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~~, North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.

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

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

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

(10) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed radioactive material, exist in concentrations:

(a) in excess of the derived air concentrations (DACs) specified in Appendix B to 10 CFR 20.1001 - 20.2401; or

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

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

(12) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in an effective dose equivalent of five rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (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), and in addition includes:

(a) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies

depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

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

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

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

(d) Any discrete source of naturally occurring radioactive material, other than source material, that

(i) the US Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection, the Secretary of Energy, the Secretary of Homeland Security, and the head of an other appropriate federal agency, determines would poses a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

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

(22) "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 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 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~~ includes 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.~~ 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~~ North Carolina to practice pharmacy (21 NCAC 46.1500).

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

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

~~(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 2.58×10^{-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:

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

~~(142)~~ (145) "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, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

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

~~(150)~~ (153) "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 paragraphs (b), (c), and (d) of the definition of "Byproduct Material" set forth in rule

.0104 of this Section, 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; and

(f) for gamma stereotactic radiosurgery:

(i) the total dose;

(ii) treatment site; and

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

~~(168)~~ (171) "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. October 1, 2013; November 1, 2007; May 1, 2006; January 1, 2005; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.

15A NCAC 11 .0105 is proposed for amendment as follows:

15A NCAC 11 .0105 OTHER DEFINITIONS

Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600, .0800, .1200, .1300, .1400, and .1500 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2205 Eff. January 4, 1990;
Amended Eff. October 1, 2013; May 1, 1993.

15A NCAC 11 .0117 is proposed for amendment 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,~~ Part 31 except 31.5, 10 CFR Part 32.2, 32.13, 32.24, 32.110, 32.201, 32.210, ~~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 except 40.12(b), 40.23, 40.27, 40.28, 40.31(j-m), 40.32(d), and parts of (e) pertaining to uranium enrichment, and (g), 40.33, 40.38, 40.41(d), (e)(1), (e)(3), (g), (h), 40.51(b)(6), 40.64, 40.66-67; ~~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 except 61.16, 61.23(i),(j), 10 CFR Part 70 except 70.1 (c), (d), (e), 70.13-14, 70.20(a), (b), 70.21(a)(1), (c), (f-h), 70.22(b), (c), (f-n), 70.23 (a)(6-12), (b), 70.23a, 70.24, 70.25(a)(1), 70.31(c-e), 70.32(a)(1), (a)(4-7), (b)(1), (b)(3), (b)(4)(c-k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), 70.52, 70.55(c), 70.59-62, 70.64-66, 70.72-74, 70.76, 70.82, 10 CFR Part 71.0, 71.1, 71.2, 71.3, 71.13, 71.4, 71.5, 71.8, 71.14(a), 71.15, 71.17(a) – (e), 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 except 150.3 Definition: Foreign Obligations, 150.7, 150.10, 150.14, 150.15, 150.15a, 150.16-17, 150.17a, 150.19, 150.21;

(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~~ N43.9 "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~~ Sixty-Seven dollars ~~($25.00)~~ ($67.00) for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts ~~0-50~~ 1-50;

(3) ~~Eighteen dollars~~ Sixty-Four ~~($18.00)~~ ($64.00) for the regulations listed in Subparagraph (a)(3) of this Rule in a volume containing 10 CFR Parts 51-199;

(4) ~~Eighteen dollars~~ Sixty-Six ~~($18.00)~~ ($66.00) for the regulations listed in Subparagraph (a)(4) of this Rule in a volume containing 21 CFR Parts 800-1299;

(5) ~~Sixteen dollars~~ Forty-Seven ~~($16.00)~~ ($47.00) 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;
http://pe.usps.gov/text/dmm300/dmm300_landing.htm

(7) ~~Thirty-one~~ Fifty-Six dollars ~~($31.00)~~ ($56.00) 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~~ Seventy dollars ~~($23.00)~~ ($70.00) for a volume containing 49 CFR Parts 100-177; and

(B) ~~Seventeen~~ Seventy dollars ~~($17.00)~~ ($70.00) 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~~ Two Hundred Eighteen dollars ~~($105.00)~~ ($218.00) 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;

(14) ~~Thirty-eight dollars~~ Twenty-Five plus five dollars shipping and handling ~~($43.00)~~ ($30.00) for the American National Standard ~~N432-1980~~ N43.9 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. October 1, 2013; November 1, 2007; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.

15A NCAC 11 .0301 is proposed for amendment as follows:

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~~ own, manufacture and produce, 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. October 1, 2013; August 1, 1998; January 1, 1994; May 1, 1992; June 1, 1989; July 1, 1982.

15A NCAC 11 .0303 is proposed for amendment as follows:

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.~~ 10 CFR 32.11.

(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 US Nuclear Regulatory Commission 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		$2X10^{-3}$

1		Ba 140		$3X10^{-4}$
2	Beryllium (4)	Be 7		$2X10^{-2}$
3	Bismuth (83)	Bi 206		$4X10^{-4}$
4	Bromine (35)	Br 82	$4X10^{-7}$	$3X10^{-3}$
5	Cadmium (48)	Cd 109		$2X10^{-3}$
6		Cd 115m		$3X10^{-4}$
7		Cd 115		$3X10^{-4}$
8	Calcium (20)	Ca 45		$9X10^{-5}$
9		Ca 47		$5X10^{-4}$
10	Carbon (6)	C 14	$1X10^{-6}$	$8X10^{-3}$
11	Cerium (58	Ce 141		$9X10^{-4}$
12		Ce 143		$4X10^{-4}$
13		Ce 144		$1X10^{-4}$
14	Cesium (55)	Cs 131		$2X10^{-2}$
15		Cs 134m		$6X10^{-2}$
16		Cs 134		$9X10^{-5}$
17	Chlorine (17)	Cl 38	$9X10^{-7}$	$4X10^{-3}$
18	Chromium (24)	Cr 51		$2X10^{-2}$
19	Cobalt (27)	Co 57		$5X10^{-3}$
20		Co 58		$1X10^{-3}$
21		Co 60		$5X10^{-4}$
22	Copper (29)	Cu 64		$3X10^{-3}$
23	Dysprosium (66)	Dy 165		$4X10^{-3}$
24		Dy 166		$4X10^{-4}$
25	Erbium (68)	Er 169		$9X10^{-4}$
26		Er 171		$1X10^{-3}$
27	Europium (63)	Eu 152		$6X10^{-4}$
28		(T1/2 =9.2 Hrs.)		
29		Eu 155		$2X10^{-3}$
30	Fluorine (9)	F 18	$2X10^{-6}$	$8X10^{-3}$
31	Gadolinium (64)	Gd 153		$2X10^{-3}$
32		Gd 159		$8X10^{-4}$
33	Gallium (31)	Ga 72		$4X10^{-4}$
34	Germanium (32)	Ge 71		$2X10^{-2}$
35	Gold (79)	Au 196		$2X10^{-3}$
36		Au 198		$5X10^{-4}$

1		Au 199		$2X10^{-3}$	
2	Hafnium (72)	Hf 181		$7X10^{-4}$	
3	Hydrogen (1)	H 3	$5X10^{-6}$	$3X10^{-2}$	
4	Indium (49)	In 113m		$1X10^{-2}$	
5		In 114m		$2X10^{-4}$	
6	Iodine (53)	I 126	$3X10^{-9}$	$2X10^{-5}$	
7		I 131	$3X10^{-9}$	$2X10^{-5}$	
8		I 132	$8X10^{-8}$	$6X10^{-4}$	
9		I 133	$1X10^{-8}$	$7X10^{-5}$	
10		I 134	$2X10^{-7}$	$1X10^{-3}$	
11	Iridium (77)	Ir 190		$2X10^{-3}$	
12		Ir 192		$4X10^{-4}$	
13		Ir 194		$3X10^{-4}$	
14	Iron (26)	Fe 55		$8X10^{-3}$	
15		Fe 59		$6X10^{-4}$	
16	Krypton (36)	Kr 85m	$1X10^{-6}$	~~$1X10^{-6}$~~	
17		Kr 85	$3X10^{-6}$	~~$3X10^{-6}$~~	
18	Lanthanum (57)	La 140		$2X10^{-4}$	
19	Lead (82)	Pb 203		$4X10^{-3}$	
20	Lutetium (71)	Lu 177		$1X10^{-3}$	
21	Manganese (25)	Mn 52		$3X10^{-4}$	
22		Mn 54		$1X10^{-3}$	
23		Mn 56		$1X10^{-3}$	
24	Mercury (80)	Hg 197m		$2X10^{-3}$	
25		Hg 197		$3X10^{-3}$	
26		Hg 203		$2X10^{-4}$	
27	Molybdenum (42)	Mo 99		$2X10^{-3}$	
28	Neodymium (60)	Nd 147		~~$6X10^{-3}$~~	$6X10^{-4}$
29		Nd 149		~~$3X10^{-4}$~~	$3X10^{-3}$
30	Nickel (28)	Ni 65		$1X10^{-3}$	
31	Niobium(Columbium)(41)	Nb 95		$1X10^{-3}$	
32		Nb 97		$9X10^{-3}$	
33	Osmium (76)	Os 185		$7X10^{-4}$	
34		Os 191m		$3X10^{-2}$	
35		Os 191		$2X10^{-3}$	
36		Os 193		$6X10^{-4}$	

Palladium (46)	Pd 103	$3X10^{-3}$	
	Pd 109	$9X10^{-4}$	
Phosphorus (15)	P 32	$2X10^{-4}$	
Platinum (78)	Pt 191	$1X10^{-3}$	
	Pt 193m	$1X10^{-2}$	
	Pt 197m	$1X10^{-2}$	
	Pt 197	$1X10^{-3}$	
~~Polonium (84)~~	~~Po 210~~	~~$7X10^{-6}$~~	
Potassium (19)	K 42	$3X10^{-3}$	
Praseodymium (59)	Pr 142	$3X10^{-4}$	
	Pr 143	$5X10^{-4}$	
Promethium (61)	Pm 147	$2X10^{-3}$	
	Pm 149	$4X10^{-4}$	
~~Radium (88)~~	~~Ra 226~~	~~$1X10^{-7}$~~	
	~~Ra 228~~	~~$3X10^{-7}$~~	
Rhenium (75)	Re 183	$6X10^{-3}$	
	Re 186	$9X10^{-4}$	
	Re 188	$6X10^{-4}$	
Rhodium (45)	Rh 103m	$1X10^{-1}$	
	Rh 105	$1X10^{-3}$	
Rubidium (37)	Rb 86	$7X10^{-4}$	
Ruthenium (44)	Ru 97	~~$4X10^{-3}$~~ $4X10^{-4}$	
	Ru 103	$8X10^{-4}$	
	Ru 105	$1X10^{-3}$	
	Ru 106	$1X10^{-4}$	
Samarium (62)	Sm 153	$8X10^{-4}$	
Scandium (21)	Sc 46	$4X10^{-4}$	
	Sc 47	$9X10^{-4}$	
	Sc 48	$3X10^{-4}$	
Selenium (34)	Se 75	$3X10^{-3}$	
Silicon (14)	Si 31	$9X10^{-3}$	
Silver (47)	Ag 105	$1X10^{-3}$	
	Ag 110m	$3X10^{-4}$	
	Ag 111	$4X10^{-4}$	
Sodium (11)	Na 24	$2X10^{-3}$	
Strontium (38)	Sr 85	~~$1X10^{-3}$~~ $1X10^{-4}$	

1		Sr 89		$1X10^{-4}$
2		Sr 91		$7X10^{-4}$
3		Sr 92		$7X10^{-4}$
4	Sulfur (16)	S 35	$9X10^{-8}$	$6X10^{-4}$
5	Tantalum (73)	Ta 182		$4X10^{-4}$
6	Technetium (43)	Tc 96m		$1X10^{-1}$
7		Tc 96		$1X10^{-3}$
8	Tellurium (52)	Te 125m		$2X10^{-3}$
9		Te 127m		$6X10^{-4}$
10		Te 127		$3X10^{-3}$
11		Te 129m		$3X10^{-4}$
12		Te 131m		$6X10^{-4}$
13		Te 132		$3X10^{-4}$
14	Terbium (65)	Tb 160		$4X10^{-4}$
15	Thallium (81)	Tl 200		$4X10^{-3}$
16		Tl 201		$3X10^{-3}$
17		Tl 202		$1X10^{-3}$
18		Tl 204		$1X10^{-3}$
19	Thulium (69)	Tm 170		$5X10^{-4}$
20		Tm 171		$5X10^{-3}$
21	Tin (50)	Sn 113		$9X10^{-4}$
22		Sn 125		$2X10^{-4}$
23	Tungsten(Wolfram) (74)	W 181		$4X10^{-3}$
24		W 187		$7X10^{-4}$
25	Vanadium (23)	V 48		$3X10^{-4}$
26	Xenon (54)	Xe 131m		$4X10^{-6}$
27		Xe 133		$3X10^{-6}$
28		Xe 135		$1X10^{-6}$
29	Ytterbium (70)	Yb 175		$1X10^{-3}$
30	Yttrium (39)	Y 90		$2X10^{-4}$
31		Y 91m		$3X10^{-2}$
32		Y 91		$3X10^{-4}$
33		Y 92		$6X10^{-4}$
34		Y 93		$3X10^{-4}$
35	Zinc (30)	Zn 65		$1X10^{-3}$
36		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)~~ (e) In Column I of the table, in Paragraph (b) of this Rule, values are given only for those materials normally used as gases.

~~(d)~~ (f) In Column II of the table, in Paragraph (b) of this Rule, the units, microcuries per gram, are used for solids.

~~(e)~~ (g) 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)~~ (h) 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. October 1, 2013; May 1, 1993; June 1, 1989.

15A NCAC 11 .0304 is proposed for amendment as follows:

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:~~ by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 for source and byproduct material.

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

~~(e)~~ (f) 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

1	Arsenic-73 (As 73)	100
2	Arsenic-74 (As 74)	10
3	Arsenic-76 (As 76)	10
4	Arsenic-77 (As 77)	100
5	Barium-131 (Ba 131)	10
6	Barium-133 (Ba 133)	10
7	Barium-140 (Ba 140)	10
8	Bismuth-210 (Bi 210)	1
9	Bromine-82 (Br 82)	10
10	Cadmium-109 (Cd 109)	10
11	Cadmium-115m (Cd 115m)	10
12	Cadmium-115 (Cd 115)	100
13	Calcium-45 (Ca 45)	10
14	Calcium-47 (Ca 47)	10
15	Carbon-14 (C 14)	100
16	Cerium-141 (Ce 141)	100
17	Cerium-143 (Ce 143)	100
18	Cerium-144 (Ce 144)	1
19	Cesium-129 (Cs 129)	100
20	Cesium-131 (Cs 131)	1,000
21	Cesium-134m (Cs 134m)	100
22	Cesium-134 (Cs 134)	1
23	Cesium-135 (Cs 135)	10
24	Cesium-136 (Cs 136)	10
25	Cesium-137 (Cs 137)	10
26	Chlorine-36 (Cl 36)	10
27	Chlorine-38 (Cl 38)	10
28	Chromium-51 (Cr 51)	1,000
29	Cobalt-57 (Co 57)	100
30	Cobalt-58m (Co 58m)	10
31	Cobalt-58 (Co 58)	10
32	Cobalt-60 (Co 60)	1
33	Copper-64 (Cu 64)	100
34	Dysprosium-165 (Dy 165)	10
35	Dysprosium-166 (Dy 166)	100
36	Erbium-169 (Er 169)	100
37	Erbium-171 (Er 171)	100

1	Europium-152 (Eu 152) 9.2h	100
2	Europium-152 (Eu 152) 13 yr	1
3	Europium-154 (Eu 154)	1
4	Europium-155 (Eu 155)	10
5	Fluorine-18 (F 18)	1,000
6	Gadolinium-153 (Gd 153)	10
7	Gadolinium-159 (Gd 159)	100
8	Gallium-67 (Ga 67)	100
9	Gallium-72 (Ga 72)	10
10	Germanium-68 (Ge 68)	10
11	Germanium-71 (Ge 71)	100
12	Gold-195 (Au 195)	10
13	Gold-198 (Au 198)	100
14	Gold-199 (Au 199)	100
15	Hafnium-181 (Hf 181)	10
16	Holmium-166 (Ho 166)	100
17	Hydrogen-3 (H 3)	1,000
18	Indium-111 (In 111)	100
19	Indium-113m (In 113m)	100
20	Indium-114m (In 114m)	10
21	Indium-115m(In 115m)	100
22	Indium-115 (In 115)	10
23	Iodine-123 (I 123)	100
24	Iodine-125 (I 125)	1
25	Iodine-126 (I 126)	1
26	Iodine-129 (I 129)	0.1
27	Iodine-131 (I 131)	1
28	Iodine-132 (I 132)	10
29	Iodine-133 (I 133)	1
30	Iodine-134 (I 134)	10
31	Iodine-135 (I 135)	10
32	Iridium-192 (Ir 192)	10
33	Iridium-194 (Ir 194)	100
34	Iron-52 (Fe 52)	10
35	Iron-55 (Fe 55)	100
36	Iron-59 (Fe 59)	10
37	Krypton-85 (Kr 85)	100

1	Krypton-87 (Kr 87)	10
2	Lanthanum-140 (La 140)	10
3	Lutetium-177 (Lu 177)	100
4	Manganese-52 (Mn 52)	10
5	Manganese-54 (Mn 54)	10
6	Manganese-56 (Mn 56)	10
7	Mercury-197m (Hg 197m)	100
8	Mercury-197 (Hg 197)	100
9	Mercury-203 (Hg 203)	10
10	Molybdenum-99 (Mo 99)	100
11	Neodymium-147 (Nd 147)	100
12	Neodymium-149 (Nd 149)	100
13	Nickel-59 (Ni 59)	100
14	Nickel-63(Ni 63)	10
15	Nickel-65 (Ni 65)	100
16	Niobium-93m (Nb 93m)	10
17	Niobium-95 (Nb 95)	10
18	Niobium-97 (Nb 97)	10
19	Osmium-185 (Os 185)	10
20	Osmium-191m (Os 191m)	100
21	Osmium-191 (Os 191)	100
22	Osmium-193 (Os 193)	100
23	Palladium-103 (Pd 103)	100
24	Palladium-109 (Pd 109)	100
25	Phosphorus-32 (P 32)	10
26	Platinum-191 (Pt 191)	100
27	Platinum-193m (Pt 193m)	100
28	Platinum-193 (Pt 193)	100
29	Platinum-197m (Pt 197m)	100
30	Platinum-197 (Pt 197)	100
31	Polonium-210 (Po 210)	0.1
32	Potassium-42 (K 42)	10
33	Potassium-43 (K 43)	10
34	Praseodymium-142 (Pr 142)	100
35	Praseodymium-143 (Pr 143)	100
36	Promethium -147 (Pm 147)	10
37	Promethium-149 (Pm 149)	10

1	Rhenium-186 (Re 186)	100
2	Rhenium-188 (Re 188)	100
3	Rhodium-103m (Rh 103m)	100
4	Rhodium-105 (Rh 105)	100
5	Rubidium-81 (Rb 81)	10
6	Rubidium-86 (Rb 86)	10
7	Rubidium-87 (Rb 87)	10
8	Ruthenium-97 (Ru 97)	100
9	Ruthenium-103 (Ru 103)	10
10	Ruthenium-105 (Ru 105)	10
11	Ruthenium-106 (Ru 106)	1
12	Samarium-151 (Sm 151)	10
13	Samarium-153 (Sm 153)	100
14	Scandium-46 (Sc 46)	10
15	Scandium-47 (Sc 47)	100
16	Scandium-48 (Sc 48)	10
17	Selenium-75 (Se 75)	10
18	Silicon-31 (Si 31)	100
19	Silver-105 (Ag 105)	10
20	Silver-110m (Ag 110m)	1
21	Silver-111 (Ag 111)	100
22	Sodium-22 (Na 22)	10
23	Sodium-24 (Na 24)	10
24	Strontium-85 (Sr 85)	10
25	Strontium-89 (Sr 89)	1
26	Strontium-90 (Sr 90)	0.1
27	Strontium-91 (Sr 91)	10
28	Strontium-92 (Sr 92)	10
29	Sulfur-35 (S 35)	100
30	Tantalum-182 (Ta 182)	10
31	Technetium-96 (Tc 96)	10
32	Technetium-97m (Tc 97m)	100
33	Technetium-97 (Tc 97)	100
34	Technetium-99m (Tc 99m)	100
35	Technetium-99 (Tc 99)	10
36	Tellurium-125m (Te 125m)	10
37	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. October 1, 2013; May 1, 1993.

15A NCAC 11 .0305 is proposed for amendment as follows:

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)~~ (b) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or distribution 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)~~(1) 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)~~(A) 25 millicuries of tritium per timepiece;

~~(ii)~~(B) five millicuries of tritium per hand;

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

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

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

~~(vi)~~(E) 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)~~(F) 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)~~(i) for wrist watches, 0.1 millirad per hour at 10 centimeters from any surface;

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

~~(III)~~(iii) for any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface or:

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

~~(B)~~(2) [Reserved for future codification] ~~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)~~(3) 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;~~ part manufactured before December 17, 2007;

~~(D)~~(4) [Reserved for future codification] ~~automobile shift quadrants containing not more than 25 millicuries of tritium;~~

~~(E)~~(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;~~ gas manufactured before December 17, 2007;

~~(F)~~(6) [Reserved for future codification] ~~thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat;~~

(7) Ionization chamber smoke detectors containing not more than 1 microcurie of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

~~(G)~~(8) electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material 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):

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

~~(ii)~~(B) one microcurie of cobalt-60;

~~(iii)~~(C) five microcuries of nickel-63;

~~(iv)~~(D) 30 microcuries of krypton-85;

~~(v)~~(E) five microcuries of cesium-137; and

~~(vi)~~(F) 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)~~; and

~~(H)~~(9) 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)~~ (f) of this ~~Section.~~ Section, and each instrument contains no more than 10 exempt quantities.

~~(I)~~(10) [Reserved for future codification] ~~spark gap irradiation containing not more than one microcurie f 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)~~(c) For purposes of Part ~~(b)(1)(H)~~ (b)(8) of this Rule, where there is involved a combination of radionuclides, the limit for the combination shall be derived as follows:

~~(A)~~(1) 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)~~ (f) of this Section for the specific radionuclide when not in combination;

~~(B)~~(2) No ratio shall exceed one and the sum of such ratios shall not exceed ~~10.~~ 10; and

~~(C)~~(3) For the purpose of Part ~~(b)(1)(H)~~ (b)(8), 0.05 microcurie of americium-241 is considered an exempt quantity under Rule .0304 of this Section.

~~(c)~~(d) 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~~ the 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)~~(e) Gas and aerosol detectors are exempt as provided in this Paragraph.

(1) Except for persons who manufacture, process, ~~or produce~~ 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~~ the 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~~ are exempt ~~under Subparagraph (d)(1) of this Rule~~ from the Rules in this Chapter, 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.~~

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

~~(1)~~(f) Except ~~as provided in Subparagraphs (2) and (3) of this Paragraph,~~ as follows, 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.~~ humans:

~~(2)~~(1) 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)~~(2) 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)~~(g) 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. October 1, 2013; 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 shall:

(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; and

(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.~~ State;

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

(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;

Retention of leakage or contamination, on-off mechanism and on-off indicator test records shall be retained for three years after the next required test is performed or until the sealed source is disposed of or transferred. Retention of other records of tests required in Subparagraph (c)(3) of this Rule shall be retained for three years from the date of the recorded test or until the device is disposed of or transferred.

~~(C) retention of leakage or contamination, on-off mechanism and on-off indicator test records for one year 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 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~~ If 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 the~~ within 30 days ~~of~~ after transfer of a device to a specific licensee 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; and~~ device (license number not applicable if exported); and

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

~~(D)~~(8) shall obtain written approval by the Agency before transferring the device to any other specific licensee not 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:

~~(1)~~(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;

~~(2)~~(B) Removes, alters, covers, or clearly and unambiguously augments (As defined in 10 CFR 31.5) 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;

~~(3)~~(C) Obtains the manufacturer's or initial transferor's information concerning maintenance that be applicable under the specific license (such as leak testing procedures); and

~~(4)~~(D) Reports the transfer under paragraph (7) of this rule.

~~(8)~~(9) 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. In this case the transferor shall give the transferee a copy of this Rule and any safety documents identified in the label of the device, and 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

~~(i) In this case the transferor shall give the transferee a copy of this Section~~ Rule ~~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)~~(10) 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~~ is exempt from the other requirements of Section .1600 of this Chapter;

~~(10)~~(11) 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)~~(12) 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)~~(13) 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~~ 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.~~ license;

~~(13)~~(14) shall report changes to the mailing address to the agency within 30 days of the effective date of the change;

~~(14)~~(15) shall report changes to the name of the general licensee to the agency within 30 days of the effective date of the change;

(16) 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. The request to extend the allotted time will be granted upon agency review of the licensee request and supporting information related to the need for extension;

~~(15)~~ (17) 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 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. October 1, 2013; January 1, 2005; January 1, 1994; June 1, 1989.

15A NCAC 11 .0317 is proposed for amendment as follows:

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 necessary for the Agency to determine if the applicant meets the requirements for a license ~~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:

(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;

(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:

(A) All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

(B) 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~~ are 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~~ If required 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. October 1, 2013; April 1, 1999; May 1, 1992; November 1, 1989.

15A NCAC 11 .0318 is proposed for amendment as follows:

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

(a) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "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,~~ Rule and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "Authorized user" means a ~~physician~~ 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), 35.590(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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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. Nuclear Regulatory Commission, 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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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 and Rule .0117 (a)(2) of this Chapter, "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.~~ work; and

(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; and

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

(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. October 1, 2013; November 1, 2007; April 1, 1999; May 1, 1993; November 1, 1989.

15A NCAC 11 .0321 is proposed for amendment as follows:

15A NCAC 11 .0321 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE OF UNSEALED RADIOACTIVE MATERIALS

(a) An application for a specific license pursuant to Rule .0318 of this Section for any diagnostic or therapeutic use of unsealed radioactive material shall be approved if:

(1) the applicant satisfies the requirements in Rule .0319 or Rule .0320 of this Section;

(2) the applicant's proposed radiation detection instrumentation is adequate for conducting the diagnostic or therapeutic procedure(s) requested;

(3) the physicians designated in the application as individual users, have clinical experience as required by Rule .0117(a)(2) of this Chapter;

(4) the physicians and all other personnel who will be involved in the preparation and use of radioactive material have training and experience in the handling of unsealed radioactive material appropriate to their use of radioactive material and as required by Rule .0117(a)(2) of this Chapter;

(5) the applicant has radiation safety operating procedures for handling and disposal of the radioactive material that provide protection to the workers, the public and the environment from radiation exposure and radioactive ~~contamination.~~ contamination; and

(6) the applicant has a clinical procedures manual, as appropriate for licensed activities.

(b) Any person authorized by Rules .0318, .0319, .0320, .0322, or .0324 of this Section for medical use of radioactive material may receive, possess and use any of the following radioactive material for check, calibration, transmission and reference use:

(1) Sealed sources net exceeding 30 millicuries (mCi)(1.11 Gigabecquerel (GBq)) each, manufactured and distributed by a person licensed under 10 CFR 32.74 or equivalent Agreement State regulations;

(2) Sealed sources, not exceeding 30 mCi (1.11 GBq) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 10 CFR 32.74, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.56 GBq);

(4) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of 200 microcuries (µCi) (7.4 Megabecquerel (MBq)) or 1000 times the quantities in Appendix C of 10 CFR Part 20; and

(5) Technetium-99m in amounts as needed.

(c) Any licensee who possesses sealed sources as calibration and reference sources pursuant to Paragraph (b) of this Rule shall test each source for leakage and contamination prior to initial use and at intervals not to exceed six months or at other intervals approved by the U.S. Nuclear Regulatory Commission or an Agreement State in the

Sealed Source and Device Registry. If there is reason for the licensee to suspect that a sealed source may have been damaged, or might be leaking, it shall be tested for leakage before further use.

(d) Leak test results shall be recorded in units of microcuries and maintained for inspection by the agency.

(e) Any licensee who possesses and uses calibration and reference sources pursuant to Paragraph (b) of this Rule shall:

(1) follow the radiation safety and handling instructions that are required by the licensing agency to be furnished by the manufacturer on the label attached to the source or permanent container thereof or in the leaflet or brochure that accompanies the source;

(2) maintain such instructions in a legible and conveniently available form; and

(3 conduct a quarterly physical inventory to account for all sources received an possessed under the license. Records of the inventories shall be maintained for inspection by the agency and shall include the quantities and kinds of radioactive material, location of the sources and the date of the inventory.

(f) Any licensee who is licensed pursuant to Rules .0318, .0319, .0320, or .0324 of this Section for medical use of unsealed radioactive material also is authorized to use radioactive material under the general license in Rule .0314 of this Chapter for the specified IN VITRO uses without filing agency forms as required by Rule .0314(b) of the Chapter, provided that the licensee is subject to the other provisions of Rule .0314 of this Chapter.

(g) For each individual receiving radiopharmaceutical therapy and hospitalized because the individual cannot be released in accordance with Rule .0358 of this Section, a licensee shall:

(1) provide a private room with a private sanitary facility;

(2) post the individual's door with a "Radioactive Materials" sign and note on the door or the individual's chart, where and how long visitors may stay in the individual's room;

(3) either monitor material or items removed from the individual's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste; and

(4) Notify the Radiation Safety Officer and authorized user as soon as feasible if the individual has a medical emergency and immediately if the patient dies.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; November 1, 2007; August 1, 2002; April 1, 1999; May 1, 1993.

15A NCAC 11 .0322 is proposed for amendment 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; or

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

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

(B) ~~Research~~ In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the ~~FDA.~~ 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.~~ Chapter and

(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. October 1, 2013; November 1, 2007.

15A NCAC 11 .0325-.0326 are proposed for repeal as follows:

15A NCAC 11 .0325 SPECIFIC LICENSES: PRODUCTS WITH EXEMPT CONCENTRATIONS

15A NCAC 11 .0326 SPECIFIC LICENSES: EXEMPT DISTRIBUTION

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, ~~1993.~~ 1993;
Repealed Eff. October 1, 2013.

15A NCAC 11 .0328 is proposed for amendment as follows:

15A NCAC 11 .0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Rule .0309 of this Section or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state ~~will~~ shall be approved if:

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

(2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) the device can be safely operated by persons not having training in radiological protection;

(B) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar ~~quarter~~ year a dose in excess of ten percent of the limits specified in the table of Rule .1604 of this Chapter; and

(C) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

(i) whole body, head and trunk, active blood-forming organs, gonads, or lens of eye: 15 rems;

(ii) hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than one square centimeter: 200 rems; or

(iii) other organs: 50 rems. and

(3) each device bears a durable, legible, ~~clearly~~ visible label or labels approved by the agency, which contain in ~~a clearly~~ an identified and separate statement:

(A) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(B) the requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(C) the information called for in the following statement in the same or substantially similar form: "The receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a general license

or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited."

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(name of manufacturer or distributor)

~~(4)~~ ~~the~~ The model, serial number, and name of manufacturer or distributor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(b) ~~In the event~~ If the applicant desires that the device ~~be required to~~ be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that ~~such~~ a longer interval is justified by performance characteristics of the device or similar devices and by design features which have a ~~significant~~ bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency ~~will~~ shall consider information which includes: ~~includes, but is not limited to:~~

(1) primary containment (source capsule);

(2) protection of primary containment;

(3) method of sealing containment;

(4) containment construction materials;

(5) form of contained radioactive material;

(6) maximum temperature withstood during prototype test;

(7) maximum pressure withstood during prototype tests;

(8) maximum quantity of contained radioactive material;

(9) radiotoxicity of contained radioactive material; and

(10) operating experience with identical devices or similarly designed and constructed devices.

(c) ~~In the event~~ If the applicant desires that the general licensee under Rule .0309 of this Section, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, or an agreement state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application:

(1) Written instructions to be followed by the general licensee;

(2) Estimated calendar quarter doses associated with ~~such~~ the activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license; and

(3) information to demonstrate that performance of such activity(ies) is unlikely to cause that individual to receive a calendar ~~quarter~~ year dose in excess of ten percent of the limits specified in Rule .1604 of this Chapter.

(d) Each person licensed under this Rule to distribute devices shall furnish a copy of the general license contained in Section 31.5 of 10 CFR Part 31 to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Rule .0309 of this Section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The copy of Section 31.5 of 10 CFR Part 31 shall be accompanied by a note explaining that the use of the device is regulated by agreement states under requirements substantially the same as those in Section 31.5 of 10 CFR Part 31. Alternatively, when transferring the devices to persons in a specific agreement state, a copy of that agreement state's equivalent regulations shall be furnished.

(e) Each person, licensed under this Rule to distribute devices, shall report to the agencies specified in Subparagraphs (e)(1), (2) and (3) of this Rule all transfers of the devices to persons generally licensed under the rules of those agencies. Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a contact with the general licensee, the type and model number of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the reports shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to generally licensed persons during the reporting period, the reports shall so indicate. The reports shall cover each calendar quarter and shall be filed within 30 days thereafter. The reports shall be submitted to:

(1) the agency for devices transferred to persons generally licensed under Rule .0309 of this Section;

(2) each agreement state for devices transferred to persons generally licensed under rules equivalent to Rule .0309 of this Section; and

(3) the U.S. Nuclear Regulatory Commission for devices transferred to persons generally licensed under Section 31.5 of 10 CFR Part 31.

(f) Each person, licensed under this Rule to distribute devices, shall maintain for agency inspection either copies of all reports required in Paragraph (e) of this Rule or a record containing substantially the same information. Such copies or records of transfer shall be maintained for at least five years after the date of each transfer of a device to a generally licensed person.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; January 1, 1994.

15A NCAC 11 .0331 is proposed for amendment as follows:

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~~ shall 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 10 microcuries ~~0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.~~ each; or

(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. October 1, 2013; January 1, 1994.

15A NCAC 11 .0333 is proposed for amendment 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.~~ 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. October 1, 2013; November 1, 2007.

15A NCAC 11 .0334 is proposed for amendment as follows:

15A NCAC 11 .0334 SPECIFIC LICENSES: GENERATORS AND REAGENT KITS

An application for a specific license to manufacture and distribute generators and reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Rule .0321 of this Section for the generators, reagent kits and associated medical uses ~~in Group III~~ ~~will~~ shall 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 applicable requirements in Section 32.73 of 10 CFR Part 32 or their equivalent.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, ~~1980.~~ 1980;
Amended Eff. October 1, 2013.

15A NCAC 11 .0338 is proposed for amendment as follows:

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)~~(a) 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)~~(b) 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)~~(c) 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)~~(d) 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.

(e) 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.

(f) 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.

(g) 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.

(h) 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:

(1) 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. and

(2) 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.

(i) 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 be:

(1) an authorized nuclear pharmacist that meets the requirements in Rule .0318 of this Section, or

(2) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule .0318 of this Section.

(j) 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.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993; May 1, 1992; June 1, 1989.

15A NCAC 11 .0352 is proposed for amendment as follows:

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~~ 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; and

(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 potentially impacted 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 quickly enough to mitigate off-site consequences;

(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~~ is established;

(B) the notification and coordination ~~shall be~~ is 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~~ commits to notify the agency ~~immediately~~ after notification of the appropriate off-site response organizations, ~~not to exceed~~ within 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~~ are not known to most exercise participants;

(D) ~~the licensee shall~~ critique of 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~~ are corrected; and

(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~~ .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)~~ (NON CO_2)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000

1	Cesium-137	.01	3,000
2	Chlorine-36	.5	100
3	Chromium-51	.01	300,000
4	Cobalt-60	.001	5,000
5	Copper-64	.01	200,000
6	Curium-242	.001	60
7	Curium-243	.001	3
8	Curium-244	.001	4
9	Curium-245	.001	2
10	Europium-152	.01	500
11	Europium-154	.01	400
12	Europium-155	.01	3,000
13	Germanium-68	.01	2,000
14	Gadolinium-153	.01	5,000
15	Gold-198	.01	30,000
16	Hafnium-172	.01	400
17	Hafnium-181	.01	7,000
18	Holmium-166 m	.01	100
19	Hydrogen-3	.5	20,000
20	Iodine-125	.5	10
21	Iodine-131	.5	10
22	Indium-114 m	.01	1,000
23	Iridium-192	.001	40,000
24	Iron-55	.01	40,000
25	Iron-59	.01	7,000
26	Krypton-85	1.0	6,000,000
27	Lead-210	.01	8
28	Manganese-56	.01	60,000
29	Mercury-203	.01	10,000
30	Molybdenum-99	.01	30,000
31	Neptunium-237	.001	2
32	Nickel-63	.01	20,000
33	Niobium-94	.01	300
34	Phosphorus-32	.5	100
35	Phosphorus-33	.5	1,000
36	Polonium-210	.01	10
37	Potassium-42	.01	9,000

1	Promethium-145	.01	4,000
2	Promethium-147	.01	4,000
3	Ruthenium-106	.01	200
4	Samarium-151	.01	4,000
5	Scandium-46	.01	3,000
6	Selenium-75	.01	10,000
7	Silver-110 m	.01	1,000
8	Sodium-22	.01	9,000
9	Sodium-24	.01	10,000
10	Strontium-89	.01	3,000
11	Strontium-90	.01	90
12	Sulfur-35	.5	900
13	Technetium-99	.01	10,000
14	Technetium-99 m	.01	400,000
15	Tellurium-127 m	.01	5,000
16	Tellurium-129 m	.01	5,000
17	Terbium-160	.01	4,000
18	Thulium-170	.01	4,000
19	Tin-113	.01	10,000
20	Tin-123	.01	3,000
21	Tin-126	.01	1,000
22	Titanium-44	.01	100
23	Vanadium-48	.01	7,000
24	Xenon-133	1.0	900,000
25	Yttrium-91	.01	2,000
26	Zinc-65	.01	5,000
27	Zirconium-93	.01	400
28	Zirconium-95	.01	5,000
29	Any other beta-gamma emitter	.01	10,000
30	Mixed fission products	.01	1,000
31	Mixed corrosion products	.01	10,000
32	Contaminated equipment beta-gamma	.001	10,000
33	Irradiated material, any form		
34	other than solid noncombustible	.01	1,000
35	Irradiated material, solid		
36	Noncombustible	.001	10,000
37	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)~~(f) 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)~~(g) 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. October 1, 2013; May 1, 1993; October 1, 1992.

15A NCAC 11 .0358 is proposed for amendment as follows:

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~~ individual, or the individual's parent or guardian, 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~~ if there ~~were~~ is 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,~~ 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,~~ 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.~~ 1998;
Amended Eff. October 1, 2013.

15A NCAC 11 .0361 is proposed for amendment 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:~~ studies, and use requiring a written directive in accordance with Rule .0104 of this chapter that is:

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

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

~~(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); or

(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 ~~containing~~ that contains; ~~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; or

(2) more than 0.02 microcurie (0.02 kilobecquerel) of strontium-82 per millicurie (megabecquerel) of rubidium-82 chloride, or 0.2 microcurie (0.2 kilobecquerel) of strontium-85 per millicurie (megabecquerel) 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) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99 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.

(d) 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)~~ (e) A licensee that must measure ~~molybdenum~~ 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:~~ include:

(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);

(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 kilobecquerel strontium-82 and strontium-85 per megabecquerel 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. October 1, 2013; November 1, 2007.

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: ~~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.~~

(1) the date of the disposal;

(2) the date on which radioactive material was placed in storage;

(3) the radionuclides disposed;

(4) the survey instrument used;

(5) the background dose rate used; and

(6) 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.~~ 1999;
Amended Eff. October 1, 2013.

15A NCAC 11 .1004 is proposed for amendment as follows:

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:

(1) be in writing;

(2) include identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number;

(3) include the individual's exposure information; and

(4) 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.

~~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.~~ 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~~ The report shall:

(1) be furnished within 30 days from the time the request is made, or within 30 days after theexposure of the individual has been determined by the licensee or registrant, whichever is later;

(2) 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

(3) shall include the dates and locations of work under the license or registration in which the worker participated during this period.

~~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 ~~.1647~~ .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.~~ in the report to the agency. ~~Such~~ The 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. October 1, 2013; January 1, 1994.

15A NCAC 11 .1604 is proposed for amendment as follows:

15A NCAC 11 .1604 OCCUPATIONAL DOSE LIMITS FOR ADULTS

(a) ~~The~~ A 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 as consistent with this Chapter. 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. October 1, 2013; May 1, 2006.

15A NCAC 11 .1626 is proposed for amendment 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:~~ that:

(1) each container of licensed radioactive material bears a durable, 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.~~ exposures; and

(2) each syringe and vial that contains unsealed radioactive material for medical use is 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,~~ them or to work in the vicinity of the ~~containers,~~ 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.~~ 1994;
Amended Eff. October 1, 2013.

15A NCAC 11 .1633 is proposed for amendment as follows:

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. 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. October 1, 2013; April 1, 1999.

15A NCAC 11 .1648 is proposed for amendment as follows:

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.~~ 1994;
Amended Eff. October 1, 2013.