) of this chapter; however the manufacturer, model number, and serial number must be retained;

(iii) Obtains the manufacturer's or initial transferor's information concerning maintenance that be applicable under the specific license (such as leak testing procedures); and

(iv) Reports the transfer under paragraph (7) of this section.

(8) shall transfer or dispose of the device only by export as provided by (c)(7) of this Rule, or by transfer to another general licensee only where the device:

(A) remains in use at a particular location.

(i) In this case the transferor shall give the transferee a copy of this Section and any safety documents identified in the label of the device;

(ii) The transferor shall, within 30 days of the transfer, report to the agency at the address in Rule .0111 of this Chapter the manufacturer's or initial transferor's name, serial number, and model number of device transferred; the name and mailing address of the transferee; and the name, title, and telephone number of the individual identified by the transferee pursuant to Subparagraph (c)(10) of this Rule as having knowledge of and authority to take actions to ensure compliance with the requirements contained in these Rules; or (B) is held in storage by the licensee or an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(9) shall comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Section .1600 of this Chapter;

(10) shall appoint an individual responsible for having knowledge of the requirements contained in these Rules and the authority for taking the actions required to comply with these Rules. The general licensee, through this individual, shall ensure the day-to-day compliance with these Rules. The

appointment of such an individual does not relieve the general licensee of any of its responsibility in this regard;

(11) shall register, when required by the agency, any source of radiation subject to a general license in accordance with the rules in this Section. Each address for a location of use represents a separate general license and requires a separate registration action;

(12) shall register, on an annual basis, all devices containing, based on the activity indicated on the label, at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37MBq) of cobalt-60, 1 mCi (37 MBq) of americium-241, 0.1 millicurie (3.7 MBq) of radium-226, or any other transuranic isotope. Each address for a location of use represents a separate general license and requires a separate registration action. Annual registration consists of verifying, correcting, or adding to the information provided in a request for annual registration within 30 days of a request from the agency. The general licensee shall furnish the following information for annual registration:

(A) the name and mailing address of the general licensee;

(B) specific information about each device to include the manufacturer or initial transferor, model number, serial number, the radioisotope, and the activity indicated on the label;

(C) the name, title, and telephone number of the responsible person designated as a representative of the general licensee in accordance with Subparagraph (c)(10) of this Rule;

(D) the address or location at which the device(s) are to be used or stored. For portable devices that are granted a general license by the agency, the address of the primary place of storage;

(E) certification by the responsible person designated by the general licensee that the information concerning the device(s) has been verified through a physical inventory and a check of label information; and

(F) certification by the responsible person designated by the general licensee that they are aware of the requirements of the general license.

(13) shall report changes to the mailing address to the agency within 30 days of the effective date of the change;

(14) shall report changes to the name of the general licensee to the agency within 30 days of the effective date of the change;

(15) shall respond to written requests from the agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency a written justification for the request;

~~(15)~~ (16) shall not hold devices that are not in use for longer than two years. If devices that have shutters are not in use, the shutter shall be locked in the closed position. Leak testing is not required during the period of storage; however, when devices are returned to service or transferred to another person, the devices must be tested for leakage and shutter operation. Devices kept in standby for future use shall be excluded from the two year time limit if quarterly physical inventories of these devices are performed while in standby.

(d) The general license in Paragraph (a) of this Rule does not authorize the manufacture or ~~distribution~~ import of devices containing radioactive material.

(e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), .0338, .0342, .0343 and .0345 of this ~~Chpter~~ Chapter and to labeling requirements in Section .1600 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2011; January 1, 2005; January 1, 1994; June 1, 1989.

15A NCAC 11 .0322 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0322 SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES

(a) In addition to the requirements set forth in Rule .0318, .0319, or .0320 of this Section, a specific license for human use of sealed sources shall be issued only if the applicant, or if the application is made by an institution, the individual user:

(1) has training and experience as required by Rule .0117(a)(2) of this Chapter, and

(2) is a physician.

(b) The licensee shall comply with the provisions of Section .0700 of this Chapter and the requirements of Subpart H of 10 CFR Part 35.

(c) For medical use, a licensee may only use:

(1) Sealed sources or devices manufactured, labeled, packaged and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State;

(2) Sealed sources or devices noncommercially transferred from a licensee licensed pursuant to Section .0300 of this Chapter, 10 CFR Part 35, or ~~equivalent regulations of~~ an Agreement State medical use licensee;

(3) Teletherapy sources manufactured and distributed in accordance with 10 CFR Part 30 or the equivalent requirements of an Agreement State;

(4) Brachytherapy sources, photon emitting remote ~~afterlaoder~~ afterloader units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses ~~as approved in~~:

(A) As approved in the Sealed Sources and Device Registry; or

(B) In research ~~Research~~ in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 10 CFR 35.49(a) are met.

(d) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released in accordance with Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and

(B) Visitation authorized by Rule .1611(e) of this Chapter.

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(e) The licensee shall retain records of the radiation safety instruction required in Paragraph (d) of this Rule for three years. The record must include:

(1) List of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. November 1, 2007;
Amended Eff. February 26, 2010.

15A NCAC 11 .1626 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .1626 LABELING REQUIREMENTS AND EXEMPTIONS

(a) The licensee shall ensure that: ~~each container of licensed radioactive material bears a durable, clearly visible label bearing the radiation symbol and the words:~~

(1) each container of licensed radioactive material bears a durable, clearly visible label bearing the radiation symbol and the words:

CAUTION
RADIOACTIVE MATERIAL

or the words:

DANGER
RADIOACTIVE MATERIAL

The label shall also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures~~.~~, and;

(2) each syringe and vial that contains unsealed radioactive material for medical use shall also be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

(b) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(c) Except as required in Paragraph (a)(2) of this rule, ~~A~~ a licensee is not required to label:

(1) containers holding licensed radioactive material in quantities less than the quantities listed in Appendix C to 10 CFR §§ 20.1001 - 20.2401;

(2) containers holding licensed radioactive material in concentrations less than those specified in Table 3 of Appendix B to 10 CFR §§ 20.1001 - 20.2401;

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

(4) containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation,

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

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

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994,~~.~~
Amended August 1, 2011.

Minor Amendments- Part 20, 30, 32, 35, 40, and 70
(71 FR 15005) RATS ID # 2006-1 Effective date 03/27/06
Date Due For State Adoption 03/27/09

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
20. Appendix B	Standards For Protection Against Radiation AList of Elements@	Incorporated by reference in 15A NCAC 11.0117(a)	A	In Appendix B to Part 20, >>List of Elements,== the Element >>Thalium,== Atomic Number 69, should be changed to read as >>Thulium.==			
20. Appendix D	Standards For Protection Against Radiation @United States Nuclear Regulatory Commission Regional Offices@		D	N/A	N/A		
' 30.6	Communications		D	N/A	N/A		
' 32.72	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct	15A NCAC 11.0333 references 32.72	B	**In ' 32.72, paragraph (b)(2)(ii) is revised to read as follows:** (b) * * * (2) * * * (ii) This individual meets the requirements specified in 10 CFR 35.55(b) and 35.59 and the licensee has received an approved license			

	material for medical use under part 35.			amendment identifying this individual as an authorized nuclear pharmacist, or * * * *			
' 32.74	Manufacture and distribution of sources or devices containing byproduct material for medical use.	15A NCAC 11 .0117 incorporates 10 CFR 32 by reference.	B	**In ' 32.74, the introductory text of paragraph (a) is revised to read as follows:** (a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in ' ' 35.400, 35.500, and 35.600 of this chapter will be approved if: * * * * *			
' 35.2	Definitions	15A NCAC 11.0318	B	*Authorized medical physicist* means an individual who: (1) Meets the requirements in ' ' 35.51(a) and 35.59; or			
' 35.2	Definitions	15A NCAC 11.0318	B	*Authorized nuclear pharmacist* means a pharmacist who: (1) Meets the requirements in ' ' 35.55(a) and 35.59; or			
' 35.2	Definitions	15A NCAC 11.0318	B	*Authorized user* means a physician, dentist, or podiatrist who: (1) Meets the requirements in ' ' 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or			
				Radiation Safety Officer means an			

' 35.2	Definitions	15A NCAC 11.0318	B	individual who (1) Meets the requirements in ' ' 35.50(a) or (c)(1) and 35.59; or			
' 35.2	Definitions		D	*Medical event*	N/A		
' 35.8	Information collection requirements: OMB approval.		D	N/A	N/A		
' 35.10	Implementation		D	N/A	N/A		
' 35.13	License Amendments		D	N/A	N/A		
' 35.14	Notifications		D	N/A	N/A		
' 35.49	Suppliers for sealed sources or devices for medical use.	15A NCAC 11.0322(c)	C	**In ' 35.49, paragraph (b) is revised to read as follows:** (b) Sealed sources or devices noncommercially transferred from a Part 35 licensee or an Agreement State medical use licensee.			
' 35.50	Training for Radiation Safety Officer.	15A NCAC 11.0318	B	**In ' 35.50, paragraph (a)(2)(ii)(B) is revised to read as follows:** (a) * * * (2) * * * (ii) * * * (B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the			

				requirements for authorized users in ' ' 35.290 or 35.390;			
' 35.51	Training for an authorized medical physicist.	15A NCAC 11.0318	B	**In ' 35.51, paragraphs (a)(2)(ii) and (b)(2) are revised to read as follows:** (a) * * * (2) * * * (ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in ' ' 35.490 or 35.690; and * * * * * (b) * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in ' 35.51, or equivalent Agreement State requirements for an authorized			

				medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and * * * * *			
' 35.59	Recentness of training.	15A NCAC 11.0318 & .0117	B	**Section 35.59 is revised to read as follows:** The training and experience specified in Subparts B, D, E, F, G, and H of this part must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.			
' 35.65	Authorization for calibration, transmission, and reference sources.		D	N/A	N/A		
' 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.	15A NCAC 11 .0361	H&S	**In ' 35.100, paragraph (b)(2) is revised to read as follows:** b) * * * (2) A physician who is an authorized user and who meets the requirements specified in ' ' 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or * * * * *			
' 35.190	Training for uptake, dilution, and excretion studies.	15A NCAC 11.0318	B	**In ' 35.190, paragraphs (b), (c)(1)(ii) and (c)(2) are revised to read as follows:** (b) Is an authorized user under ' ' 35.290, 35.390, or equivalent Agreement State requirements; or (c)(1)* * *			

				(ii) Work experience, under the supervision of an authorized user who meets the requirements in ' ' 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving C * * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in ' ' 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under ' 35.100.			
' 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.	15A NCAC 11.0361	H&S	**In ' 35.200, paragraph (b)(2) is revised to read as follows:** (b) * * * (2) A physician who is an authorized user and who meets the requirements specified in ' 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or * * * * *			
' 35.290	Training for imaging and localization studies.	15A NCAC 11.0318	B	**In ' 35.290, paragraphs (a)(1), (b), the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (a) * * * (1) Complete 700 hours of training and experience in basic radionuclide			

				handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and * * * * * (b) Is an authorized user under ' 35.390 and meets the requirements in 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or (c)(1) * * * (ii) Work experience, under the supervision of an authorized user, who meets the requirements in '' 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements, involvingC * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in '' 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under '' 35.100 and 35.200.			

' 35.300	Use of unsealed byproduct material for which a written directive is required.	15A NCAC 11.0361	H&S	**In ' 35.300, paragraph (b)(2) is revised to read as follows:** (b) * * * (2) A physician who is an authorized user and who meets the requirements specified in ' ' 35.290, 35.390, or * * * * *			

' 35.390	Training for use of unsealed byproduct material for which a written directive is required.	15A NCAC 11.0318	B	**In ' 35.390, paragraphs (b)(1)(ii) introductory text, (b)(1)(ii)(G)(*3*), and (b)(2) are revised to read as follows:** (b)(1) * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in ' 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in ' 35.390(b), must also have experiencein administering dosages in the same dosage category or categories (*i.e.*,35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involveC * * * * * (G) * * * (*3*) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a			

				photon energy less than 150 keV, for which a written directive is required; and/or * * * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under ' 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in ' 35.390 or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in ' 35.390(b) must have experience in administering dosages in the same dosage category or categories (*i.e.*, ' 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.			
' 35.392	Training for the oral administration of sodium iodide IB131 requiring a written directive	15A NCAC 11.0318	B	**In ' 35.392, paragraph (b), the introductory text of paragraph 8)(2) and paragraph (c)(3) are revised to read as follows:** (b) Is an authorized user under '			

	in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).			35.390 for uses listed in ' 35.390(b)(1)(ii)(G)(*1*) or (*2*), ' 35.394, or equivalent Agreement State requirements; or (c) * * *(2) Has work experience, under the supervision of an authorized user who meets the requirements in ' ' 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in ' 35.390(b) must also have experience in administering dosages as specified in ' 35.390(b)(1)(ii)(G)(*1*) or (*2*). The work experience must involveC * * * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under ' 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in ' ' 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in ' 35.390(b), must also have experience in			

				administering dosages as specified in ' 35.390(b)(1)(ii)(G)(*1*) or (*2*).			
' 35.394	Training for the oral administration of sodium iodide IB131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).	15A NCAC 11 .0318	B	**In ' 35.394, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:** (b) Is an authorized user under ' 35.390 for uses listed in ' 35.390(b)(1)(ii)(G)(*2*) or equivalent Agreement State requirements; or (c) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in ' ' 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in ' 35.390(b), must also have experience in administering dosages as specified in ' 35.390(b)(1)(ii)(G)(*2*). The work experience must involveC * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under ' 35.300. The written attestation must be signed by a			

				preceptor authorized user who meets the requirements in ' ' 35.390, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in ' 35.390(b), must also have experience in administering dosages as specified in ' 35.390(b)(1)(ii)(G)(*2*).			
' 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.	15A NCAC 11.0318	B	**In ' 35.396, the introductory paragraph, paragraphs (a), (b), (c), the introductory text of paragraphs (d)(1) and (d)(2), paragraph (d)(2)(vi), and paragraph (d)(3) are revised to read as follows:** Except as provided in ' 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who: (a) Is an authorized user under ' 35.390 for uses listed in ' ' 35.390(b)(1)(ii)(G)(*3*) or 35.390(b)(1)(ii)(G)(*4*), or equivalent Agreement State requirements; or (b) Is an authorized user under ' ' 35.490, 35.690, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or (c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under ' ' 35.490 or 35.690, and who meets			

				the requirements in paragraph (d) of this section. (d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include* * * * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in '' 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in ' 35.390 must have experience in administering dosages as specified in '' 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*). The work experience must involve* * * * * *			

				(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in ' ' 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in ' 35.390, must have experience in administering dosages as specified in ' ' 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*).			
' 35.490	Training for use of	15A	B	**In ' 35.490, the introductory text of paragraph (b)(1)(ii), and paragraphs**			

	manual brachytherapy sources.	NCAC 11.0318		**(b)(2), and (b)(3) are revised to read as follows:** (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in ' 35.490 or equivalent Agreement State requirements at a medical institution, involvingC * * * * * (2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in ' 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in ' 35.490 or			

				equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under ' 35.400.			
35.491	Training for ophthalmic use of strontium-90.	15A NCAC 11.0318	B	**In ' 35.491, paragraphs (a) and (b)(3) are revised to read as follows:** (a) Is an authorized user under ' 35.490 or equivalent Agreement State requirements; or(b) * * * (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in '' 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.			
35.690	Training for use of remote afterloader units, teletherapy units, and gamma	15A NCAC 11.0318	B	**In ' 35.690, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2), and (b)(3) are revised to read as follows:**			

	stereotactic radiosurgery units.			(b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in ' 35.690 or, equivalent Agreement State requirements at a medical institution, involving* * * * * * (2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in ' 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, and has achieved a level of			

				competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in ' 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and * * * * *			
' 40.5	Communications		D	N/A	N/A		
' 70.5	Communications		D	N/A	N/A		
' 70.14	Foreign military aircraft		D	N/A	N/A		

15A NCAC 11 .0117 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0117 INCORPORATION BY REFERENCE

(a) For the purpose of the rules in this Chapter, the following rules, standards and other requirements are hereby incorporated by reference including any subsequent amendments and editions:

(1) Appendix A, Appendix B, Appendix C, and Appendix G to 10 CFR Parts 20.1001 - 20.2401;

(2) 10 CFR Part 21, 10 CFR Part 30.1, 30.4, 30.10, 10 CFR Part 31, 10 CFR Part 32, Subpart J of 10 CFR Part 35, 10 CFR 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, Subpart H of 10 CFR Part 35, 35.1000, 10 CFR Part 36, 10 CFR Part 40~~ and 10 CFR Part 50~~;

~~(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71, 10 CFR Part 73, 10 CFR Part 110, 10 CFR Part 140 and 10 CFR Part 150;~~

(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71.0, 71.1, 71.2, 71.3, 71.4, 71.5, 71.8, 71.14(a), 71.15, 71.17(a) – (d), 71.20, 71.21, 71.22, 71.23, 71.47, Subpart G of 10 CFR Part 71, 10 CFR 71.101(a) – (c)(1), 71.101(f), 71.101(g), 71.103, 71.105, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, Appendix A to 10 CFR Part 71, and 10 CFR Part 150;

(4) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040;

(5) 39 CFR Part 14 and 39 CFR Part 15;

(6) Postal Service Manual (Domestic Mail Manual) Section 124.3 [incorporated by reference in 39 CFR Section 111.11];

(7) 40 CFR Part 261;

(8) 49 CFR Parts 100-189;

(9) "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended", signed July 21, 1964;

(10) "Standards and Specifications for Geodetic Control Networks (September 1984);

(11) "Geometric Geodetic Survey Accuracy Standards and Specifications for Geodetic Surveys Using GPS Relative Positioning Techniques";

(12) "Reference Man: Anatomical, Physiological and Metabolic Characteristics" (ICRP Publication No. 23) of the International Commission on Radiological Protection;

(13) "10 CFR, Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 FR 7540"; and

(14) American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography".

(b) The rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule are available for inspection at the ~~Department of Environment and Natural Resources, Division of Radiation Protection~~ Agency at the address listed in Rule .0111 of this Section. Except as noted in the Subparagraphs of this Paragraph, copies of the rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 at a cost as follows:

(1) Three dollars ($3.00) for the appendixes listed in Subparagraph (a)(1) of this Rule, available from the ~~Division of Radiation Protection~~ Agency;

(2) Twenty-five dollars ($25.00) for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts 0-50;

(3) Eighteen dollars ($18.00) for the regulations listed in Subparagraph (a)(3) of this Rule in a volume containing 10 CFR Parts 51-199;

(4) Eighteen dollars ($18.00) for the regulations listed in Subparagraph (a)(4) of this Rule in a volume containing 21 CFR Parts 800-1299;

(5) Sixteen dollars ($16.00) for the regulations listed in Subparagraph (a)(5) of this Rule in a volume containing 39 CFR;

(6) Thirty-six dollars ($36.00) for the manual listed in Subparagraph (a)(6) of this Rule;

(7) Thirty-one dollars ($31.00) for the regulations listed in Subparagraph (a)(7) of this Rule in a volume containing 40 CFR Parts 260-299;

(8) For the regulations listed in Subparagraph (a)(8) of this Rule:

(A) Twenty-three dollars ($23.00) for a volume containing 49 CFR Parts 100-177; and

(B) Seventeen dollars ($17.00) for a volume containing 49 CFR Parts 178-199;

(9) One dollar ($1.00) for the agreement in Subparagraph (a)(9) of this Rule, available from the ~~Division of Radiation Protection~~ Agency;

(10) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(10) of this Rule, available from the National Geodetic Information Center, N/CG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(11) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(11) of this Rule, available from the National Geodetic Information Center, NCG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(12) One hundred and five dollars ($105.00) for the ICRP Publication No. 23 in Subparagraph (a)(12) of this Rule, available from Pergamon Press, Inc., Maxwell House, Fairview Park, Elmsford, NY 10523;

(13) Two dollars ($2.00) for the document in Subparagraph (a)(13) of this Rule, available from the ~~Division of Radiation Protection~~ Agency; and

(14) Thirty-eight dollars plus five dollars shipping and handling ($43.00) for the American National Standard N432-1980 in Subparagraph (a)(14) of this Rule, available from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, telephone number (212) 642-4900.

(c) Nothing in this incorporation by reference of 10 CFR Part 61 in Subparagraph (a)(3) of this Rule shall limit or affect the continued applicability of G.S. 104E-25(a) and (b).

History Note: *Authority G.S. 104E-7; 104E-15(a); 150B-21.6;*
Eff. June 1, 1993;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff., *August 1, 2011;* *November 1, 2007; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.*

15A NCAC 11 .0318 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE

(a) For the purposes of this Rule "Authorized medical physicist" means an individual who:

(1) Meets the requirements in 10 CFR 35.51(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.961(a), or (b), and 35.59;~~ or

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

(A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State;

(B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material licensee;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

(b) For the purposes of this Rule, "Authorized nuclear pharmacist" means a pharmacist who:

(1) Meets the requirements in 10 CFR 35.55(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.980(a) and 35.59;~~ or

(2) Is identified as an authorized nuclear pharmacist on:

(A) A specific license issued by the U.S. Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(B) A permit issued by the U.S. Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use license that authorizes medical use or the practice of nuclear pharmacy; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

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

(4) Is designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(4).

(c) For the purposes of this Rule "Authorized user" means a physician, dentist, or podiatrist who:

(1) Meets the requirements in 10 CFR 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), 35.491(a), 35.590(a), or 35.690(a); ~~or on or before October 24, 2005, met the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59;~~ or

(2) Is identified as an authorized user on:

(A) A U.S. Nuclear Regulatory Commission or Agreement State license that authorizes medical use of radioactive material;

(B) A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(d) For the purposes of this Rule "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.

(e) For the purposes of this Rule "Brachytherapy source" means a radioactive source or a manufacture-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(f) For the purposes of this Rule "High dose-rate remote afterloader" 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.

(g) For the purposes of this Rule "Low dose-rate remote afterloader" 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.

(h) For the purposes of this Rule "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., 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.

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

(j) For the purposes of this Rule "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.

(k) For the purposes of this Rule "Pulsed dose-rate 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:

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

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

(l) For the purposes of this Rule "Radiation safety officer" as used in this Section, means an individual who:

(1) Meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59; ~~or, before October 24, 2005, met the requirements of 10 CFR 35.900(a) and 35.59, as incorporated by reference in 15A NCAC 11 .0117;~~ or

(2) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the U.S. or an Agreement State; or

(B) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(m) For the purposes of this Rule "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.

(n) For the purposes of this Rule "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.

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

(p) License required:

(1) A person shall not manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific license issued by the agency or as allowed pursuant to Subparagraphs (p)(2) and (p)(3) of this Rule.

(2) An individual may receive, possess, use, or transfer radioactive material in accordance with the rules of this Section under the supervision of an authorized user as provided in this Section unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the rules of this Section under the supervision of a pharmacist who is an authorized user or physician who is an authorized user as provided in this Section unless prohibited by license condition.

(q) A license application for human use of radioactive material shall be approved if the agency determines that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;

(3) The issuance of the license will not be inimical to the health and safety of the public;

(4) The following training and supervisory relationship are adhered to:

(A) the user of radioisotopes applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a specific license, including a specific license of broad scope.

(B) An authorized physician may delegate only to persons who are physicians under the supervision of the authorized physician, the following:

(i) the approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope

sources;

(ii) the prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered;

(iii) the determination of the route of administration; and

(iv) the interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

(C) The authorized physician shall review the work of the supervised individual as it pertains to the delegated work in Subparagraph (q)(4) of this Rule and the records kept reflecting that work.

(5) the applicant satisfies any applicable requirements in Rules .0319 to .0322 of this Section.

(r) Subject to the provisions of Subparagraph (q)(4) and Paragraphs (s) to (v) of this Rule, an authorized physician may permit technicians and other paramedic personnel to perform the following activities:

(1) preparation and quality control testing of radiopharmaceuticals and sources of radiation;

(2) measurement of radiopharmaceutical doses prior to administration;

(3) use of appropriate instrumentation for the collection of data to be used by the physician;

(4) administration of radiopharmaceuticals and radiation from radioisotope sources to patients.

(s) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (r) of this Rule shall:

(1) prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with training in the following subjects, as applicable to the duties assigned:

(A) general characteristics of radiation and radioactive materials;

(B) physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used;

(C) mathematics and calculations basic to the use and measurement of radioactivity, including units of radiation dose and radiation exposure;

(D) use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;

(E) principles and practices of radiation protection;

(F) additional training in the above subjects, as appropriate, when new duties are added.

(2) assure that the technicians and other paramedical personnel receive retraining in the subjects listed in Subparagraph (s)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;

(3) keep records showing the bases for the determinations of proper training;

(4) retain responsibility as licensee or authorized user for the satisfactory performance of the activites; and

(5) review the work of the supervised individual and the records kept reflecting that work.

(t) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medicine technology by the Nuclear Medicine Technologist Certification Board or the Society of Nuclear Medicine shall be deemed to satisfy the training requirements in Subparagraphs (s)(1) and (2) of this Rule.

(u) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (r) of this Rule and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.

(v) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be immediately accessible, but not necessarily a physician authorized by the agency to be a user of radioisotopes.

(w) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall:

(1) In addition to the requirements in Rule .1003 of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, this Chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for ~~medial~~ medical uses of radioactive material, written radiation protection procedures established by the

licensee, written directive procedures, rules of this Chapter, and license conditions with respect to the medical use of radioactive material.

(x) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user shall:

(1) In addition to the requirements in Paragraph (s) of this Rule and Rule .1003 of this Chapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules of this Chapter, and license conditions.

(y) A licensee that permits supervised activities under Paragraphs (r) and (s) of this Rule is responsible for the acts and omissions of the supervised individual.

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

(aa) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(bb) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and management prerogative to:

(1) identify radiation safety problems;

(2) investigate radiation safety problems such as overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, medical events, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(3) initiate, recommend or provide corrective actions for radiation safety problems;

(4) verify implementation of corrective actions; and

(5) retain records of items listed in Subparagraphs (1) through (4) of this Paragraph.

(cc) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released in accordance with the requirements of Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and

(B) Visitation authorized by Rule .1611(e) of this Chapter;

(3) Contamination control;

(4) Waste control;

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(dd) The licensee shall retain records of the radiation safety instructions required by Paragraphs (w), (x), and (cc) for three years. The record must include:

(1) List of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2011, November 1, 2007; April 1, 1999; May 1, 1993; November 1, 1989.

15A NCAC 11 .0322 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0322 SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES

(a) In addition to the requirements set forth in Rule .0318, .0319, or .0320 of this Section, a specific license for human use of sealed sources shall be issued only if the applicant, or if the application is made by an institution, the individual user:

(1) has training and experience as required by Rule .0117(a)(2) of this Chapter, and

(2) is a physician.

(b) The licensee shall comply with the provisions of Section .0700 of this Chapter and the requirements of Subpart H of 10 CFR Part 35.

(c) For medical use, a licensee may only use:

(1) Sealed sources or devices manufactured, labeled, packaged and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State;

(2) Sealed sources or devices noncommercially transferred from a licensee licensed pursuant to Section .0300 of this Chapter, 10 CFR Part 35, or ~~equivalent regulations of~~ an Agreement State medical use licensee;

(3) Teletherapy sources manufactured and distributed in accordance with 10 CFR Part 30 or the equivalent requirements of an Agreement State;

(4) Brachytherapy sources, photon emitting remote ~~afterlaoder~~ afterloader units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses ~~as approved in~~:

(A) As approved in the Sealed Sources and Device Registry; or

(B) In research ~~Research~~ in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 10 CFR 35.49(a) are met.

(d) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released in accordance with Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and

(B) Visitation authorized by Rule .1611(e) of this Chapter.

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(e) The licensee shall retain records of the radiation safety instruction required in Paragraph (d) of this Rule for three years. The record must include:

(1) List of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. November 1, 2007;
Amended Eff. February 26, 2010.

15A NCAC 11 .0333 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS

An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule .0318, .0319, or .0320 of this Section for ~~the radiopharmaceuticals and associated uses in Groups I, II or IV~~ medical use shall be approved subject to the following conditions:

(1) the applicant satisfies the requirements of Rule .0317 of this Section; and

(2) the applicant meets the applicable requirements in Section 32.72 of 10 CFR Part 32, and Section 30.32 (j) of 10 CFR Part 30.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. November 1, 2007
Amended August 1, 2011.

15A NCAC 11 .0361 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL

(a) A licensee may use any unsealed radioactive material prepared for use for uptake, dilution, or excretion studies, imaging and localization studies and radiopharmaceutical therapy that is:

(1) Obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements; or

(2) ~~Prepared by:~~ A positron emission tomography (PET) radioactive drug producer licensed under 10 CFR 30.32(j), 15A NCAC 11 .0333, or equivalent Agreement State requirements; or

~~(A) An authorized nuclear pharmacist;~~

~~(B) A physician who is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0117(a)(2);~~

~~(C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(2)(A) of this Rule or the physician who is an authorized user in Part (a)(2)(B) of this Rule;~~

(3) Excluding production of PET radionuclides, prepared by:

(A) An authorized nuclear pharmacist;

(B) A physician who is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0117(a)(2);

(C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(2)(A) of this Rule or the physician who is an authorized user in Part (a)(2)(B) of this Rule;

~~(3)~~ (4) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA; or

~~(4)~~ (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA.

(b) A licensee shall not administer to humans a radiopharmaceutical that contains: ~~containing more than 0.15 microcurie (0.15 kilobecquerel) of molybdenum-99 per millicurie (megabecquerel) of technetium-99m.~~

(1) more than 0.15 microcurie (0.15 kilobecquerel) of molybdenum-99 per millicurie (megabecquerel) of technetium-99m.

(2) more than 0.02 microcurie (0.02 kilobequerel) of strontium-82 per millicurie (megabequerel) of rubidium-82 chloride, or 0.2 microcurie (0.2 kilobequerel) of strontium-85 per millicurie (megabequerel) of rubidium-82 chloride.

~~(c) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in the first eluate after receipt of a generator to demonstrate compliance with Paragraph (b) of this Rule.~~

(c) (1) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in the first eluate after receipt of a generator to demonstrate compliance with Paragraph (b) of this Rule.

(2) A licensee that uses strontium-82/rubidium-82 generators for preparing a rubidium-82 radiopharmaceutical shall measure the concentrations of strontium-82 and strontium-85 before the first patient use of the day to demonstrate compliance with Paragraph (b) of this Rule.

(d) A licensee that must measure molybdenum-99, or strontium-82 and strontium-85, concentration shall retain a record of each measurement for three years. The record shall include: ~~for each measured elution of technetium-99m:~~

(1) for each measured elution of technetium-99m: the ratio of the measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m (or kilobecquerels of molybdenum-99 per megabecquerel of technetium-99m); or

(2) for each measured elution of rubidium-82: the ratio of the measures expressed as microcuries of strontium-82 and strontium-85 per millicurie of rubidium-82 (or kilobequerel strontium-82 and strontium-85 per megabequerel rubidium-82); and

~~(2)~~(3) the time and date of the measurement; and

~~(3)~~(4) the initials of the individual who made the measurement.

History Note Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12;
Eff. April 1, 1999;
Amended Eff. August 1, 2011, November 1, 2007.

Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
(72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
Date Due for State Adoption 10/29/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
'32.72 (b)(5)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.	.0333 and .0117	B	**In Sec. 32.72, paragraph (b)(5) is revised to read as follows:** (b) * * * (5) Shall provide to the Commission a copy of each individual's: (i)(A) Certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in Sec. 35.55(a) of this chapter with the written attestation signed by a preceptor as required by Sec. 35.55(b)(2) of this chapter; or (B) The Commission or Agreement State license; or (C) The permit issued by a licensee of broad scope; and (ii) State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.			

Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
(72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
Date Due for State Adoption 10/29/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
'32.74(a)	Manufacture and distribution of sources or devices containing byproduct material for medical use	0117. OK, Part 32 incorporated by reference	B	**In Sec. 32.74, the introductory text of paragraph (a) is revised to read as follows:** (a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in Sec. Sec. 35.400, 35.500, 35.600, and 35.1000 of this chapter will be approved if: * * * * *			
'35.2	Definitions: Medium dose-rate remote afterloader		D	N/A	N/A		No action needed, but is defined in .0318
'35.41(b)(4)	Procedures for administrations requiring a written directive		D	N/A	N/A		No action needed, but is in .0356
'35.75(a)	Release of individuals containing	.0358 No change required	C	**In Sec. 35.75, the text of paragraph (a) is republished and footnote 1**			

Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
(72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
Date Due for State Adoption 10/29/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
	unsealed byproduct material or implants containing byproduct material			**is revised to read as follows:** a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).\1\ * * * * * \1\ The current revision of NUREG-1556, Vol. 9, ``Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses'' describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).			
'35.92	Decay-in-storage is an: "H&S" for States authorizing this	.0362, $T_{1/2}$ increased to 275 days as desired by	H & S	**In Sec. 35.92, the introductory text of paragraph (a) is revised to read as follows:**			

Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
(72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
Date Due for State Adoption 10/29/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
	activity and "D" for States that do not authorize this activity	the NC RPC.		(a) A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it-- * * * * *			
'35.190	Training for uptake, dilution, and excretion studies	.0318.	B	**In Sec. 35.190, paragraph (a)(1) is revised to read as follows:** (a) * * * (1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and * * * * *			
'35.290	Training for imaging and localization studies	0318	B	**10. In Sec. 35.290, paragraph (a)(1) is revised to read as follows:** (a) * * * (1) Complete 700 hours of			

Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
(72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
Date Due for State Adoption 10/29/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and * * * * *			

15A NCAC 11 .0117 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0117 INCORPORATION BY REFERENCE

(a) For the purpose of the rules in this Chapter, the following rules, standards and other requirements are hereby incorporated by reference including any subsequent amendments and editions:

(1) Appendix A, Appendix B, Appendix C, and Appendix G to 10 CFR Parts 20.1001 - 20.2401;

(2) 10 CFR Part 21, 10 CFR Part 30.1, 30.4, 30.10, 10 CFR Part 31, 10 CFR Part 32, Subpart J of 10 CFR Part 35, 10 CFR 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, Subpart H of 10 CFR Part 35, 35.1000, 10 CFR Part 36, 10 CFR Part 40~~ and 10 CFR Part 50~~;

~~(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71, 10 CFR Part 73, 10 CFR Part 110, 10 CFR Part 140 and 10 CFR Part 150;~~

(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71.0, 71.1, 71.2, 71.3, 71.4, 71.5, 71.8, 71.14(a), 71.15, 71.17(a) – (d), 71.20, 71.21, 71.22, 71.23, 71.47, Subpart G of 10 CFR Part 71, 10 CFR 71.101(a) – (c)(1), 71.101(f), 71.101(g), 71.103, 71.105, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, Appendix A to 10 CFR Part 71, and 10 CFR Part 150;

(4) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040;

(5) 39 CFR Part 14 and 39 CFR Part 15;

(6) Postal Service Manual (Domestic Mail Manual) Section 124.3 [incorporated by reference in 39 CFR Section 111.11];

(7) 40 CFR Part 261;

(8) 49 CFR Parts 100-189;

(9) "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended", signed July 21, 1964;

(10) "Standards and Specifications for Geodetic Control Networks (September 1984);

(11) "Geometric Geodetic Survey Accuracy Standards and Specifications for Geodetic Surveys Using GPS Relative Positioning Techniques";

(12) "Reference Man: Anatomical, Physiological and Metabolic Characteristics" (ICRP Publication No. 23) of the International Commission on Radiological Protection;

(13) "10 CFR, Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 FR 7540"; and

(14) American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography".

(b) The rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule are available for inspection at the ~~Department of Environment and Natural Resources, Division of Radiation Protection~~ Agency at the address listed in Rule .0111 of this Section. Except as noted in the Subparagraphs of this Paragraph, copies of the rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 at a cost as follows:

(1) Three dollars ($3.00) for the appendixes listed in Subparagraph (a)(1) of this Rule, available from the ~~Division of Radiation Protection~~ Agency;

(2) Twenty-five dollars ($25.00) for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts 0-50;

(3) Eighteen dollars ($18.00) for the regulations listed in Subparagraph (a)(3) of this Rule in a volume containing 10 CFR Parts 51-199;

(4) Eighteen dollars ($18.00) for the regulations listed in Subparagraph (a)(4) of this Rule in a volume containing 21 CFR Parts 800-1299;

(5) Sixteen dollars ($16.00) for the regulations listed in Subparagraph (a)(5) of this Rule in a volume containing 39 CFR;

(6) Thirty-six dollars ($36.00) for the manual listed in Subparagraph (a)(6) of this Rule;

(7) Thirty-one dollars ($31.00) for the regulations listed in Subparagraph (a)(7) of this Rule in a volume containing 40 CFR Parts 260-299;

(8) For the regulations listed in Subparagraph (a)(8) of this Rule:

(A) Twenty-three dollars ($23.00) for a volume containing 49 CFR Parts 100-177; and

(B) Seventeen dollars ($17.00) for a volume containing 49 CFR Parts 178-199;

(9) One dollar ($1.00) for the agreement in Subparagraph (a)(9) of this Rule, available from the ~~Division of Radiation Protection~~ Agency;

(10) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(10) of this Rule, available from the National Geodetic Information Center, N/CG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(11) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(11) of this Rule, available from the National Geodetic Information Center, NCG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(12) One hundred and five dollars ($105.00) for the ICRP Publication No. 23 in Subparagraph (a)(12) of this Rule, available from Pergamon Press, Inc., Maxwell House, Fairview Park, Elmsford, NY 10523;

(13) Two dollars ($2.00) for the document in Subparagraph (a)(13) of this Rule, available from the ~~Division of Radiation Protection~~ Agency; and

(14) Thirty-eight dollars plus five dollars shipping and handling ($43.00) for the American National Standard N432-1980 in Subparagraph (a)(14) of this Rule, available from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, telephone number (212) 642-4900.

(c) Nothing in this incorporation by reference of 10 CFR Part 61 in Subparagraph (a)(3) of this Rule shall limit or affect the continued applicability of G.S. 104E-25(a) and (b).

History Note: *Authority G.S. 104E-7; 104E-15(a); 150B-21.6;*
Eff. June 1, 1993;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff., *August 1, 2011;* *November 1, 2007; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.*

15A NCAC 11 .0318 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE

(a) For the purposes of this Rule "Authorized medical physicist" means an individual who:

(1) Meets the requirements in 10 CFR 35.51(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.961(a), or (b), and 35.59;~~ or

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

(A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State;

(B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material licensee;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

(b) For the purposes of this Rule, "Authorized nuclear pharmacist" means a pharmacist who:

(1) Meets the requirements in 10 CFR 35.55(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.980(a) and 35.59;~~ or

(2) Is identified as an authorized nuclear pharmacist on:

(A) A specific license issued by the U.S. Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(B) A permit issued by the U.S. Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use license that authorizes medical use or the practice of nuclear pharmacy; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

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

(4) Is designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(4).

(c) For the purposes of this Rule "Authorized user" means a physician, dentist, or podiatrist who:

(1) Meets the requirements in 10 CFR 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), 35.491(a), 35.590(a), or 35.690(a); ~~or on or before October 24, 2005, met the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59;~~ or

(2) Is identified as an authorized user on:

(A) A U.S. Nuclear Regulatory Commission or Agreement State license that authorizes medical use of radioactive material;

(B) A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(d) For the purposes of this Rule "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.

(e) For the purposes of this Rule "Brachytherapy source" means a radioactive source or a manufacture-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(f) For the purposes of this Rule "High dose-rate remote afterloader" 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.

(g) For the purposes of this Rule "Low dose-rate remote afterloader" 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.

(h) For the purposes of this Rule "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., 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.

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

(j) For the purposes of this Rule "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.

(k) For the purposes of this Rule "Pulsed dose-rate 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:

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

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

(l) For the purposes of this Rule "Radiation safety officer" as used in this Section, means an individual who:

(1) Meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59; ~~or, before October 24, 2005, met the requirements of 10 CFR 35.900(a) and 35.59, as incorporated by reference in 15A NCAC 11 .0117;~~ or

(2) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the U.S. or an Agreement State; or

(B) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(m) For the purposes of this Rule "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.

(n) For the purposes of this Rule "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.

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

(p) License required:

(1) A person shall not manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific license issued by the agency or as allowed pursuant to Subparagraphs (p)(2) and (p)(3) of this Rule.

(2) An individual may receive, possess, use, or transfer radioactive material in accordance with the rules of this Section under the supervision of an authorized user as provided in this Section unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the rules of this Section under the supervision of a pharmacist who is an authorized user or physician who is an authorized user as provided in this Section unless prohibited by license condition.

(q) A license application for human use of radioactive material shall be approved if the agency determines that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;

(3) The issuance of the license will not be inimical to the health and safety of the public;

(4) The following training and supervisory relationship are adhered to:

(A) the user of radioisotopes applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a specific license, including a specific license of broad scope.

(B) An authorized physician may delegate only to persons who are physicians under the supervision of the authorized physician, the following:

(i) the approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope

sources;

(ii) the prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered;

(iii) the determination of the route of administration; and

(iv) the interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

(C) The authorized physician shall review the work of the supervised individual as it pertains to the delegated work in Subparagraph (q)(4) of this Rule and the records kept reflecting that work.

(5) the applicant satisfies any applicable requirements in Rules .0319 to .0322 of this Section.

(r) Subject to the provisions of Subparagraph (q)(4) and Paragraphs (s) to (v) of this Rule, an authorized physician may permit technicians and other paramedic personnel to perform the following activities:

(1) preparation and quality control testing of radiopharmaceuticals and sources of radiation;

(2) measurement of radiopharmaceutical doses prior to administration;

(3) use of appropriate instrumentation for the collection of data to be used by the physician;

(4) administration of radiopharmaceuticals and radiation from radioisotope sources to patients.

(s) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (r) of this Rule shall:

(1) prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with training in the following subjects, as applicable to the duties assigned:

(A) general characteristics of radiation and radioactive materials;

(B) physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used;

(C) mathematics and calculations basic to the use and measurement of radioactivity, including units of radiation dose and radiation exposure;

(D) use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;

(E) principles and practices of radiation protection;

(F) additional training in the above subjects, as appropriate, when new duties are added.

(2) assure that the technicians and other paramedical personnel receive retraining in the subjects listed in Subparagraph (s)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;

(3) keep records showing the bases for the determinations of proper training;

(4) retain responsibility as licensee or authorized user for the satisfactory performance of the activites; and

(5) review the work of the supervised individual and the records kept reflecting that work.

(t) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medicine technology by the Nuclear Medicine Technologist Certification Board or the Society of Nuclear Medicine shall be deemed to satisfy the training requirements in Subparagraphs (s)(1) and (2) of this Rule.

(u) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (r) of this Rule and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.

(v) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be immediately accessible, but not necessarily a physician authorized by the agency to be a user of radioisotopes.

(w) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall:

(1) In addition to the requirements in Rule .1003 of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, this Chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for ~~medial~~ medical uses of radioactive material, written radiation protection procedures established by the

licensee, written directive procedures, rules of this Chapter, and license conditions with respect to the medical use of radioactive material.

(x) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user shall:

(1) In addition to the requirements in Paragraph (s) of this Rule and Rule .1003 of this Chapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules of this Chapter, and license conditions.

(y) A licensee that permits supervised activities under Paragraphs (r) and (s) of this Rule is responsible for the acts and omissions of the supervised individual.

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

(aa) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(bb) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and management prerogative to:

(1) identify radiation safety problems;

(2) investigate radiation safety problems such as overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, medical events, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(3) initiate, recommend or provide corrective actions for radiation safety problems;

(4) verify implementation of corrective actions; and

(5) retain records of items listed in Subparagraphs (1) through (4) of this Paragraph.

(cc) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released in accordance with the requirements of Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and

(B) Visitation authorized by Rule .1611(e) of this Chapter;

(3) Contamination control;

(4) Waste control;

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(dd) The licensee shall retain records of the radiation safety instructions required by Paragraphs (w), (x), and (cc) for three years. The record must include:

(1) List of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2011, November 1, 2007; April 1, 1999; May 1, 1993; November 1, 1989.

15A NCAC 11 .0333 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS

An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule .0318, .0319, or .0320 of this Section for ~~the radiopharmaceuticals and associated uses in Groups I, II or IV~~ medical use shall be approved subject to the following conditions:

(1) the applicant satisfies the requirements of Rule .0317 of this Section; and

(2) the applicant meets the applicable requirements in Section 32.72 of 10 CFR Part 32, and Section 30.32 (j) of 10 CFR Part 30.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. November 1, 2007
Amended August 1, 2011.

15A NCAC 11 .0358 RELEASE OF PATIENTS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS

(a) A licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (5 mSv).

(b) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 100 millirem (1 mSv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1 mSv) assuming there were no interruption of breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the consequences of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at one meter;

(3) Using the biological or effective half-live; or

(4) Considering the shielding by tissue.

(d) The licensee shall maintain a record, for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 500 millirem (5 mSv).

History Note: Authority G.S. 104E-7(a)(8);
Eff. August 1, 1998.

15A NCAC 11 .0362 IS PROPOSED FOR AMENDMENT AS FOLLOWS:

15A NCAC 11 .0362 DECAY-IN-STORAGE

(a) A licensee may hold radioactive material with a physical half-life of less than ~~165~~ 275 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of Rule .1628 of this Chapter if the licensee:

(1) holds radioactive material for decay a minimum of 10 half-lives;

(2) monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter capable of detecting a dose rate of 0.1 millirem (1 microsievert) per hour and with no interposed shielding; and

(3) removes or obliterates all radiation labels.

(b) A licensee shall retain a record of each disposal permitted under Paragraph (a) of this Rule for three years. The record shall include the date of the disposal, the date on which radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate used, and the dose rate measured at the surface of each waste container.

History Note: *Authority G.S. 104E-7(a)(2); 104E-10(b);*
Eff. April 1, 1999;
Amended August 1, 2011.

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§30.14	Exempt Concentrations	.0303	B	**In Sec. 30.14, paragraphs (c) and (d) are revised to read as follows:** (c) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in §30.70 and introduced into the product or material by a licensee holding a specific license issued by the Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or			

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				other commodity or product designed for ingestion or inhalation by, or application to, a human being. (d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11 of this chapter.			
§30.15	Certain items containing byproduct material	.0305	B	**In Sec. 30.15, paragraphs (a)(2), (a)(4), (a)(6), and (a)(10) are removed and reserved, paragraphs (a)(3) and (a)(5) are revised, and paragraph (a)(7) is added to read as follows:** (a)*** (2) [Reserved]			

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				(3) Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007. (4) [Reserved] (5) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007. (6) [Reserved] (7) Ionization chamber smoke detectors containing not more than 1 microcurie (µCi) of americium-241 per detector in			

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				the form of a foil and designed to protect life and property from fires.*** (10) [Reserved]			
§30.16	Resins containing scandium-46 and designed for sand consolidation in oil wells	.0305	B	[Removed]			
§30.18	Exempt quantities	.0304	B	**In Sec. 30.18 paragraph (a) is revised and paragraph (e) is added to read as follows:** (a) Except as provided in paragraphs (c) through (e) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in part 30 through 34, 36 and 39 of this chapter to			

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				the extent that such person receives, posses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in §30.71, Schedule B. (e) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in § 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§31.5	Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere	.0309	B	**In Sec. 31.5, paragraph (c)(8)(ii) introductory text and paragraph (c)(8)(iii) are revised to read as follows:** (c)*** (8)*** (ii) Shall within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in §30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/ GLTS. The report must contain- *** (iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(I) of this section; however a			

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				holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder: (A) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use; (B) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by (c)(1) of this section) so that the device is labeled in compliance with §20.1904 of this chapter; however the manufacturer, model number, and serial number must be retained; (C) Obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak			

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				testing procedures); and (D) Reports the transfer under paragraph (c)(8)(ii) of this section.			
§32.8	Information collection requirements: OMB approval		D	N/A	N/A		NA
§32.11	Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.		NRC*** **(***please note all of 10 CFR 32.11 has been changed from a Compatibility Category C/B to a Compatibility Category NRC)**	**In Sec. 32.11, paragraph (a) is revised to read as follows:** (a) Satisfies the general requirements specified in § 30.33(a)(2) and (3) do not apply to an application for a license to introduce byproduct material into a product or material owned by or in the possession of the license or another and the transfer of ownership or possession of the product or material containing byproduct material, if the possession and use of the byproduct material to be introduced is authorized by a license issued by an Agreement			NA-NRC NA-NRC

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				State;			
§32.12	Same: Records and material transfer reports		NRC*** **(***please note 10 CFR 32.12 has been changed from a Compatibility Category C to a Compatibility Category NRC)**	**Sec. 32.12 is revised to read as follows:** (a) Each person licensed under §32.11 shall maintain records of transfer of byproduct material and file a report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in §30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/ Exempt Distribution. (1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee. (2) The report must indicate that the byproduct material is			NA-NRC NA-NRC

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				transferred for use under §30.14 of this chapter or equivalent regulations of an Agreement State. (b) The report must identify the: (1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period; (2) Name and address of the person who owned or possessed the product or material into which byproduct material has been introduced, at the time of the introduction; (3) The type and quantity of radionuclide introduced into each product or material; and (4) The initial concentrations of the radionuclide in the product or material at the time of transfer to the byproduct material by the licensee.			NA-NRC

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				(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission or to an Agreement State. (2) Licensees who permanently discontinue activities authorized by the license issued under §32.11 shall file a report for the current calendar year within 30 days after ceasing distribution. (d) if no transfers of byproduct material have been made under §32.11 during the reporting period, the report must so indicate. (e)The license shall maintain the record of a transfer for one			NA-NRC

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				year after the transfer is included in a report to the Commission.			
§32.13	Same: Prohibition of introduction	.0303	C	**Sec. 32.13 is revised to read as follows:** No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under §30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under §32.11.			
§32.14	Certain items containing byproduct material; Requirements for license to apply or initially transfer		NRC	**Sec. 32.14 paragraph (d) is revised to read as follows:** d) The Commission determines that the byproduct material is properly contained in the product under the most severe conditions that are likely to be			NA-NRC NA-NRC

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				encountered in normal use and handling.			
§32.15	Same: Quality assurance prohibition of transfer, and labeling		NRC	**Sec. 32.15, paragraph (d) is revised to read as follows:** * * * * (d)(1) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. (2) For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that: (i) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing: (A) The following statement:			NA-NRC NA-NRC

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				‘‘CONTAINS RADIOACTIVE MATERIAL’’; (B) The name of the radionuclide (‘‘americium-241’’ or ‘‘Am-241’’) and the quantity of activity; and (C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State. (ii) The labeling or marking specified in paragraph (d)(2)(I) of this section is located where it will be readily visible when the detector is removed from its mounting. (iii) The external surface of the point of sale package has a legible, readily visible label or marking containing: (A) The name of the radionuclide and quantity of			NA-NRC

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				activity; (B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and (C) The following or a substantially similar statement: ‘‘THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.’’ (iv) Each detector and point-of-sale package is provided with such other information as may be required by the Commission.			
§32.16	Certain items containing byproduct material: Records and reports of		NRC	**Section 32.16 is revised to read as follows:** (a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct			NA-NRC NA-NRC

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	transfer			material and file a report with the Director of the Office of Federal and State Material and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution. (1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee. (2) The report must indicate that the products are transferred for use under § 30.15 of this chapter, giving the specific paragraph designation, or equivalent regulations of an Agreement State. (b) The report must include the following information on			NA-NRC

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				products transferred to other persons for use under § 30.15 or equivalent regulations of an Agreement State: (1) A description or identification of the type of each product and the model number(s), if applicable; (2) For each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide; and (3) The number of units of each type of product transferred during the reporting period by model number, if applicable. (c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not			NA-NRC

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				previously reported to the Commission. (2) Licensees who permanently discontinue activities authorized by the license issued under § 32.14 shall file a report for the current calendar year within 30 days after ceasing distribution. (d) If no transfers of byproduct material have been made under § 32.14 during the reporting period, the report must so indicate. (e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.			
§32.17	Resins containing scandium-46 and designed for sand-consolidation in oil wells: requirements	.0305	B	**[Removed]**			.

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	for license to manufacture, or initially transfer for sale or distribution.						
§32.20	Same: Records and material transfer reports		NRC	**Section 32.20 is revised to read as follows:** (a) Each person licensed under § 32.18 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred. (b) The licensee shall file a summary report with the Director of the Office of Federal and State Materials and			NA-NRC NA-NRC

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				Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution. (1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee. (2) The report must indicate that the materials are transferred for use under § 30.18 or equivalent regulations of an Agreement State. (c) For each radionuclide in each physical form, the report shall indicate the total quantity of each radionuclide and the physical form, transferred under the specific license. (d)(1) The licensee shall file the			NA-NRC

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				report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include the total quantity of each radionuclide transferred for transfers in prior years not previously reported to the Commission. (2) Licensees who permanently discontinue activities authorized by the license issued under § 32.18 shall file a report for the current calendar year within 30 days after ceasing distribution. (e) If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate. (f) The licensee shall maintain the record of a transfer for one year after the transfer is included in a summary report to the Commission.			NA-NRC

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§32.25	Conditions of licenses issued under §32.22: Quality control, labeling, and reports of transfer		NRC	**Sec. 32.25, paragraph (c) is revised to read as follows:** (c) Maintain records of all transfers and file a report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution. (1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee. (2) The report must indicate that the products are transferred for use under § 30.19 of this chapter or equivalent regulations of an Agreement State.			NA-NRC NA-NRC

Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements
10 CFR Parts 30, 31, 32, and 150
(72 FR 58473) RATS ID # 2007-2 Effective date 12/17/07
Date Due for State Adoption 12/17/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				(3) The report must include the following information on products transferred to other persons for use under § 30.19 or equivalent regulations of an Agreement State: (i) A description or identification of the type of each product and the model number(s); (ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide; (iii) The number of units of each type of product transferred during the reporting period by model number. (4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for			NA-NRC

Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements
10 CFR Parts 30, 31, 32, and 150
(72 FR 58473) RATS ID # 2007-2 Effective date 12/17/07
Date Due for State Adoption 12/17/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				transfers in prior years not previously reported to the Commission. (ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.22 shall file a report for the current calendar year within 30 days after ceasing distribution. (5) If no transfers of byproduct material have been made under § 32.22 during the reporting period, the report must so indicate. (6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.			
§32.29	Conditions of licenses issued under §32.26: Quality control, labeling, and reports of		NRC	**Sec. 32.26: Quality control, labeling, and reports of transfer.** (c) Maintain records of all transfers and file a report with			NA-NRC NA-NRC

Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements
10 CFR Parts 30, 31, 32, and 150
(72 FR 58473) RATS ID # 2007-2 Effective date 12/17/07
Date Due for State Adoption 12/17/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
	transfer			the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution. (1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee. (2) The report must indicate that the products are transferred for use under § 30.20 of this chapter or equivalent regulations of an Agreement State. (3) The report must include the following information on products transferred to other persons for use under § 30.20 or equivalent			NA-NRC

Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements
10 CFR Parts 30, 31, 32, and 150
(72 FR 58473) RATS ID # 2007-2 Effective date 12/17/07
Date Due for State Adoption 12/17/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				regulations of an Agreement State: (i) A description or identification of the type of each product and the model number(s); (ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide; (iii) The number of units of each type of product transferred during the reporting period by model number. (4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission. (ii) Licensees who permanently discontinue activities authorized			NA-NRC

Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements
10 CFR Parts 30, 31, 32, and 150
(72 FR 58473) RATS ID # 2007-2 Effective date 12/17/07
Date Due for State Adoption 12/17/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				by the license issued under § 32.26 shall file a report for the current calendar year within 30 days after ceasing distribution. (5) If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate. (6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.			
§32.40	Schedule A--prototype tests for automobile lock illuminators.		NRC	[Removed]			NA-NRC
§150.20	Recognition of Agreement State licenses.	.0345 (not amended-seems OK as is)	C	**In Sec. 150.20 paragraph (b) introductory text, and paragraph (b)(3) are revised to read as follows:** (b) Not withstanding any			

Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				provision to the contrary in any specific license issued by an Agreement State to a person engaging in activities in a non-Agreement State, or in offshore waters under the general license provided in this section, the general licenses provided in this section are subject to all provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including provisions of §§30.7(a) through (f), 30.9, 30.10, 30.34, 30.41, and 30.51 through 30.63 of this chapter; §§40.7(a) through (f), 40.9, 40.10, 40.41, 40.51, 40.61 through 40.63, 40.71, and 40.81 of this chapter; §§70.7(a) through (f), 70.9 70.10, 70.32, 7042, 70.52, 70.55, 70.56, 70.60 through 70.62 of this chapter; §§74.11, 74.15, and 74.19 of this chapter; and to the			

Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements
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Date Due for State Adoption 12/17/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				provisions of 10 CFR parts 19, 20 and 71 and subparts C through H of part 34, §§39.15 and 39.31 through39.77 of this chapter. In addition, any person engaging in activities in non-Agreement States, in areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters under the general licenses provided in this section: *** (3) Shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general licenses provided in this section, except by transfer to a person who is specifically licensed by the Commission to receive this material.			

15A NCAC 11 .0303 has been amended to maintain required compatibility with 10 CFR 30.14

15A NCAC 11 .0303 EXEMPT CONCENTRATIONS: OTHER THAN SOURCE MATERIAL

(a) No person shall introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Paragraph (~~b~~)(d) of this Rule or equivalent regulations of the U.S. Nuclear Regulatory Commission or any agreement state, except in accordance with a specific license issued pursuant to Rule .0325 of this Section.

(b) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in these rules to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in paragraph (d) of this rule, and introduced into the product or material by a licensee holding a specific license issued by the Agency expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.

(c) This rule shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(~~b~~) (d) Except as provided in Paragraph (a) and (b) of this Rule, any person is exempt from these Rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in the following table:

EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration microcurie/ml	Column II Liquid and solid concentration microcurie/ml
Antimony (51)	Sb 122		$3X10^{-4}$
	Sb 124		$2X10^{-4}$
	Sb 125		$1X10^{-3}$
Argon (18)	Ar 37	$1X10^{-3}$	
Ar 41	$4X10^{-7}$		
Arsenic (33)	As 73		$5X10^{-3}$
	As 74		$5X10^{-4}$
	As 76		$2X10^{-4}$
	As 77		$8X10^{-4}$
Barium (56)	Ba 131		$2X10^{-3}$
	Ba 140		$3X10^{-4}$
Beryllium (4)	Be 7		$2X10^{-2}$
Bismuth (83)	Bi 206		$4X10^{-4}$
Bromine (35)	Br 82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd 109		$2X10^{-3}$
	Cd 115m		$3X10^{-4}$
	Cd 115		$3X10^{-4}$
Calcium (20)	Ca 45		$9X10^{-5}$
	Ca 47		$5X10^{-4}$
Carbon (6)	C 14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce 141		$9X10^{-4}$
	Ce 143		$4X10^{-4}$
	Ce 144		$1X10^{-4}$
Cesium (55)	Cs 131		$2X10^{-2}$
	Cs 134m		$6X10^{-2}$
	Cs 134		$9X10^{-5}$
Chlorine (17)	Cl 38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr 51		$2X10^{-2}$

1	Cobalt (27)	Co 57		$5X10^{-3}$
2		Co 58		$1X10^{-3}$
3		Co 60		$5X10^{-4}$
4	Copper (29)	Cu 64		$3X10^{-3}$
5	Dysprosium (66)	Dy 165		$4X10^{-3}$
6		Dy 166		$4X10^{-4}$
7	Erbium (68)	Er 169		$9X10^{-4}$
8		Er 171		$1X10^{-3}$
9	Europium (63)	Eu 152		$6X10^{-4}$
10		(T1/2 =9.2 Hrs.)		
11		Eu 155		$2X10^{-3}$
12	Fluorine (9)	F 18	$2X10^{-6}$	$8X10^{-3}$
13	Gadolinium (64)	Gd 153		$2X10^{-3}$
14		Gd 159		$8X10^{-4}$
15	Gallium (31)	Ga 72		$4X10^{-4}$
16	Germanium (32)	Ge 71		$2X10^{-2}$
17	Gold (79)	Au 196		$2X10^{-3}$
18		Au 198		$5X10^{-4}$
19		Au 199		$2X10^{-3}$
20	Hafnium (72)	Hf 181		$7X10^{-4}$
21	Hydrogen (1)	H 3	$5X10^{-6}$	$3X10^{-2}$
22	Indium (49)	In 113m		$1X10^{-2}$
23		In 114m		$2X10^{-4}$
24	Iodine (53)	I 126	$3X10^{-9}$	$2X10^{-5}$
25		I 131	$3X10^{-9}$	$2X10^{-5}$
26		I 132	$8X10^{-8}$	$6X10^{-4}$
27		I 133	$1X10^{-8}$	$7X10^{-5}$
28		I 134	$2X10^{-7}$	$1X10^{-3}$
29	Iridium (77)	Ir 190		$2X10^{-3}$
30		Ir 192		$4X10^{-4}$
31		Ir 194		$3X10^{-4}$
32	Iron (26)	Fe 55		$8X10^{-3}$
33		Fe 59		$6X10^{-4}$
34	Krypton (36)	Kr 85m		$1X10^{-6}$
35		Kr 85		$3X10^{-6}$
36	Lanthanum (57)	La 140		$2X10^{-4}$
37	Lead (82)	Pb 203		$4X10^{-3}$
38	Lutetium (71)	Lu 177		$1X10^{-3}$
39	Manganese (25)	Mn 52		$3X10^{-4}$
40		Mn 54		$1X10^{-3}$
41		Mn 56		$1X10^{-3}$
42	Mercury (80)	Hg 197m		$2X10^{-3}$
43		Hg 197		$3X10^{-3}$
44		Hg 203		$2X10^{-4}$
45	Molybdenum (42)	Mo 99		$2X10^{-3}$
46	Neodymium (60)	Nd 147		$6X10^{-3}$
47		Nd 149		$3X10^{-4}$
48	Nickel (28)	Ni 65		$1X10^{-3}$
49	Niobium(Columbium)(41)	Nb 95		$1X10^{-3}$
50		Nb 97		$9X10^{-3}$
51	Osmium (76)	Os 185		$7X10^{-4}$
52		Os 191m		$3X10^{-2}$
53		Os 191		$2X10^{-3}$

1		Os 193		$6X10^{-4}$
2	Palladium (46)	Pd 103		$3X10^{-3}$
3		Pd 109		$9X10^{-4}$
4	Phosphorus (15)	P 32		$2X10^{-4}$
5	Platinum (78)	Pt 191		$1X10^{-3}$
6		Pt 193m		$1X10^{-2}$
7		Pt 197m		$1X10^{-2}$
8		Pt 197		$1X10^{-3}$
9	Polonium (84)	Po 210		$7X10^{-6}$
10	Potassium (19)	K 42		$3X10^{-3}$
11	Praseodymium (59)	Pr 142		$3X10^{-4}$
12		Pr 143		$5X10^{-4}$
13	Promethium (61)	Pm 147		$2X10^{-3}$
14		Pm 149		$4X10^{-4}$
15	Radium (88)	Ra 226		$1X10^{-7}$
16		Ra 228		$3X10^{-7}$
17	Rhenium (75)	Re 183		$6X10^{-3}$
18		Re 186		$9X10^{-4}$
19		Re 188		$6X10^{-4}$
20	Rhodium (45)	Rh 103m		$1X10^{-1}$
21		Rh 105		$1X10^{-3}$
22	Rubidium (37)	Rb 86		$7X10^{-4}$
23	Ruthenium (44)	Ru 97		$4X10^{-3}$
24		Ru 103		$8X10^{-4}$
25		Ru 105		$1X10^{-3}$
26		Ru 106		$1X10^{-4}$
27	Samarium (62)	Sm 153		$8X10^{-4}$
28	Scandium (21)	Sc 46		$4X10^{-4}$
29		Sc 47		$9X10^{-4}$
30		Sc 48		$3X10^{-4}$
31	Selenium (34)	Se 75		$3X10^{-3}$
32	Silicon (14)	Si 31		$9X10^{-3}$
33	Silver (47)	Ag 105		$1X10^{-3}$
34		Ag 110m		$3X10^{-4}$
35		Ag 111		$4X10^{-4}$
36	Sodium (11)	Na 24		$2X10^{-3}$
37	Strontium (38)	Sr 85		$1X10^{-3}$
38		Sr 89		$1X10^{-4}$
39		Sr 91		$7X10^{-4}$
40		Sr 92		$7X10^{-4}$
41	Sulfur (16)	S 35	$9X10^{-8}$	$6X10^{-4}$
42	Tantalum (73)	Ta 182		$4X10^{-4}$
43	Technetium (43)	Tc 96m		$1X10^{-1}$
44		Tc 96		$1X10^{-3}$
45	Tellurium (52)	Te 125m		$2X10^{-3}$
46		Te 127m		$6X10^{-4}$
47		Te 127		$3X10^{-3}$
48		Te 129m		$3X10^{-4}$
49		Te 131m		$6X10^{-4}$
50		Te 132		$3X10^{-4}$
51	Terbium (65)	Tb 160		$4X10^{-4}$
52	Thallium (81)	Tl 200		$4X10^{-3}$
53		Tl 201		$3X10^{-3}$

	Tl 202		$1X10^{-3}$
	Tl 204		$1X10^{-3}$
Thulium (69)	Tm 170		$5X10^{-4}$
	Tm 171		$5X10^{-3}$
Tin (50)	Sn 113		$9X10^{-4}$
	Sn 125		$2X10^{-4}$
Tungsten(Wolfram)	W 181		$4X10^{-3}$
(74)	W 187		$7X10^{-4}$
Vanadium (23)	V 48		$3X10^{-4}$
Xenon (54)	Xe 131m		$4X10^{-6}$
	Xe 133		$3X10^{-6}$
	Xe 135		$1X10^{-6}$
Ytterbium (70)	Yb 175		$1X10^{-3}$
Yttrium (39)	Y 90		$2X10^{-4}$
	Y 91m		$3X10^{-2}$
	Y 91		$3X10^{-4}$
	Y 92		$6X10^{-4}$
	Y 93		$3X10^{-4}$
Zinc (30)	Zn 65		$1X10^{-3}$
	Zn 69m		$7X10^{-4}$
	Zn 69		$2X10^{-2}$
Zirconium (40)	Zr 95		$6X10^{-4}$
	Zr 97		$2X10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		$1X10^{-10}$	$1X10^{-6}$

(c) In Column I of the table, in Paragraph (b) of this Rule, values are given only for those materials normally used as gases.
(d) In Column II of the table, in Paragraph (b) of this Rule, the units, microcuries per gram, are used for solids.
(e) Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Paragraph (b) of this Rule, the activity stated is that of the parent isotope and takes into account the daughters.
(f) For purposes of this Rule, where a combination of isotopes is involved, the limit for the combination shall be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Paragraph (b) of this Rule for the specific isotope when not in combination. The sum of the ratios shall not exceed unity. An example of this is:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \text{ less than or equal to } 1$$

History Note: Authority G.S. 104E-7; 104E-10; 104E-20;
Eff. February 1, 1980;
Amended Eff. August 1, 2011, May 1, 1993; June 1, 1989.

15A NCAC 11 .0304 has been amended to maintain required compatibility with 10 CFR 30.18

15A NCAC 11 .0304 EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL

(a) Any person who possesses radioactive material received or acquired under the general license formerly provided in Rule .0303(b) of this Section is exempt from the requirements for a license set forth in this Section to the extent that such person possesses, uses, transfers or owns such radioactive material.

(b) This Rule does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(c) No person shall, for the purposes of commercial distribution, transfer individual quantities of radioactive materials to persons exempt from regulation in Paragraph (a) of this Rule except in accordance with a specific license issued by:

(1) the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 for source and byproduct material;

(2) the agency pursuant to Rule .0326 for radioactive material other than source, byproduct and special nuclear material; or

(3) any agreement state pursuant to equivalent regulation for radioactive material other than source, byproduct and special nuclear material.

(d) Licensees for commercial distribution shall not transfer the quantities of radioactive material to persons exempt under Paragraph (~~e~~ f) of this Rule if the licensee knows or has reason to believe that the recipient will redistribute the quantities to persons exempt under Paragraph (~~e~~ f) of this Rule.

(e) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits in paragraph (f) of this Rule, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this section.

(f) ~~(e)~~ Except as provided in Paragraphs (b) and (c) of this Rule, any person is exempt from the rules of this Chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in the following table:

EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000

1	Cesium-134m (Cs 134m)	100
2	Cesium-134 (Cs 134)	1
3	Cesium-135 (Cs 135)	10
4	Cesium-136 (Cs 136)	10
5	Cesium-137 (Cs 137)	10
6	Chlorine-36 (Cl 36)	10
7	Chlorine-38 (Cl 38)	10
8	Chromium-51 (Cr 51)	1,000
9	Cobalt-57 (Co 57)	100
10	Cobalt-58m (Co 58m)	10
11	Cobalt-58 (Co 58)	10
12	Cobalt-60 (Co 60)	1
13	Copper-64 (Cu 64)	100
14	Dysprosium-165 (Dy 165)	10
15	Dysprosium-166 (Dy 166)	100
16	Erbium-169 (Er 169)	100
17	Erbium-171 (Er 171)	100
18	Europium-152 (Eu 152) 9.2h	100
19	Europium-152 (Eu 152) 13 yr	1
20	Europium-154 (Eu 154)	1
21	Europium-155 (Eu 155)	10
22	Fluorine-18 (F 18)	1,000
23	Gadolinium-153 (Gd 153)	10
24	Gadolinium-159 (Gd 159)	100
25	Gallium-67 (Ga 67)	100
26	Gallium-72 (Ga 72)	10
27	Germanium-68 (Ge 68)	10
28	Germanium-71 (Ge 71)	100
29	Gold-195 (Au-195)	10
30	Gold-198 (Au 198)	100
31	Gold-199 (Au 199)	100
32	Hafnium-181 (Hf 181)	10
33	Holmium-166 (Ho 166)	100
34	Hydrogen-3 (H 3)	1,000
35	Indium-111 (In 111)	100
36	Indium-113m (In 113m)	100
37	Indium-114m (In 114m)	10
38	Indium-115m(In 115m)	100
39	Indium-115 (In 115)	10
40	Iodine-123 (I 123)	100
41	Iodine-125 (I 125)	1
42	Iodine-126 (I 126)	1
43	Iodine-129 (I 129)	0.1
44	Iodine-131 (I 131)	1
45	Iodine-132 (I 132)	10
46	Iodine-133 (I 133)	1
47	Iodine-134 (I 134)	10
48	Iodine-135 (I 135)	10
49	Iridium-192 (Ir 192)	10
50	Iridium-194 (Ir 194)	100
51	Iron-52 (Fe 52)	10
52	Iron-55 (Fe 55)	100
53	Iron-59 (Fe 59)	10
54	Krypton-85 (Kr 85)	100
55	Krypton-87 (Kr 87)	10
56	Lanthanum-140 (La 140)	10

1	Lutetium-177 (Lu 177)	100
2	Manganese-52 (Mn 52)	10
3	Manganese-54 (Mn 54)	10
4	Manganese-56 (Mn 56)	10
5	Mercury-197m (Hg 197m)	100
6	Mercury-197 (Hg 197)	100
7	Mercury-203 (Hg 203)	10
8	Molybdenum-99 (Mo 99)	100
9	Neodymium-147 (Nd 147)	100
10	Neodymium-149 (Nd 149)	100
11	Nickel-59 (Ni 59)	100
12	Nickel-63(Ni 63)	10
13	Nickel-65 (Ni 65)	100
14	Niobium-93m (Nb 93m)	10
15	Niobium-95 (Nb 95)	10
16	Niobium-97 (Nb 97)	10
17	Osmium-185 (Os 185)	10
18	Osmium-191m (Os 191m)	100
19	Osmium-191 (Os 191)	100
20	Osmium-193 (Os 193)	100
21	Palladium-103 (Pd 103)	100
22	Palladium-109 (Pd 109)	100
23	Phosphorus-32 (P 32)	10
24	Platinum-191 (Pt 191)	100
25	Platinum-193m (Pt 193m)	100
26	Platinum-193 (Pt 193)	100
27	Platinum-197m (Pt 197m)	100
28	Platinum-197 (Pt 197)	100
29	Polonium-210 (Po 210)	0.1
30	Potassium-42 (K 42)	10
31	Potassium-43 (K 43)	10
32	Praseodymium-142 (Pr 142)	100
33	Praseodymium-143 (Pr 143)	100
34	Promethium -147 (Pm 147)	10
35	Promethium-149 (Pm 149)	10
36	Rhenium-186 (Re 186)	100
37	Rhenium-188 (Re 188)	100
38	Rhodium-103m (Rh 103m)	100
39	Rhodium-105 (Rh 105)	100
40	Rubidium-81 (Rb 81)	10
41	Rubidium-86 (Rb 86)	10
42	Rubidium-87 (Rb 87)	10
43	Ruthenium-97 (Ru 97)	100
44	Ruthenium-103 (Ru 103)	10
45	Ruthenium-105 (Ru 105)	10
46	Ruthenium-106 (Ru 106)	1
47	Samarium-151 (Sm 151)	10
48	Samarium-153 (Sm 153)	100
49	Scandium-46 (Sc 46)	10
50	Scandium-47 (Sc 47)	100
51	Scandium-48 (Sc 48)	10
52	Selenium-75 (Se 75)	10
53	Silicon-31 (Si 31)	100
54	Silver-105 (Ag 105)	10
55	Silver-110m (Ag 110m)	1
56	Silver-111 (Ag 111)	100

Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulfur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20;*

Eff. February 1, 1980;
Amended Eff. May 1, 1993; July 28, 2011.

15A NCAC 11 .0305 has been amended to maintain required compatibility with 10 CFR 30.15

15A NCAC 11 .0305 EXEMPT ITEM CONTAINING OTHER THAN SOURCE MATERIAL

(a) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from the rules of this Chapter may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(b) Certain items containing radioactive material are exempt as provided in this Paragraph.

(1) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from the rules of this Chapter to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:

(A) timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(i) 25 millicuries of tritium per timepiece;

(ii) five millicuries of tritium per hand;

(iii) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);

(iv) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece;

(v) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand;

(vi) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

(vii) the levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(I) for wrist watches, 0.1 millirad per hour at 10 centimeters from any surface;

(II) for pocket watches, 0.1 millirad per hour at one centimeter from any surface;

(III) for any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(viii) 1 microcurie of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(B) [Reserved] ~~lock illuminators containing not more than 15 millicuries of tritium or not more than two millicuries of promethium-147 installed in automobile locks (the levels of radiation from each lock illuminator containing promethium-147 shall not exceed one millirad per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber);~~

(C) balances of precision containing not more than one millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007;

(D) [Reserved] ~~automobile shift quadrants containing not more than 25 millicuries of tritium;~~

(E) marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007;

(F) [Reserved] ~~thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat;~~

(G) electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material:

(i) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(ii) one microcurie of cobalt-60;

(iii) five microcuries of nickel-63;

(iv) 30 microcuries of krypton-85;

(v) five microcuries of cesium-137;

(vi) 30 microcuries of promethium-147; and provided further, that the levels of radiation from each electron tube containing radioactive material does not exceed one millirad per

hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber (for purposes of this Subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents);

(H) ionizing radiation measuring instruments containing for purposes of internal calibration or standardization, sources of radioactive material each not exceeding the applicable quantity set forth in Rule .0304(e) of this Section, and each instrument contains no more than 10 exempt quantities.

(I) [Reserved] ~~spark gap irradiation containing not more than one microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons (11.4 liters) per hour.~~

(2) For purposes of Part (b)(1)(H) of this Rule, where there is involved a combination of radionuclides, the limit for the combination shall be derived as follows:

(A) Determine for each radionuclide in an ionizing radiation measuring instrument the ratio between the quantity present in the instrument and the exempt quantity established in Rule .0304(e) of this Section for the specific radionuclide when not in combination;

(B) No ratio shall exceed one and the sum of such ratios shall not exceed 10.

(C) For the purpose of Part (b)(1)(H) 0.05 microcurie of americium-241 is considered an exempt quantity under Rule .0304 of this Section.

(c) Self-luminous products are exempt as provided in this Paragraph.

(1) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from the rules of this Chapter to the extent that any person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.

(2) The exemption in Subparagraph (c)(1) of this Rule does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

(d) Gas and aerosol detectors are exempt as provided in this Paragraph.

(1) Except for persons who manufacture, process, ~~or~~ produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the rules of this Chapter to the extent that any person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall be manufactured, ~~imported~~, processed, produced,or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or any agreement state, pursuant to Section 32.26 of 10 CFR 32, or equivalent, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(2) Gas and aerosol detectors previously manufactured and distributed to general licensees before November 30, 2007 in accordance with a specific license issued by an agreement state shall be considered exempt under Subparagraph (d)(1) of this Rule, provided that the devices are labeled in accordance with the specific license authorizing distribution of the general licensed device, and providing further that the devices meet the requirements of Rule .0327 of this Section.

~~(e) Resins containing scandium-46 are exempt as provided in this Paragraph.~~

~~(1) Any person is exempt from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. These resins shall be manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall be manufactured in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.~~

~~(2) This exemption does not authorize the manufacture of any resins containing scandium-46.~~

(e) ~~(f)~~ Capsules containing Carbon-14 urea for "in-vivo" diagnostic use for humans are exempt as provided in this Paragraph:

(1) Except as provided in Subparagraphs (2) and (3) of this Paragraph, any person is exempt from the requirements for a license set forth in this Section provided that such person receives, possesses, uses, transfers, owns or acquires capsules containing approximately one microcurie (37kBq) Carbon-14 urea each for "in-vivo" diagnostic use for humans.

(2) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license from the agency.

(3) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license from the U.S. Nuclear Regulatory Commission.

(4) Nothing in this Rule relieves persons from complying with applicable FDA and other federal regulations, and North Carolina requirements governing the receipt, administration, and use of drugs.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-20.;
Eff. February 1, 1980;

Amended Eff. August 1, 2011; April 1, 1999; June 1, 1993; October 1, 1982; September 1, 1981.

15A NCAC 11 .0309 IS PROPOSED FOR AMENDMENT AS FOLLOWS:

15A NCAC 11 .0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES

(a) A general license shall be issued to commercial and industrial firms; research, educational and medical institutions; individuals in the conduct of their business; and federal, state, or local government agencies to acquire, receive, possess, use, or transfer in accordance with Paragraphs (b), (c), and (d) of this Rule, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license in Paragraph (a) of this Rule applies only to radioactive material contained in devices which have been:

(1) manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to Rule .0328 of this Section or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes distribution of the devices to persons generally licensed pursuant to equivalent regulations; and

(2) received from one of the specific licensees referenced in Subparagraph (b)(1) of this Rule or through a transfer completed in accordance with Subparagraph (c)(8) of this Rule.

(c) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license issued under Paragraph (a) of this Rule:

(1) shall assure that all labels, affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by the labels;

(2) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, except as follows:

(A) Devices containing only krypton need not be tested for leakage of radioactive material;

(B) Devices containing only tritium or not more than 100 microcuries of other beta, gamma, or beta and gamma emitting material or ten microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) shall assure that the tests required by Subparagraph (c)(2) of this Rule and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment are performed:

(A) in accordance with the instructions provided on labels affixed to the device, except that tests for leakage or contamination may be performed by the general licensee using leak test kits provided and analyzed by a specific licensee who is authorized to provide leak test kit services; or

(B) by a person holding a specific license or registration which authorizes the providing of services required by this Rule and which is issued pursuant to Rules .0205 and .0306 of this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.

(4) shall maintain records, showing compliance with the requirements in Subparagraphs (c)(2) and (3) of this Rule, to include:

(A) the name of the person(s) performing the test(s) and the date(s) of the test(s);

(B) the name of the person(s) performing installation, servicing and removal of any radioactive material, shielding or containment;

(C) retention of leakage or contamination, on-off mechanism and on-off indicator test records for ~~one year~~ three years after the next required test is performed or until the sealed source is disposed of or transferred~~, whichever is shorter~~;

(D) retention of other records of tests required in Subparagraph (c)(3) of this Rule for ~~two~~ three years from the date of the recorded test or until the device is disposed of or transferred.

(5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been:

(A) repaired by the manufacturer or other person authorized to repair the device(s) by a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state; or

(B) disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device; and within 30 days, furnish to the agency at the address in Rule .0111 of this Chapter a report containing a brief description of the event and the remedial action taken. In the event that 0.005 microcurie or more of removable radioactive contamination is detected, or if the failure of or damage to a source of radiation is likely to result in the contamination of the facility or the environment, a plan for ensuring that the facility and the environment are acceptable for unrestricted use shall be submitted to the agency at the address in Rule .0111 of this Chapter.

(6) shall not abandon the device containing radioactive material;

(7) except as provided in Subparagraph (c)(8) of this Rule, shall transfer or dispose of the device containing radioactive material only by export in accordance with 10 CFR Part 110 or by transfer to a person holding a specific license authorizing receipt of the device; and, ~~prior to~~ within 30 days ~~of~~ after transfer of a device to a specific licesnee or export ~~the transfer~~ of a device ~~to a specific licensee~~, shall furnish to the agency at the address in Rule .0111 of this Chapter, a report that contains:

(A) the identification of the device by manufacturer's or initial transferor's name, model number, and serial number;

(B) the name, address and specific license number of the person receiving the device (license number not applicable if exported); ~~and~~

(C) the date of the transfer~~.~~; and

(D) shall obtain written approval by the agency before transferring the device to any other specific licensee not specifically identified in this Rule; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(i) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(ii) Removes, alters, covers, or clearly and unambiguously augments the existing label otherwise required by paragraph (c)(1) of this section so that the device is labeled in compliance with § .0328(a)(3) of this chapter; however the manufacturer, model number, and serial number must be retained;

(iii) Obtains the manufacturer's or initial transferor's information concerning maintenance that be applicable under the specific license (such as leak testing procedures); and

(iv) Reports the transfer under paragraph (7) of this section.

(8) shall transfer or dispose of the device only by export as provided by (c)(7) of this Rule, or by transfer to another general licensee only where the device:

(A) remains in use at a particular location.

(i) In this case the transferor shall give the transferee a copy of this Section and any safety documents identified in the label of the device;

(ii) The transferor shall, within 30 days of the transfer, report to the agency at the address in Rule .0111 of this Chapter the manufacturer's or initial transferor's name, serial number, and model number of device transferred; the name and mailing address of the transferee; and the name, title, and telephone number of the individual identified by the transferee pursuant to Subparagraph (c)(10) of this Rule as having knowledge of and authority to take actions to ensure compliance with the requirements contained in these Rules; or (B) is held in storage by the licensee or an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(9) shall comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Section .1600 of this Chapter;

(10) shall appoint an individual responsible for having knowledge of the requirements contained in these Rules and the authority for taking the actions required to comply with these Rules. The general licensee, through this individual, shall ensure the day-to-day compliance with these Rules. The

appointment of such an individual does not relieve the general licensee of any of its responsibility in this regard;

(11) shall register, when required by the agency, any source of radiation subject to a general license in accordance with the rules in this Section. Each address for a location of use represents a separate general license and requires a separate registration action;

(12) shall register, on an annual basis, all devices containing, based on the activity indicated on the label, at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37MBq) of cobalt-60, 1 mCi (37 MBq) of americium-241, 0.1 millicurie (3.7 MBq) of radium-226, or any other transuranic isotope. Each address for a location of use represents a separate general license and requires a separate registration action. Annual registration consists of verifying, correcting, or adding to the information provided in a request for annual registration within 30 days of a request from the agency. The general licensee shall furnish the following information for annual registration:

(A) the name and mailing address of the general licensee;

(B) specific information about each device to include the manufacturer or initial transferor, model number, serial number, the radioisotope, and the activity indicated on the label;

(C) the name, title, and telephone number of the responsible person designated as a representative of the general licensee in accordance with Subparagraph (c)(10) of this Rule;

(D) the address or location at which the device(s) are to be used or stored. For portable devices that are granted a general license by the agency, the address of the primary place of storage;

(E) certification by the responsible person designated by the general licensee that the information concerning the device(s) has been verified through a physical inventory and a check of label information; and

(F) certification by the responsible person designated by the general licensee that they are aware of the requirements of the general license.

(13) shall report changes to the mailing address to the agency within 30 days of the effective date of the change;

(14) shall report changes to the name of the general licensee to the agency within 30 days of the effective date of the change;

(15) shall respond to written requests from the agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency a written justification for the request;

~~(15)~~ (16) shall not hold devices that are not in use for longer than two years. If devices that have shutters are not in use, the shutter shall be locked in the closed position. Leak testing is not required during the period of storage; however, when devices are returned to service or transferred to another person, the devices must be tested for leakage and shutter operation. Devices kept in standby for future use shall be excluded from the two year time limit if quarterly physical inventories of these devices are performed while in standby.

(d) The general license in Paragraph (a) of this Rule does not authorize the manufacture or ~~distribution~~ import of devices containing radioactive material.

(e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), .0338, .0342, .0343 and .0345 of this ~~Chpter~~ Chapter and to labeling requirements in Section .1600 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2011; January 1, 2005; January 1, 1994; June 1, 1989.

15A NCAC 11 .0345 RECIPROCAL RECOGNITION OF LICENSES

(a) Subject to these Rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that the following requirements are satisfied:

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(2) The out-of-state licensee notifies the agency in writing at least three days prior to engaging in such activity; such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document; if, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, including but not limited to adverse impact on the business of the licensee or his customer, he may upon application to the agency, obtain permission to proceed sooner; the agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this Rule if the agency determines that such written notifications are not necessary to ensure compliance with the rules in this Chapter or to protect the public;

(3) The out-of-state licensee complies with all applicable rules of the agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency;

(4) The out-of-state licensee supplies such other information as the agency may request; and

(5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this Rule except by transfer to a person:

(A) specifically licensed by the agency or by the U.S. Nuclear Regulatory Commission to receive the material, or

(B) exempt from the requirements for a license for the material under Rule .0303 of this Section.

(b) Additional reciprocity is provided in Rule .0310 of this Section.

(c) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that the action is necessary in order to prevent undue hazard to public health and safety or property.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1993.

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
(72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07
Date Due for State Adoption 11/30/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
' 20.1003	Definition: Accelerator-produced radioactive material	.0104	H&S	**In § 20.1003, the definition of *Accelerator-produced radioactive material,* is added to read as follows:** *Accelerator-produced radioactive material* means any material made radioactive by a particle accelerator.			
' 20.1003	Definition: Byproduct Material	.0104	[H&S]*** **(***please note 10 CFR 20.1003 Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)**	**In § 20.1003, the definition of *Byproduct material* is revised to read as follows:** *Byproduct material* means— (1) 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; (2) The tailings or wastes produced by the extraction or concentration of uranium or			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
(72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07
Date Due for State Adoption 11/30/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				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; (3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that— (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
(72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07
Date Due for State Adoption 11/30/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				(4) Any discrete source of naturally occurring radioactive material, other than source material, that— (i) The Commission, 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 (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity. * * * *			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
(72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07
Date Due for State Adoption 11/30/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
' 20.1003	Definition: Discrete Source	.0104	H&S	**In § 20.1003, the definition of *Discrete source* is added to read as follows:** *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.			
' 20.1003	Definition: Particle Accelerator	.0104	H&S	**In § 20.1003, the definition of *Particle accelerator* is added to read as follows:** *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 megaelectron volt. For purposes of this definition, ‘‘accelerator’’ is			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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				an equivalent term.			
' 20.1003	Definition: Waste	.0104	B	**In § 20.1003, the definition of *Waste* is added to read as follows:** *Waste* means those low-level radioactive wastes containing source, special nuclear, or byproduct 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 byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.			
' 20.1009	List of OMB approved information collections		D	N/A	N/A		

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'20.2001 (a)(4)	General requirements	.1628 (Not Amended)	C	**In § 20.2001, paragraph (a)(4) is revised to read as follows:** a) * * * (4) As authorized under §§20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.			
'20.2006 (e)	Transfer for disposal and manifests	.1633	B	**In § 20.2006, paragraph (e) is added to read as follows:** (e) Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in § 20.1003 intended for ultimate disposal at a land disposal facility licensed under part 61 of this chapter must document the information required on the NRC's Uniform Low- Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended			

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				consignee in accordance with appendix G to this part.			
'20.2008	Disposal of 11e.(3) and 11e.(4) byproduct material	.1633	B	**Section 20.2008 is added to read as follows:** (a) Licensed material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in §20.1003 may be disposed of in accordance with part 61 of this chapter, even though it is not defined as low level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under part 61 of this chapter, must meet the requirements of §20.2006. (b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in §20.1003, at a disposal			

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				facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.			
Part 20 Appendix B	Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage	.0117 (inc. by reference)	A	**In Appendix B to part 20, the List of Elements table is amended by adding Nitrogen and Oxygen in alphabetical order, and page 1 of Tables 1, 2, and 3 following the List of Elements is revised to read as follows:** See tables at the end of the document.			

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'30.3(a)	Activities requiring license	.0301 (not amended-seems OK)	C	**Section 30.3(a) is revised to read as follows:** (a) Except as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter.			
'30.3(b) (1), (2), & (3)	Activities requiring license		NRC	**Section 30.3(b)(1), (2), & (3) is revised to read as follows:** (b)(1) The requirements, including provisions that are specific to licensees, in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33,			NA-NRC

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				34, 36, or 39, respectively, shall apply to Government agencies or Federally recognized Indian Tribes on November 30, 2007, when conducting activities under the authority provided by paragraphs (b)(2) and (b)(3) of this section. (2) A specifically licensed Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.			NA-NRC

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				(3) A Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination provided that the agency or Indian Tribe submits an application for a license authorizing activities involving these materials on or before December 1, 2008.			NA-NRC
'30.3(c) (1), (2), (3), & (d)	Activities requiring license		D	N/A	N/A		
'30.4	Definition: Accelerator produced radioactive material	.0104	H&S	**In § 30.4, the definition of *Accelerator-produced radioactive material,* is added to read as follows:**			

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				Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.			
' 30.4	Definition: Byproduct material	.0104	[H&S]*** **(***please note 10 CFR 30.4 Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)**	**In § 30.4, the definition of *Byproduct material* is revised, to read as follows:** *Byproduct material* means— (1) 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; (2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that (A) Has been made radioactive by			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and (3) Any discrete source of naturally occurring radioactive material, other than source material, that— (i) The Commission, 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 (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research			

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				activity.			
'30.4	Definition: Consortium	.0104	C	**In § 30.4, the definition of *Consortium,* is added to read as follows:** *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.			
'30.4	Definition:		D	N/A	N/A		

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	Cyclotron						
' 30.4	Definition: Discrete Source	.0104	H&S	**In § 30.4, the definition of *Discrete source*, is added to read as follows:** *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.			
' 30.4	Definition: Particle accelerator	.0104	H&S	**In § 30.4, the definition of *Particle accelerator* is added to read as follows:** *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			

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				megaelectron volt. For purposes of this definition, accelerator is an equivalent term.			
'30.15 (a)(1)(viii)	Certain items containing byproduct material	.0305(b)(1)(A).	B	**In § 30.15, paragraph (a)(1)(viii) is added to read as follows:** (a) * * * (1) * * * (viii) 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.			
'30.18 (b)	Exempt quantities	.0304 (not amended – seems OK as is)	B	**In § 30.18, paragraph (b) is revised to read as follows:** (b) Any person, who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in § 31.4 of this chapter or similar general license of a State, is exempt from the requirements for a license set forth			

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				in section 81 of the Act and from the regulations in parts 30 through 34, 36 and 39 of this chapter to the extent that this person possesses, uses, transfers, or owns byproduct material.			
'30.20(a)	Gas and aerosol detectors containing byproduct material	.0305(d)	B	**In § 30.20, paragraph (a) is revised to read as follows:** (a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, and 30 through 36, and 39 of this chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne			

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				hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.			

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' 30.32(g)	Application for specific licenses	.0317	C	**In § 30.32, paragraphs (g)(1) and (g)(2) are revised and paragraphs (g)(3) are added to read as follows:** (g) * * * (1) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or (2) Contain the information identified in § 32.210(c) of this chapter; or (3) For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to			

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				November 30, 2007 that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in §32.210(c) of this chapter, the applicant must provide: (i) All available information identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and (ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a			

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				recent leak test.			
'30.32(j)	Application for specific licenses	.0333. Part 32 incorporated by reference. We do not distinguish between commercial and non-commercial distribution of radiopharmaceuticals. 15A NCAC	B	**In § 30.32, paragraph (j) is added to read as follows:** (j) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under part 35 of this chapter or equivalent Agreement State requirements shall include: (1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under part 30 of this chapter or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.			

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		11.0333 requires all radiopharmaceutical for medical use to be manufactured in accordance with 10 CFR 32.72, and 30.32 (j).		(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in § 32.72(a)(2) of this chapter. (3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in § 32.72(b)(2) of this chapter. (4) Information identified in § 32.72 (a)(3) of this chapter on the PET drugs to be noncommercially transferred to members of its consortium.			

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' 30.34 (g)	Terms and conditions of licenses	.0338 revised	H&S*** **(***please note 10 CFR 30.34(g) Terms and Conditions of Licenses was changed from a Compatibility Category D to a Compatibility Category H&S)**	**In § 30.34, paragraph (g) is revised to read as follows:** (g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made.			
' 30.34(j)	Terms and conditions of licenses	..0338 revised.	B	**In § 30.34, paragraph (j) is added to read as follows:** (j)(1) Authorization under § 30.32(j) to produce Positron Emission Tomography (PET)			

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		Labeling requirements are in .1626 as proposed.		radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs. (2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall: (i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium. (ii) Possess and use instrumentation to measure the			

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				radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter. (3) A licensee that is a pharmacy authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be: (i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of this chapter, or (ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.			

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				(4) A pharmacy, authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter.			
'30.71	Schedule B	.0304	B	**Section 30.71 is amended by adding Cesium 129 (Cs 129), Cobalt 57 (Co 57), Gallium 67 (Ga 67), Germanium 68 (Ge 68), Gold 195 (Au 195), Indium 111 (In 111), Iodine 123 (I 123), Iron 52n (Fe 52), Potassium 43 (K 43), Rubidium 81 (Rb 81), Sodium 22 (Na 22), Yttrium 87 (Y 87), and Yttrium 88 (Y 88) in alphabetical order by element as follows:**			

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				See table at end of document.			
' 30.72	Schedule C – Quantities of radioactive material requiring consideration of the need for an emergency plan for responding to a release	0352, Ra-226 is not specifically listed but falls under 'any other alpha emitter' with limits of .001 and 2Ci which is more conservative than Schedule C 30.72	H&S	**Section 30.72 is amended by adding radium-226 in alphabetical order to read as follows:** See table at end of document.			.

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'31.4	List of OMB approved Information collections		D	N/A	N/A		
'31.5 (b)(1) & (c)(13)	Certain detecting, measuring, gauging, or controlling devices and/or an ionizing atmosphere	.0309(c)(12)	B	**In § 31.5, paragraphs (b)(1)(i), (b)(1)(ii), and (c)(13)(i) are revised and paragraph (b)(1)(iii) is added to read as follows:** (b)(1) * * * (i) A specific license issued under § 32.51 of this chapter; or (ii) An equivalent specific license issued by an Agreement State; or (iii) An equivalent specific license issued by a State with provisions comparable to § 32.51 of this chapter. * * * * * (c) * * * (13)(i) Shall register, in accordance with paragraphs (c)(13)(ii) and (iii) of this section, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels			

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				(0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.			
'31.8	Americium-241 in the form of calibration and reference sources		D	N/A	N/A		

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'31.11	General license for use of byproduct material for certain in vivo clinical and laboratory testing		D	N/A	N/A		
'31.12	General license for certain items and self-luminous products containing radium-226	.0117 (10CFR 31 inc by referenc e)	C	**Sections 31.12, 31.13, and 31.14 are redesignated as § 31.21, § 31.22, and § 31.23, respectively, §§31.13 through 31.20 are reserved, and a new § 31.12 is added to read as follows:** (a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, radium-226 contained			

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				in the following products manufactured prior to November 30, 2007. (1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads. (2) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces. (3) Luminous items installed in air, marine, or land vehicles. (4) All other luminous products, provided that no more than 100 items are used or stored at the			

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				same location at any one time. (5) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, ‘‘small radium sources’’ means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC. (b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph (a) of this section are exempt from the provisions of 10 CFR parts 19, 20, and 21, and § 30.50 and 30.51 of this chapter, to the extent that the receipt,			

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				possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter. (c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section: (1) Shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Office of Federal and State Materials and Environmental Management			

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				Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days. (2) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to § 20.2008 of this chapter or by transfer to a person authorized by a specific license to receive the radium- 226 in the product or as otherwise approved by the NRC. (3) Shall not export products containing radium-226 except in accordance with part 110 of this chapter. (4) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under			

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				the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under part 30 of this chapter, or equivalent regulations of an Agreement State, or as otherwise approved by the NRC. (5) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for			

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				the request. (d) The general license in paragraph (a) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.			
'32.1 (c)(1)	Purpose and scope		NRC	**In § 32.1, paragraph (c) is added to read as follows:** (c)(1) The requirements in this part, including provisions that are specific to licensees, shall apply to Government agencies and Federally recognized Indian Tribes with respect to accelerator-produced radioactive material or discrete sources of radium- 226 on November 30, 2007 except that the agency or tribe may continue to manufacture or initially transfer			NA-NRC NA-NRC

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				items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and radioactive drugs and sources and devices to medical use licensees, until the date of the NRC's final licensing determination, provided that the agency or tribe submits a new license application for these activities on or before December 1, 2008 or an amendment application for these activities on or before June 2, 2008.			
'32.1 (c)(2)	Purpose and scope		D	N/A	N/A		

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'32.57	Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer	.0330 (includes reference to 32.57).	B	**In § 32.57, the heading and the introductory text are revised to read as follows:** An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium- 226, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:			
'32.58	Same: labeling of devices	.0330 (includes reference to 32.58).	B	**Section 32.58 is revised to read as follows:** Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following			

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				statement or a substantially similar statement which contains the information called for in the following statement: The receipt, possession, use, and transfer of this source, Model , Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. CAUTION-RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE _____ (Name of manufacturer or initial transferor)			

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'32.59	Same: Leak testing of each source	.0330 (includes reference to 32.59).	B	**Section 32.59 is revised to read as follows:** Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-			

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				226 and shall not be transferred to a general licensee under § 31.8 of this chapter or equivalent regulations of an Agreement State.			
'32.71 (b)(8) & (c)(1)	Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license	.0331	B	**In § 32.71, paragraph (b)(8) is added, and paragraph (c)(1) is revised to read as follows:** (b) * * * (8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each. (c) * * * (1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (10 microcuries) of iodine-131, iodine-125, selenium-75, or carbon-14; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel			

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				(20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and			
'32.72 (a)(2)(i), (iii), (iv), (v), & (b)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for certain in vitro clinical or laboratory testing under general license	.0333 (Part 32 referenced in rule)	B	**In § 32.72, paragraphs (a)(2)(i), (a)(2)(iii), (a)(2)(iv), (b)(2)(ii), (b)(4), and (b)(5) are revised, and a new paragraph (a)(2)(v) is added to read as follows:** (a) * * * (2) * * * (i) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);			

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				* * * * * (iii) Licensed as a pharmacy by a State Board of Pharmacy; (iv) Operating as a nuclear pharmacy within a Federal medical institution; or (v) A Positron Emission Tomography (PET) drug production facility registered with a State agency. * * * * * (b) * * * (2) * * * (ii) This individual meets the requirements specified in § 35.55(b) and 35.59 of this chapter, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or * * * * * (4) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if:			

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				(i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and (ii) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC. (5) Shall provide to the Commission: (i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter with the written attestation signed by a preceptor as required by § 35.55(b)(2) of this chapter; or (ii) The Commission or Agreement			

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				State license, or (iii) Commission master materials licensee permit, or (iv) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or (v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and (vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to			

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				work as an authorized nuclear pharmacist.			
'32.102	Schedule-C prototype tests for calibration or reference sources containing americium-241	.0117 (Part 32 inc. by referenc e)	B	**In § 32.102, the heading and the introductory paragraph are revised to read as follows:** An applicant for a license under § 32.57 shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:			
'33.100	Schedule A		D	N/A	N/A		
'35.2	Definition: Cyclotron		D	N/A	N/A		

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'35.2	Definition: Positron Emission Tomography (PET) radionuclide production facility	.0104	H&S	**In § 35.2, new definition for *Positron Emission Tomography (PET) radionuclide production facility* is added to read as follows:** *Positron Emission Tomography (PET) radionuclide production facility* is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.			K
'35.10(a) & (g)	Implementation		D	N/A	N/A		
'35.11(a)	License required	.0318(p), OK as currently exists.	C	**In § 35.11, paragraph (a) is revised to read as follows:** (a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as			

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				allowed in paragraph (b) or (c) of this section.			
'35.11 (c)(1)	License required		NRC	**In § 35.11 paragraph (c) is added to read as follows:** (c)(1) A Government agency or a Federally recognized Indian Tribe, that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use such materials for medical uses until the date of the NRC's final licensing determination, provided that the person submits a medical use license application on or before December 1, 2008.			NA-NRC
'35.11 (c)(2)	License required		D	N/A	N/A		

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'35.13 (a)(1)	License amendments		NRC	**In § 35.13, paragraphs (a)(1) is revised to read as follows:** (a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but is not authorized on the licensee's current license issued under this part; except that— (1) A Government agency or a Federally recognized Indian Tribe licensee who possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 may continue to use such material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.			NA-NRC
'35.13 (a)(2), (b)(5), (e),	License amendments		D	N/A	N/A		
'35.14 (a)	Notifications		D	N/A	N/A		

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& (b)(5)							
'35.15 (f)	Exemptions regarding Type A specific licenses of broad scope		D	N/A	N/A		
'35.57 (a)(3) & (b)(3)	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist		D	N/A	N/A		
'35.63 (b)(2)(ii), (b)(2)(iii), & (c)(3)	Determination of dosages of unsealed byproduct material for medical use	.0361 and .0359(.0359 Not Amended)	H&S	**In § 35.63, paragraphs (b)(2)(ii) and (c)(3) are revised, and paragraph (b)(2)(iii) is added to read as follows:** (b) * * * (2) * * * (ii) An NRC or Agreement State			OK

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				licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or (iii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements. (c) * * * (3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by: (i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (ii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.			

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'35.100 (a) & (b)	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required	.0361	H&S	**In § 35.100, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:** (a) Obtained from: (1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or (b) Excluding production of PET radionuclides, prepared by:			
'35.200 (a) & (b)	Use of unsealed byproduct material for imaging and localization studies for which a	.0361	H&S	**In § 35.200, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:** (a) Obtained from: (1) A manufacturer or preparer licensed under § 32.72 of this			

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	written directive is not required.			chapter or equivalent Agreement State requirements; or (2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or (b) Excluding production of PET radionuclides, prepared by:			
'35.204 (a)	Permissible molybdenum-99 concentrations	.0361	H&S	**In § 35.204, the heading and paragraph (a) are revised to read as follows:** (a) A licensee may not administer to humans a radiopharmaceutical that contains: (1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or (2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82			

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				chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).			
'35.204 (c) & (d)	Permissible molybdenum-99 concentrations		D	N/A	N/A		
' 35.300 (a) & (b)	Use of unsealed byproduct material for which a written directive is required	.0361	H&S	**In § 35.300, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:** (a) Obtained from: (1) A manufacturer or preparer licensed under § 32.72 of this			

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				chapter or equivalent Agreement State requirements; or (2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or (b) Excluding production of PET radionuclides, prepared by:			
'35.2204	Records of molybdenum-99 concentrations		D	N/A	N/A		
'50.2	Definition: Byproduct Material		NRC	**In § 50.2, the definition of *Byproduct material* is revised to read as follows:** *Byproduct material* means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by,			NA-NRC NA-NRC

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				exposure to the radiation incident to the process of producing or using special nuclear material; (2)(i) Any discrete source of radium- 226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that— (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and (3) Any discrete source of naturally occurring radioactive material, other than source material, that— (i) The Commission, in consultation with the Administrator of the Environmental Protection			NA-NRC

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
(72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07
Date Due for State Adoption 11/30/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				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 (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.			
' 61.2	Definition: Waste	.0104	B	**In § 61.2, the definition for *Waste* is revised to read as follows:** *Waste* means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				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 byproduct material as defined in paragraphs (2), (3), and (4) of the definition of *Byproduct material* set forth in § 20.1003 of this chapter.			
' 62.2	Definition: Low- Level radioactive waste		NRC	**In § 62.2, the definition for *Low-level radioactive waste (LLW)* is revised to read as follows:** *Low-level radioactive waste (LLW)* means radioactive material that— (1) Is not high-level radioactive waste, spent nuclear fuel, or byproduct material (as defined in paragraphs (2), (3), and (4) of the definition of *Byproduct Material* set forth in § 20.1003 of this chapter); and (2) The NRC, consistent with existing law and in accordance			NA-NRC

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				with paragraph (1) of this definition, classifies as low level radioactive waste.			
' 72.3	Definition: Byproduct Material		NRC	**In § 72.3, the definition for *Byproduct material* is revised to read as follows:** *Byproduct material* means— (1) 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; (2)(i) Any discrete source of radium- 226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that— (A) Has been made radioactive by use of a particle accelerator; and			NA-NRC

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and (3) Any discrete source of naturally occurring radioactive material, other than source material, that— (i) The Commission, 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 (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
' 110.2	Definition: Accelerator produced radioactive material		NRC	**In § 110.2, definition of *Accelerator-produced radioactive material* is added to read as follows:** *Accelerator-produced radioactive material* means any material made radioactive by a particle accelerator.			NA-NRC
' 110.2	Definition: Discrete Source		NRC	In § 110.2, definition of *Discrete source* is added to read as follows: *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.			NA-NRC
' 110.2	Definition: Particle accelerator		NRC	**In § 110.2, definition of *Particle accelerator* is added to read as follows:** *Particle accelerator* means any			NA-NRC NA-NRC

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				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 megaelectron volt. For purposes of this definition, ‘‘accelerator’’ is an equivalent term.			
' 150.3	Definition: Byproduct material	.0104	H&S*** **(***please note 10 CFR 150.3 Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)**	**In § 150.3, the definition of *Byproduct material* is revised to read as follows:** *Byproduct material* means— (1) 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; (2) The tailings or wastes produced by the extraction or concentration of uranium or			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				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; (3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that— (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				(4) Any discrete source of naturally occurring radioactive material, other than source material, that— (i) The Commission, 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 (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
' 150.3	Definition: Discrete source	.0104	H&S	**In § 150.3, the definition of *Discrete source* is added to read as follows:** *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.			

Appendix B

List of Elements

Name	Atomic	
	Symbol	No.
*****	**	**
Nitrogen	N	7
******	**	**
Oxygen	O	8
******	**	**

			Table 1 Occupational Values			Table 2 Effluent Concentration		Table 3 Releases to Sewers
			Col 1	Col 2	Col 3	Col 1	Col. 2	
			Oral Ingestion	Inhalation				
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi/ml)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T_2) Submersion[1] Use above values as HT and T_2 oxidize in air and in the body to HTO						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see ^{7}Be	1E+3 LLI wall	2E+2	6E-8	2E-10	-	-
			(1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{7}Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11[2]	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
8	Oxygen-15[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
9	Fluorine-18[2]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5e+4 St wall	7E+4	3E-5	1E-7	-	-
			(5E+4)	-	-	-	7E-4	7E3
		W, fluorides of Be, Mg Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Nm, Tc, and Re	-	9e+4	4e-5	1e-7	-	-
		y, LANTHANUM FLUORIDE	-	8e+4	3e-5	1e-7	-	-
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides,	-	9E+1	4E-8	1E-10	-	-

Footnotes

1 ‘‘Submersion’’ means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.
2 These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class ‘‘Submersion,’’ are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do not include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E–7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See § 20.1203.)
* * * * *

30.71 Schedule B

Byproduct material	Microcuries
* * * * *	
Cesium 129 (Cs 129)	100
* * * * *	
Cobalt 57 (Co 57)	100
* * * * *	
Gallium 67 (Ga 67)	100
* * * * *	
Germanium 68 (Ge 68)	10
* * * * *	
Gold 195 (Au 195)	10
* * * * *	
Indium 111 (In 111)	100
* * * * *	
Iodine 123 (I 123)	100
* * * * *	
Iron 52 (Fe 52)	10
* * * * *	
Potassium 43 (K 43)	10
* * * * *	
Rubidium 81 (Rb 81)	10
* * * * *	
Sodium 22 (Na 22)	10
* * * * *	
Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
* * * * *	

30.72 Schedule C

Radioactive material 1	Release fraction	Quantity (curies)
*	*	*
Radium-226	0.001	100
*	*	*

15A NCAC 11 .0104 IS PROPOSED FOR AMENDMENT 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, 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. (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 counting) or by analysis and evaluation of materials excreted or removed from the human body.

(21) "Byproduct material" has the meaning as defined in G.S. 104E-5(4).

(22) "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) "Clinical procedures manual" means a collection of documented 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 including the 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 documented procedure(s) for all clinical procedures using radioactive material not requiring a written directive performed at the facility.

~~(23)~~(24) "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) "Commission" has the meaning as defined in G.S. 104E-5(5).

~~(25)~~(26) "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) "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) 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.

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

~~(28)~~(30) "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) "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) "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) "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) "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) "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) "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) "Department" has the meaning as defined in G.S. 104E-5(6).

~~(36)~~(38) "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) "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) "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) 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) "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) "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) "Dose" (or radiation dose) is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, effective dose equivalent, or total effective dose equivalent, as defined in other Items of this Rule.

~~(43)~~(45) "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) "Dose limits" (see "Limits" defined in this Rule).

~~(45)~~(47) "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) "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) "Embryo/fetus" means the developing human organism from conception until the time of birth.

~~(48)~~(50) "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) "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) "Exposure" means being exposed to ionizing radiation or to radioactive material.

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

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

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

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

~~(55)~~(57) "Filtering facepiece (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) "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) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

~~(58)~~(60) "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;), 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) "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) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

~~(61)~~(63) "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) "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) "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) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

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

~~(66)~~(68) "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., DAC-hours; or

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

~~(67)~~(69) "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) "Inhalation class" (see "Class" defined in this Rule).

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

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

~~(71)~~(73) "Lens dose equivalent" 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) "License", except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.

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

~~(74)~~(76) "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 licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).

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

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

~~(77)~~(79) "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.

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

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

~~(80)~~(82) "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.

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

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

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

~~(84)~~(86) "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) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

~~(86)~~(88) "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) "Nonstochastic effect" means health effects, 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 (also called a deterministic effect).

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

~~(89)~~(91) "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 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)~~(92) "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 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

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

~~(92)~~(94) "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 received by the individual.

~~(93)~~(95) "Pharmacist" means a person licensed by this state to practice pharmacy.

~~(94)~~(96) "Physician" means an individual licensed to practice medicine in this state.

~~(95)~~(97) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

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

99 "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) "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.

~~(98)~~

(101) "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) "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) "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) "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.

~~(102)~~

(105) "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) "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) "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) "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) 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) "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) "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) "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) "Radiation dose" means dose.

~~(111)~~

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

~~(112)~~

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

~~(113)~~

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

~~(114)~~

(117) "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) "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) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.

~~(117)~~

(120) "Radiobioassay" means bioassay.

~~(118)~~

(121) "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) "Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.

~~(120)~~

(123) "Registration" means registration with the agency in accordance with these Rules.

~~(121)~~

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

~~(122)~~

(125) "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) 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) "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 at the site, even if the burials were made in accordance with the provisions of Section .1600 of this Chapter.

~~(125)~~

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

~~(126)~~

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

~~(128)~~

(131) "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) "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) "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) "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) "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) "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) "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) "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) "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) "Source material" has the meaning as defined in G.S. 104E-5(15).

~~(138)~~

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

~~(139)~~

(142) "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) "Special nuclear material" has the meaning as defined in G.S. 104E-5(16).

~~(141)~~

(144) "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. For example, the following quantities in combination would not exceed the limitations and are within the formula, as follows:

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

~~(142)~~

(145) "State" means the State of North Carolina.

~~(143)~~

(146) "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) "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) "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.

~~(146)~~

(149) "These Rules" means Chapter 11 of this Title.

~~(147)~~

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

~~(148)~~

(151) "To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable effort.

~~(149)~~

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

~~(150)~~

(153) "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).

~~(151)~~

(154) "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 Rule .0113 of this Section. All quantities of radioactive material greater than a Type A quantity are Type B.

~~(152)~~

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

~~(154)~~

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

~~(155)~~

(158) "User seal check (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) "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) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

~~(157)~~

(160) "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 .0104 (21), 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) "Week" means seven consecutive days starting on Sunday.

~~(162)~~

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

~~(164)~~

(167) "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) "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) "Working level month" (WLM) means an exposure to one working level for 170 hours.

~~(167)~~

(170) "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;

(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) "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);
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. August 1, 2011; November 1, 2007; May 1, 2006; January 1, 2005; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.

15A NCAC 11 .0117 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0117 INCORPORATION BY REFERENCE

(a) For the purpose of the rules in this Chapter, the following rules, standards and other requirements are hereby incorporated by reference including any subsequent amendments and editions:

(1) Appendix A, Appendix B, Appendix C, and Appendix G to 10 CFR Parts 20.1001 - 20.2401;

(2) 10 CFR Part 21, 10 CFR Part 30.1, 30.4, 30.10, 10 CFR Part 31, 10 CFR Part 32, Subpart J of 10 CFR Part 35, 10 CFR 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, Subpart H of 10 CFR Part 35, 35.1000, 10 CFR Part 36, 10 CFR Part 40~~ and 10 CFR Part 50~~;

~~(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71, 10 CFR Part 73, 10 CFR Part 110, 10 CFR Part 140 and 10 CFR Part 150;~~

(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71.0, 71.1, 71.2, 71.3, 71.4, 71.5, 71.8, 71.14(a), 71.15, 71.17(a) – (d), 71.20, 71.21, 71.22, 71.23, 71.47, Subpart G of 10 CFR Part 71, 10 CFR 71.101(a) – (c)(1), 71.101(f), 71.101(g), 71.103, 71.105, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, Appendix A to 10 CFR Part 71, and 10 CFR Part 150;

(4) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040;

(5) 39 CFR Part 14 and 39 CFR Part 15;

(6) Postal Service Manual (Domestic Mail Manual) Section 124.3 [incorporated by reference in 39 CFR Section 111.11];

(7) 40 CFR Part 261;

(8) 49 CFR Parts 100-189;

(9) "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended", signed July 21, 1964;

(10) "Standards and Specifications for Geodetic Control Networks (September 1984);

(11) "Geometric Geodetic Survey Accuracy Standards and Specifications for Geodetic Surveys Using GPS Relative Positioning Techniques";

(12) "Reference Man: Anatomical, Physiological and Metabolic Characteristics" (ICRP Publication No. 23) of the International Commission on Radiological Protection;

(13) "10 CFR, Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 FR 7540"; and

(14) American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography".

(b) The rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule are available for inspection at the ~~Department of Environment and Natural Resources, Division of Radiation Protection~~ Agency at the address listed in Rule .0111 of this Section. Except as noted in the Subparagraphs of this Paragraph, copies of the rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 at a cost as follows:

(1) Three dollars ($3.00) for the appendixes listed in Subparagraph (a)(1) of this Rule, available from the ~~Division of Radiation Protection~~ Agency;

(2) Twenty-five dollars ($25.00) for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts 0-50;

(3) Eighteen dollars ($18.00) for the regulations listed in Subparagraph (a)(3) of this Rule in a volume containing 10 CFR Parts 51-199;

(4) Eighteen dollars ($18.00) for the regulations listed in Subparagraph (a)(4) of this Rule in a volume containing 21 CFR Parts 800-1299;

(5) Sixteen dollars ($16.00) for the regulations listed in Subparagraph (a)(5) of this Rule in a volume containing 39 CFR;

(6) Thirty-six dollars ($36.00) for the manual listed in Subparagraph (a)(6) of this Rule;

(7) Thirty-one dollars ($31.00) for the regulations listed in Subparagraph (a)(7) of this Rule in a volume containing 40 CFR Parts 260-299;

(8) For the regulations listed in Subparagraph (a)(8) of this Rule:

(A) Twenty-three dollars ($23.00) for a volume containing 49 CFR Parts 100-177; and

(B) Seventeen dollars ($17.00) for a volume containing 49 CFR Parts 178-199;

(9) One dollar ($1.00) for the agreement in Subparagraph (a)(9) of this Rule, available from the ~~Division of Radiation Protection~~ Agency;

(10) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(10) of this Rule, available from the National Geodetic Information Center, N/CG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(11) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(11) of this Rule, available from the National Geodetic Information Center, NCG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(12) One hundred and five dollars ($105.00) for the ICRP Publication No. 23 in Subparagraph (a)(12) of this Rule, available from Pergamon Press, Inc., Maxwell House, Fairview Park, Elmsford, NY 10523;

(13) Two dollars ($2.00) for the document in Subparagraph (a)(13) of this Rule, available from the ~~Division of Radiation Protection~~ Agency; and

(14) Thirty-eight dollars plus five dollars shipping and handling ($43.00) for the American National Standard N432-1980 in Subparagraph (a)(14) of this Rule, available from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, telephone number (212) 642-4900.

(c) Nothing in this incorporation by reference of 10 CFR Part 61 in Subparagraph (a)(3) of this Rule shall limit or affect the continued applicability of G.S. 104E-25(a) and (b).

History Note: *Authority G.S. 104E-7; 104E-15(a); 150B-21.6;*
Eff. June 1, 1993;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff., *August 1, 2011;* *November 1, 2007; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.*

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SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL

This Section .0300, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0300); LICENSING OF RADIOACTIVE MATERIAL; has been transferred and recodified from Section .2400, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2400), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

15A NCAC 11 .0301 PURPOSE AND SCOPE

(a) This Section provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to, or as otherwise provided in, this Section.

(b) In addition to the requirements of this Section,

(1) All licensees are subject to the requirements of Sections .1000 and .1600 of this Chapter, except as otherwise provided in the rules of this Section;

(2) Licensees engaged in industrial radiographic operations are subject to the requirements of Section .0500 of this Chapter;

(3) Licensees using sealed sources in the healing arts are subject to the requirements of Section .0700 of this Chapter;

(4) Licensees engaged in the operation of radioactive waste disposal facilities are subject to the requirements of Section .1200 of this Chapter;

(5) Licensees engaged in well-logging operations are subject to the requirements of Section .1300 of this Chapter; and

(6) Licensees engaged in the operation of panoramic and underwater irradiators are subject to the requirements of Section .0100 of this Chapter.

(c) In addition to the requirements of this Section, all licensees are subject to the annual fee provisions contained in Section .1100 of this Chapter.

(d) The rules in this Section do not apply to persons licensed pursuant to the rules in Section .1200 of this Chapter except as specifically provided otherwise in Section .1200.

History Note: *Authority G.S. 104E-7; 104E-9(8); 104E-10(b); 104E-19;*
Eff. February 1, 1980;
Amended Eff. August 1, 1998; January 1, 1994; May 1, 1992; June 1, 1989; July 1, 1982.

15A NCAC 11 .0304 has been amended to maintain required compatibility with 10 CFR 30.18

15A NCAC 11 .0304 EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL

(a) Any person who possesses radioactive material received or acquired under the general license formerly provided in Rule .0303(b) of this Section is exempt from the requirements for a license set forth in this Section to the extent that such person possesses, uses, transfers or owns such radioactive material.

(b) This Rule does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(c) No person shall, for the purposes of commercial distribution, transfer individual quantities of radioactive materials to persons exempt from regulation in Paragraph (a) of this Rule except in accordance with a specific license issued by:

(1) the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 for source and byproduct material;

(2) the agency pursuant to Rule .0326 for radioactive material other than source, byproduct and special nuclear material; or

(3) any agreement state pursuant to equivalent regulation for radioactive material other than source, byproduct and special nuclear material.

(d) Licensees for commercial distribution shall not transfer the quantities of radioactive material to persons exempt under Paragraph (~~e~~ f) of this Rule if the licensee knows or has reason to believe that the recipient will redistribute the quantities to persons exempt under Paragraph (~~e~~ f) of this Rule.

(e) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits in paragraph (f) of this Rule, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this section.

(f) ~~(e)~~ Except as provided in Paragraphs (b) and (c) of this Rule, any person is exempt from the rules of this Chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in the following table:

EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000

1	Cesium-134m (Cs 134m)	100
2	Cesium-134 (Cs 134)	1
3	Cesium-135 (Cs 135)	10
4	Cesium-136 (Cs 136)	10
5	Cesium-137 (Cs 137)	10
6	Chlorine-36 (Cl 36)	10
7	Chlorine-38 (Cl 38)	10
8	Chromium-51 (Cr 51)	1,000
9	Cobalt-57 (Co 57)	100
10	Cobalt-58m (Co 58m)	10
11	Cobalt-58 (Co 58)	10
12	Cobalt-60 (Co 60)	1
13	Copper-64 (Cu 64)	100
14	Dysprosium-165 (Dy 165)	10
15	Dysprosium-166 (Dy 166)	100
16	Erbium-169 (Er 169)	100
17	Erbium-171 (Er 171)	100
18	Europium-152 (Eu 152) 9.2h	100
19	Europium-152 (Eu 152) 13 yr	1
20	Europium-154 (Eu 154)	1
21	Europium-155 (Eu 155)	10
22	Fluorine-18 (F 18)	1,000
23	Gadolinium-153 (Gd 153)	10
24	Gadolinium-159 (Gd 159)	100
25	Gallium-67 (Ga 67)	100
26	Gallium-72 (Ga 72)	10
27	Germanium-68 (Ge 68)	10
28	Germanium-71 (Ge 71)	100
29	Gold-195 (Au-195)	10
30	Gold-198 (Au 198)	100
31	Gold-199 (Au 199)	100
32	Hafnium-181 (Hf 181)	10
33	Holmium-166 (Ho 166)	100
34	Hydrogen-3 (H 3)	1,000
35	Indium-111 (In 111)	100
36	Indium-113m (In 113m)	100
37	Indium-114m (In 114m)	10
38	Indium-115m(In 115m)	100
39	Indium-115 (In 115)	10
40	Iodine-123 (I 123)	100
41	Iodine-125 (I 125)	1
42	Iodine-126 (I 126)	1
43	Iodine-129 (I 129)	0.1
44	Iodine-131 (I 131)	1
45	Iodine-132 (I 132)	10
46	Iodine-133 (I 133)	1
47	Iodine-134 (I 134)	10
48	Iodine-135 (I 135)	10
49	Iridium-192 (Ir 192)	10
50	Iridium-194 (Ir 194)	100
51	Iron-52 (Fe 52)	10
52	Iron-55 (Fe 55)	100
53	Iron-59 (Fe 59)	10
54	Krypton-85 (Kr 85)	100
55	Krypton-87 (Kr 87)	10
56	Lanthanum-140 (La 140)	10

1	Lutetium-177 (Lu 177)	100
2	Manganese-52 (Mn 52)	10
3	Manganese-54 (Mn 54)	10
4	Manganese-56 (Mn 56)	10
5	Mercury-197m (Hg 197m)	100
6	Mercury-197 (Hg 197)	100
7	Mercury-203 (Hg 203)	10
8	Molybdenum-99 (Mo 99)	100
9	Neodymium-147 (Nd 147)	100
10	Neodymium-149 (Nd 149)	100
11	Nickel-59 (Ni 59)	100
12	Nickel-63(Ni 63)	10
13	Nickel-65 (Ni 65)	100
14	Niobium-93m (Nb 93m)	10
15	Niobium-95 (Nb 95)	10
16	Niobium-97 (Nb 97)	10
17	Osmium-185 (Os 185)	10
18	Osmium-191m (Os 191m)	100
19	Osmium-191 (Os 191)	100
20	Osmium-193 (Os 193)	100
21	Palladium-103 (Pd 103)	100
22	Palladium-109 (Pd 109)	100
23	Phosphorus-32 (P 32)	10
24	Platinum-191 (Pt 191)	100
25	Platinum-193m (Pt 193m)	100
26	Platinum-193 (Pt 193)	100
27	Platinum-197m (Pt 197m)	100
28	Platinum-197 (Pt 197)	100
29	Polonium-210 (Po 210)	0.1
30	Potassium-42 (K 42)	10
31	Potassium-43 (K 43)	10
32	Praseodymium-142 (Pr 142)	100
33	Praseodymium-143 (Pr 143)	100
34	Promethium -147 (Pm 147)	10
35	Promethium-149 (Pm 149)	10
36	Rhenium-186 (Re 186)	100
37	Rhenium-188 (Re 188)	100
38	Rhodium-103m (Rh 103m)	100
39	Rhodium-105 (Rh 105)	100
40	Rubidium-81 (Rb 81)	10
41	Rubidium-86 (Rb 86)	10
42	Rubidium-87 (Rb 87)	10
43	Ruthenium-97 (Ru 97)	100
44	Ruthenium-103 (Ru 103)	10
45	Ruthenium-105 (Ru 105)	10
46	Ruthenium-106 (Ru 106)	1
47	Samarium-151 (Sm 151)	10
48	Samarium-153 (Sm 153)	100
49	Scandium-46 (Sc 46)	10
50	Scandium-47 (Sc 47)	100
51	Scandium-48 (Sc 48)	10
52	Selenium-75 (Se 75)	10
53	Silicon-31 (Si 31)	100
54	Silver-105 (Ag 105)	10
55	Silver-110m (Ag 110m)	1
56	Silver-111 (Ag 111)	100

Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulfur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20;*

Eff. February 1, 1980;
Amended Eff. May 1, 1993; July 28, 2011.

15A NCAC 11 .0309 IS PROPOSED FOR AMENDMENT AS FOLLOWS:

15A NCAC 11 .0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES

(a) A general license shall be issued to commercial and industrial firms; research, educational and medical institutions; individuals in the conduct of their business; and federal, state, or local government agencies to acquire, receive, possess, use, or transfer in accordance with Paragraphs (b), (c), and (d) of this Rule, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license in Paragraph (a) of this Rule applies only to radioactive material contained in devices which have been:

(1) manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to Rule .0328 of this Section or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes distribution of the devices to persons generally licensed pursuant to equivalent regulations; and

(2) received from one of the specific licensees referenced in Subparagraph (b)(1) of this Rule or through a transfer completed in accordance with Subparagraph (c)(8) of this Rule.

(c) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license issued under Paragraph (a) of this Rule:

(1) shall assure that all labels, affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by the labels;

(2) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, except as follows:

(A) Devices containing only krypton need not be tested for leakage of radioactive material;

(B) Devices containing only tritium or not more than 100 microcuries of other beta, gamma, or beta and gamma emitting material or ten microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) shall assure that the tests required by Subparagraph (c)(2) of this Rule and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment are performed:

(A) in accordance with the instructions provided on labels affixed to the device, except that tests for leakage or contamination may be performed by the general licensee using leak test kits provided and analyzed by a specific licensee who is authorized to provide leak test kit services; or

(B) by a person holding a specific license or registration which authorizes the providing of services required by this Rule and which is issued pursuant to Rules .0205 and .0306 of this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.

(4) shall maintain records, showing compliance with the requirements in Subparagraphs (c)(2) and (3) of this Rule, to include:

(A) the name of the person(s) performing the test(s) and the date(s) of the test(s);

(B) the name of the person(s) performing installation, servicing and removal of any radioactive material, shielding or containment;

(C) retention of leakage or contamination, on-off mechanism and on-off indicator test records for ~~one year~~ three years after the next required test is performed or until the sealed source is disposed of or transferred~~, whichever is shorter~~;

(D) retention of other records of tests required in Subparagraph (c)(3) of this Rule for ~~two~~ three years from the date of the recorded test or until the device is disposed of or transferred.

(5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been:

(A) repaired by the manufacturer or other person authorized to repair the device(s) by a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state; or

(B) disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device; and within 30 days, furnish to the agency at the address in Rule .0111 of this Chapter a report containing a brief description of the event and the remedial action taken. In the event that 0.005 microcurie or more of removable radioactive contamination is detected, or if the failure of or damage to a source of radiation is likely to result in the contamination of the facility or the environment, a plan for ensuring that the facility and the environment are acceptable for unrestricted use shall be submitted to the agency at the address in Rule .0111 of this Chapter.

(6) shall not abandon the device containing radioactive material;

(7) except as provided in Subparagraph (c)(8) of this Rule, shall transfer or dispose of the device containing radioactive material only by export in accordance with 10 CFR Part 110 or by transfer to a person holding a specific license authorizing receipt of the device; and, ~~prior to~~ within 30 days ~~of~~ after transfer of a device to a specific licesnee or export ~~the transfer~~ of a device ~~to a specific licensee~~, shall furnish to the agency at the address in Rule .0111 of this Chapter, a report that contains:

(A) the identification of the device by manufacturer's or initial transferor's name, model number, and serial number;

(B) the name, address and specific license number of the person receiving the device (license number not applicable if exported); ~~and~~

(C) the date of the transfer~~.~~; and

(D) shall obtain written approval by the agency before transferring the device to any other specific licensee not specifically identified in this Rule; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(i) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(ii) Removes, alters, covers, or clearly and unambiguously augments the existing label otherwise required by paragraph (c)(1) of this section so that the device is labeled in compliance with § .0328(a)(3) of this chapter; however the manufacturer, model number, and serial number must be retained;

(iii) Obtains the manufacturer's or initial transferor's information concerning maintenance that be applicable under the specific license (such as leak testing procedures); and

(iv) Reports the transfer under paragraph (7) of this section.

(8) shall transfer or dispose of the device only by export as provided by (c)(7) of this Rule, or by transfer to another general licensee only where the device:

(A) remains in use at a particular location.

(i) In this case the transferor shall give the transferee a copy of this Section and any safety documents identified in the label of the device;

(ii) The transferor shall, within 30 days of the transfer, report to the agency at the address in Rule .0111 of this Chapter the manufacturer's or initial transferor's name, serial number, and model number of device transferred; the name and mailing address of the transferee; and the name, title, and telephone number of the individual identified by the transferee pursuant to Subparagraph (c)(10) of this Rule as having knowledge of and authority to take actions to ensure compliance with the requirements contained in these Rules; or (B) is held in storage by the licensee or an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(9) shall comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Section .1600 of this Chapter;

(10) shall appoint an individual responsible for having knowledge of the requirements contained in these Rules and the authority for taking the actions required to comply with these Rules. The general licensee, through this individual, shall ensure the day-to-day compliance with these Rules. The

appointment of such an individual does not relieve the general licensee of any of its responsibility in this regard;

(11) shall register, when required by the agency, any source of radiation subject to a general license in accordance with the rules in this Section. Each address for a location of use represents a separate general license and requires a separate registration action;

(12) shall register, on an annual basis, all devices containing, based on the activity indicated on the label, at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37MBq) of cobalt-60, 1 mCi (37 MBq) of americium-241, 0.1 millicurie (3.7 MBq) of radium-226, or any other transuranic isotope. Each address for a location of use represents a separate general license and requires a separate registration action. Annual registration consists of verifying, correcting, or adding to the information provided in a request for annual registration within 30 days of a request from the agency. The general licensee shall furnish the following information for annual registration:

(A) the name and mailing address of the general licensee;

(B) specific information about each device to include the manufacturer or initial transferor, model number, serial number, the radioisotope, and the activity indicated on the label;

(C) the name, title, and telephone number of the responsible person designated as a representative of the general licensee in accordance with Subparagraph (c)(10) of this Rule;

(D) the address or location at which the device(s) are to be used or stored. For portable devices that are granted a general license by the agency, the address of the primary place of storage;

(E) certification by the responsible person designated by the general licensee that the information concerning the device(s) has been verified through a physical inventory and a check of label information; and

(F) certification by the responsible person designated by the general licensee that they are aware of the requirements of the general license.

(13) shall report changes to the mailing address to the agency within 30 days of the effective date of the change;

(14) shall report changes to the name of the general licensee to the agency within 30 days of the effective date of the change;

(15) shall respond to written requests from the agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency a written justification for the request;

~~(15)~~ (16) shall not hold devices that are not in use for longer than two years. If devices that have shutters are not in use, the shutter shall be locked in the closed position. Leak testing is not required during the period of storage; however, when devices are returned to service or transferred to another person, the devices must be tested for leakage and shutter operation. Devices kept in standby for future use shall be excluded from the two year time limit if quarterly physical inventories of these devices are performed while in standby.

(d) The general license in Paragraph (a) of this Rule does not authorize the manufacture or ~~distribution~~ import of devices containing radioactive material.

(e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), .0338, .0342, .0343 and .0345 of this ~~Chpter~~ Chapter and to labeling requirements in Section .1600 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2011; January 1, 2005; January 1, 1994; June 1, 1989.

15A NCAC 11 .0317 has been amended to as required for compliance with 10 CFR 30.32

15A NCAC 11 .0317 SPECIFIC LICENSES: FILING APPLICATION AND GENERAL REQUIREMENT

(a) Applications for specific licenses shall be filed on an agency form. Completed applications shall include the following information and other information required by the agency form:

(1) name, address and use location of the applicant;
(2) training and experience of radioactive material users and of the person responsible for radiation protection;
(3) types, quantities and uses of radioactive materials;
(4) description of facilities, equipment and safety program;
(5) procedures for disposal of radioactive material; and
(6) how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practical, the generation of radioactive waste.

(b) The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either:

(1) Identify the source or device by manufacturer and model number as registered with the US Nuclear Regulatory Commission under10 CFR 32.210 , with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material, with a State under provisions comparable to 10 CFR 32.210; or
(2) Contain the information identified in 10 CFR 32.210(c); or
(3) For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the US Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must provide:
(i) All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and
(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(~~e~~)(f) Applications and documents submitted to the agency may be made available for public inspection except as may be determined otherwise by the agency pursuant to the provisions of G.S. 104E-9(4).

(~~f~~)(g) A license application shall be approved if the agency determines that:

(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules in such a manner as to minimize danger to public health and safety or property;
(2) the applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;
(3) the issuance of the license will not be inimical to the health and safety of the public; and
(4) the applicant satisfies any applicable special requirements in Rules .0318 to .0336 of this Section.

(~~g~~)(h) As provided by Rule .0353 of this Section, certain applications for specific licenses filed under this Section must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before the effective date of this Rule, this submittal may follow the renewal application but must be submitted on or before the effective date of this Rule.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12; 104E-18;
Eff. February 1, 1980;

Amended Eff. August 1, 2011; April 1, 1999; May 1, 1992; November 1, 1989.

15A NCAC 11 .0318 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE

(a) For the purposes of this Rule "Authorized medical physicist" means an individual who:

(1) Meets the requirements in 10 CFR 35.51(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.961(a), or (b), and 35.59;~~ or

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

(A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State;

(B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material licensee;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

(b) For the purposes of this Rule, "Authorized nuclear pharmacist" means a pharmacist who:

(1) Meets the requirements in 10 CFR 35.55(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.980(a) and 35.59;~~ or

(2) Is identified as an authorized nuclear pharmacist on:

(A) A specific license issued by the U.S. Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(B) A permit issued by the U.S. Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use license that authorizes medical use or the practice of nuclear pharmacy; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

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

(4) Is designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(4).

(c) For the purposes of this Rule "Authorized user" means a physician, dentist, or podiatrist who:

(1) Meets the requirements in 10 CFR 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), 35.491(a), 35.590(a), or 35.690(a); ~~or on or before October 24, 2005, met the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59;~~ or

(2) Is identified as an authorized user on:

(A) A U.S. Nuclear Regulatory Commission or Agreement State license that authorizes medical use of radioactive material;

(B) A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(d) For the purposes of this Rule "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.

(e) For the purposes of this Rule "Brachytherapy source" means a radioactive source or a manufacture-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(f) For the purposes of this Rule "High dose-rate remote afterloader" 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.

(g) For the purposes of this Rule "Low dose-rate remote afterloader" 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.

(h) For the purposes of this Rule "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., 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.

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

(j) For the purposes of this Rule "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.

(k) For the purposes of this Rule "Pulsed dose-rate 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:

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

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

(l) For the purposes of this Rule "Radiation safety officer" as used in this Section, means an individual who:

(1) Meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59; ~~or, before October 24, 2005, met the requirements of 10 CFR 35.900(a) and 35.59, as incorporated by reference in 15A NCAC 11 .0117;~~ or

(2) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the U.S. or an Agreement State; or

(B) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(m) For the purposes of this Rule "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.

(n) For the purposes of this Rule "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.

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

(p) License required:

(1) A person shall not manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific license issued by the agency or as allowed pursuant to Subparagraphs (p)(2) and (p)(3) of this Rule.

(2) An individual may receive, possess, use, or transfer radioactive material in accordance with the rules of this Section under the supervision of an authorized user as provided in this Section unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the rules of this Section under the supervision of a pharmacist who is an authorized user or physician who is an authorized user as provided in this Section unless prohibited by license condition.

(q) A license application for human use of radioactive material shall be approved if the agency determines that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;

(3) The issuance of the license will not be inimical to the health and safety of the public;

(4) The following training and supervisory relationship are adhered to:

(A) the user of radioisotopes applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a specific license, including a specific license of broad scope.

(B) An authorized physician may delegate only to persons who are physicians under the supervision of the authorized physician, the following:

(i) the approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope

sources;

(ii) the prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered;

(iii) the determination of the route of administration; and

(iv) the interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

(C) The authorized physician shall review the work of the supervised individual as it pertains to the delegated work in Subparagraph (q)(4) of this Rule and the records kept reflecting that work.

(5) the applicant satisfies any applicable requirements in Rules .0319 to .0322 of this Section.

(r) Subject to the provisions of Subparagraph (q)(4) and Paragraphs (s) to (v) of this Rule, an authorized physician may permit technicians and other paramedic personnel to perform the following activities:

(1) preparation and quality control testing of radiopharmaceuticals and sources of radiation;

(2) measurement of radiopharmaceutical doses prior to administration;

(3) use of appropriate instrumentation for the collection of data to be used by the physician;

(4) administration of radiopharmaceuticals and radiation from radioisotope sources to patients.

(s) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (r) of this Rule shall:

(1) prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with training in the following subjects, as applicable to the duties assigned:

(A) general characteristics of radiation and radioactive materials;

(B) physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used;

(C) mathematics and calculations basic to the use and measurement of radioactivity, including units of radiation dose and radiation exposure;

(D) use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;

(E) principles and practices of radiation protection;

(F) additional training in the above subjects, as appropriate, when new duties are added.

(2) assure that the technicians and other paramedical personnel receive retraining in the subjects listed in Subparagraph (s)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;

(3) keep records showing the bases for the determinations of proper training;

(4) retain responsibility as licensee or authorized user for the satisfactory performance of the activites; and

(5) review the work of the supervised individual and the records kept reflecting that work.

(t) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medicine technology by the Nuclear Medicine Technologist Certification Board or the Society of Nuclear Medicine shall be deemed to satisfy the training requirements in Subparagraphs (s)(1) and (2) of this Rule.

(u) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (r) of this Rule and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.

(v) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be immediately accessible, but not necessarily a physician authorized by the agency to be a user of radioisotopes.

(w) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall:

(1) In addition to the requirements in Rule .1003 of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, this Chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for ~~medial~~ medical uses of radioactive material, written radiation protection procedures established by the

licensee, written directive procedures, rules of this Chapter, and license conditions with respect to the medical use of radioactive material.

(x) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user shall:

(1) In addition to the requirements in Paragraph (s) of this Rule and Rule .1003 of this Chapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules of this Chapter, and license conditions.

(y) A licensee that permits supervised activities under Paragraphs (r) and (s) of this Rule is responsible for the acts and omissions of the supervised individual.

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

(aa) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(bb) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and management prerogative to:

(1) identify radiation safety problems;

(2) investigate radiation safety problems such as overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, medical events, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(3) initiate, recommend or provide corrective actions for radiation safety problems;

(4) verify implementation of corrective actions; and

(5) retain records of items listed in Subparagraphs (1) through (4) of this Paragraph.

(cc) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released in accordance with the requirements of Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and

(B) Visitation authorized by Rule .1611(e) of this Chapter;

(3) Contamination control;

(4) Waste control;

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(dd) The licensee shall retain records of the radiation safety instructions required by Paragraphs (w), (x), and (cc) for three years. The record must include:

(1) List of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2011, November 1, 2007; April 1, 1999; May 1, 1993; November 1, 1989.

15A NCAC 11 .0330 SPECIFIC LICENSES: MANUFACTURE OF CALIBRATION SOURCES

An application for a specific license to manufacture calibration sources containing americium-241 and plutonium for distribution to persons generally licensed under Rule .0312 of this Section will be approved subject to the following conditions:

(1) the applicant satisfies the general requirements of Rule .0317 of this Section; and

(2) the applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.60 and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980.

15A NCAC 11 .0331 has been amended to correct an error, and to incorporate requirements of 10 CFR 32.71 for compatibility:

15A NCAC 11 .0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS

An application for a specific license to manufacture or distribute radioactive material for use under the general license in Rule .0314 of this Section will be approved if the following requirements are satisfied:

(1) The applicant satisfies the general requirements specified in Rule .0317 of this Section.

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) iodine-125 in units not exceeding ten microcuries each;

(b) iodine-131 in units not exceeding ten microcuries each;

(c) carbon-14 in units not exceeding ten microcuries each;

(d) hydrogen-3 (tritium) in units not exceeding 50 microcuries each;

(e) iron-59 in units not to exceed 20 microcuries each;

(f) cobalt-57 in units not to exceed ten microcuries each;

(g) selenium-75 in units not exceeding ten microcuries each.

(h) mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed the appropriate limit in Item (2) of this Rule, and

(b) displaying the radiation caution symbol described in Rule .1623 of this Chapter and the words, "CAUTION, RADIOACTIVE MATERIAL", and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS".

(4) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for IN VITRO clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or a state with which the Commission has entered into an agreement for the exercise of regulatory authority. (Name of Manufacturer)

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Rule .1628 of this Chapter.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;

Amended Eff. August 1, 2011, January 1, 1994.

15A NCAC 11 .0333 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS

An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule .0318, .0319, or .0320 of this Section for ~~the radiopharmaceuticals and associated uses in Groups I, II or IV~~ medical use shall be approved subject to the following conditions:

(1) the applicant satisfies the requirements of Rule .0317 of this Section; and

(2) the applicant meets the applicable requirements in Section 32.72 of 10 CFR Part 32, and Section 30.32 (j) of 10 CFR Part 30.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. November 1, 2007
Amended August 1, 2011.

15A NCAC 11 .0338 is proposed to be amended to maintain required compliance with US Nuclear Regulatory Commission rule 10 CFR 30.349J):

15A NCAC 11 .0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES

(a) Each license issued pursuant to the rules in this Section shall be subject to all the provisions of the Act, now or hereafter in effect, to all rules adopted pursuant to provisions of the Act and to orders of the agency.

(b) No license issued or granted pursuant to this Section and no right to possess or utilize radioactive material granted by any license issued pursuant to this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency, after securing full information, finds that the transfer is in accordance with the provisions of the Act, and gives its consent in writing.

(c) Each person licensed by the agency pursuant to this Section shall confine his use and possession of the radioactive material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) licensee;

(2) an entity [as that term is defined in 11 U.S.C. 101(14)] controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.

(e) The notification in Paragraph (d) of this Rule shall indicate:

(1) the bankruptcy court in which the petition for bankruptcy was filed; and

(2) the date of the filing of the petition.

(f) Licensees required to submit emergency plans pursuant to Rule .0352 of this Section shall follow the emergency plan approved by the agency. The licensees may change the approved plan without agency approval only if the licensee believes the changes do not decrease the effectiveness of the plan and are submitted to the agency no later than 20 calendar days after the changes are made. The licensee shall furnish the change to affected off-site response organizations within six months after the change is made. Proposed changes that the licensee believes are likely to decrease, or may potentially decrease, the effectiveness of the approved emergency plan shall not be implemented without prior application to and prior approval by the agency.

<u>(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule .0361 of this Section. The licensee shall record the results of each test and retain each record for 3 years after the record is made.</u>

<u>(h) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.</u>

<u>(i)(1) Authorization under Rule .0333 of this Section to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.</u>

<u>(2) Each licensee authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:</u>

<u>(i) Satisfy the labeling requirements in Rule .1626 of this Chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.</u>

<u>(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Rule .0333 of this Section.</u>

<u>(3) A licensee that is a pharmacy authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:</u>

<u>(i) an authorized nuclear pharmacist that meets the requirements in Rule .0318 of this Section, or</u>

<u>(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule .0318 of this Section.</u>

<u>(4) A pharmacy, authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of Rule .0318 of this Section.</u>

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. August 1, 2011; May 1, 1993; May 1, 1992; June 1, 1989.

15A NCAC 11 .0352 EMERGENCY PLANS

(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in the table in Subparagraph (e)(1) of this Rule must contain either:

(1) an evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or

(2) an emergency plan for responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under Subparagraph (a)(1) of this Rule:

(1) the radioactive material is physically separated so that only a portion could be involved in an accident;

(2) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(3) the release fraction in the respirable size range would be lower than the release fraction shown in Subparagraph (e)(1) of this Rule due to the chemical or physical form of the material;

(4) the solubility of the radioactive material would reduce the dose received;

(5) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Subparagraph (e)(1) of this Rule;

(6) operating restrictions or procedures would prevent a release fraction as large as that shown in Subparagraph (e)(1) of this Rule; or

(7) other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under Subparagraph (a)(2) of this Rule must include the following information:

(1) brief description of the licensee's facility and area near the site;

(2) identification of each type of radioactive materials accident for which protective actions may be needed;

(3) classification system for classifying accidents as alerts or site area emergencies;

(4) identification of the means of detecting each type of accident in a timely manner;

(5) brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining the equipment;

(6) brief description of the methods and equipment to assess releases of radioactive materials;

(7) brief description of the responsibilities of licensee personnel, should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the agency, and responsibilities for developing, maintaining, and updating the plan;

(8) brief description of notification and coordination, to include a commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate, provided that:

(A) a control point shall be established;

(B) the notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination;

(C) the licensee shall also commit to notify the agency immediately after notification of the appropriate off-site response organizations, not to exceed one hour after the licensee declares an emergency; and

(D) the reporting requirements in Subparagraph (c)(8) of this Rule do not substitute for or relieve the licensee from responsibility for complying with the requirements in the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements;

(9) brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the agency;

(10) brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency, including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel, where such training shall:

(A) familiarize personnel with site-specific emergency procedures; and

(B) thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios;

(11) brief description of the means of restoring the facility to a safe condition after an accident;

(12) brief description of provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies where such provisions shall meet the following specific requirements:

(A) quarterly communications checks with off-site response organizations shall include the check and update of all necessary telephone numbers;

(B) while participation of off-site response organizations in biennial exercises is encouraged but not required, the licensee shall invite off-site response organizations to participate in the biennial exercises;

(C) accident scenarios for biennial exercises shall not be known to most exercise participants;

(D) the licensee shall critique each exercise using individuals who do not have direct implementation responsibility for the plan; and

(E) critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response; and

(F) deficiencies found by the critiques in Part (c)(12)(E) of this Rule shall be corrected;

(13) certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(d) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 day comment period to the agency with the emergency plan.

(e) Quantities of radioactive material requiring consideration of the need for an emergency plan for responding to a release as used in this Rule and special instructions for use are:

(1) TABLE

RADIOACTIVE MATERIAL	RELEASE FRACTION	QUANTITY (CURIES)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242 .	001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14 (NON CO)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500

Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166 m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114 m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110 m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99 m	.01	400,000
Tellurium-127 m	.01	5,000
Tellurium-129 m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000

Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha	.0001	20

(2) For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in the table in Subparagraph (e)(1) of this Rule exceeds one.

(3) Waste packaged in Type B containers, as defined in 10 CFR Part 71.4, does not require an emergency plan.

History Note: *Authority G.S. 104E-7; 104E-18;*
Eff. May 1, 1992;
Amended Eff. May 1, 1993; October 1, 1992.

15A NCAC 11 .0359 MEASUREMENTS/DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE

(a) A licensee shall possess and use a dose calibrator to measure the radioactivity of dosages of photon-emitting radionuclides prior to administration to each individual. A licensee shall:

(1) develop, maintain, and implement written procedures for use of the dose calibrator;

(2) calibrate each dose calibrator in accordance with the requirements of 10 CFR 35.60(b).

(b) A licensee shall retain a record of each check, test, and calibration performed in accordance with this Rule for a period of three years following the test.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12;
Eff. April 1, 1999;
Amended Eff. November 1, 2007.

15A NCAC 11 .0361 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL

(a) A licensee may use any unsealed radioactive material prepared for use for uptake, dilution, or excretion studies, imaging and localization studies and radiopharmaceutical therapy that is:

(1) Obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements; or

(2) ~~Prepared by:~~ A positron emission tomography (PET) radioactive drug producer licensed under 10 CFR 30.32(j), 15A NCAC 11 .0333, or equivalent Agreement State requirements; or

~~(A) An authorized nuclear pharmacist;~~

~~(B) A physician who is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0117(a)(2);~~

~~(C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(2)(A) of this Rule or the physician who is an authorized user in Part (a)(2)(B) of this Rule;~~

(3) Excluding production of PET radionuclides, prepared by:

(A) An authorized nuclear pharmacist;

(B) A physician who is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0117(a)(2);

(C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(2)(A) of this Rule or the physician who is an authorized user in Part (a)(2)(B) of this Rule;

~~(3)~~ (4) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA; or

~~(4)~~ (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA.

(b) A licensee shall not administer to humans a radiopharmaceutical that contains: ~~containing more than 0.15 microcurie (0.15 kilobecquerel) of molybdenum-99 per millicurie (megabecquerel) of technetium-99m.~~

(1) more than 0.15 microcurie (0.15 kilobecquerel) of molybdenum-99 per millicurie (megabecquerel) of technetium-99m.

(2) more than 0.02 microcurie (0.02 kilobequerel) of strontium-82 per millicurie (megabequerel) of rubidium-82 chloride, or 0.2 microcurie (0.2 kilobequerel) of strontium-85 per millicurie (megabequerel) of rubidium-82 chloride.

~~(c) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in the first eluate after receipt of a generator to demonstrate compliance with Paragraph (b) of this Rule.~~

(c) (1) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in the first eluate after receipt of a generator to demonstrate compliance with Paragraph (b) of this Rule.

(2) A licensee that uses strontium-82/rubidium-82 generators for preparing a rubidium-82 radiopharmaceutical shall measure the concentrations of strontium-82 and strontium-85 before the first patient use of the day to demonstrate compliance with Paragraph (b) of this Rule.

(d) A licensee that must measure molybdenum-99, or strontium-82 and strontium-85, concentration shall retain a record of each measurement for three years. The record shall include: ~~for each measured elution of technetium-99m:~~

(1) for each measured elution of technetium-99m: the ratio of the measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m (or kilobecquerels of molybdenum-99 per megabecquerel of technetium-99m); or

(2) for each measured elution of rubidium-82: the ratio of the measures expressed as microcuries of strontium-82 and strontium-85 per millicurie of rubidium-82 (or kilobequerel strontium-82 and strontium-85 per megabequerel rubidium-82); and

~~(2)~~(3) the time and date of the measurement; and

~~(3)~~(4) the initials of the individual who made the measurement.

History Note Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12;
Eff. April 1, 1999;
Amended Eff. August 1, 2011, November 1, 2007.

15A NCAC 11 .1626 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .1626 LABELING REQUIREMENTS AND EXEMPTIONS

(a) The licensee shall ensure that: ~~each container of licensed radioactive material bears a durable, clearly visible label bearing the radiation symbol and the words:~~

(1) each container of licensed radioactive material bears a durable, clearly visible label bearing the radiation symbol and the words:

CAUTION
RADIOACTIVE MATERIAL

or the words:

DANGER
RADIOACTIVE MATERIAL

The label shall also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures~~.~~, and;

(2) each syringe and vial that contains unsealed radioactive material for medical use shall also be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

(b) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(c) Except as required in Paragraph (a)(2) of this rule, ~~A~~ a licensee is not required to label:

(1) containers holding licensed radioactive material in quantities less than the quantities listed in Appendix C to 10 CFR §§ 20.1001 - 20.2401;

(2) containers holding licensed radioactive material in concentrations less than those specified in Table 3 of Appendix B to 10 CFR §§ 20.1001 - 20.2401;

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

(4) containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation,

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

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

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994,~~.~~
Amended August 1, 2011.

15A NCAC 11 .1628 GENERAL REQUIREMENTS FOR WASTE DISPOSAL

(a) A licensee shall dispose of licensed radioactive material only:

(1) by transfer to an authorized recipient as provided in Section .0300 of this Chapter;

(2) by decay in storage;

(3) by release in effluents within the limits in Rule .1611 of this Section; or

(4) as authorized by Rules .1629, .1630, .1631, or .1632 of this Section; or

(5) a land disposal facility licensed under Section .1200 of this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.

(b) Except as provided in Section .1200 of this Chapter, no licensee shall receive radioactive waste from other persons for:

(1) treatment prior to disposal;

(2) treatment or disposal by incineration;

(3) decay in storage; or

(4) disposal.

History Note: Authority G.S. 104E-7(a)(2);
Eff. January 1, 1994.

15A NCAC 11 .1633 is proposed to be amended to include requirements in 10 CFR 20.2006 and 20.2008 to maintain required compatibility:

15A NCAC 11 .1633 TRANSFER FOR DISPOSAL AND MANIFESTS

(a) The requirements of this Rule and Appendix G to 10 CFR 20, incorporated by reference in Rule .0117 of this Chapter, are designed to:

(1) control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix G to 10 CFR 20, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste disposal facility, as defined in Rule .1202 of this Chapter;

(2) establish a manifest tracking system; and

(3) supplement existing requirements concerning transfers and recordkeeping for those wastes.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with this Rule and Appendix G to 10 CFR 20.

(c) Each shipment manifest shall include a certification by the waste generator as specified in Appendix G to 10 CFR 20.

(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in this Rule and Appendix G to 10 CFR 20.

(e) Reports and notifications required to be made to the nearest regional administrator by Appendix G to 10 CFR 20 shall, instead, be made to the agency.

(f) Any licensee shipping radioactive material as defined in Rule .0104 of this Chapter intended for ultimate disposal at a land disposal facility as defined in Rule .1202 of this Chapter must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this 10 CFR 20.

(g) Radioactive material as defined in Rule .0104 of this Chapter may be disposed of in accordance with Rule .1628 of this Section, even though it is not defined as low-level radioactive waste. Therefore, any licensed radioactive material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61 , must meet the requirements of this Rule.

(h) A licensee may dispose of radioactive material as defined in Rule .0104 of this Chapter, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

History Note: Authority G.S. 104E-7(a)(2),(a)(3); 104E-12(a);

Eff. January 1, 1994;

Amended Eff. August 1, 2011; April 1, 1999.

Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent Parts – 19 and 20
(72 FR 68043) RATS ID # 2008-1 Effective date 02/15/08
Date Due for State Adoption 02/15/11

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
' 19.13	Notification and reports to individuals	.1004	C	**In § 19.13, paragraphs (b) and (d) are revised to read as follows:** (b) Each licensee shall make dose information available to workers as shown in records maintained by the licensee under the provisions of 10 CFR 20.2106. The licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if: (1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or (2) The individual requests his or her annual dose report. * * * * * (d) When a licensee is required by §§ 20.2202, 20.2203 or 20.2204 of this chapter to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee			

Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent Parts – 19 and 20
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				shall also provide the individual a report on his or her exposure data included in the report to the Commission. This report must be transmitted no later than the transmittal to the Commission.			
' 20.1003	Definition: Total Effective Dose Equivalent (TEDE)	.0104	A	**In § 20.1003, the definition of *Total Effective Dose Equivalent (TEDE)* is revised to read as follows:** *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).			

Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent Parts – 19 and 20
(72 FR 68043) RATS ID # 2008-1 Effective date 02/15/08
Date Due for State Adoption 02/15/11

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
' 20.1201	Occupational Dose Limits for Adults	.1604	A	**In § 20.1201, paragraph (c) is revised to read as follows:** (c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the			

Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent Parts – 19 and 20
(72 FR 68043) RATS ID # 2008-1 Effective date 02/15/08
Date Due for State Adoption 02/15/11

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.			
' 20.1905 (g)	Exemptions to Labeling Requirements		NRC (*****please note Part 20.1905 (a) – (f) still remains a Compatibility Category A only the newly added paragraph (g) is a Compatibility Category NRC)**	**In § 20.1905 paragraph (g) is added to read as follows:** (g) Containers holding licensed material (other than sealed sources that are either specifically or generally licensed) at a facility licensed under Parts 50 or 52 of this chapter, not including non-power reactors, that are within an area posted under the requirements in § 20.1902 if the containers are: (1) Conspicuously marked (such as by providing a system of color coding of containers) commensurate with the radiological hazard; (2) Accessible only to individuals who have sufficient instruction to			NA-NRC

Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent Parts – 19 and 20
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Date Due for State Adoption 02/15/11

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				minimize radiation exposure while handling or working in the vicinity of the containers; and (3) Subject to plant procedures to ensure they are appropriately labeled, as specified at § 20.1904 before being removed from the posted area.			
' 20.2104	Determination of Prior Occupational Dose		D	N/A	N/A		
' 20.2205	Reports to Individuals of Exceeding Dose Limits	.1648 amended, already covered in .1647	C	**Section 20.2205 is revised to read as follows:** When a licensee is required by §§ 20.2203 or 20.2204 to report to the Commission any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the			

Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent Parts – 19 and 20
(72 FR 68043) RATS ID # 2008-1 Effective date 02/15/08
Date Due for State Adoption 02/15/11

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				report to Commission. This report must be transmitted no later than the transmittal to the Commission.			

15A NCAC 11 .0104 IS PROPOSED FOR AMENDMENT 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, 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. (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 counting) or by analysis and evaluation of materials excreted or removed from the human body.

(21) "Byproduct material" has the meaning as defined in G.S. 104E-5(4).

(22) "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) "Clinical procedures manual" means a collection of documented 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 including the 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 documented procedure(s) for all clinical procedures using radioactive material not requiring a written directive performed at the facility.

~~(23)~~(24) "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) "Commission" has the meaning as defined in G.S. 104E-5(5).

~~(25)~~(26) "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) "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) 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.

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

~~(28)~~(30) "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) "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) "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) "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) "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) "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) "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) "Department" has the meaning as defined in G.S. 104E-5(6).

~~(36)~~(38) "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) "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) "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) 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) "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) "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) "Dose" (or radiation dose) is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, effective dose equivalent, or total effective dose equivalent, as defined in other Items of this Rule.

~~(43)~~(45) "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) "Dose limits" (see "Limits" defined in this Rule).

~~(45)~~(47) "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) "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) "Embryo/fetus" means the developing human organism from conception until the time of birth.

~~(48)~~(50) "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) "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) "Exposure" means being exposed to ionizing radiation or to radioactive material.

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

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

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

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

~~(55)~~(57) "Filtering facepiece (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) "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) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

~~(58)~~(60) "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;), 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) "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) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

~~(61)~~(63) "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) "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) "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) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

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

~~(66)~~(68) "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., DAC-hours; or

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

~~(67)~~(69) "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) "Inhalation class" (see "Class" defined in this Rule).

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

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

~~(71)~~(73) "Lens dose equivalent" 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) "License", except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.

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

~~(74)~~(76) "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 licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).

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

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

~~(77)~~(79) "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.

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

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

~~(80)~~(82) "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.

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

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

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

~~(84)~~(86) "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) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

~~(86)~~(88) "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) "Nonstochastic effect" means health effects, 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 (also called a deterministic effect).

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

~~(89)~~(91) "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 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)~~(92) "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 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

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

~~(92)~~(94) "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 received by the individual.

~~(93)~~(95) "Pharmacist" means a person licensed by this state to practice pharmacy.

~~(94)~~(96) "Physician" means an individual licensed to practice medicine in this state.

~~(95)~~(97) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

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

99 "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) "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.

~~(98)~~

(101) "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) "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) "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) "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.

~~(102)~~

(105) "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) "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) "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) "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) 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) "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) "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) "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) "Radiation dose" means dose.

~~(111)~~

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

~~(112)~~

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

~~(113)~~

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

~~(114)~~

(117) "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) "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) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.

~~(117)~~

(120) "Radiobioassay" means bioassay.

~~(118)~~

(121) "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) "Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.

~~(120)~~

(123) "Registration" means registration with the agency in accordance with these Rules.

~~(121)~~

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

~~(122)~~

(125) "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) 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) "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 at the site, even if the burials were made in accordance with the provisions of Section .1600 of this Chapter.

~~(125)~~

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

~~(126)~~

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

~~(128)~~

(131) "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) "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) "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) "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) "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) "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) "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) "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) "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) "Source material" has the meaning as defined in G.S. 104E-5(15).

~~(138)~~

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

~~(139)~~

(142) "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) "Special nuclear material" has the meaning as defined in G.S. 104E-5(16).

~~(141)~~

(144) "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. For example, the following quantities in combination would not exceed the limitations and are within the formula, as follows:

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

~~(142)~~

(145) "State" means the State of North Carolina.

~~(143)~~

(146) "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) "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) "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.

~~(146)~~

(149) "These Rules" means Chapter 11 of this Title.

~~(147)~~

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

~~(148)~~

(151) "To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable effort.

~~(149)~~

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

~~(150)~~

(153) "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).

~~(151)~~

(154) "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 Rule .0113 of this Section. All quantities of radioactive material greater than a Type A quantity are Type B.

~~(152)~~

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

~~(154)~~

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

~~(155)~~

(158) "User seal check (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) "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) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

~~(157)~~

(160) "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 .0104 (21), 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) "Week" means seven consecutive days starting on Sunday.

~~(162)~~

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

~~(164)~~

(167) "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) "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) "Working level month" (WLM) means an exposure to one working level for 170 hours.

~~(167)~~

(170) "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;

(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) "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);
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. August 1, 2011; November 1, 2007; May 1, 2006; January 1, 2005; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.

15A NCAC 11 .1004 is proposed to be amended to include revisions required for compatibility with 10 CFR 19.13

15A NCAC 11 .1004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of any individual shall be reported to the individual as specified in this Rule. The information reported shall include data and results obtained pursuant to rules of this Chapter, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to provisions of this Chapter. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number; include the individual's exposure information; and contain the following statement:

This report is furnished to you under the provisions of Section 15A NCAC 11 .1000; NOTICES, INSTRUCTIONS, REPORTS AND INSPECTIONS. You should preserve this report for further reference.

~~(b) At the request of any worker, each licensee or registrant shall advise such worker annually of the worker's radiation dosage and exposure to radioactive materials as shown in records maintained by the licensee or registrant pursuant to Paragraphs (a) and (c) of this Rule.~~

(b) Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of Rule .1640 of this Chapter. The licensee or registrant shall provide an annual report to each individual monitored under Rule .1614 of this Chapter of the dose received in that monitoring year if:

(1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or

(2) The individual requests his or her annual dose report.

(c) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's radiation dosage and exposure to radioactive materials. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the agency; and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to Rule .1646.1647, or .1648 of this Chapter to report to the agency any overexposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time no later than the transmittal to the agency.

History Note: Authority G.S. 104E-7; 104E-10; 104E-12;
Eff. February 1, 1980;

Amended Eff. August 1, 2011; January 1, 1994.

15A NCAC 11 .1604 is proposed to be amended to include requirements to maintain required compatibility with 10 CFR 20.1201:

15A NCAC 11 .1604 OCCUPATIONAL DOSE LIMITS FOR ADULTS

(a) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures as provided in Rule .1608 of this Section, to the following dose limits:

(1) an annual limit, which is the more limiting of:

(A) the total effective dose equivalent being equal to five rems (0.05Sv); or

(B) the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv); and

(2) the annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:

(A) an eye dose equivalent of 15 rems (0.15 Sv), and

(B) a shallow-dose equivalent of 50 rems (0.50 Sv) to the skin of the whole body or to the skin of any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. Dose limits for planned special exposures are provided in Item (5) of Rule .1608 of this Section.

~~(c) The assigned deep-dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, eye-dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.~~

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

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 1 of Appendix B to 10 CFR §§ 20.1001 - 20.2401 and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. Requirements for annual limits on intake for uranium are provided in Appendix B to 10 CFR §§ 20.1001 - 20.2401.

(f) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Requirements for determining prior occupational exposure are provided in Rule .1638(e) of this Section.

History Note: Authority G.S. 104E-7(a)(2);
Eff. January 1, 1994;
Amended Eff.August 1, 2011; May 1, 2006.

15A NCAC 11 .1647 REPORTS OF RADIATION EXCEEDING THE LIMITS

(a) In addition to the notification required by Rule .1646 of this Section, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(1) any incident for which notification is required by Rule .1646 of this Section;

(2) doses in excess of any of the following:

(A) the occupational dose limits for adults in Rule .1604 of this Section;

(B) the occupational dose limits for a minor in Rule .1609 of this Section;

(C) the limits for an embryo/fetus of a declared pregnant woman in Rule .1610 of this Section;

(D) the limits for an individual member of the public in Rule .1611 of this Section;

(E) any applicable limit in the license; or

(F) The ALARA constraints for air emissions established in Rule .1603 of this Section;

(3) levels of radiation or concentrations of radioactive material in:

(A) a restricted area in excess of any applicable limit in the license; or

(B) an unrestricted area in excess of 10 times any applicable limit set forth in this Section or in the license, whether or not involving exposure of any individual in excess of the limits in Rule .1611 of this Section.

(b) Each report required by Paragraph (a) of this Rule shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(1) estimates of each individual's dose;

(2) the levels of radiation and concentrations of radioactive material involved;

(3) the cause of the elevated exposures, dose rates, or concentrations; and

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

(c) Each report filed pursuant to Paragraph (a) of this Rule shall include for each occupationally overexposed individual: the name, social security account number, and date of birth. With respect to the limit for the embryo/fetus required by Rule .1610 of this Section, the identifying information shall be that of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable part of the report.

(d) Reports made by licensees or registrants in response to the requirements of this Rule shall be addressed to the agency as specified in Rule .0111 of this Chapter.

(e) Any reports made by licensees or registrants in response to the requirements of this Rule shall also be provided to the exposed individual. The copy submitted to the exposed individual shall be transmitted at a time no later than the transmittal to the agency.

History Note: *Authority G.S. 104E-7(a)(2); 104E-12(a);*
Eff. January 1, 1994;
Amended Eff. April 1, 1999; August 1, 1998.

15A NCAC 11 .1648 is proposed to be amended to maintain required compatibility with 10 CFR 20.2205:

15A NCAC 11 .1648 REPORTS OF PLANNED SPECIAL EXPOSURES

(a) -The licensee or registrant shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with Rule .1608 of this Section, informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Rule .1639 of this Section.

(b) When a licensee or registrant is required by this Rule to report to the agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide the individual a report on his or her exposure data included in the report to the agency. This report must be transmitted no later than the transmittal to the agency.

History Note: Authority G.S. 104E-7(a)(2); 104E-12(a);
Eff. January 1, 1994.
Amended Eff. August 1, 2011

Medical Use of Byproduct Material—Authorized User Clarification, Part 35
(74 FR 33901) RATS ID # 2009-1 Effective date 09/28/09
Date Due for State Adoption 09/28/12

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§ 35.50	Training for Radiation Safety Officer	All incorporated by reference in .0318	B	**In § 35.50, paragraph (a)(2)(ii)(B) is revised to read as follows:** * * * * * (a) * * * (2) * * * (ii) * * * (B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390;			
§ 35.51	Training for an authorized medical physicist.	All incorporated by reference in .0318	B	**In § 35.51, paragraphs (a)(2)(ii) and (b)(2) are revised to read as follows:** (a) * * * (2) * * * (ii) In clinical radiation facilities providing high-energy, external			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690; and * * * * * (b) * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (a)(2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				therapeutic medical unit for which the individual is requesting authorized medical physicist status; and * * * * *			
§ 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist**.**	All incorporated by reference in .0318	B	**In § 35.57, a new paragraph (c) is added to read as follows:** (c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.			
§ 35.190	Training for uptake, dilution, and excretion studies.	All incorporated by reference in .0318	B	**In § 35.190, the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (c)(1) * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57,			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving— * * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.			
§ 35.290	Training for imaging and localization studies.	All incorporated by reference in .0318	B	**In § 35.290, the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (c)(1) * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57,			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, involving— * * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.			
§ 35.390	Training for use of unsealed byproduct material for which a written directive is required.	All incorporated by reference in .0318	B	**In § 35.390, the introductory text of paragraph (b)(1)(ii) and paragraph (b)(2) are revised to read as follows:** (b)(1) * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57,			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve— * * * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. The preceptor			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				authorized user, who meets the requirements in § 35.390(b) must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.			
§ 35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).	All incorporated by reference in .0318	B	**In § 35.392, the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:** (c) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2). The work experience must involve— * * * * * (3) Has obtained written			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2).			
§ 35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in	All incorporated by reference in .0318	B	**In § 35.394, the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:** (c) * * * (2) Has work experience, under the supervision of an			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
	quantities greater than 1.22 gigabecquerels (33 millicuries).			authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve— * * * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				the requirements in § 35.390(b), must also have experience in administering osages as specified in § 35.390(b)(1)(ii)(G)(2).			
§ 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.	All incorporated by reference in .0318	B	**In § 35.396, the introductory text of paragraph (d)(2) and paragraph (d)(3) are revised to read as follows:** (d) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in § 35.390 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				35.390(b)(1)(ii)(G)(4). The work experience must involve— * * * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4).			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§ 35.490	Training for use of manual brachytherapy sources.	All incorporated by reference in .0318	B	**In § 35.490, the introductory text of paragraph (b)(1)(ii) and paragraphs (b)(2) and (b)(3) are revised to read as follows**: (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements at a medical institution, involving— * * * * * (2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1), or paragraphs (b)(1) and (b)(2), of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§ 35.491	Training for ophthalmic use of strontium-90.	All incorporated by reference in .0318	B	**In § 35.491, paragraph (b)(3) is revised to read as follows:** (b) * * * (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.			
§ 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	All incorporated by reference in .0318	B	**In § 35.690, the introductory text of paragraph (b)(1)(ii) and paragraphs (b)(2) and (b)(3) are revised to read as follows:** (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				at a medical institution, involving— * * * * * (2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (a)(1) or paragraphs (b)(1) and			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				(b)(2), and paragraph (c), of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and			

15A NCAC 11 .0318 IS PROPOSED TO BE AMENDED AS FOLLOWS:

15A NCAC 11 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE

(a) For the purposes of this Rule "Authorized medical physicist" means an individual who:

(1) Meets the requirements in 10 CFR 35.51(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.961(a), or (b), and 35.59;~~ or

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

(A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State;

(B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material licensee;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

(b) For the purposes of this Rule, "Authorized nuclear pharmacist" means a pharmacist who:

(1) Meets the requirements in 10 CFR 35.55(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.980(a) and 35.59;~~ or

(2) Is identified as an authorized nuclear pharmacist on:

(A) A specific license issued by the U.S. Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(B) A permit issued by the U.S. Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use license that authorizes medical use or the practice of nuclear pharmacy; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

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

(4) Is designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(4).

(c) For the purposes of this Rule "Authorized user" means a physician, dentist, or podiatrist who:

(1) Meets the requirements in 10 CFR 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), 35.491(a), 35.590(a), or 35.690(a); ~~or on or before October 24, 2005, met the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59;~~ or

(2) Is identified as an authorized user on:

(A) A U.S. Nuclear Regulatory Commission or Agreement State license that authorizes medical use of radioactive material;

(B) A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(d) For the purposes of this Rule "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.

(e) For the purposes of this Rule "Brachytherapy source" means a radioactive source or a manufacture-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(f) For the purposes of this Rule "High dose-rate remote afterloader" 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.

(g) For the purposes of this Rule "Low dose-rate remote afterloader" 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.

(h) For the purposes of this Rule "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., 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.

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

(j) For the purposes of this Rule "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.

(k) For the purposes of this Rule "Pulsed dose-rate 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:

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

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

(l) For the purposes of this Rule "Radiation safety officer" as used in this Section, means an individual who:

(1) Meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59; ~~or, before October 24, 2005, met the requirements of 10 CFR 35.900(a) and 35.59, as incorporated by reference in 15A NCAC 11 .0117;~~ or

(2) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the U.S. or an Agreement State; or

(B) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(m) For the purposes of this Rule "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.

(n) For the purposes of this Rule "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.

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

(p) License required:

(1) A person shall not manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific license issued by the agency or as allowed pursuant to Subparagraphs (p)(2) and (p)(3) of this Rule.

(2) An individual may receive, possess, use, or transfer radioactive material in accordance with the rules of this Section under the supervision of an authorized user as provided in this Section unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the rules of this Section under the supervision of a pharmacist who is an authorized user or physician who is an authorized user as provided in this Section unless prohibited by license condition.

(q) A license application for human use of radioactive material shall be approved if the agency determines that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;

(3) The issuance of the license will not be inimical to the health and safety of the public;

(4) The following training and supervisory relationship are adhered to:

(A) the user of radioisotopes applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a specific license, including a specific license of broad scope.

(B) An authorized physician may delegate only to persons who are physicians under the supervision of the authorized physician, the following:

(i) the approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope

sources;

(ii) the prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered;

(iii) the determination of the route of administration; and

(iv) the interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

(C) The authorized physician shall review the work of the supervised individual as it pertains to the delegated work in Subparagraph (q)(4) of this Rule and the records kept reflecting that work.

(5) the applicant satisfies any applicable requirements in Rules .0319 to .0322 of this Section.

(r) Subject to the provisions of Subparagraph (q)(4) and Paragraphs (s) to (v) of this Rule, an authorized physician may permit technicians and other paramedic personnel to perform the following activities:

(1) preparation and quality control testing of radiopharmaceuticals and sources of radiation;

(2) measurement of radiopharmaceutical doses prior to administration;

(3) use of appropriate instrumentation for the collection of data to be used by the physician;

(4) administration of radiopharmaceuticals and radiation from radioisotope sources to patients.

(s) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (r) of this Rule shall:

(1) prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with training in the following subjects, as applicable to the duties assigned:

(A) general characteristics of radiation and radioactive materials;

(B) physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used;

(C) mathematics and calculations basic to the use and measurement of radioactivity, including units of radiation dose and radiation exposure;

(D) use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;

(E) principles and practices of radiation protection;

(F) additional training in the above subjects, as appropriate, when new duties are added.

(2) assure that the technicians and other paramedical personnel receive retraining in the subjects listed in Subparagraph (s)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;

(3) keep records showing the bases for the determinations of proper training;

(4) retain responsibility as licensee or authorized user for the satisfactory performance of the activites; and

(5) review the work of the supervised individual and the records kept reflecting that work.

(t) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medicine technology by the Nuclear Medicine Technologist Certification Board or the Society of Nuclear Medicine shall be deemed to satisfy the training requirements in Subparagraphs (s)(1) and (2) of this Rule.

(u) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (r) of this Rule and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.

(v) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be immediately accessible, but not necessarily a physician authorized by the agency to be a user of radioisotopes.

(w) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall:

(1) In addition to the requirements in Rule .1003 of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, this Chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for ~~medial~~ medical uses of radioactive material, written radiation protection procedures established by the

licensee, written directive procedures, rules of this Chapter, and license conditions with respect to the medical use of radioactive material.

(x) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user shall:

(1) In addition to the requirements in Paragraph (s) of this Rule and Rule .1003 of this Chapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules of this Chapter, and license conditions.

(y) A licensee that permits supervised activities under Paragraphs (r) and (s) of this Rule is responsible for the acts and omissions of the supervised individual.

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

(aa) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(bb) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and management prerogative to:

(1) identify radiation safety problems;

(2) investigate radiation safety problems such as overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, medical events, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(3) initiate, recommend or provide corrective actions for radiation safety problems;

(4) verify implementation of corrective actions; and

(5) retain records of items listed in Subparagraphs (1) through (4) of this Paragraph.

(cc) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released in accordance with the requirements of Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and

(B) Visitation authorized by Rule .1611(e) of this Chapter;

(3) Contamination control;

(4) Waste control;

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(dd) The licensee shall retain records of the radiation safety instructions required by Paragraphs (w), (x), and (cc) for three years. The record must include:

(1) List of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2011, November 1, 2007; April 1, 1999; May 1, 1993; November 1, 1989.