

1 15A NCAC 11 .0104 is proposed for amendment as follows:
2

3 **15A NCAC 11 .0104 DEFINITIONS**

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

- 5 (1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated
6 material. The units of absorbed dose are the rad and the gray (Gy).
- 7 (2) "Accelerator produced material" means any material made radioactive by use of a particle
8 accelerator.
- 9 (3) "Act" means North Carolina Radiation Protection Act as defined in G.S. 104E-1.
- 10 (4) "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units
11 of activity are the curie (Ci) and the becquerel (Bq).
- 12 (5) "Adult" means an individual 18 or more years of age.
- 13 (6) "Agency" means the ~~North Carolina Department of Environment and Natural Resources, Division~~
14 ~~of Environmental Health, North Carolina Department of Health and Human Services, Division of~~
15 Health Service Regulation, Radiation Protection Section.
- 16 (7) "Agreement state" has the meaning as defined in G.S. 104E-5(2).
- 17 (8) "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that
18 removes specific air contaminants by passing ambient air through the air-purifying element.
- 19 (9) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of
20 dusts, fumes, particulates, mists, vapors, or gases.
- 21 (10) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive
22 materials, composed wholly or partly of licensed radioactive material, exist in concentrations:
23 (a) in excess of the derived air concentrations (DACs) specified in Appendix B to 10 CFR
24 20.1001 - 20.2401; or
25 (b) to such a degree that an individual present in the area without respiratory protective
26 equipment could exceed, during the hours an individual is present in a week, an intake of
27 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.
- 28 (11) "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable
29 effort to maintain exposures to radiation as far below the dose limits in the rules of this Chapter as
30 is practical consistent with the purpose for which the licensed or registered activity is undertaken,
31 taking into account the state of technology, the economics of improvements in relation to benefits
32 to the public health and safety, and other societal and socioeconomic considerations, and in
33 relation to utilization of sources of radiation in the public interest.
- 34 (12) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material
35 taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller
36 value of intake of a given radionuclide in an effective dose equivalent of five rems (0.05 Sv) or a
37 committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for

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

- 3 (13) "Annually" means either:
4 (a) at intervals not to exceed 12 consecutive months; or
5 (b) once per year at the same time each year (completed during the same month each year
6 over a period of multiple years).
- 7 (14) "Assigned protection factor (APF)" means the expected workplace level of respiratory protection
8 that would be provided by a properly functioning respirator or a class of respirators to properly
9 fitted and trained users. APF can be divided into the ambient airborne concentrations to estimate
10 inhaled air concentrations.
- 11 (15) "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with
12 breathing air from a source independent of the ambient atmosphere and includes supplied-air
13 respirators (SARs) and self-contained breathing apparatus (SCBA) units.
- 14 (16) "Authorized representative" means an employee of the agency, or an individual outside the agency
15 when the individual is ~~specifically~~ so designated by the agency under Rule .0112 of this Section.
- 16 (17) "Authorized user" means an individual who is authorized by license or registration condition to
17 use a source of radiation.
- 18 (18) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive
19 materials, including radon (except as a decay product of source or special nuclear material); and
20 global fallout as it exists in the environment from the testing of nuclear explosive devices or from
21 past nuclear accidents such as Chernobyl that ~~contribute to background radiation and~~ are not under
22 the control of the licensee or registrant. "Background radiation" does not include sources of
23 radiation regulated by the agency.
- 24 (19) "Becquerel" is the SI unit of radioactivity. One becquerel is equal to one disintegration per second
25 (s-1).
- 26 (20) "Bioassay" or "radiobioassay" means the determination of kinds, quantities or concentrations, and,
27 in some cases, the locations of radioactive material in the human body, whether by direct
28 measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed
29 from the human body.
- 30 (21) "Byproduct material" has the meaning as defined in G.S. 104E-5(4), and in addition includes:
31 (a) Any radioactive material (except special nuclear material) yielded in, or made radioactive
32 by, exposure to the radiation incident to the process of producing or using special nuclear
33 material;
34 (b) The tailings or wastes produced by the extraction or concentration of uranium or thorium
35 from ore processed primarily for its source material content, including discrete surface
36 wastes resulting from uranium solution extraction processes. Underground ore bodies

1 depleted by these solution extraction operations do not constitute "byproduct material"
2 within this definition:

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

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

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

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

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

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

18 (22) "Class", "lung class" or "inhalation class" means a classification scheme for inhaled material
19 according to its rate of clearance from the pulmonary region of the lung. Materials are classified
20 as D, W, or Y, which applies to a range of clearance half-times as follows:

21 CLASSIFICATION OF INHALED MATERIAL

22 Class	Clearance half-time
23 Class D (Day)	less than 10 days
24 Class W (Weeks)	10 days to 100 days
25 Class Y (Years)	greater than 100 days

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

33
34 ~~(23)~~ (24) "Collective dose" is the sum of the individual doses received in a given period of time by
35 a specified population from exposure to a specified source of radiation.

36 ~~(24)~~ (25) "Commission" has the meaning as defined in G.S. 104E-5(5).

- 1 ~~(25)~~ (26) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of
2 reference (T) that will be received from an intake of radioactive material by an individual
3 during the 50-year period following the intake.
- 4 ~~(26)~~ (27) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting
5 factors applicable to each of the body organs or tissues that are irradiated and the
6 committed dose equivalent to these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).
- 7 (28) "Consortium" means an association of medical use licensees and a PET radionuclide production
8 facility in the same geographical area that jointly own or share in the operation and maintenance
9 cost of the PET radionuclide production facility that produces PET radionuclides for use in
10 producing radioactive drugs within the consortium for noncommercial distributions among its
11 associated members for medical use. The PET radionuclide production facility within the
12 consortium must be located at an educational institution or a Federal facility or a medical facility.
- 13 ~~(27)~~ (29) "Constraint (dose constraint)" means a value above which specified licensee actions are
14 required.
- 15 ~~(28)~~ (30) "Controlled area" means an area, outside of a restricted area but inside the site boundary,
16 access to which can be limited by the licensee or registrant for any reason.
- 17 ~~(29)~~ (31) "Critical group" means the group of individuals reasonably expected to receive the
18 greatest exposure to residual radioactivity for any applicable set of circumstances.
- 19 ~~(30)~~ (32) "Curie" is the special unit of radioactivity. One curie is equal to 3.7×10^{10}
20 disintegrations per second = 3.7×10^{10} becquerels = 2.22×10^{12} disintegrations per
21 minute.
- 22 ~~(31)~~ (33) "Declared pregnant woman" means a woman who has voluntarily informed the licensee
23 or registrant, in writing, of her pregnancy and the estimated date of conception. The
24 declaration remains in effect until the declared pregnant woman withdraws the
25 declaration in writing or is no longer pregnant.
- 26 ~~(32)~~ (34) "Decommission" means to remove (as a facility) safely from service and reduce residual
27 radioactivity to a level that permits release of the property for either unrestricted use and
28 termination of the license or for restricted use and termination of the license.
- 29 ~~(33)~~ (35) "Deep-dose equivalent" (H_d), which applies to external whole-body exposure, is the dose
30 equivalent at a tissue depth of one cm (1000 mg/cm^2).
- 31 ~~(34)~~ (36) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air
32 to the facepiece only when a negative pressure is created inside the facepiece by
33 inhalation.
- 34 ~~(35)~~ (37) "Department" has the meaning as defined in G.S. 104E-5(6).
- 35 ~~(36)~~ (38) "Depleted uranium" means the source material uranium in which the isotope
36 uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted
37 uranium does not include special nuclear material.

1 ~~(45)~~ (47) "Dosimetry processor" means an individual or an organization that processes and
2 evaluates individual monitoring equipment in order to determine the radiation dose
3 delivered to the equipment.

4 ~~(46)~~ (48) "Effective dose equivalent" (H_E) is the sum of the products of the dose equivalent to the
5 organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs
6 or tissues that are irradiated ($H_E = \sum w_T H_T$).

7 ~~(47)~~ (49) "Embryo/fetus" means the developing human organism from conception until the time of
8 birth.

9 ~~(48)~~ (50) "Entrance or access point" means any location through which an individual could gain
10 access to radiation areas or to a source of radiation. This includes entry or exit portals of
11 sufficient size to permit human entry, irrespective of their intended use.

12 ~~(49)~~ (51) "Equipment services" means the selling, installation, rebuilding, conversion, repair,
13 inspection, testing, survey or calibration of equipment which can affect compliance with
14 these Rules by a licensee or registrant.

15 ~~(50)~~ (52) "Exposure" means being exposed to ionizing radiation or to radioactive material.

16 ~~(51)~~ (53) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

17 ~~(52)~~ (54) "External dose" means that portion of the dose equivalent received from radiation
18 sources outside the body.

19 ~~(53)~~ (55) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

20 ~~(54)~~ (56) "Eye dose equivalent" (See "Lens dose equivalent" as defined in this Rule).

21 ~~(55)~~ (57) "Filtering facepiece (dust mask)" means a negative pressure particulate respirator with a
22 filter as an integral part of the facepiece or with the entire facepiece composed of the
23 filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

24 ~~(56)~~ (58) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific
25 individual, and typically estimates the ratio of the concentration of a substance in ambient
26 air to its concentration inside the respirator when worn.

27 ~~(57)~~ (59) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of
28 a respirator on an individual.

29 ~~(58)~~ (60) "Generally applicable environmental radiation standards" means standards issued by the
30 U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy
31 Act of 1954 (42 U.S.C. 2D11 et seq;), as amended, that impose limits on radiation
32 exposures or levels, or concentrations or quantities of radioactive material, in the general
33 environment outside the boundaries of locations under the control of persons possessing
34 or using sources of radiation.

35 ~~(59)~~ (61) "Gray" (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of
36 one joule/kilogram (100 rads).

1 ~~(60)~~ (62) "Helmet" means a rigid respiratory inlet covering that also provides head protection
2 against impact and penetration.

3 ~~(61)~~ (63) "High radiation area" means an area, accessible to individuals, in which radiation levels
4 from sources external to the body could result in an individual receiving a dose
5 equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation
6 source or from any surface that the radiation penetrates.

7 ~~(62)~~ (64) "Hood" means a respiratory inlet covering that completely covers the head and neck and
8 may also cover portions of the shoulders and torso.

9 ~~(63)~~ (65) "Hospital" means a facility that provides as its primary functions diagnostic services and
10 intensive medical and nursing care in the treatment of acute stages of illness.

11 ~~(64)~~ (66) "Human use" means the internal or external administration of radiation or radioactive
12 materials to human beings.

13 ~~(65)~~ (67) "Individual" means any human being.

14 ~~(66)~~ (68) "Individual monitoring" means:

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

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

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

21 ~~(67)~~ (69) "Individual monitoring devices" or "individual monitoring equipment" means devices
22 designed to be worn by a single individual for the assessment of dose equivalent such as
23 film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and
24 personal ("lapel") air sampling devices.

25 ~~(68)~~ (70) "Inhalation class" (see "Class" defined in this Rule).

26 ~~(69)~~ (71) "Inspection" means an ~~official~~ examination or observation to determine compliance with
27 rules, orders, requirements and conditions of the agency or the Commission.

28 ~~(70)~~ (72) "Internal dose" means that portion of the dose equivalent received from radioactive
29 material taken into the body.

30 ~~(71)~~ (73) "Lens dose equivalent" or "LDE" applies to the external exposure of the lens of the eye
31 and is taken as the dose equivalent at a tissue depth of 0.3 cm (300 mg/cm²).

32 ~~(72)~~ (74) "License", except where otherwise specified, means a license issued pursuant to Section
33 .0300 of this Chapter.

34 ~~(73)~~ (75) "Licensee" means any person who is licensed by the agency pursuant to Section .0300 of
35 this Chapter.

36 ~~(74)~~ (76) "Licensing state" means any state designated as such by the Conference of Radiation
37 Control Program Directors, Inc. Unless the context indicates otherwise, use of the term

1 Agreement State in this Chapter ~~shall be deemed to include~~ includes licensing state with
2 respect to naturally occurring and accelerator produced radioactive material (NARM).
3 ~~(75)~~ (77) "Limits" or "dose limits" means the permissible upper bounds of radiation doses.
4 ~~(76)~~ (78) "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a
5 partial seal with the face.
6 ~~(77)~~ (79) "Lost or missing licensed radioactive material" means licensed radioactive material
7 whose location is unknown. It includes material that has been shipped but has not
8 reached its destination and whose location cannot be readily traced in the transportation
9 system.
10 ~~(78)~~ (80) "Lung class" (see "Class" as defined in this Rule).
11 ~~(79)~~ (81) "Medical event" means an event that meets the criteria in Rule .0364 of this Chapter.
12 ~~(80)~~ (82) "Medical use" means the intentional internal or external administration of radioactive
13 material or the radiation therefrom to patients or human research subjects under the
14 supervision of an authorized user.
15 ~~(81)~~ (83) "Member of the public" means any individual except when that individual is receiving an
16 occupational dose.
17 ~~(82)~~ (84) "Minor" means an individual less than 18 years of age.
18 ~~(83)~~ (85) "Mobile nuclear medicine service" means the transportation and medical use of
19 radioactive material.
20 ~~(84)~~ (86) "Monitoring", "radiation monitoring" or "radiation protection monitoring" means the
21 measurement of radiation levels, concentrations, surface area concentrations or quantities
22 of radioactive material and the use of the results of these measurements to evaluate
23 potential exposures and doses.
24 ~~(85)~~ (87) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
25 ~~(86)~~ (88) "Negative pressure respirator" means a tight-fitting respirator in which the air pressure
26 inside the facepiece is negative during inhalation with respect to the ambient air pressure
27 outside of the respirator.
28 ~~(87)~~ (89) "Nonstochastic effect" means health effects, the severity of which varies with the dose
29 and for which a threshold is believed to exist. Radiation-induced cataract formation is an
30 example of a nonstochastic effect (also called a deterministic effect).
31 ~~(88)~~ (90) "NRC" means the United States Nuclear Regulatory Commission or its authorized
32 representatives.
33 ~~(89)~~ (91) "Occupational dose" means the dose received by an individual in the course of
34 employment in which the individual's assigned duties involve exposure to radiation or
35 radioactive material from licensed and unlicensed sources of radiation, whether in the
36 possession of the licensee or registrant or other person. Occupational dose does not
37 include dose received from background radiation, as a patient from medical practices,

1 from exposure to individuals administered radioactive material and released in
2 accordance with Rule .0358 of this Chapter, from voluntary participation in medical
3 research programs, or as a member of the general public.

4 ~~(90)~~ (92) "Particle accelerator" means any machine capable of accelerating electrons, protons,
5 deuterons, or other charged ~~particles.~~ particles, in a vacuum and of discharging the
6 resultant particulate or other radiation into a medium at energies usually in excess of 1
7 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

8 ~~(91)~~ (93) "Person" has the meaning as defined in G.S. 104E-5(11).

9 ~~(92)~~ (94) "Personnel monitoring equipment" means devices, such as film badges, pocket
10 dosimeters, and thermoluminescent dosimeters, designed to be worn or carried by an
11 individual for the purpose of estimating the dose received by the individual.

12 ~~(93)~~ (95) "Pharmacist" means a person licensed by ~~this state~~ North Carolina to practice pharmacy
13 (21 NCAC 46.1500).

14 ~~(94)~~ (96) "Physician" means an individual licensed to practice medicine in ~~this state~~ North Carolina
15 (NC G.S. Chapter 90, Article 1).

16 ~~(95)~~ (97) "Planned special exposure" means an infrequent exposure to radiation, separate from and
17 in addition to the annual dose limits as defined in Rule .1608 of this Chapter.

18 ~~(96)~~ (98) "Positive pressure respirator" means a respirator in which the pressure inside the
19 respiratory inlet covering exceeds the ambient air pressure outside the respirator.

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

22 ~~(97)~~ (100) "Powered air-purifying respirator (PAPR)" means an air-purifying respirator that uses a
23 blower to force the ambient air through air-purifying elements to the inlet covering.

24 ~~(98)~~ (101) "Prescribed dosage" means the specified activity or range of activity of unsealed
25 radioactive material as documented:

- 26 (a) In a written directive; or
27 (b) In accordance with the directions of an authorized user.

28 ~~(99)~~ (102) "Prescribed dose" means:

- 29 (a) for teletherapy or accelerator radiation:
30 (i) the total dose; and
31 (ii) the dose per fraction as documented in the written directive;

- 32 (b) for brachytherapy:
33 (i) the total source strength and exposure time; or
34 (ii) the total dose, as documented in the written directive;

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

- 1 (d) for remote brachytherapy afterloaders, the total dose and dose per fraction as
2 documented in a written directive.
- 3 ~~(100)~~(103) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator
4 that admits breathing air to the facepiece when the positive pressure is reduced inside the
5 facepiece by inhalation.
- 6 ~~(101)~~(104) "Public dose" means the dose received by a member of the public from exposure to
7 radiation or radioactive material released by a licensee or registrant, or ~~to~~ another source
8 of radiation within a licensee's or registrant's control. It does not include occupational
9 dose or doses received from background radiation, as a patient from medical practices,
10 from exposure to individuals administered radioactive material and released in
11 accordance with Rule .0358 of this Chapter, or from voluntary participation in medical
12 research programs.
- 13 ~~(102)~~(105) "Qualitative fit test (QLFT)" means a pass/fail fit test to assess the adequacy of respirator
14 fit that relies on the individual's response to the test agent.
- 15 ~~(103)~~(106) "Quality factor" (Q) means the modifying factor that is used to derive dose equivalent
16 from absorbed dose. Quality factors are provided in the definition of rem in this Rule.
- 17 ~~(104)~~(107) "Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by
18 numerically measuring the amount of leakage into the respirator.
- 19 ~~(105)~~(108) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee
20 or registrant (approximately 13 consecutive weeks), providing that the beginning of the
21 first quarter in a year coincides with the starting date of the year and that no day is
22 omitted or duplicated in consecutive quarters.
- 23 ~~(106)~~(109) Quarterly" means either:
24 (a) at intervals not to exceed 13 weeks; or
25 (b) once per 13 weeks at about the same time during each 13 week period (completed during
26 the same month of the quarter (first month, second month or third month) each quarter
27 over a time period of several quarters.
- 28 ~~(107)~~(110) "Rad" is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100
29 ergs/gram or 0.01 joule/kilogram (0.01 gray).
- 30 ~~(108)~~(111) "Radiation" (~~ionizing radiation~~), except as otherwise defined in Section .1400 of this
31 Chapter, has the meaning as defined in G.S. 104E-5(12).
- 32 ~~(109)~~(112) "Radiation area" means an area, accessible to individuals, in which radiation levels could
33 result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in
34 one hour at 30 centimeters from the radiation source or from any surface that the
35 radiation penetrates.
- 36 ~~(110)~~(113) "Radiation dose" means dose.
- 37 ~~(111)~~(114) "Radiation machine" has the meaning as defined in G.S. 104E-5(13).

- 1 ~~(112)~~ (115) "Radiation safety officer" means one who has the knowledge and responsibility to apply
- 2 appropriate radiation protection rules.
- 3 ~~(113)~~ (116) "Radioactive material" has the meaning as defined in G.S. 104E-5(14).
- 4 ~~(114)~~ (117) "Radioactive waste disposal facility" means any low-level radioactive waste disposal
- 5 facility, as defined in G.S. 104E-5(9c), established for the purpose of receiving low-level
- 6 radioactive waste, as defined in Rule .1202 of this Chapter, generated by another licensee
- 7 for the purpose of disposal.
- 8 ~~(115)~~ (118) "Radioactive waste processing facility" means any low-level radioactive waste facility,
- 9 as defined in G.S. 104E-5(9b), established for the purpose of receiving waste, as defined
- 10 in this Rule, generated by another licensee to be stored, compacted, incinerated or treated.
- 11 ~~(116)~~ (119) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of
- 12 radiation.
- 13 ~~(117)~~ (120) "Radiobioassay" means bioassay.
- 14 ~~(118)~~ (121) "Reference man" means a hypothetical aggregation of human physical and physiological
- 15 characteristics arrived at by international consensus as published by the International
- 16 Commission on Radiological Protection. These characteristics may be used by
- 17 researchers and public health workers to standardize results of experiments and to relate
- 18 biological insult to a common base.
- 19 ~~(119)~~ (122) "Registrant" means any person who is registered with the agency as required by
- 20 provisions of these Rules or the Act.
- 21 ~~(120)~~ (123) "Registration" means registration with the agency in accordance with these Rules.
- 22 ~~(121)~~ (124) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR
- 23 Parts 100-189.
- 24 ~~(122)~~ (125) "Rem" is the special unit of any of the quantities expressed as dose equivalent. The dose
- 25 equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1
- 26 rem = 0.01 sievert). As used in this Chapter, the quality factors for converting absorbed
- 27 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		

1	particles, fission fragments		
2	and heavy particles of unknown		
3	charge	20	0.05
4	Neutrons of unknown energy	10	0.1
5	High-energy protons	10	0.1

6

7 ^a Absorbed dose in rad equal to one rem or the absorbed dose in gray equal to one sievert.

8

9 If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in

10 rems per hour or sieverts per hour, one rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of

11 the rules of this Chapter, be assumed to result from a total fluence of 25 million neutrons per square centimeter

12 incident upon the body.

13 If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or

14 registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from the following table to

15 convert a measured tissue dose in rads to dose equivalent in rems:

16

17 MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE

18 EQUIVALENT FOR MONOENERGETIC NEUTRONS

19

20	Neutron	Quality	Fluence per Unit
21	Energy	Factor ^a	Dose Equivalent ^b
22	(MeV)	(Q)	(neutrons cm ⁻² rem ⁻¹)
23			
24	(thermal) 2.5 x 10 ⁻⁸	2	980 x 10 ⁶
25	1 x 10 ⁻⁷	2	980 x 10 ⁶
26	1 x 10 ⁻⁶	2	810 x 10 ⁶
27	1 x 10 ⁻⁵	2	810 x 10 ⁶
28	1 x 10 ⁻⁴	2	840 x 10 ⁶
29	1 x 10 ⁻³	2	980 x 10 ⁶
30	1 x 10 ⁻²	2.5	1010 x 10 ⁶
31	1 x 10 ⁻¹	7.5	170 x 10 ⁶
32	5 x 10 ⁻¹	11	39 x 10 ⁶
33	1	11	27 x 10 ⁶
34	2.5	9	29 x 10 ⁶
35	5	8	23 x 10 ⁶
36	7	7	24 x 10 ⁶
37	10	6.5	24 x 10 ⁶

1	14	7.5	17×10^6
2	20	8	16×10^6
3	40	7	14×10^6
4	60	5.5	16×10^6
5	1×10^2	4	20×10^6
6	2×10^2	3.5	19×10^6
7	3×10^2	3.5	16×10^6
8	4×10^2	3.5	14×10^6
9			

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

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

13 ~~(123)~~ (126) "Research and development" means:

14 (a) theoretical analysis, exploration, or experimentation; or

15 (b) the extension of investigative findings and theories of a scientific or technical nature into
 16 practical application for experimental and demonstration purposes, including the
 17 experimental production and testing of models, devices, equipment, materials, and
 18 processes.

19 Research and development does not include the internal or external administration of radiation or
 20 radioactive material to human beings.

21 ~~(124)~~ (127) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater,
 22 and other media at a site resulting from activities under the licensee's control. This
 23 includes radioactivity from all licensed and unlicensed sources used by the licensee, but
 24 excludes background radiation. It also includes radioactive materials remaining at the
 25 site as a result of routine or accidental releases of radioactive material at the site and
 26 previous burials at the site, even if the burials were made in accordance with the
 27 provisions of Section .1600 of this Chapter.

28 ~~(125)~~ (128) "Respiratory protective device" means an apparatus, such as a respirator, used to reduce
 29 the individual's intake of airborne radioactive materials.

30 ~~(126)~~ (129) "Restricted area" means an area, access to which is controlled by the licensee or
 31 registrant for purposes of protecting individuals against undue risks from exposure to
 32 radiation and radioactive materials. Restricted area does not include areas used as
 33 residential quarters, but separate rooms in a residential building may be set apart as a
 34 restricted area.

35 ~~(127)~~ (130) "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58×10^{-4}
 36 coulombs/kilogram of air.

1 ~~(128)~~ (131) "Sanitary sewerage" means a system of public sewers for carrying off waste water and
2 refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or
3 operated by the licensee.

4 ~~(129)~~ (132) "Sealed source" means radioactive material that is ~~permanently bonded, fixed or~~
5 ~~encapsulated so as to prevent release and dispersal of the radioactive material under the~~
6 ~~most severe conditions which are likely to be encountered in normal use and handling.~~
7 encased in a capsule designed to prevent leakage or escape of the radioactive material.

8 ~~(130)~~ (133) "Sealed source and device registry" means the national registry that contains all the
9 registration certificates, generated by both NRC and the Agreement States, that
10 summarize the radiation safety information for the sealed sources and devices and
11 describe the licensing and use conditions approved for the product.

12 ~~(131)~~ (134) "Self-contained breathing apparatus (SCBA)" means an atmosphere-supplying respirator
13 for which the breathing air source is designed to be carried by the user.

14 ~~(132)~~ (135) "Semiannually" means either:
15 (a) at intervals not to exceed six months; or
16 (b) once per six months at about the same time during each six month period (completed
17 during the sixth month of each six month period over multiple six month periods).

18 ~~(133)~~ (136) "Shallow-dose equivalent" (H_s), which applies to the external exposure of the skin of the
19 whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of
20 0.007 centimeter (7 mg/cm^2).

21 ~~(134)~~ (137) "SI unit" means a unit of measure from the International System of Units as established
22 by the General Conference of Weights and Measures.

23 ~~(135)~~ (138) "Sievert" is the SI unit of any of the quantities expressed as dose equivalent. The dose
24 equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality
25 factor ($1 \text{ Sv} = 100 \text{ rems}$).

26 ~~(136)~~ (139) "Site boundary" means that line beyond which the land or property is not owned, leased,
27 or otherwise controlled by the licensee or registrant.

28 ~~(137)~~ (140) "Source material" has the meaning as defined in G.S. 104E-5(15).

29 ~~(138)~~ (141) "Source of radiation" means any radioactive material, or any device or equipment
30 emitting or capable of producing radiation.

31 ~~(139)~~ (142) "Special form radioactive material" means radioactive material which satisfies the
32 following conditions:
33 (a) It is either a single solid piece or is contained in a sealed capsule that can be opened only
34 by destroying the capsule;
35 (b) The piece or capsule has at least one dimension not less than five millimeters (0.197
36 inch); and

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

8 ~~(140)~~ (143) "Special nuclear material" has the meaning as defined in G.S. 104E-5(16).

9 ~~(141)~~ (144) "Special nuclear material in quantities not sufficient to form a critical mass" means
10 uranium enriched in the isotope uranium-235 in quantities not exceeding 350 grams of
11 contained uranium-235; uranium-233 in quantities not exceeding 200 grams; plutonium
12 in quantities not exceeding 200 grams; or any combination of uranium-235, uranium
13 enriched in uranium-235 and plutonium in accordance with the following formula: For
14 each kind of special nuclear material, determine the ratio between the quantity of that
15 special nuclear material and the quantity specified in this Rule for the same kind of
16 special nuclear material. The sum of these ratios for all the kinds of special nuclear
17 material in combination shall not exceed unity. For example, the following quantities in
18 combination would not exceed the limitations and are within the formula, as follows:

19
20
$$\frac{175 \text{ (gram contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} \text{ is } < \text{ or } = 1$$

21
22
23 ~~(142)~~ (145) "State" means the State of North Carolina.

24 ~~(143)~~ (146) "Stochastic effects" means health effects that occur randomly and for which the
25 probability of the effect occurring, rather than its severity, is assumed to be a linear
26 function of dose without threshold. Hereditary effects and cancer incidence are examples
27 of stochastic effects.

28 ~~(144)~~ (147) "Supplied-air respirator (SAR or airline respirator)" means an atmosphere-supplying
29 respirator for which the source of breathing air is not designed to be carried by the user.

30 ~~(145)~~ (148) "Survey" means an evaluation of the radiological conditions and potential hazards
31 incident to the production, use, transfer, release, disposal, or presence of sources of
32 radiation. When appropriate, such an evaluation includes a physical survey of the
33 location of sources of radiation and measurements or calculations of levels of radiation,
34 or concentrations or quantities of radioactive material present.

35 ~~(146)~~ (149) "These Rules" means Chapter 11 of this Title.

36 ~~(147)~~ (150) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal
37 with the face.

1 .0104 of this Section, and licensed naturally occurring and accelerator produced
2 radioactive material which is not subject to regulation by the U.S. Nuclear Regulatory
3 Commission under the Atomic Energy Act of 1954, as amended, except as defined
4 differently in Rule .1202 of this Chapter.

5 ~~(158)~~ (161) "Waste, Class A" is defined in Rule .1650 of this Chapter.

6 ~~(159)~~ (162) "Waste, Class B" is defined in Rule .1650 of this Chapter.

7 ~~(160)~~ (163) "Waste, Class C" is defined in Rule .1650 of this Chapter.

8 ~~(161)~~ (164) "Week" means seven consecutive days starting on Sunday.

9 ~~(162)~~ (165) "Weighting factor", w_T , for an organ or tissue (T) is the proportion of the risk of
10 stochastic effects resulting from irradiation of that organ or tissue to the total risk of
11 stochastic effects when the whole body is irradiated uniformly. For calculating the
12 effective dose equivalent, the values of w_T are:

13 ORGAN DOSE WEIGHTING FACTORS

14 Organ or	
15 Tissue	16 w_T
17 Gonads	18 0.25
19 Breast	20 0.15
21 Red bone marrow	22 0.12
23 Lung	24 0.12
25 Thyroid	26 0.03
27 Bone surfaces	28 0.03
29 Remainder	30 0.30 ^a
31 Whole body	32 1.00 ^b

33 ^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
34 highest doses.

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

37 ~~(163)~~ (166) "Whole body" means, for purposes of external exposure, head, trunk (including male
38 gonads), arms above the elbow, or legs above the knee.

39 ~~(164)~~ (167) "Worker" means an individual engaged in work under a license or registration issued by
40 the agency and controlled by a licensee or registrant, but does not include the licensee or
41 registrant.

1 (D) total source strength and exposure time; and

2 (E) total dose; and

3 (f) for gamma stereotactic radiosurgery:

4 (i) the total dose;

5 (ii) treatment site; and

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

8 ~~(168)~~ (171) "Year" means the period of time beginning in January used to determine compliance with
9 the provisions of Section .1600 of this Chapter. The licensee or registrant may change the
10 starting date of the year used to determine compliance by the licensee or registrant
11 provided that the change is made at the beginning of the year and that no day is omitted
12 or duplicated in consecutive years.

13
14 *History Note: Authority G.S. 104E-7(a)(2);*

15 *Eff. February 1, 1980;*

16 *Amended Eff. November 1, 1989; June 1, 1989; October 1, 1984;*

17 *Transferred and Recodified from 10 NCAC 3G .2204 Eff. January 4, 1990;*

18 *Amended Eff. January 1, 1994; May 1, 1992;*

19 *Temporary Amendment Eff. August 20, 1994, for a Period of 180 Days or until the permanent rule*
20 *becomes effective, whichever is sooner;*

21 *Amended Eff. October 1, 2013; November 1, 2007; May 1, 2006; January 1, 2005; August 1,*
22 *2002; April 1, 1999; August 1, 1998; May 1, 1995.*

1 15A NCAC 11 .0105 is proposed for amendment as follows:

2

3 **15A NCAC 11 .0105 OTHER DEFINITIONS**

4

5 Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600,
6 .0800, .1200, .1300, .1400, and .1500 of this Chapter.

7

8

9 *History Note: Authority G.S. 104E-7;*

10 *Eff. February 1, 1980;*

11 *Amended Eff. June 1, 1989;*

12 *Transferred and Recodified from 10 NCAC 3G .2205 Eff. January 4, 1990;*

13 *Amended Eff. October 1, 2013; May 1, 1993.*

1 15A NCAC 11 .0117 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0117 INCORPORATION BY REFERENCE**

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

- 6 (1) Appendix A, Appendix B, Appendix C, and Appendix G to 10 CFR Parts 20.1001 - 20.2401;
- 7 (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
8 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
9 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,
10 35.457, 35.490, 35.491, 35.500, 35.590, Subpart H of 10 CFR Part 35, 35.1000, 10 CFR Part 36,
11 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)
12 pertaining to uranium enrichment, and (g), 40.33, 40.38, 40.41(d), (e)(1), (e)(3), (g), (h),
13 40.51(b)(6), 40.64, 40.66-67; and 10 CFR Part 50;
- 14 ~~(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71, 10 CFR Part 73, 10 CFR Part 110, 10 CFR Part~~
15 ~~140 and 10 CFR Part 150;~~
- 16 (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,
17 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,
18 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),
19 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,
20 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,
21 71.47, Subpart G of 10 CFR Part 71, 10 CFR 71.101(a) – (c)(1), 71.101(f), 71.101(g), 71.103,
22 71.105, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, Appendix A to 10 CFR Part 71, and 10
23 CFR Part 150 except 150.3 Definition: Foreign Obligations, 150.7, 150.10, 150.14, 150.15,
24 150.15a, 150.16-17, 150.17a, 150.19, 150.21;
- 25 (4) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040;
- 26 (5) 39 CFR Part 14 and 39 CFR Part 15;
- 27 (6) Postal Service Manual (Domestic Mail Manual) Section 124.3 [incorporated by reference in 39
28 CFR Section 111.11];
- 29 (7) 40 CFR Part 261;
- 30 (8) 49 CFR Parts 100-189;
- 31 (9) "Agreement Between the United States Atomic Energy Commission and the State of North
32 Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility
33 within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended", signed
34 July 21, 1964;
- 35 (10) "Standards and Specifications for Geodetic Control Networks (September 1984);
- 36 (11) "Geometric Geodetic Survey Accuracy Standards and Specifications for Geodetic Surveys Using
37 GPS Relative Positioning Techniques";

- 1 (12) "Reference Man: Anatomical, Physiological and Metabolic Characteristics" (ICRP Publication
2 No. 23) of the International Commission on Radiological Protection;
- 3 (13) "10 CFR, Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 FR 7540";
4 and
- 5 (14) American National Standard ~~N432-1980~~ N43.9 "Radiological Safety for the Design and
6 Construction of Apparatus for Gamma Radiography".

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

- 13 (1) Three dollars (\$3.00) for the appendixes listed in Subparagraph (a)(1) of this Rule, available from
14 the ~~Division of Radiation Protection Agency~~;
- 15 (2) ~~Twenty-five~~ Sixty-Seven dollars (~~\$25.00~~) (\$67.00) for the regulations listed in Subparagraph
16 (a)(2) of this Rule in a volume containing 10 CFR Parts ~~0-50~~ 1-50;
- 17 (3) ~~Eighteen dollars~~ Sixty-Four (~~\$18.00~~) (\$64.00) for the regulations listed in Subparagraph (a)(3) of
18 this Rule in a volume containing 10 CFR Parts 51-199;
- 19 (4) ~~Eighteen dollars~~ Sixty-Six (~~\$18.00~~) (\$66.00) for the regulations listed in Subparagraph (a)(4) of
20 this Rule in a volume containing 21 CFR Parts 800-1299;
- 21 (5) ~~Sixteen dollars~~ Forty-Seven (~~\$16.00~~) (\$47.00) for the regulations listed in Subparagraph (a)(5) of
22 this Rule in a volume containing 39 CFR;
- 23 (6) Thirty-six dollars (\$36.00) for the manual listed in Subparagraph (a)(6) of this Rule;
24 http://pe.usps.gov/text/dmm300/dmm300_landing.htm
25
- 26 (7) ~~Thirty-one~~ Fifty-Six dollars (~~\$31.00~~) (\$56.00) for the regulations listed in Subparagraph (a)(7) of
27 this Rule in a volume containing 40 CFR Parts 260-299;
- 28 (8) For the regulations listed in Subparagraph (a)(8) of this Rule:
- 29 (A) ~~Twenty-three~~ Seventy dollars (~~\$23.00~~) (\$70.00) for a volume containing 49 CFR Parts
30 100-177; and
- 31 (B) ~~Seventeen~~ Seventy dollars (~~\$17.00~~) (\$70.00) for a volume containing 49 CFR Parts 178-
32 199;
- 33 (9) One dollar (\$1.00) for the agreement in Subparagraph (a)(9) of this Rule, available from the
34 ~~Division of Radiation Protection Agency~~;
- 35 (10) Two dollars and eighty-five cents (\$2.85) for the standards and specifications in Subparagraph
36 (a)(10) of this Rule, available from the National Geodetic Information Center, N/CG174,
37 Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

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

4 (12) ~~One hundred and five~~ Two Hundred Eighteen dollars ~~(\$105.00)~~ (\$218.00) for the ICRP
5 Publication No. 23 in Subparagraph (a)(12) of this Rule, available from Pergamon Press, Inc.,
6 Maxwell House, Fairview Park, Elmsford, NY 10523;

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

9 (14) ~~Thirty eight dollars~~ Twenty-Five plus five dollars shipping and handling ~~(\$43.00)~~ (\$30.00) for the
10 American National Standard ~~N432-1980~~ N43.9 in Subparagraph (a)(14) of this Rule, available
11 from the American National Standards Institute, Inc., 1430 Broadway, New York, New York
12 10018, telephone number (212) 642-4900.

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

15
16 *History Note:* Authority G.S. 104E-7; 104E-15(a); 150B-21.6;

17 *Eff. June 1, 1993;*

18 *Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule*
19 *becomes effective, whichever is sooner;*

20 *Amended Eff. October 1, 2013; November 1, 2007; August 1, 2002; April 1, 1999; August 1, 1998;*
21 *May 1, 1995.*

1 15A NCAC 11 .0301 is proposed for amendment as follows:
2

3 **SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL**
4

5 This Section .0300, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0300);
6 LICENSING OF RADIOACTIVE MATERIAL; has been transferred and recodified from Section .2400,
7 Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2400), effective January 4, 1990.
8 The recodification was pursuant to G.S. 143B-279.3.
9
10

11 **15A NCAC 11 .0301 PURPOSE AND SCOPE**

12 (a) This Section provides for the licensing of radioactive material. No person shall receive, possess, use, transfer,
13 ~~own~~ own, manufacture and produce, or acquire radioactive material except as authorized in a specific or general
14 license issued pursuant to, or as otherwise provided in, this Section.

15 (b) In addition to the requirements of this Section,

- 16 (1) All licensees are subject to the requirements of Sections .1000 and .1600 of this Chapter, except as
17 otherwise provided in the rules of this Section;
18 (2) Licensees engaged in industrial radiographic operations are subject to the requirements of Section
19 .0500 of this Chapter;
20 (3) Licensees using sealed sources in the healing arts are subject to the requirements of Section .0700
21 of this Chapter;
22 (4) Licensees engaged in the operation of radioactive waste disposal facilities are subject to the
23 requirements of Section .1200 of this Chapter;
24 (5) Licensees engaged in well-logging operations are subject to the requirements of Section .1300 of
25 this Chapter; and
26 (6) Licensees engaged in the operation of panoramic and underwater irradiators are subject to the
27 requirements of Section .0100 of this Chapter.

28 (c) In addition to the requirements of this Section, all licensees are subject to the annual fee provisions contained in
29 Section .1100 of this Chapter.

30 (d) The rules in this Section do not apply to persons licensed pursuant to the rules in Section .1200 of this Chapter
31 except as specifically provided otherwise in Section .1200.
32

33 *History Note: Authority G.S. 104E-7; 104E-9(8); 104E-10(b); 104E-19;*
34 *Eff. February 1, 1980;*
35 *Amended Eff. October 1, 2013; August 1, 1998; January 1, 1994; May 1, 1992; June 1, 1989; July*
36 *1, 1982.*

1 15A NCAC 11 .0303 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0303 EXEMPT CONCENTRATIONS: OTHER THAN SOURCE MATERIAL**

4 (a) No person shall introduce radioactive material into a product or material knowing or having reason to believe
5 that it will be transferred to persons exempt under Paragraph ~~(b)~~ (d) of this Rule or equivalent regulations of the U.S.
6 Nuclear Regulatory Commission or any agreement state, except in accordance with a specific license issued
7 pursuant to ~~Rule .0325 of this Section.~~ 10 CFR 32.11.

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

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

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

20
21 EXEMPT CONCENTRATIONS

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

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

1	Palladium (46)	Pd 103	3×10^{-3}
2		Pd 109	9×10^{-4}
3	Phosphorus (15)	P 32	2×10^{-4}
4	Platinum (78)	Pt 191	1×10^{-3}
5		Pt 193m	1×10^{-2}
6		Pt 197m	1×10^{-2}
7		Pt 197	1×10^{-3}
8	Polonium (84)	Po 210	7×10^{-6}
9	Potassium (19)	K 42	3×10^{-3}
10	Praseodymium (59)	Pr 142	3×10^{-4}
11		Pr 143	5×10^{-4}
12	Promethium (61)	Pm 147	2×10^{-3}
13		Pm 149	4×10^{-4}
14	Radium (88)	Ra 226	1×10^{-7}
15		Ra 228	3×10^{-7}
16	Rhenium (75)	Re 183	6×10^{-3}
17		Re 186	9×10^{-4}
18		Re 188	6×10^{-4}
19	Rhodium (45)	Rh 103m	1×10^{-1}
20		Rh 105	1×10^{-3}
21	Rubidium (37)	Rb 86	7×10^{-4}
22	Ruthenium (44)	Ru 97	4×10^{-3} <u>4×10^{-4}</u>
23		Ru 103	8×10^{-4}
24		Ru 105	1×10^{-3}
25		Ru 106	1×10^{-4}
26	Samarium (62)	Sm 153	8×10^{-4}
27	Scandium (21)	Sc 46	4×10^{-4}
28		Sc 47	9×10^{-4}
29		Sc 48	3×10^{-4}
30	Selenium (34)	Se 75	3×10^{-3}
31	Silicon (14)	Si 31	9×10^{-3}
32	Silver (47)	Ag 105	1×10^{-3}
33		Ag 110m	3×10^{-4}
34		Ag 111	4×10^{-4}
35	Sodium (11)	Na 24	2×10^{-3}
36	Strontium (38)	Sr 85	1×10^{-3} <u>1×10^{-4}</u>

1		Sr 89		1×10^{-4}
2		Sr 91		7×10^{-4}
3		Sr 92		7×10^{-4}
4	Sulfur (16)	S 35	9×10^{-8}	6×10^{-4}
5	Tantalum (73)	Ta 182		4×10^{-4}
6	Technetium (43)	Tc 96m		1×10^{-1}
7		Tc 96		1×10^{-3}
8	Tellurium (52)	Te 125m		2×10^{-3}
9		Te 127m		6×10^{-4}
10		Te 127		3×10^{-3}
11		Te 129m		3×10^{-4}
12		Te 131m		6×10^{-4}
13		Te 132		3×10^{-4}
14	Terbium (65)	Tb 160		4×10^{-4}
15	Thallium (81)	Tl 200		4×10^{-3}
16		Tl 201		3×10^{-3}
17		Tl 202		1×10^{-3}
18		Tl 204		1×10^{-3}
19	Thulium (69)	Tm 170		5×10^{-4}
20		Tm 171		5×10^{-3}
21	Tin (50)	Sn 113		9×10^{-4}
22		Sn 125		2×10^{-4}
23	Tungsten(Wolfram) (74)	W 181		4×10^{-3}
24		W 187		7×10^{-4}
25	Vanadium (23)	V 48		3×10^{-4}
26	Xenon (54)	Xe 131m		4×10^{-6}
27		Xe 133		3×10^{-6}
28		Xe 135		1×10^{-6}
29	Ytterbium (70)	Yb 175		1×10^{-3}
30	Yttrium (39)	Y 90		2×10^{-4}
31		Y 91m		3×10^{-2}
32		Y 91		3×10^{-4}
33		Y 92		6×10^{-4}
34		Y 93		3×10^{-4}
35	Zinc (30)	Zn 65		1×10^{-3}
36		Zn 69m		7×10^{-4}

1		Zn 69	2X10 ⁻²
2	Zirconium (40)	Zr 95	6X10 ⁻⁴
3		Zr 97	2X10 ⁻⁴
4	Beta and/or gamma emitting		1X10 ⁻¹⁰
5	radioactive material not		1X10 ⁻⁶
6	listed above with half-life		
7	less than 3 years		

9 (e) In Column I of the table, in Paragraph (b) of this Rule, values are given only for those materials normally
10 used as gases.

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

12 (g) Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in
13 Paragraph (b) of this Rule, the activity stated is that of the parent isotope and takes into account the daughters.

14 (h) For purposes of this Rule, where a combination of isotopes is involved, the limit for the combination shall be
15 derived as follows: Determine for each isotope in the product the ratio between the concentration present in the
16 product and the exempt concentration established in Paragraph (b) of this Rule for the specific isotope when not in
17 combination. The sum of the ratios shall not exceed unity. An example of this is:

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

26 *History Note: Authority G.S. 104E-7; 104E-10; 104E-20;*
27 *Eff. February 1, 1980;*
28 *Amended Eff. October 1, 2013; May 1, 1993; June 1, 1989.*

1 15A NCAC 11 .0304 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0304 EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL**

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

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

10 (c) No person shall, for the purposes of commercial distribution, transfer individual quantities of radioactive
11 materials to persons exempt from regulation in Paragraph (a) of this Rule except in accordance with a specific
12 license issued ~~by~~ by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 for
13 source and byproduct material.

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

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

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

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

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

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

30
31 EXEMPT QUANTITIES

<u>Radioactive Material</u>	<u>Microcuries</u>
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	<u>Germanium-68 (Ge 68)</u>	<u>10</u>
11	Germanium-71 (Ge 71)	100
12	<u>Gold-195 (Au 195)</u>	<u>10</u>
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

1	Tellurium-127 (Te 127)	100
2	Tellurium-129m (Te 129m)	10
3	Tellurium-129 (Te 129)	100
4	Tellurium-131m (Te 131m)	10
5	Tellurium-132 (Te 132)	10
6	Terbium-160 (Tb 160)	10
7	Thallium-200 (Tl 200)	100
8	Thallium-201 (Tl 201)	100
9	Thallium-202 (Tl 202)	100
10	Thallium-204 (Tl 204)	10
11	Thulium-170 (Tm 170)	10
12	Thulium-171 (Tm 171)	10
13	Tin-113 (Sn 113)	10
14	Tin-125 (Sn 125)	10
15	Tungsten-181 (W 181)	10
16	Tungsten-185 (W 185)	10
17	Tungsten-187 (W 187)	100
18	Vanadium-48 (V 48)	10
19	Xenon-131m (Xe 131m)	1,000
20	Xenon-133 (Xe 133)	100
21	Xenon-135 (Xe 135)	100
22	Ytterbium-175 (Yb 175)	100
23	Yttrium-87 (Y 87)	10
24	<u>Yttrium-88 (Y 88)</u>	<u>10</u>
25	Yttrium-90 (Y 90)	10
26	Yttrium-91 (Y 91)	10
27	Yttrium-92 (Y 92)	100
28	Yttrium-93 (Y 93)	100
29	Zinc-65 (Zn 65)	10
30	Zinc-69m (Zn 69m)	100
31	Zinc-69 (Zn 69)	1,000
32	Zirconium-93 (Zr 93)	10
33	Zirconium-95 (Zr 95)	10
34	Zirconium-97 (Zr 97)	10
35	Any radioactive material	
36	not listed above other than	
37	alpha emitting radioactive	

1
2
3
4
5

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.*

1 15A NCAC 11 .0305 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0305 EXEMPT ITEM CONTAINING OTHER THAN SOURCE MATERIAL**

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

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

9 ~~(b)~~ (b) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into
10 the following products, or persons who initially transfer for sale or distribution the following products, any person is
11 exempt from the rules of this Chapter to the extent that he receives, possesses, uses, transfers, owns, or acquires the
12 following products:

13 ~~(A)(1)~~ (1) timepieces or hands or dials containing not more than the following ~~specified~~ quantities of
14 radioactive material and not exceeding the following ~~specified~~ levels of radiation:

15 ~~(i)(A)~~ (A) 25 millicuries of tritium per timepiece;

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

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

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

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

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

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

27 ~~(i)~~ (i) for wrist watches, 0.1 millirad per hour at 10 centimeters from any
28 surface;

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

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

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

35 ~~(B)(2)~~ (2) [Reserved for future codification] lock illuminators containing not more than 15 millicuries of
36 tritium or not more than two millicuries of promethium 147 installed in automobile locks (the
37 levels of radiation from each lock illuminator containing promethium 147 shall not exceed one

1 millirad per hour at one centimeter from any surface when measured through 50 milligrams per
2 square centimeter of absorber);

3 ~~(C)~~(3) balances of precision containing not more than one millicurie of tritium per balance or not more
4 than 0.5 millicurie of tritium per balance ~~part~~; part manufactured before December 17, 2007;

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

7 ~~(E)~~(5) marine compasses containing not more than 750 millicuries of tritium gas and other marine
8 navigational instruments containing not more than 250 millicuries of tritium ~~gas~~; gas
9 manufactured before December 17, 2007;

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

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

14 ~~(G)~~(8) electron tubes, provided that each tube does not contain more than one of the following specified
15 quantities of radioactive material and provided further, that the levels of radiation from each
16 electron tube containing radioactive material does not exceed one millirad per hour at one
17 centimeter from any surface when measured through seven milligrams per square centimeter of
18 absorber (for purposes of this Subparagraph, "electron tubes" include spark gap tubes, power
19 tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup
20 tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or
21 control electrical currents):

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

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

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

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

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

28 ~~(vi)~~(F) 30 microcuries of promethium-147; and provided further, that the levels of
29 radiation from each electron tube containing radioactive material does not
30 exceed one millirad per hour at one centimeter from any surface when measured
31 through seven milligrams per square centimeter of absorber (for purposes of this
32 Subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes
33 including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup
34 tubes, radiation detection tubes and any other completely sealed tube that is
35 designed to conduct or control electrical currents); and

36 ~~(H)~~(9) ionizing radiation measuring instruments containing for purposes of internal calibration or
37 standardization, sources of radioactive material each not exceeding the applicable quantity set

1 forth in Rule .0304~~(e)~~ (f) of this ~~Section~~. Section, and each instrument contains no more than 10
2 exempt quantities.

3 ~~(4)(10)~~ [Reserved for future codification] spark-gap irradiation containing not more than one microcurie of
4 cobalt-60 per spark-gap irradiator for use in electrically ignited fuel oil burners having a firing rate
5 of at least three gallons (11.4 liters) per hour.

6 ~~(2)(c)~~ For purposes of Part ~~(b)(1)(H)~~ (b)(8) of this Rule, where there is involved a combination of radionuclides, the
7 limit for the combination shall be derived as follows:

8 ~~(A)(1)~~ Determine for each radionuclide in an ionizing radiation measuring instrument the ratio between
9 the quantity present in the instrument and the exempt quantity established in Rule .0304~~(e)~~ (f) of
10 this Section for the specific radionuclide when not in combination;

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

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

14 ~~(e)(d)~~ Self-luminous products are exempt as provided in this Paragraph.

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

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

24 ~~(4)(e)~~ Gas and aerosol detectors are exempt as provided in this Paragraph.

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

34 (2) Gas and aerosol detectors previously manufactured and distributed to general licensees before
35 November 30, 2007 in accordance with a specific license issued by an agreement state ~~shall be~~
36 ~~considered~~ are exempt ~~under Subparagraph (d)(1) of this Rule~~ from the Rules in this Chapter,
37 provided that the devices are labeled in accordance with the specific license authorizing

1 distribution of the general licensed device, and providing further that the devices meet the
2 requirements of Rule .0327 of this Section.

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

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

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

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

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

19 ~~(2)(1) Any person who desires to use the capsules for research involving human subjects shall apply for~~
20 ~~and receive a specific license from the agency.~~

21 ~~(3)(2) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer~~
22 ~~for commercial distribution such capsules shall apply for and receive a specific license from the~~
23 ~~U.S. Nuclear Regulatory Commission.~~

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

26
27 *History Note: Authority G.S. 104E-7; 104E-10(b); 104E-20.;*

28 *Eff. February 1, 1980;*

29 *Amended Eff. October 1, 2013; April 1, 1999; June 1, 1993; October 1, 1982;*

30 *September 1, 1981.*

1 15A NCAC 11 .0309 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES**

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

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

- 12 (1) manufactured or initially transferred and labeled in accordance with the specifications contained in
13 a specific license issued pursuant to Rule .0328 of this Section or in accordance with the
14 specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission
15 or an agreement state which authorizes distribution of the devices to persons generally licensed
16 pursuant to equivalent regulations; and
17 (2) received from one of the specific licensees referenced in Subparagraph (b)(1) of this Rule or
18 through a transfer completed in accordance with Subparagraph (c)(8) of this Rule.

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

- 21 (1) ~~shall~~ assure that all labels, affixed to the device at the time of receipt and bearing a statement that
22 removal of the label is prohibited, are maintained thereon and shall comply with all instructions
23 and precautions provided by the labels;
24 (2) ~~shall~~ assure that the device is tested for leakage of radioactive material and proper operation of the
25 on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other
26 intervals as are specified in the label, except as follows:
27 (A) Devices containing only krypton need not be tested for leakage of radioactive material;
28 and
29 (B) Devices containing only tritium or not more than 100 microcuries of other beta, gamma,
30 or beta and gamma emitting material or ten microcuries of alpha emitting material and
31 devices held in storage in the original shipping container prior to initial installation need
32 not be tested for any purpose;
33 (3) ~~shall~~ assure that the tests required by Subparagraph (c)(2) of this Rule and other testing,
34 installation, servicing and removal from installation involving the radioactive materials, its
35 shielding or containment are performed:
36 (A) in accordance with the instructions provided on labels affixed to the device, except that
37 tests for leakage or contamination may be performed by the general licensee using leak

1 test kits provided and analyzed by a specific licensee who is authorized to provide leak
2 test kit services; or

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

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

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

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

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

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

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

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

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

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

- 1 (6) shall not abandon the device containing radioactive material;
- 2 (7) except as provided in Subparagraph (c)(8) of this Rule, shall transfer or dispose of the device
3 containing radioactive material only by export in accordance with 10 CFR Part 110 or by transfer
4 to a person holding a specific license authorizing receipt of the device; and, prior to the within 30
5 days of after transfer of a device to a specific licensee or export ~~the transfer~~ of a device ~~to a~~
6 ~~specific licensee~~, shall furnish to the agency at the address in Rule .0111 of this Chapter, a report
7 that contains:
- 8 (A) the identification of the device by manufacturer's or initial transferor's name, model
9 number, and serial number;
- 10 (B) the name, address and specific license number of the person receiving the ~~device; and~~
11 device (license number not applicable if exported); and
- 12 (C) the date of the ~~transfer.~~ transfer; and
- 13 ~~(D)(8)~~ shall obtain written approval by the Agency before transferring the device to any other specific
14 licensee not identified in this Rule; however, a holder of a specific license may transfer a device
15 for possession and use under its own specific license without prior approval, if the holder:
- 16 ~~(1)(A)~~ Verifies that the specific license authorizes the possession and use, or applies for
17 and obtains an amendment to the license authorizing the possession and use;
- 18 ~~(2)(B)~~ Removes, alters, covers, or clearly and unambiguously augments (As defined in
19 10 CFR 31.5) the existing label otherwise required by paragraph (c)(1) of this
20 section so that the device is labeled in compliance with § .0328(a)(3) of this
21 chapter; however, the manufacturer, model number, and serial number must be
22 retained;
- 23 ~~(3)(C)~~ Obtains the manufacturer's or initial transferor's information concerning
24 maintenance that be applicable under the specific license (such as leak testing
25 procedures); and
- 26 ~~(4)(D)~~ Reports the transfer under paragraph (7) of this rule.
- 27 ~~(8)(9)~~ shall transfer or dispose of the device only by export as provided by (c)(7) of this Rule, or by
28 transfer to another general licensee only where the device:
- 29 (A) remains in use at a particular location. In this case the transferor shall give the
30 transferee a copy of this Rule and any safety documents identified in the label of
31 the device, and the transferor shall, within 30 days of the transfer, report to the
32 agency at the address in Rule .0111 of this Chapter the manufacturer's or initial
33 transferor's name, serial number, and model number of device transferred; the
34 name and mailing address of the transferee; and the name, title, and telephone
35 number of the individual identified by the transferee pursuant to Subparagraph
36 (c)(10) of this Rule as having knowledge of and authority to take actions to
37 ensure compliance with the requirements contained in these Rules; or

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

3 (ii) ~~The transferor shall, within 30 days of the transfer, report to the agency at the~~
4 ~~address in Rule .0111 of this Chapter the manufacturer's or initial transferor's~~
5 ~~name, serial number, and model number of device transferred; the name and~~
6 ~~mailing address of the transferee; and the name, title, and telephone number of~~
7 ~~the individual identified by the transferee pursuant to Subparagraph (c)(10) of~~
8 ~~this Rule as having knowledge of and authority to take actions to ensure~~
9 ~~compliance with the requirements contained in these Rules; or~~

10 (B) is held in storage by the licensee or an intermediate person in the original shipping
11 container at its intended location of use prior to initial use by a general licensee.

12 ~~(9)(10)~~ shall comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting
13 radiation incidents, theft or loss of licensed material, but ~~shall be~~ is exempt from the other
14 requirements of Section .1600 of this Chapter;

15 ~~(10)(11)~~ shall appoint an individual responsible for having knowledge of the requirements contained in
16 these Rules and the authority for taking the actions required to comply with these Rules. The
17 general licensee, through this individual, shall ensure the day-to-day compliance with these Rules.
18 The appointment of such an individual does not relieve the general licensee of any of its
19 responsibility in this regard;

20 ~~(11)(12)~~ shall register, when required by the agency, any source of radiation subject to a general license in
21 accordance with the rules in this Section. Each address for a location of use represents a separate
22 general license and requires a separate registration action;

23 ~~(12)(13)~~ shall register, on an annual basis, all devices containing, based on the activity indicated on the
24 label, at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi
25 (37MBq) of cobalt-60, 1 mCi (37 MBq) of ~~americium-241~~ americium-241, 0.1 millicurie (3.7
26 MBq) of radium-226, or any other transuranic isotope. Each address for a location of use
27 represents a separate general license and requires a separate registration action. Annual
28 registration consists of verifying, correcting, or adding to the information provided in a request for
29 annual registration within 30 days of a request from the agency. The general licensee shall furnish
30 the following information for annual registration:

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

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

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

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

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

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

9 ~~(13)~~(14) shall report changes to the mailing address to the agency within 30 days of the effective date of the
10 change;

11 ~~(14)~~(15) shall report changes to the name of the general licensee to the agency within 30 days of the
12 effective date of the change;

13 (16) shall respond to written requests from the Agency to provide information relating to the general
14 license within 30 calendar days of the date of the request, or other time specified in the request. If
15 the general licensee cannot provide the requested information within the allotted time, it shall,
16 within that same time period, request a longer period to supply the information by providing the
17 Agency a written justification for the request. The request to extend the allotted time will be
18 granted upon agency review of the licensee request and supporting information related to the need
19 for extension;

20 ~~(15)~~ (17) shall not hold devices that are not in use for longer than two years. If devices that have
21 shutters are not in use, the shutter shall be locked in the closed position. Leak testing is
22 not required during the period of storage; however, when devices are returned to service
23 or transferred to another person, the devices must be tested for leakage and shutter
24 operation. Devices kept in standby for future use shall be excluded from the two year
25 time limit if quarterly physical inventories of these devices are performed while in
26 standby.

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

29 (e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a),
30 .0338, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.

31
32 *History Note: Authority G.S. 104E-7; 104E-10(b);*

33 *Eff. February 1, 1980;*

34 *Amended Eff. October 1, 2013; January 1, 2005; January 1, 1994; June 1, 1989.*

1 15A NCAC 11 .0317 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0317 SPECIFIC LICENSES: FILING APPLICATION AND GENERAL**
4 **REQUIREMENT**

5 (a) Applications for specific licenses shall be filed on an agency form. Completed applications shall include the
6 following information and other information necessary for the Agency to determine if the applicant meets the
7 requirements for a license required by the agency form:

- 8 (1) name, address and use location of the applicant;
- 9 (2) training and experience of radioactive material users and of the person responsible for radiation
10 protection;
- 11 (3) types, quantities and uses of radioactive materials;
- 12 (4) description of facilities, equipment and safety program;
- 13 (5) procedures for disposal of radioactive material; and
- 14 (6) how facility design and procedures for operation will minimize, to the extent practical,
15 contamination of the facility and the environment, facilitate eventual decommissioning, and
16 minimize, to the extent practical, the generation of radioactive waste.

17 (b) The agency may at any time after the filing of the original application, and before the expiration of the license,
18 require further statements in order to enable the agency to determine whether the application should be granted or
19 denied or whether a license should be modified or revoked.

20 (c) Each application shall be signed by the applicant or licensee or a person duly authorized to act on his behalf.

21 (d) An application for a license may include a request for a license authorizing one or more activities.

22 (e) An application for a specific license to use byproduct material in the form of a sealed source or in a device that
23 contains the sealed source must:

- 24 (1) Identify the source or device by manufacturer and model number as registered with the US
25 Nuclear Regulatory Commission under 10 CFR 32.210, with an Agreement State, or for a source
26 or a device containing radium-226 or accelerator-produced radioactive material, with a State under
27 provisions comparable to 10 CFR 32.210;
- 28 (2) Contain the information identified in 10 CFR 32.210(c); or
- 29 (3) For sources or devices containing naturally occurring or accelerator-produced radioactive material
30 manufactured prior to November 30, 2007 that are not registered with the US Nuclear Regulatory
31 Commission under 10 CFR 32.210 or with an Agreement State, and for which the applicant is
32 unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must
33 provide:
 - 34 (A) All available information identified in 10 CFR 32.210(c) concerning the source, and, if
35 applicable, the device; and
 - 36 (B) Sufficient additional information to demonstrate that there is reasonable assurance that
37 the radiation safety properties of the source or device are adequate to protect health and

1 minimize danger to life and property. Such information must include a description of the
2 source or device, a description of radiation safety features, the intended use and
3 associated operating experience, and the results of a recent leak test.

4 ~~(e)~~ (f) Applications and documents submitted to the agency may be made available for public inspection except as
5 ~~may be~~ are determined otherwise by the agency pursuant to the provisions of G.S. 104E-9(4).

6 ~~(f)~~ (g) A license application shall be approved if the agency determines that:

7 (1) the applicant is qualified by reason of training and experience to use the material in question for
8 the purpose requested in accordance with these Rules in such a manner as to minimize danger to
9 public health and safety or property;

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

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

13 (4) the applicant satisfies any applicable special requirements in Rules .0318 to .0336 of this Section.

14 ~~(g)~~ (h) ~~As provided~~ If required by Rule .0353 of this Section, certain applications for specific licenses filed under
15 this Section must contain a proposed decommissioning funding plan or a certification of financial assurance for
16 decommissioning. ~~In the case of renewal applications submitted before the effective date of this Rule, this submittal~~
17 ~~may follow the renewal application but must be submitted on or before the effective date of this Rule.~~

18
19 *History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12; 104E-18;*

20 *Eff. February 1, 1980;*

21 *Amended Eff. October 1, 2013; April 1, 1999; May 1, 1992; November 1, 1989.*

1 15A NCAC 11 .0318 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE**

4 (a) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Authorized medical physicist" means an
5 individual who:

- 6 (1) Meets the requirements in 10 CFR 35.51(a) and 35.59; ~~or, before October 24, 2005, met the~~
7 ~~requirements in 10 CFR 35.961(a), or (b), and 35.59; or~~
- 8 (2) Is identified as an authorized medical physicist or teletherapy physicist on:
- 9 (A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission or
10 Agreement State;
- 11 (B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material
12 licensee;
- 13 (C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad
14 scope medical use licensee; or
- 15 (D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad
16 scope medical use permittee.

17 (b) For the purposes of this ~~Rule~~, Rule and Rule .0117 (a)(2) of this Chapter, "Authorized nuclear pharmacist"
18 means a pharmacist who:

- 19 (1) Meets the requirements in 10 CFR 35.55(a) and 35.59; ~~or, before October 24, 2005, met the~~
20 ~~requirements in 10 CFR 35.980(a) and 35.59; or~~
- 21 (2) Is identified as an authorized nuclear pharmacist on:
- 22 (A) A specific license issued by the U.S. Nuclear Regulatory Commission or Agreement
23 State that authorizes medical use or the practice of nuclear pharmacy;
- 24 (B) A permit issued by the U.S. Nuclear Regulatory Commission master material licensee
25 that authorizes medical use or the practice of nuclear pharmacy;
- 26 (C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad
27 scope medical use license that authorizes medical use or the practice of nuclear
28 pharmacy; or
- 29 (D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad
30 scope medical use permittee that authorizes medical use or the practice of nuclear
31 pharmacy; ~~or~~
- 32 (3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been
33 authorized to identify authorized nuclear pharmacists; or
- 34 (4) Is designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(4).

35 (c) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Authorized user" means a ~~physician~~
36 physician, dentist, or podiatrist who:

- 1 (1) Meets the requirements in 10 CFR 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a),
2 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~~
3 ~~requirements in 10 CFR 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and~~
4 ~~35.59;~~ or
- 5 (2) Is identified as an authorized user on:
- 6 (A) A U.S. Nuclear Regulatory Commission or Agreement State license that authorizes
7 medical use of radioactive material;
- 8 (B) A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that
9 is authorized to permit the medical use of radioactive material;
- 10 (C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State specific
11 licensee of broad scope that is authorized to permit the medical use of radioactive
12 material; or
- 13 (D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad
14 scope permittee that is authorized to permit the medical use of byproduct material.
- 15 (d) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Brachytherapy" means a method of
16 radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by
17 surface, intracavitary, intraluminal or interstitial application.
- 18 (e) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Brachytherapy source" means a radioactive
19 source or a manufacture-assembled source train or a combination of these sources that is designed to deliver a
20 therapeutic dose within a distance of a few centimeters.
- 21 (f) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "High dose-rate remote afterloader" means a
22 brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or
23 surface where the dose is prescribed.
- 24 (g) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Low dose-rate remote afterloader" means a
25 brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the
26 point or surface where the dose is prescribed.
- 27 (h) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Manual brachytherapy" means a type of
28 brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted
29 either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.
- 30 (i) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Medium dose-rate remote afterloader"
31 means a brachytherapy device that remotely delivers a dose rate of greater than 200 rads (2 gray), but less than 1200
32 rads (12 gray) per hour at the point or surface where the dose is prescribed.
- 33 (j) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Patient intervention" means actions by the
34 patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment
35 devices or prematurely terminating the administration.

1 (k) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Pulsed dose-rate afterloader" means a type
2 of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high
3 dose-rate" range, but:

- 4 (1) is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
- 5 (2) is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a
6 given fraction of each hour.

7 (l) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Radiation safety officer" ~~as used in this~~
8 ~~Section~~, means an individual who:

- 9 (1) Meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59; ~~or, before October 24,~~
10 ~~2005, met the requirements of 10 CFR 35.900(a) and 35.59, as incorporated by reference in 15A~~
11 ~~NCAC 11 .0117~~; or
- 12 (2) Is identified as a Radiation Safety Officer on:
 - 13 (A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission, or an
14 Agreement State; or
 - 15 (B) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material
16 licensee.

17 (m) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Stereotactic radiosurgery" means the use
18 of external radiation in conjunction with a stereotactic guidance device to precisely deliver a therapeutic dose to a
19 tissue volume.

20 (n) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Therapeutic dosage" means a dosage of
21 unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for
22 palliative or curative treatment.

23 (o) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Treatment site" means the anatomical
24 description of the tissue intended to receive a radiation dose, as described in a written directive.

25 (p) License required:

- 26 (1) A person shall not manufacture, produce, acquire, receive, possess, use or transfer radioactive
27 material for medical use except in accordance with a specific license issued by the agency or as
28 allowed pursuant to Subparagraphs (p)(2) and (p)(3) of this Rule.
- 29 (2) An individual may receive, possess, use, or transfer radioactive material in accordance with the
30 rules of this Section under the supervision of an authorized user as provided in this Section unless
31 prohibited by license condition.
- 32 (3) An individual may prepare unsealed radioactive material for medical use in accordance with the
33 rules of this Section under the supervision of a pharmacist who is an authorized user or physician
34 who is an authorized user as provided in this Section unless prohibited by license condition.

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

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

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

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

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

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

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

10 (i) the approval of procedures involving the administration to patients of
11 radiopharmaceuticals or the application to patients of radiation from
12 radioisotope sources;

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

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

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

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

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

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

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

25 (2) measurement of radiopharmaceutical doses prior to administration;

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

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

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

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

34 (A) general characteristics of radiation and radioactive materials;

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

- 1 (C) mathematics and calculations basic to the use and measurement of radioactivity,
2 including units of radiation dose and radiation exposure;
- 3 (D) use of radiation instrumentation for measurements and monitoring including operating
4 procedures, calibration of instruments, and limitations of instruments;
- 5 (E) principles and practices of radiation protection; and
- 6 (F) additional training in the above subjects, as appropriate, when new duties are ~~added.~~
7 added;
- 8 (2) assure that the technicians and other paramedical personnel receive retraining in the subjects listed
9 in Subparagraph (s)(1) of this Rule to maintain proficiency and to keep abreast of developments in
10 the field of nuclear medical technology;
- 11 (3) keep records showing the bases for the determinations of proper training;
- 12 (4) retain responsibility as licensee or authorized user for the satisfactory performance of the ~~activities~~;
13 activities; and
- 14 (5) review the work of the supervised individual and the records kept reflecting that work.
- 15 (t) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear
16 medicine technology by the Nuclear Medicine Technologist Certification Board or the Society of Nuclear Medicine
17 shall be deemed to satisfy the training requirements in Subparagraphs (s)(1) and (2) of this Rule.
- 18 (u) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit
19 technicians or other paramedical personnel to perform activities pursuant to Paragraph (r) of this Rule and, if so,
20 shall include in his application for license, license amendment, or license renewal a statement of the activities to be
21 so performed and a description of an adequate program for training the personnel, including retraining as required to
22 keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to
23 perform their duties.
- 24 (v) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection,
25 a physician shall be ~~immediately~~ accessible, but not necessarily a physician authorized by the agency to be a user of
26 radioisotopes.
- 27 (w) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under
28 the supervision of an authorized user shall:
- 29 (1) In addition to the requirements in Rule .1003 of this Chapter, instruct the supervised individual in
30 the licensee's written radiation protection procedures, written directive procedures, this Chapter,
31 and license conditions with respect to the use of radioactive material; and
- 32 (2) Require the supervised individual to follow the instructions of the supervising authorized user for
33 ~~medical~~ medical uses of radioactive material, written radiation protection procedures established by
34 the licensee, written directive procedures, rules of this Chapter, and license conditions with respect
35 to the medical use of radioactive material.
- 36 (x) A licensee that permits the preparation of radioactive material for medical use by an individual under the
37 supervision of an authorized nuclear pharmacist or physician who is an authorized user shall:

- 1 (1) In addition to the requirements in Paragraph (s) of this Rule and Rule .1003 of this Chapter,
2 instruct the supervised individual in the preparation of radioactive material for medical use, as
3 appropriate to that individual's involvement with radioactive material; and
- 4 (2) Require the supervised individual to follow the instructions of the supervising authorized user or
5 authorized nuclear pharmacist regarding the preparation of radioactive material for medical use,
6 written radiation protection procedures established by the licensee, the rules of this Chapter, and
7 license conditions.
- 8 (y) A licensee that permits supervised activities under Paragraphs (r) and (s) of this Rule is responsible for the acts
9 and omissions of the supervised individual.
- 10 (z) A licensee's management shall appoint a Radiation Safety Officer (RSO) who agrees in writing to be responsible
11 for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety
12 activities are being performed in accordance with approved procedures and regulatory requirements in the daily
13 operation of the licensee's radioactive material program.
- 14 (aa) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.
- 15 (bb) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and
16 management prerogative to:
- 17 (1) identify radiation safety problems;
- 18 (2) investigate radiation safety problems such as overexposures, accidents, spills, losses, thefts,
19 unauthorized receipts, uses, transfers, disposals, medical events, and other deviations from
20 approved radiation safety practice and implement corrective actions as necessary;
- 21 (3) initiate, recommend or provide corrective actions for radiation safety problems;
- 22 (4) verify implementation of corrective actions; and
- 23 (5) retain records of items listed in Subparagraphs (1) through (4) of this Paragraph.
- 24 (cc) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety
25 instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be
26 released in accordance with the requirements of Rule .0358 of this Section. To satisfy this requirement, the
27 instruction must be commensurate with the duties of the personnel and include:
- 28 (1) Patient or human research subject control;
- 29 (2) Visitor control, including
- 30 (A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule
31 .1611(a)(1) of this Chapter; and
- 32 (B) Visitation authorized by Rule .1611(e) of this Chapter;
- 33 (3) Contamination control;
- 34 (4) Waste control; and
- 35 (5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient
36 or the human research subject has a medical emergency or dies.

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

- 3 (1) List of topics covered;
- 4 (2) The date of the instruction;
- 5 (3) The name(s) of the attendee(s); and
- 6 (4) The name(s) of the individual(s) who provided the instruction.

7

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

9 *Eff. February 1, 1980;*

10 *Amended Eff. October 1, 2013; November 1, 2007; April 1, 1999; May 1, 1993; November 1,*

11 *1989.*

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

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

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

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

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

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

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

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

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

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

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

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

29
30
31 *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.

1 15A NCAC 11 .0322 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0322 SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES**

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

- 7 (1) has training and experience as required by Rule .0117(a)(2) of this Chapter, and
- 8 (2) is a physician.

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

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

- 12 (1) Sealed sources or devices manufactured, labeled, packaged and distributed in accordance with a
13 license issued under 10 CFR Part 30 and 10 CFR 32.74 or equivalent requirements of an
14 Agreement State;
- 15 (2) Sealed sources or devices noncommercially transferred from a licensee licensed pursuant to
16 Section .0300 of this Chapter, 10 CFR Part 35, or ~~equivalent regulations of~~ an Agreement State
17 medical use licensee;
- 18 (3) Teletherapy sources manufactured and distributed in accordance with 10 CFR Part 30 or the
19 equivalent requirements of an Agreement State; or
- 20 (4) Brachytherapy sources, photon emitting remote ~~afterloader~~ afterloader units, teletherapy units or
21 gamma stereotactic radiosurgery units for therapeutic medical uses; use as approved in:
 - 22 (A) As approved in the Sealed Sources and Device Registry; or
 - 23 (B) ~~Research~~ In research in accordance with an active Investigational Device Exemption
24 (IDE) application accepted by the ~~FDA~~ FDA provided the requirements of 10 CFR
25 35.49(a) are met.

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

- 30 (1) Size and appearance of the brachytherapy sources;
- 31 (2) Safe handling and shielding instructions;
- 32 (3) Patient or human research subject control;
- 33 (4) Visitor control, including both:
 - 34 (A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule
35 .1611(a)(1) of this Chapter; and
 - 36 (B) Visitation authorized by Rule .1611(e) of this ~~Chapter~~ Chapter and

1 15A NCAC 11 .0325-.0326 are proposed for repeal as follows:

2

3 **15A NCAC 11 .0325** **SPECIFIC LICENSES: PRODUCTS WITH EXEMPT CONCENTRATIONS**

4 **15A NCAC 11 .0326** **SPECIFIC LICENSES: EXEMPT DISTRIBUTION**

5

6

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

8 *Eff. February 1, 1980;*

9 *Amended Eff. June 1, ~~1993~~, 1993;*

10 *Repealed Eff. October 1, 2013.*

1 15A NCAC 11 .0328 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED**

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

- 7 (1) the applicant satisfies the general requirements of Rule .0317 of this Section;
- 8 (2) the applicant submits sufficient information relating to the design, manufacture, prototype testing,
9 quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety
10 instructions, and potential hazards of the device to provide reasonable assurance that:
- 11 (A) the device can be safely operated by persons not having training in radiological
12 protection;
- 13 (B) under ordinary conditions of handling, storage, and use of the device, the radioactive
14 material contained in the device will not be released or inadvertently removed from the
15 device, and it is unlikely that any person will receive in any period of one calendar
16 ~~quarter~~ year a dose in excess of ten percent of the limits specified in the table of Rule
17 .1604 of this Chapter; and
- 18 (C) under accident conditions (such as fire and explosion) associated with handling, storage,
19 and use of the device, it is unlikely that any person would receive an external radiation
20 dose or dose commitment in excess of the following organ doses:
- 21 (i) whole body, head and trunk, active blood-forming organs, gonads, or lens of
22 eye: 15 rems;
- 23 (ii) hands and forearms, feet and ankles, localized areas of skin averaged over areas
24 no larger than one square centimeter: 200 rems; or
- 25 (iii) other organs: 50 rems. and
- 26 (3) each device bears a durable, legible, ~~clearly~~ visible label or labels approved by the agency, which
27 contain in ~~a clearly~~ an identified and separate statement:
- 28 (A) instructions and precautions necessary to assure safe installation, operation, and servicing
29 of the device (documents such as operating and service manuals may be identified in the
30 label and used to provide this information);
- 31 (B) the requirement, or lack of requirement, for leak testing, or for testing any on-off
32 mechanism and indicator, including the maximum time interval for such testing, and the
33 identification of radioactive material by isotope, quantity of radioactivity, and date of
34 determination of the quantity; and
- 35 (C) the information called for in the following statement in the same or substantially similar
36 form: "The receipt, possession, use, and transfer of this device Model
37 _____, Serial No. _____, are subject to a general license

1 or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an
2 agreement state. This label shall be maintained on the device in a legible condition.
3 Removal of this label is prohibited."
4

5 CAUTION - RADIOACTIVE MATERIAL

6 (name of manufacturer or distributor)
7

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

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

- 17 (1) primary containment (source capsule);
- 18 (2) protection of primary containment;
- 19 (3) method of sealing containment;
- 20 (4) containment construction materials;
- 21 (5) form of contained radioactive material;
- 22 (6) maximum temperature withstood during prototype test;
- 23 (7) maximum pressure withstood during prototype tests;
- 24 (8) maximum quantity of contained radioactive material;
- 25 (9) radiotoxicity of contained radioactive material; and
- 26 (10) operating experience with identical devices or similarly designed and constructed devices.

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

- 32 (1) Written instructions to be followed by the general licensee;
- 33 (2) Estimated calendar quarter doses associated with ~~such the~~ the activity or activities by an individual
34 untrained in radiological protection, in addition to other handling, storage and use of devices under
35 the general license; and

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

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

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

- 22 (1) the agency for devices transferred to persons generally licensed under Rule .0309 of this Section;
23 (2) each agreement state for devices transferred to persons generally licensed under rules equivalent to
24 Rule .0309 of this Section; and
25 (3) the U.S. Nuclear Regulatory Commission for devices transferred to persons generally licensed
26 under Section 31.5 of 10 CFR Part 31.

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

31
32 *History Note: Authority G.S. 104E-7; 104E-10(b);*
33 *Eff. February 1, 1980;*
34 *Amended Eff. October 1, 2013; January 1, 1994.*

1 15A NCAC 11 .0331 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS**

4 An application for a specific license to manufacture or distribute radioactive material for use under the general
5 license in Rule .0314 of this Section ~~will~~ shall be approved if the following requirements are satisfied:

- 6 (1) The applicant satisfies the general requirements specified in Rule .0317 of this Section.
- 7 (2) The radioactive material is to be prepared for distribution in prepackaged units of:
- 8 (a) iodine-125 in units not exceeding ten microcuries each;
- 9 (b) iodine-131 in units not exceeding ten microcuries each;
- 10 (c) carbon-14 in units not exceeding ten microcuries each;
- 11 (d) hydrogen-3 (tritium) in units not exceeding 50 microcuries each;
- 12 (e) iron-59 in units not to exceed 20 microcuries each;
- 13 (f) cobalt-57 in units not to exceed ten microcuries each;
- 14 (g) selenium-75 in units not exceeding 10 microcuries ~~0.05 microcurie of iodine-129 and~~
15 ~~0.005 microcurie of americium-241 each.~~ each; or
- 16 (h) mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005
17 microcurie of americium-241 each.
- 18 (3) Each prepackaged unit bears a durable, ~~clearly~~ clearly visible label:
- 19 (a) identifying the radioactive contents as to chemical form and radionuclide, and indicating
20 that the amount of radioactivity does not exceed the appropriate limit in Item (2) of this
21 Rule, and
- 22 (b) displaying the radiation caution symbol described in Rule .1623 of this Chapter and the
23 words, "CAUTION, RADIOACTIVE MATERIAL", and "NOT FOR INTERNAL OR
24 EXTERNAL USE IN HUMANS OR ANIMALS".
- 25 (4) The following statement, or a ~~substantially similar~~ statement which contains the information called
26 for in the following statement, appears on a label affixed to each prepackaged unit or appears in a
27 leaflet or brochure which accompanies the package:

28 This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or
29 hospitals and only for IN VITRO clinical or laboratory tests not involving internal or external administration of the
30 material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and
31 transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or a state
32 with which the Commission has entered into an agreement for the exercise of regulatory authority. (Name of
33 Manufacturer)

- 34 (5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains
35 ~~adequate~~ information as to the precautions to be observed in handling and storing such radioactive
36 material. In the case of the mock iodine-125 reference or calibration source, the information

1 accompanying the source must also contain directions to the licensee regarding the waste disposal
2 requirements set out in Rule .1628 of this Chapter.

3

4

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

6 *Eff. February 1, 1980;*

7 *Amended Eff. October 1, 2013; January 1, 1994.*

1 15A NCAC 11 .0333 is proposed for amendment as follows:

2

3 **15A NCAC 11 .0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS**

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

- 8 (1) the applicant satisfies the requirements of Rule .0317 of this Section; and
9 (2) the applicant meets the applicable requirements in Section 32.72 of 10 CFR ~~Part 32.~~ Part 32, and
10 Section 30.32(j) of 10 CFR Part 30.

11

12

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

14 *Eff. February 1, 1980;*

15 *Amended Eff. October 1, 2013; November 1, 2007.*

1 15A NCAC 11 .0334 is proposed for amendment as follows:

2

3 **15A NCAC 11 .0334 **SPECIFIC LICENSES: GENERATORS AND REAGENT KITS****

4 An application for a specific license to manufacture and distribute generators and reagent kits containing radioactive
5 material for preparation of radiopharmaceuticals by persons licensed pursuant to Rule .0321 of this Section for the
6 generators, reagent kits and associated medical uses ~~in Group III will~~ shall be approved subject to the following
7 conditions:

- 8 (1) the applicant satisfies the general requirements of Rule .0317 of this Section, and
9 (2) the applicant satisfies the applicable requirements in Section 32.73 of 10 CFR Part 32 or their
10 equivalent.

11

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

13 *Eff. February 1, ~~1980~~. 1980;*

14 *Amended Eff. October 1, 2013.*

1 15A NCAC 11 .0338 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES**

4 ~~(a) Each license issued pursuant to the rules in this Section shall be subject to all the provisions of the Act, now or~~
5 ~~hereafter in effect, to all rules adopted pursuant to provisions of the Act and to orders of the agency.~~

6 ~~(b) No license issued or granted pursuant to this Section and no right to possess or utilize radioactive material~~
7 ~~granted by any license issued pursuant to this Section shall be transferred, assigned, or in any manner disposed of,~~
8 ~~either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person~~
9 ~~unless the agency, after securing full information, finds that the transfer is in accordance with the provisions of the~~
10 ~~Act, and gives its consent in writing.~~

11 ~~(a)~~ Each person licensed by the agency pursuant to this Section shall confine his use and possession of the
12 radioactive material licensed to the locations and purposes authorized in the license.

13 ~~(b)~~ Each licensee shall notify the agency in writing immediately following the filing of a voluntary or
14 involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or
15 against:

- 16 (1) licensee;
- 17 (2) an entity [as that term is defined in 11 U.S.C. 101(14)] controlling the licensee or listing the
18 license or licensee as property of the estate; or
- 19 (3) an affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.

20 ~~(c)~~ The notification in Paragraph (d) of this Rule shall indicate:

- 21 (1) the bankruptcy court in which the petition for bankruptcy was filed; and
- 22 (2) the date of the filing of the petition.

23 ~~(d)~~ Licensees required to submit emergency plans pursuant to Rule .0352 of this Section shall follow the
24 emergency plan approved by the agency. The licensees may change the approved plan without agency approval
25 only if the licensee believes the changes do not decrease the effectiveness of the plan and are submitted to the
26 agency no later than 20 calendar days after the changes are made. The licensee shall furnish the change to affected
27 off-site response organizations within six months after the change is made. Proposed changes that the licensee
28 believes are likely to decrease, or may potentially decrease, the effectiveness of the approved emergency plan shall
29 not be implemented without prior application to and prior approval by the agency.

30 (e) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m
31 generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for
32 molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with
33 Rule .0361 of this Section. The licensee shall record the results of each test and retain each record for 3 years after
34 the record is made.

35 (f) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible
36 barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control
37 and constant surveillance of the licensee.

1 (g) Authorization under Rule .0333 of this Section to produce Positron Emission Tomography (PET) radioactive
2 drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from
3 complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

4 (h) Each licensee authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial
5 transfer to medical use licensees in its consortium shall:

6 (1) Satisfy the labeling requirements in Rule .1626 of this Chapter for each PET radioactive drug
7 transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive
8 drug intended for noncommercial distribution to members of its consortium. and

9 (2) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs
10 intended for noncommercial distribution to members of its consortium and meet the procedural,
11 radioactivity measurement, instrument test, instrument check, and instrument adjustment
12 requirements in Rule .0333 of this Section.

13 (i) A licensee that is a pharmacy authorized under Rule .0333 of this Section to produce PET radioactive drugs for
14 noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET
15 radioactive drugs be:

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

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

19 (j) A pharmacy, authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial
20 transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear
21 pharmacist, shall meet the requirements of Rule .0318 of this Section.

22
23
24 *History Note: Authority G.S. 104E-7; 104E-10(b);*

25 *Eff. February 1, 1980;*

26 *Amended Eff. October 1, 2013; May 1, 1993; May 1, 1992; June 1, 1989.*

1 15A NCAC 11 .0352 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0352 EMERGENCY PLANS**

4 (a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass
5 in excess of the quantities in the table in Subparagraph (e)(1) of this Rule must contain either:

- 6 (1) an evaluation showing that the maximum dose to a person off-site due to a release of radioactive
7 materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or
8 (2) an emergency plan for responding to a release of radioactive material.

9 (b) ~~One or more of the~~ The following factors may be used to support an evaluation submitted under Subparagraph
10 (a)(1) of this Rule:

- 11 (1) the radioactive material is physically separated so that only a portion could be involved in an
12 accident;
13 (2) all or part of the radioactive material is not subject to release during an accident because of the
14 way it is stored or packaged;
15 (3) the release fraction in the respirable size range would be lower than the release fraction shown in
16 Subparagraph (e)(1) of this Rule due to the chemical or physical form of the material;
17 (4) the solubility of the radioactive material would reduce the dose received;
18 (5) facility design or engineered safety features in the facility would cause the release fraction to be
19 lower than shown in Subparagraph (e)(1) of this Rule; and
20 (6) operating restrictions or procedures would prevent a release fraction as large as that shown in
21 Subparagraph (e)(1) of this Rule; or
22 (7) ~~other~~ factors appropriate for the specific facility.

23 (c) An emergency plan for responding to a release of radioactive material submitted under Subparagraph (a)(2) of
24 this Rule must include the following information:

- 25 (1) ~~brief~~ description of the licensee's facility and potentially impacted area near the site;
26 (2) identification of each type of radioactive materials accident for which protective actions may be
27 needed;
28 (3) classification system for classifying accidents as alerts or site area emergencies;
29 (4) identification of the means of detecting each type of accident in a timely manner quickly enough
30 to mitigate off-site consequences;
31 (5) ~~brief~~ description of the means and equipment for mitigating the consequences of each type of
32 accident, including those provided to protect workers on-site, and a description of the program for
33 maintaining the equipment;
34 (6) ~~brief~~ description of the methods and equipment to assess releases of radioactive materials;
35 (7) ~~brief~~ description of the responsibilities of licensee personnel, should an accident occur, including
36 identification of personnel responsible for ~~promptly~~ notifying off-site response organizations and
37 the agency, and responsibilities for developing, maintaining, and updating the plan;

- 1 (8) ~~brief~~ description of notification and coordination, to include a commitment to and a brief
2 description of the means to ~~promptly~~ notify off-site response organizations and request off-site
3 assistance, including medical assistance for the treatment of contaminated injured on-site workers
4 when appropriate, provided that:
- 5 (A) a control point ~~shall be~~ is established;
 - 6 (B) the notification and coordination ~~shall be~~ is planned so that unavailability of some
7 personnel, parts of the facility, and some equipment will not prevent the notification and
8 coordination;
 - 9 (C) the licensee ~~shall also commit~~ commits to notify the agency ~~immediately~~ after
10 notification of the appropriate off-site response organizations, ~~not to exceed~~ within one
11 hour after the licensee declares an emergency; and
 - 12 (D) the reporting requirements in Subparagraph (c)(8) of this Rule do not substitute for or
13 relieve the licensee from responsibility for complying with the requirements in the
14 Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law
15 99-499 or other state or federal reporting requirements;
- 16 (9) ~~brief~~ description of the types of information on facility status, radioactive releases, and
17 recommended protective actions, if necessary, to be given to off-site response organizations and to
18 the agency;
- 19 (10) ~~brief~~ description of the frequency, performance objectives and plans for the training that the
20 licensee will provide workers on how to respond to an emergency, including any ~~special~~
21 instructions and orientation tours the licensee would offer to fire, police, medical and other
22 emergency personnel, where such training shall:
- 23 (A) familiarize personnel with site-specific emergency procedures; and
 - 24 (B) ~~thoroughly~~ prepare site personnel for their responsibilities in the event of accident
25 scenarios postulated as most probable for the specific site, including the use of team
26 training for such scenarios;
- 27 (11) ~~brief~~ description of the means of restoring the facility to a safe condition after an accident;
- 28 (12) ~~brief~~ description of provisions for conducting quarterly communications checks with off-site
29 response organizations and biennial on-site exercises to test response to simulated emergencies
30 where such provisions ~~shall~~ meet the following ~~specific~~ requirements:
- 31 (A) quarterly communications checks with off-site response organizations ~~shall~~ include the
32 check and update of all necessary telephone numbers;
 - 33 (B) while participation of off-site response organizations in biennial exercises is ~~encouraged~~
34 ~~but~~ not required, ~~the licensee shall~~ invite off-site response organizations to participate in
35 the biennial exercises;
 - 36 (C) accident scenarios for biennial exercises ~~shall not be~~ are not known to most exercise
37 participants;

1 (D) ~~the licensee shall~~ critique of each exercise using individuals who do not have direct
2 implementation responsibility for the plan; ~~and~~

3 (E) critiques of exercises ~~shall~~ evaluate the appropriateness of the plan, emergency
4 procedures, facilities, equipment, training of personnel, and overall effectiveness of the
5 response; and

6 (F) deficiencies found by the critiques in Part (c)(12)(E) of this Rule ~~shall be~~ are corrected;
7 and

8 (13) certification that the applicant has met its responsibilities under the Emergency Planning and
9 Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the
10 applicant's activities at the proposed place of use of the radioactive material.

11 (d) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to
12 comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any
13 comments received within the 60 day comment period to the agency with the emergency plan.

14 (e) Quantities of radioactive material requiring ~~consideration of the need for~~ an emergency plan for responding to a
15 release as used in this Rule and ~~special~~ instructions for use are:

16 (±) TABLE

18 RADIOACTIVE MATERIAL	RELEASE	QUANTITY
	FRACTION	(CURIES)
20 Actinium-228	0.001	4,000
21 Americium-241	.001	2
22 Americium-242	0.01 <u>.001</u>	2
23 Americium-243	.001	2
24 Antimony-124	.01	4,000
25 Antimony-126	.01	6,000
26 Barium-133	.01	10,000
27 Barium-140	.01	30,000
28 Bismuth-207	.01	5,000
29 Bismuth-210	.01	600
30 Cadmium-109	.01	1,000
31 Cadmium-113	.01	80
32 Calcium-45	.01	20,000
33 Californium-252	.001	9 (20 mg)
34 Carbon-14 (NON CO) (<u>NON CO₂</u>)	.01	50,000
35 Cerium-141	.01	10,000
36 Cerium-144	.01	300
37 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		

1	beta-gamma	.01	1,000
2	Packaged mixed waste, beta-gamma	.001	10,000
3	Any other alpha emitter	.001	2
4	Contaminated equipment, alpha	.0001	20
5	Packaged waste, alpha	.0001	20

6

7 ~~(2)(f)~~ For combinations of radioactive materials, ~~consideration of the need for~~ an emergency plan is required if the
8 sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material
9 in the table in Subparagraph (e)(1) of this Rule exceeds one.

10 ~~(3)(g)~~ Waste packaged in Type B containers, as defined in 10 CFR Part 71.4, does not require an emergency plan.

11

12 *History Note: Authority G.S. 104E-7; 104E-18;*
13 *Eff. May 1, 1992;*
14 *Amended Eff. October 1, 2013; May 1, 1993; October 1, 1992.*

1 15A NCAC 11 .0361 is proposed for amendment as follows:

2
3 **15A NCAC 11 .0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL**

4 (a) A licensee may use any unsealed radioactive material prepared for use for uptake, dilution, or excretion studies,
5 imaging and localization ~~studies and radiopharmaceutical therapy that is:~~ studies, and use requiring a written
6 directive in accordance with Rule .0104 of this chapter that is:

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

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

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

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

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

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

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

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

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

29 (3) (4) Obtained from and prepared by an NRC or Agreement State licensee for use in research in
30 accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational
31 New Drug (IND) protocol accepted by the FDA; or

32 (4) (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research
33 Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the
34 FDA.

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

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

3 (2) more than 0.02 microcurie (0.02 kilobecquerel) of strontium-82 per millicurie (megabecquerel) of
4 rubidium-82 chloride, or 0.2 microcurie (0.2 kilobecquerel) of strontium-85 per millicurie
5 (megabecquerel) of rubidium-82 chloride.

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

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

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

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

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

21 (2) for each measured elution of rubidium-82: the ratio of the measures expressed as microcuries of
22 strontium-82 and strontium-85 per millicurie of rubidium-82 (or kilobecquerel strontium-82 and
23 strontium-85 per megabecquerel rubidium-82); and

24 ~~(3)~~ (3) the time and date of the measurement; and

25 ~~(4)~~ (4) the initials of the individual who made the measurement.

26
27 *History Note: Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12;*

28 *Eff. April 1, 1999;*

29 *Amended Eff. October 1, 2013; November 1, 2007.*

1 15A NCAC 11 .0362 is proposed for amendment as follows:

2

3 **15A NCAC 11 .0362 DECAy-IN-STORAGE**

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

- 6 (1) holds radioactive material for decay a minimum of 10 half-lives;
7 (2) monitors radioactive material at the container surface before disposal as ordinary trash and
8 determines that its radioactivity cannot be distinguished from the background radiation level with
9 a radiation detection survey meter capable of detecting a dose rate of 0.1 millirem (1 microsievert)
10 per hour and with no interposed shielding; and
11 (3) removes or obliterates all radiation labels.

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

- 16 (1) the date of the disposal;
17 (2) the date on which radioactive material was placed in storage;
18 (3) the radionuclides disposed;
19 (4) the survey instrument used;
20 (5) the background dose rate used; and
21 (6) the dose rate measured at the surface of each waste container.

22

23

24 *History Note: Authority G.S. 104E-7(a)(2); 104E-10(b);*

25 *Eff. April 1, 1999. 1999;*

26 *Amended Eff. October 1, 2013.*

1 15A NCAC 11 .1004 is proposed for amendment as follows:

2
3 **15A NCAC 11 .1004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS**

4 (a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of
5 radioactive material deposited or retained in the body of any individual shall be reported to the individual as
6 specified in this Rule. The information reported shall include data and results obtained pursuant to rules of this
7 Chapter, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to
8 provisions of this Chapter. Each notification and report shall:

9 (1) be in writing;

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

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

13 (4) contain the following statement: This report is furnished to you under the provisions of Section
14 15A NCAC 11 .1000; NOTICES, INSTRUCTIONS, REPORTS AND INSPECTIONS. You
15 should preserve this report for further reference.

16 ~~be in writing; include appropriate identifying data such as the name of the licensee or registrant, the name of the~~
17 ~~individual, and the individual's social security number; include the individual's exposure information; and contain~~
18 ~~the following statement:~~

19 ~~This report is furnished to you under the provisions of Section 15A NCAC 11 .1000; NOTICES, INSTRUCTIONS,~~
20 ~~REPORTS AND INSPECTIONS. You should preserve this report for further reference.~~

21 ~~(b) At the request of any worker, each licensee or registrant shall advise such worker annually of the worker's~~
22 ~~radiation dosage and exposure to radioactive materials as shown in records maintained by the licensee or registrant~~
23 ~~pursuant to Paragraphs (a) and (c) of this Rule. Each licensee or registrant shall make dose information available to~~
24 ~~workers as shown in records maintained by the licensee or registrant under the provisions of Rule .1640 of this~~
25 ~~Chapter. The licensee or registrant shall provide an annual report to each individual monitored under Rule .1614 of~~
26 ~~this Chapter of the dose received in that monitoring year if:~~

27 (1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to
28 any individual organ or tissue; or

29 (2) The individual requests his or her annual dose report.

30 (c) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or
31 registrant shall furnish to the worker a report of the worker's radiation dosage and exposure to radioactive materials.

32 ~~Such~~ The report shall:

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

35 (2) shall cover, within the period of time specified in the request, each calendar quarter in which the
36 worker's activities involved exposure to radiation from radioactive material licensed by, or
37 radiation machines registered with the agency; and

1 15A NCAC 11 .1604 is proposed for amendment as follows:

2
3 **15A NCAC 11 .1604 OCCUPATIONAL DOSE LIMITS FOR ADULTS**

4 (a) ~~The A~~ licensee or registrant shall control the occupational dose to individual adults, except for planned special
5 exposures as provided in Rule .1608 of this Section, to the following dose limits:

6 (1) an annual limit, which is the more limiting of:

7 (A) the total effective dose equivalent being equal to five rems (0.05Sv); or

8 (B) the sum of the deep-dose equivalent and the committed dose equivalent to any individual
9 organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv); and

10 (2) the annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the
11 extremities which are:

12 (A) an eye dose equivalent of 15 rems (0.15 Sv), and

13 (B) a shallow-dose equivalent of 50 rems (0.50 Sv) to the skin of the whole body or to the
14 skin of any extremity.

15 (b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and
16 planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may
17 receive during the current year and during the individual's lifetime. Dose limits for planned special exposures are
18 provided in Item (5) of Rule .1608 of this Section.

19 ~~(c) The assigned deep dose equivalent shall be for the part of the body receiving the highest exposure. The
20 assigned shallow dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin
21 receiving the highest exposure. The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be
22 assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the
23 occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or
24 the results of individual monitoring are unavailable.~~

25 (c) When the external exposure is determined by measurement with an external personal monitoring device, the
26 deep-dose equivalent must be used in place of the effective dose equivalent unless the effective dose equivalent is
27 determined by a dosimetry method approved by the agency as consistent with this Chapter. The assigned deep-dose
28 equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent
29 must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The
30 deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other
31 radiation measurements for the purpose of demonstrating compliance with the occupational dose limits if the
32 individual monitoring device was not in the region of highest potential exposure or the results of individual
33 monitoring are unavailable.

34 (d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 1 of Appendix
35 B to 10 CFR §§ 20.1001 - 20.2401 and may be used to determine the individual's dose and to demonstrate
36 compliance with the occupational dose limits.

1 (e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10
2 milligrams in a week in consideration of chemical toxicity. Requirements for annual limits on intake for uranium
3 are provided in Appendix B to 10 CFR §§ 20.1001 - 20.2401.

4 (f) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year
5 by the amount of occupational dose received while employed by any other person. Requirements for determining
6 prior occupational exposure are provided in Rule .1638(e) of this Section.

7

8 *History Note: Authority G.S. 104E-7(a)(2);*

9 *Eff. January 1, 1994;*

10 *Amended Eff. October 1, 2013; May 1, 2006.*

1 15A NCAC 11 .1626 is proposed for amendment as follows:

2
3 **15A NCAC 11 .1626 LABELING REQUIREMENTS AND EXEMPTIONS**

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

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

8 CAUTION

9 RADIOACTIVE MATERIAL

10 or the words:

11 DANGER

12 RADIOACTIVE MATERIAL

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

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

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

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

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

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

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

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

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

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

2

3 *History Note:* *Authority G.S. 104E-7(a)(2);*

4 *Eff. January 1, ~~1994~~, 1994;*

5 *Amended Eff. October 1, 2013.*

1 15A NCAC 11 .1633 is proposed for amendment as follows:

2
3 **15A NCAC 11 .1633 TRANSFER FOR DISPOSAL AND MANIFESTS**

4 (a) The requirements of this Rule and Appendix G to 10 CFR 20, incorporated by reference in Rule .0117 of this
5 Chapter, are designed to:

- 6 (1) control transfers of low-level radioactive waste by any waste generator, waste collector, or waste
7 processor licensee, as defined in Appendix G to 10 CFR 20, who ships low-level waste either
8 directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste
9 disposal facility, as defined in Rule .1202 of this Chapter;
- 10 (2) establish a manifest tracking system; and
- 11 (3) supplement existing requirements concerning transfers and recordkeeping for those wastes.

12 (b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall
13 document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive
14 Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with this
15 Rule and Appendix G to 10 CFR 20.

16 (c) Each shipment manifest shall include a certification by the waste generator as specified in Appendix G to 10
17 CFR 20.

18 (d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste
19 collector, waste processor, and disposal facility operator, shall comply with the requirements specified in this Rule
20 and Appendix G to 10 CFR 20.

21 (e) Reports and notifications required to be made to the nearest regional administrator by Appendix G to 10 CFR 20
22 shall, instead, be made to the agency.

23 (f) Any licensee shipping radioactive material as defined in Rule .0104 of this Chapter intended for ultimate
24 disposal at a land disposal facility as defined in Rule .1202 of this Chapter must document the information required
25 on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this
26 recorded manifest information to the intended consignee in accordance with appendix G to this 10 CFR 20.(g)
27 Radioactive material as defined in Rule .0104 of this Chapter may be disposed of in accordance with Rule .1628 of
28 this Section, even though it is not defined as low-level radioactive waste. Any licensed radioactive material being
29 disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61, must meet
30 the requirements of this Rule.

31 (h) A licensee may dispose of radioactive material as defined in Rule .0104 of this Chapter, at a disposal facility
32 authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law,
33 including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

34
35
36 *History Note: Authority G.S. 104E-7(a)(2),(a)(3); 104E-12(a);*
37 *Eff. January 1, 1994;*

1 15A NCAC 11 .1648 is proposed for amendment as follows:

2

3 **15A NCAC 11 .1648 REPORTS OF PLANNED SPECIAL EXPOSURES**

4 (a) The licensee or registrant shall submit a written report to the agency within 30 days following any planned
5 special exposure conducted in accordance with Rule .1608 of this Section, informing the agency that a planned
6 special exposure was conducted and indicating the date the planned special exposure occurred and the information
7 required by Rule .1639 of this Section.

8 (b) When a licensee or registrant is required by this Rule to report to the agency any exposure of an identified
9 occupationally exposed individual or an identified member of the public to radiation or radioactive material, the
10 licensee or registrant shall also provide the individual a report on his or her exposure data included in the report to
11 the agency. This report must be transmitted no later than the transmittal to the agency.

12

13

14 *History Note: Authority G.S. 104E-7(a)(2); 104E-12(a);*

15 *Eff. January 1, ~~1994~~. 1994;*

16 *Amended Eff. October 1, 2013.*