Josephine M Piccone, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Piccone:

Enclosed is a copy of the proposed revisions to the *North Carolina Regulations for Protection Against Radiation, 15A NCAC 11.* The proposed revisions have not yet been made available for public comment but are scheduled to be submitted to the Radiation Protection Commission on February 27, 2004 for approval to publish for comment. The regulations will then be published in the North Carolina State Register, a hearing will be held in April followed by the 60-day public comment period. Once the comments have been considered, the regulations will be submitted to the North Carolina Rules Review Commission (RRC). Once approved by the RRC, the new rules will become effective on the first day of the next calendar month. The proposed regulations are identified by line-in/underline and correspond to the following equivalent amendments to NRC's regulations: 1999-3; 2000-1; 2000-2; and 2001-1. An Excel spreadsheet outlining the correlation between the NRC regulations and our 15A NCAC 11 regulations has been included.

The following are items that we would like the NRC to consider:

1) *Appendix A to 10 CFR Part 20 is adopted by reference in 15A NCAC 11.0117(a)(1); therefore individual changes do not need to be addressed in this package.*
2) The requirements of 10 CFR 39.77(c)(1)(ii) and 10 CFR 39.77(d)(9) are Compatibility Category "C"; however, they were not included in this revision. These regulations address the abandonment of a source prior to receiving approval based on immediate health and safety considerations. North Carolina only has one licensee of this type and can respond to an incident involving a source lost downhole long before proper abandonment could be accomplished.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

If you have any questions, please feel free to contact me at 919-571-4141 ext. 201 or Lee Cox of my staff at the same number with extension 250 or lee.cox@ncmail.net.

Sincerely,

Beverly O. Hall, Chief
North Carolina Radiation Protection Section

Enclosures:
Previously submitted

15A NCAC 11 .0104 is proposed to be amended as follows:

15A NCAC 11 .0104 DEFINITIONS

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

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

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

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

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

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

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

(7) "Agreement state" means any state which has consummated an agreement with the United States Nuclear Regulatory Commission under the authority of section 274 of the Atomic Energy Act of 1954 as amended, as authorized by compatible state legislation providing for acceptance by that state of licensing authority for agreement materials and the discontinuance of such licensing activities by the United States Nuclear Regulatory Commission, as defined in G.S. 104E-5(2).

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

~~(8)~~ (9) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

~~(9)~~ (10) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed radioactive material, exist in concentrations:

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

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

~~(10)~~ (11) "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in the rules of this Chapter as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

~~(11)~~ (12) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in an effective dose equivalent of five rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix B to 10 CFR 20.1001 - 20.2401).

~~(12)~~ (13) "Annually" means either:

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

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

(14) "Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(15) "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

~~(13)~~ (16) "Authorized representative" means an employee of the agency, or an individual outside the agency when the individual is specifically so designated by the agency under Rule .0112 of this Section.

~~(14)~~ (17) "Authorized user" means an individual who is authorized by license or registration condition to use a source of radiation.

~~(15)~~ (18) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation regulated by the agency.

~~(16)~~ (19) "Becquerel" is the SI unit of radioactivity. One becquerel is equal to one disintegration per second (s^{-1}).

~~(17)~~ (20) "Bioassay" or "radiobioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

~~(18)~~ (21) "Byproduct material" means any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, as defined in G.S. 104E-5(4).

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

CLASSIFICATION OF INHALED MATERIAL

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

~~(20)~~ (23) "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

~~(21)~~ (24) "Commission" means the North Carolina Radiation Protection Commission.

~~(22)~~ (25) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

~~(23)~~ (26) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).

~~(24)~~ (27) "Constraint (dose constraint)" means a value above which specified licensee actions are required.

~~(25)~~ (28) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

~~(26)~~ (29) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

~~(27)~~ (30) "Curie" is the special unit of radioactivity. One curie is equal to 3.7×10^{10} disintegrations per second = 3.7×10^{10} becquerels = 2.22×10^{12} disintegrations per minute.

~~(28)~~ (31) "Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

~~(29)~~ (32) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for either unrestricted use and termination of the license or for restricted use and termination of the license.

~~(30)~~ (33) "Deep-dose equivalent" (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm^2).

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

~~(31)~~ (35) "Department" means the North Carolina Department of Environment and Natural Resources.

~~(32)~~ (36) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

~~(33)~~ (37) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of ALI. DAC values are given in Table 1, Column 3, of Appendix B to 10 CFR 20.1001 - 20.2401).

~~(34)~~ (38) "Derived air concentration-hour" (DAC-hour) is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of five rems (0.05 Sv).

~~(35)~~ (39) "Diagnostic clinical procedures manual" means a collection of written procedures governing the use of radioactive material that describes each method by which the licensee performs diagnostic clinical procedures and includes other instructions and precautions. Each diagnostic clinical procedure including but not limited in content to the radiopharmaceutical, dosage and route of administration, shall be approved by an authorized user prior to inclusion in the manual. The radiation safety officer shall ensure that the

manual includes the approved written procedure for all diagnostic clinical procedures performed at the facility.

(40) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

~~(36)~~ (41) "Distinguishable from Background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using measurement technology, survey and statistical techniques as defined in 10 CFR 20.1003.

~~(37)~~ (42) "Dose" (or radiation dose) is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, effective dose equivalent, or total effective dose equivalent, as defined in other Items of this Rule.

~~(38)~~ (43) "Dose equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

~~(39)~~ (44) "Dose limits" (see "Limits" defined in this Rule).

~~(40)~~ (45) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

~~(41)~~ (46) "Effective dose equivalent" (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = Ów_T H_T$).

~~(42)~~ (47) "Embryo/fetus" means the developing human organism from conception until the time of birth.

~~(43)~~ (48) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

~~(44)~~ (49) "Equipment services" means the selling, installation, rebuilding, conversion, repair, inspection, testing, survey or calibration of equipment which can affect compliance with these Rules by a licensee or registrant.

~~(45)~~ (50) "Exposure" means being exposed to ionizing radiation or to radioactive material.

~~(46)~~ (51) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

~~(47)~~ (52) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

~~(48)~~ (53) "Extremity" means hand, elbow, arm, arm below the elbow, foot, knee, or leg below the knee.

~~(49)~~ (54) "Eye dose equivalent" (See "Lens dose equivalent" as defined in this Rule).

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

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

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

~~(50)~~ (58) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954 (42 U.S.C. 2D11 et seq;), as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using sources of radiation.

~~(51)~~ (59) "Gray" (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule/kilogram (100 rads).

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

~~(52)~~ (61) "High radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

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

~~(53)~~ (63) "Hospital" means a facility that provides as its primary functions diagnostic services and intensive medical and nursing care in the treatment of acute stages of illness.

~~(54)~~ (64) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

~~(55)~~ (65) "Individual" means any human being.

~~(56)~~ (66) "Individual monitoring" means:

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

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

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

~~(57)~~ (67) "Individual monitoring devices" or "individual monitoring equipment" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

~~(58)~~ (68) "Inhalation class" (see "Class" defined in this Rule).

~~(59)~~ (69) "Inspection" means an official examination or observation to determine compliance with rules, orders, requirements and conditions of the agency or the Commission.

~~(60)~~ (70) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

~~(61)~~ (71) "Lens dose equivalent" or "LDE" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm (300 mg/cm^2).

~~(62)~~ (72) "License", except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.

~~(63)~~ (73) "Licensee" means any person who is licensed by the agency pursuant to Section .0300 of this Chapter.

~~(64)~~ (74) "Licensing state" means any state designated as such by the Conference of Radiation Control Program Directors, Inc. Unless the context clearly indicates otherwise, use of the term Agreement State in this Chapter shall be deemed to include licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).

~~(65)~~ (75) "Limits" or "dose limits" means the permissible upper bounds of radiation doses.

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

~~(66)~~ (76) "Lost or missing licensed radioactive material" means licensed radioactive material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

~~(67)~~ (77) "Lung class" (see "Class" as defined in this Rule).

~~(68)~~ (78) "Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

~~(69)~~ (79) "Member of the public" means any individual except when that individual is receiving an occupational dose.

~~(70)~~ (80) "Minor" means an individual less than 18 years of age.

~~(71)~~ (81) "Misadministration" means the administration of the following:

(a) a diagnostic radiopharmaceutical dosage:

(i) involving a dose to the patient that exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ; and

(A) the wrong patient;

(B) the wrong radiopharmaceutical;

(C) the wrong route of administration; or

(D) an administered dosage that differs from the prescribed dosage by more than 20 percent of the prescribed dosage; or

(ii) for sodium iodide I-125 or I-131 involving:

(A) the wrong patient or wrong radiopharmaceutical; or

(B) an administered dosage that differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries;

(b) a therapeutic radiopharmaceutical dosage:

(i) involving:

(A) the wrong patient;

(B) wrong radiopharmaceutical;

(C) wrong route of administration; or

(D) when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage; or

(ii) when the administered dosage of sodium iodide I-125 or I-131 differs from the prescribed dosage by more than 20 percent of the prescribed dosage;

(c) a teletherapy or accelerator radiation dose:

(i) involving:

(A) the wrong patient;

(B) the wrong mode of treatment; or

(C) wrong treatment site;

(ii) when the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(iii) when the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

(iv) when the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

(d) a brachytherapy radiation dose:

(i) involving:

(A) the wrong patient;

(B) the wrong radioisotope; or

(C) the wrong treatment site. This excludes, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site;

(ii) involving a sealed source that is leaking;

(iii) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose; or

(e) a gamma stereotactic radiosurgery radiation dose:

(i) involving the wrong patient or wrong treatment site; or

(ii) when the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

~~(72)~~ (82) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

~~(73)~~ (83) "Monitoring", "radiation monitoring" or "radiation protection monitoring" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

~~(74)~~ (84) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

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

~~(75)~~ (86) "Nonstochastic effect" means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

~~(76)~~ (87) "NRC" means the United States Nuclear Regulatory Commission or its duly authorized representatives.

~~(77)~~ (88) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or registrant or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, from voluntary participation in medical research programs, or as a member of the general public.

~~(78)~~ (89) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles.

~~(79)~~ (90) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, other than the United States Nuclear Regulatory Commission, or any successor thereto, and other than federal government agencies licensed by the United States Nuclear Regulatory Commission, or any successor thereto, as defined in G.S. 104E-5(11).

~~(80)~~ (91) "Personnel monitoring equipment" means devices, such as film badges, pocket dosimeters, and thermoluminescent dosimeters, designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.

~~(81)~~ (92) "Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions and poisons.

~~(82)~~ (93) "Physician" means an individual currently licensed to practice medicine in this state.

~~(83)~~ (94) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

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

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

~~(84)~~ (97) "Prescribed dosage" means the quantity of radiopharmaceutical activity documented in a written directive by an authorized user.

~~(85)~~ (98) "Prescribed dose" means:

(a) for teletherapy or accelerator radiation:

(i) the total dose; and

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

(b) for brachytherapy:

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

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

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

(99) "Presure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

~~(86)~~ (100) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee or registrant, or to another source of radiation within a licensee's or registrant's control. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, or from voluntary participation in medical research programs.

(101) "Qualitative fit test (QLFT)" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

~~(87)~~ (102) "Quality factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem in this Rule.

(103) "Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

~~(88)~~ (104) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee or registrant (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

~~(89)~~ (105) Quarterly" means either:

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

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

~~(90)~~ (106) "Rad" is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

~~(91)~~ (107) "Radiation" (ionizing radiation), except as otherwise defined in Section .1400 of this Chapter, means gamma rays and x-rays, alpha and beta particles, high-speed electrons, protons, neutrons, and other nuclear particles, and electromagnetic radiation consisting of associated and interacting electric and magnetic waves including those with frequencies between three times 10 to the eighth power cycles per second and three times 10 to the twenty-fourth power cycles per second and wavelengths between one times 10 to the minus fourteenth power centimeters and 100 centimeters as defined in G.S. 104E-5(12).

~~(92)~~ (108) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

~~(93)~~ (109) "Radiation dose" means dose.

~~(94)~~ (110) "Radiation machine" means any device designed to produce or which produces radiation or nuclear particles when the associated control devices of the machine are operated as defined in G.S. 104E-5(13).

~~(95)~~ (111) "Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection rules.

~~(96)~~ (112) "Radioactive material" means any solid, liquid, or gas, which emits ionizing radiation spontaneously as defined in G.S. 104E-5(14).

~~(97)~~ (113) "Radioactive waste disposal facility" means any low-level radioactive waste disposal facility, as defined in G.S. 104E-5(9c), established for the purpose of receiving low-level radioactive waste, as defined in Rule .1202 of this Chapter, generated by another licensee for the purpose of disposal.

~~(98)~~ (114) "Radioactive waste processing facility" means any low-level radioactive waste facility, as defined in G.S. 104E-5(9b), established for the purpose of receiving waste, as defined in this Rule, generated by another licensee to be stored, compacted, incinerated or treated.

~~(99)~~ (115) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.

~~(100)~~ (116) "Radiobioassay" means bioassay.

~~(101)~~ (117) "Recordable event" means the administration of the following:

(a) a radiopharmaceutical or radiation from a licensed source without a written directive where a written directive is required by Sub-items 146(a)(i) and 146(b)-(f) of this Rule;

(b) a radiopharmaceutical or radiation from a licensed source where a written directive is required by Sub-items 146(a)(i) and 146(b)-(f) of this Rule without recording each administered radiopharmaceutical dosage or radiation dose in the appropriate record on a daily basis;

(c) a radiopharmaceutical dosage of greater than 30 microcuries of sodium iodide I-125 and I-131 when:

(i) the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage; and

(ii) the difference between the administered dosage and prescribed dose exceeds 15 microcuries;

(d) a therapeutic dosage of any radiopharmaceutical dosage other than sodium iodide I-125 or I-131 when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(e) a teletherapy or accelerator radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or

(f) a brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

~~(102)~~ (118) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus as published by the International Commission on Radiological Protection. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

~~(103)~~ (119) "Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.

~~(104)~~ (120) "Registration" means registration with the agency in accordance with these Rules.

~~(105)~~ (121) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

~~(106)~~ (122) "Rem" is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). As used in this Chapter, the quality factors for converting absorbed dose to dose equivalent are as follows:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

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

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

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

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

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

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})
(thermal)	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}
	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}
	5	8	23×10^{6}
	7	7	24×10^{6}
	10	6.5	24×10^{6}
	14	7.5	17×10^{6}
	20	8	16×10^{6}
	40	7	14×10^{6}
	60	5.5	16×10^{6}
	1×10^{2}	4	20×10^{6}
	2×10^{2}	3.5	19×10^{6}
	3×10^{2}	3.5	16×10^{6}
	4×10^{2}	3.5	14×10^{6}

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

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

~~(107)~~ (123) Research and development" means:

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

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

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

~~(108)~~ (124) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if the burials were made in accordance with the provisions of Section .1600 of this Chapter.

~~(109)~~ (125) "Respiratory protective device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

~~(110)~~ (126) Restricted area" means an area, access to which is controlled by the licensee or registrant for purposes of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

~~(111)~~ (127) "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58 x 10^{-4} coulombs/kilogram of air.

~~(112)~~ (128) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

~~(113)~~ (129) "Sealed source" means radioactive material that is permanently bonded, fixed or encapsulated so as to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

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

~~(114)~~ (131) "Semiannually" means either:

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

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

~~(115)~~ (132) "Shallow-dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of one square centimeter.

~~(116)~~ (133) "SI unit" means a unit of measure from the International System of Units as established by the General Conference of Weights and Measures.

~~(117)~~ (134) "Sievert" is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

~~(118)~~ (135) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

~~(119)~~ (136) "Source material" means:

(a) uranium or thorium or any other material which the Department declares to be source material after the United States Nuclear Regulatory Commission, or any successor thereto has determined the material to be such; or

(b) ores containing one or more of the foregoing materials, in such concentrations as the Department declares to be source material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material in such concentration to be source material as defined in G.S. 104E-5(15).

~~(120)~~ (137) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

~~(121)~~ (138) "Special form radioactive material" means radioactive material which satisfies the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than five millimeters (0.197 inch); and

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

constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

~~(122)~~ (139) "Special nuclear material" means:

(a) plutonium, uranium 233,uranium 235, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Department declares to be special nuclear material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material to be such, but does not include source material; or

(b) any material artificially enriched by any of the foregoing, but does not include source material as defined in G.S. 104E-5(16).

~~(123)~~ (140) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope uranium-235 in quantities not exceeding 350 grams of contained uranium-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of uranium-235, uranium enriched in uranium-235 and plutonium in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified in this Rule for the same kind of special nuclear material. The sum of these ratios for all the kinds of special nuclear material in combination shall not exceed unity. For example, the following quantities in combination would not exceed the limitations and are within the formula, as follows:

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

~~(124)~~ (141) "State" means the State of North Carolina.

~~(125)~~ (142) "Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

(143) "Supplied-air respirator (SAR)" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

~~(126)~~ (144) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of sources of radiation and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

~~(127)~~ (145) "These Rules" means Chapter 11 of this Title.

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

~~(128)~~ (147) "To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable effort.

~~(129)~~ (148) "Total effective dose equivalent" (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

~~(130)~~ (149) "Toxic or hazardous constituent of the waste" means the nonradioactive content of waste which, notwithstanding the radioactive content, would be classified as "hazardous waste" as defined in G.S. 130A-290(8).

~~(131)~~ (150) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Rule .0113 of this Section or may be determined by procedures described in Rule .0113 of this Section. All quantities of radioactive material greater than a Type A quantity are Type B.

~~(132)~~ (151) "Unit dosage" means a dosage intended for medical use in an individual that has been obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent agreement state requirements.

~~(133)~~ (152) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

~~(134)~~ (153) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.

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

~~(135)~~ (155) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at one meter from a radiation source or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

~~(136)~~ (156) "Waste" means low-level radioactive waste as defined in G.S. 104E-5(9a) and includes licensed naturally occurring and accelerator produced radioactive material which is not subject to regulation by the U.S. Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended, except as defined differently in Rule .1202 of this Chapter.

~~(137)~~ (157) "Waste, Class A" is defined in Rule .1650 of this Chapter.

~~(138)~~ (158) "Waste, Class B" is defined in Rule .1650 of this Chapter.

~~(139)~~ (159) "Waste, Class C" is defined in Rule .1650 of this Chapter.

~~(140)~~ (160) "Week" means seven consecutive days starting on Sunday.

~~(141)~~ (161) "Weighting factor", w_T, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole body	1.00[b]

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

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

~~(142)~~ (162) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

~~(143)~~ (163) "Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

~~(144)~~ (164) "Working level" (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy.

~~(145)~~ (165) "Working level month" (WLM) means an exposure to one working level for 170 hours.

~~(146)~~ (166) "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation from a licensed source, except as specified in Sub-item (e) of this definition, containing the following information:

(a) for the diagnostic administration of a radiopharmaceutical:

(i) if greater than 30 microcuries of sodium iodide I-125 or I-131, the dosage to be administered in accordance with the diagnostic clinical procedures manual; or

(ii) if not subject to Sub-item (a)(i) of this Item, the type of study to be performed in accordance with the diagnostic clinical procedures manual;

(b) for the therapeutic administration of a radiopharmaceutical:

(i) radiopharmaceutical;

(ii) dosage; and

(iii) route of administration;

(c) for teletherapy or accelerator radiation therapy:

(i) total dose;

(ii) dose per fraction;

(iii) treatment site; and

(iv) overall treatment period;

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

(i) radioisotope;

(ii) treatment site; and

(iii) total dose;

(e) for all other brachytherapy:

(i) prior to implantation:

(A) radioisotope;

(B) number of sources to be implanted; and

(C) source strengths in millicuries; and

(ii) after implantation but prior to completion of the procedure:

(A) radioisotope;

(B) treatment site; and

(C) either:

(I) total source strength and exposure time; or

(II) total dose;

(f) for gamma stereotactic radiosurgery:

(i) target coordinates;

(ii) collimator size;

(iii) plug pattern; and

(iv) total dose.

~~(147)~~ (167) "Year" means the period of time beginning in January used to determine compliance with the provisions of Section .1600 of this Chapter. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. February 1, 1980;
Amended Eff. November 1, 1989; June 1, 1989; October 1, 1984;
Transferred and Recodified from 10 NCAC 3G .2204 Eff. January 4, 1990;
Amended Eff. January 1, 1994; May 1, 1992;
Temporary Amendment Eff. August 20, 1994, For a Period of 180 Days or Until the Permanent Rule Becomes Effective, Whichever is Sooner;
Amended Eff. August 1, 2004; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.

15A NCAC 11 .0306 is proposed to be amended as follows:

15A NCAC 11 .0306 TYPES OF LICENSES: GENERAL AND SPECIFIC

(a) General licenses provided in this Section are effective without the filing of applications with the agency or the issuance of licensing documents to the general licensee, although registration with the agency may be required by the particular general license. The general license is subject to all other applicable rules in this Chapter and any limitations contained in ~~the~~ a general ~~license.~~ license document, if issued.

(b) Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable rules of this Chapter as well as any limitations and requirements specified in the licensing document.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2004.

15A NCAC 11 .0308 is proposed to be amended as follows:

15A NCAC 11 .0308 GENERAL LICENSES: OTHER THAN SOURCE MATERIAL

(a) A general license shall be issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31:

(1) static elimination devices designed for use as static eliminators which contain as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device;

(2) ion generating tube designed for ionization of air and containing, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

(b) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), ~~.0337,~~ .0338, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2004; January 1, 1994.

15A NCAC 11.0309 is proposed to be amended as follows:

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

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

~~(b) The general license in Paragraph (a) of this Rule applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued pursuant to Rule .0328 of this Section or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes distribution of the devices to persons generally licensed pursuant to equivalent regulations.~~

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

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

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

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

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

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

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

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

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

performed:

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

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

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

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

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

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

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

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

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

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

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

(7) except as provided in Subparagraph (c)(8) of this Rule, shall transfer or dispose of the device containing radioactive material only by transfer to a person holding a specific license authorizing receipt of the device; and, within 30 days after transfer of a device to a specific licensee, shall furnish to the agency at the address in Rule .0111 of this Chapter, ~~identification of the device by manufacturer's name and model number and the name and address of the person receiving the device, except no report is required if the device is~~

~~transferred to the specifically licensed manufacturer or distributor in order to obtain a replacement device;~~ a report that contains:

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

(B) the name, address and specific license number of the person receiving the device; and

(C) the date of the transfer.

(8) shall transfer the device to another general licensee only where the device:

(A) remains in use at a particular location.

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

(ii) The transferor shall, within 30 days of the transfer, report to the agency at the address in Rule .0111 of this Chapter, the manufacturer's or initial transferor's name, serial number, and model number of device transferred, the name and mailing address of the transferee, and ~~the name and position of an individual who may constitute a point of contact between the Commission and the transferee.~~ name, title, and telephone number of the individual identified by the transferee as having knowledge of and authority to take actions to ensure compliance with applicable regulations and requirements; or

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

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

(10) shall appoint an individual responsible for having knowledge of the applicable regulations and requirements and the authority for taking the actions required to comply with the applicable regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with the applicable regulations and requirements. The appointment of such an individual does not relieve the general licensee of any of its responsibility in this regard.

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

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

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

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

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

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

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

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

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

(14) shall report changes to the name of the general licensee to the agency within 30 days of the effective date of the change. For portable devices that are granted a general license by the agency, only a change in the primary place of storage requires a notification.

(15) shall not hold devices that are not in use for longer than 2 years. If devices that have shutters are not in use, the shutter shall be locked in the closed position. Leak testing is not required during the period of storage; however, when devices are returned to service of transferred to another person, the devices must be tested for leakage and shutter operation.

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

(e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), ~~.0337,~~ .0338, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2004; January 1, 1994; June 1, 1989.

15A NCAC 11 .0310 is proposed to be amended as follows:

15A NCAC 11 .0310 GENERAL LICENSES: MANUFACTURE, TRANSFER, INSTALL GENERALLY LICENSED DEVICES

Any person who is authorized to manufacture, install or service a device described in Rule .0309 of this Section pursuant to a specific license issued by the agency, the U.S. Nuclear Regulatory Commission or an agreement state is hereby granted a general license to install and service the device described in Rule .0309, provided the following requirements are met:

(1) The person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee, to whom the device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(2) The device is manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the U.S. Nuclear Regulatory Commission or an agreement state;

(3) The person shall assure that any labels satisfy the requirements in Rule .0309 of this Section and shall furnish to each general licensee, to whom he transfers a device or on whose premises he installs a device, a copy of the general license contained in Rule .0309 of this Section.

(4) The person shall ensure that each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number, the isotope and quantity, the words "Caution: Radioactive Material," the radiation symbol described in Rule .1623 of this Chapter, and the name of the manufacturer or initial distributor.

(5) The person shall ensure that each device meeting the criteria of Rule .0309 of this Chapter bears a permanently embossed, etched, stamped or engraved label affixed to the source housing, if separable, or the device if the source housing is not separable. The label shall include the words, "Caution: Radioactive Materials," and ,if practicable, the radiation symbol described in Rule .1623 of this Chapter.

(6) If a device is to be transferred for use on the general license granted in Rule .0309 of this Chapter, each person that is licensed under this Rule shall provide the following information to each person to whom the device is being transferred prior to the device being transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to the initial transfer to the intermediate person. The required information includes:

(a) a copy of the general license contained in Rule .0309 of this Chapter. If the prospective general licensee is in the jurisdiction of the Nuclear Regulatory Commission or another Agreement State, the notification shall include a statement advising the person receiving the device of the agency that has jurisdiction over the device.

(b) a copy of this Rule. If the prospective general licensee is in the jurisdiction of the Nuclear Regulatory Commission or another Agreement State, the notification of transfer shall include the name or title, address, and telephone number of the contact at the proper regulatory agency that has jurisdiction over the person receiving the device;

(c) a list of services that can only be performed by a specific licensee;

(d) information on acceptable disposal options, including estimated cost of disposal; and

(e) an indication that loss or improper disposal of the device may result in formal enforcement actions.

(7) Each device transferred after August 1, 2004 shall meet the labelling requirements.

(8) Each person licensed to initially transfer generally licensed devices to other persons shall comply with the requirements of this Paragraph.

(a) The person shall report, on a quarterly basis, all transfers of devices to persons for use under a general license and all receipts of devices from generally licensed persons. The reports shall be provided to the agency at the address listed in Rule .0111. The information shall be provided either on the Nuclear Regulatory Commission's Form 653-"Transfers of Industrial Devices Report" or in a clear and legible report that contains all of the information required by the form. The required information includes:

(i) the identity of each general licensee by name and mailing address for the location of use. If there is no mailing address at the location of use, an alternate address for the general licensee shall be submitted along with the information on the actual location of use;

(ii) the name, title and telephone number of the person identified by the general licensee as having knowledge of and authority to ensure compliance with the applicable regulations and requirements;

(iii) the date of transfer;

(iv) the type, model number, and serial number of the device transferred; and

(v) the quantity and type of radioactive material contained in the device.

(b) If one or more intermediate persons will temporarily possess the device at the intended use location prior to its use by the end user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(c) For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number and serial number of the device received, and, in the case of devices not initially transferred by the licensee submitting the report, the name of the manufacturer or initial transferor.

(d) If the licensee makes changes to a device possessed by a general licensee such that the label must be changed to update required information, the report shall identify the general licensee, the device, and the changes to the information on the label.

(e) The report shall cover a calendar quarter and must be filed within 30 days of the end of the calendar quarter. The report shall clearly identify the period covered by the report.

(f) The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(g) If no transfers have been made to or from persons generally licensed during the reporting period, the report shall so indicate.

(9) The person providing the reports shall maintain all information concerning the transfers and receipts of devices required by this Rule for a period of three years following the date of the recorded event.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 2004.

15A NCAC 11 .0510 is proposed to be amended as follows:

15A NCAC 11 .0510 LIMITATIONS

(a) The licensee or registrant shall not permit any person to act as a radiographer until the person:

(1) has been instructed in the subjects outlined in Rule .0519 of this Section and has demonstrated understanding thereof by successful completion of a written test. ~~Within two years after the effective date of this Rule, the~~ The person shall also have a minimum of two months of on-the-job training, and be certified through a radiography certification program by a certifying entity in accordance with the requirements of Rule .0525 of this Section;

(2) has received copies of and instruction in the rules contained in this Section and in the applicable rules of Sections .0200, .0300, .0900 and .1600 of this Chapter, in applicable U.S. Department of Transportation regulations referenced in Rule .0117 of this Chapter, and the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof by successful completion of a written test;

(3) has received training in the use of the licensee or registrant's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments;

(4) has demonstrated competence to use the radiographic exposure devices, sealed sources, related handling tools, radiation machines and survey instruments which will be employed in his assignment by successful completion of a practical examination covering this material; and

(5) has demonstrated understanding of the instructions in Paragraph (a) of this Rule by successful completion of a written test on the subjects covered.

(b) The licensee or registrant shall not permit any person to act as a radiographer's assistant until the person:

(1) has received copies of and instructions in the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof by successful completion of a written or oral test and practical examination on the subjects covered;

(2) has demonstrated competence to use under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, related handling tools, radiation machines and radiation survey instruments which will be employed in his assignment; and

(3) has demonstrated understanding of the instructions in Paragraph (b) of this Rule by successfully completing a written or oral test and a field examination on the subjects covered.

(c) Records of the training including copies of written tests and dates of oral tests and field examinations shall be maintained in accordance with Rule .0523 of this Section.

(d) Each licensee or registrant shall conduct an internal audit program to ensure that the agency's radioactive material license, registration conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits shall be performed and records maintained by the licensee or registrant as specified in Items (3) and (4) of Rule .0323 of this Chapter.

(e) The licensee or registrant shall provide periodic training for radiographers and radiographer's assistants at least once during every 12 months.

(f) Whenever radiography is performed outside of a permanent radiographic installation, the radiographer shall be accompanied by another radiographer or an individual with, at least, the qualifications of a radiographer's assistant. This person's responsibilities shall include but not be limited to observing the operations and being capable and prepared to provide immediate assistance to prevent unauthorized entry.

(g) A licensee or registrant may conduct lay-barge, off-shore platform, or underwater radiography only if detailed procedures have been developed and submitted to the agency that ensure radiation exposure to the workers and the public are ALARA during the radiographic operation.

(h) The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

(1) The radiation safety officer's qualifications shall include:

(A) completion of the training and testing requirements of Paragraph (a) of this Rule; and

(B) Two thousand hours documented experience in industrial radiographic operations, with at least 40 hours of classroom training with respect to the establishment and maintenance of radiation protection programs; or

(C) an equivalent combination of education and experience.

(2) The specific duties and authorities of the radiation safety officer shall include, but are not limited to the following:

(A) to establish and oversee operating, emergency and ALARA procedures, and to review them regularly to assure that the procedures are current and conform with these Rules and to the license conditions;

(B) to oversee and approve all phases of the training of radiographic personnel so that appropriate and effective radiation protection practices are taught;

(C) to ensure that required radiation surveys and leak tests are performed and documented in accordance with this Rule, including any corrective measures when levels of radiation exceed established limits;

(D) to ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Rule .1646 of this Chapter;

(E) to assure that operations are conducted safely and to assume control and have the authority to institute corrective actions including stopping of operations when necessary in emergency situations or unsafe conditions.

History Note: *Filed as a Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*

Authority G.S. 104E-7; 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540; 10 C.F.R. 34.43; 10 C.F.R. Appendix A;
Eff. February 1, 1980;
Amended Eff. August 1, 2004; April 1, 1999; May 1, 1995; June 1, 1993; June 1, 1989.

15A NCAC 11 .0512 is proposed to be amended as follows:

15A NCAC 11 .0512 PERSONNEL MONITORING

(a) The licensee or registrant shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each such individual wears on the trunk of the body a direct reading pocket dosimeter, an operating alarm ratemeter, and ~~either a film badge or a thermoluminescent dosimeter (TLD).~~ a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiography facilities where other alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters shall have a range from zero to 200 milliroentgens (2 millisieverts) and shall be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters. Each ~~film badge and TLD~~ personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be exchanged at least monthly and ~~TLDs~~ other personnel dosimeters processed and evaluated by an accredited NVLAP processor shall be exchanged at least once each three months. After exchange, each ~~film badge or TLD~~ personnel dosimeter shall be promptly processed.

(b) Direct reading dosimeters such as electronic dosimeters or pocket dosimeters shall be read and exposures recorded at the beginning and end of each shift.

(c) Pocket dosimeters or electronic personal dosimeters shall be checked at periods not to exceed 12 months for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure.

(d) If an individual's pocket dosimeter is found to be off-scale or if the individual's electronic personal dosimeter reads greater than 200 millirem (2 millisieverts), and the possibility of radiation exposure cannot be ruled out as the cause, their ~~film badge or TLD~~ personnel dosimeter shall be immediately sent for processing. In addition, the individual shall not work with sealed sources until a determination of his radiation exposure has been made by the radiation safety officer or his designee.

(e) If a ~~film badge or TLD~~ personnel dosimeter is lost or damaged, the worker shall cease work immediately until a replacement ~~film badge or TLD~~ personnel dosimeter is provided and exposure is calculated for the time period from issuance to loss or damage of the ~~film badge or TLD~~ personnel dosimeter.

(f) Each alarm ratemeter shall:

(1) be checked to ensure that the alarm functions properly prior to use at the start of each shift;

(2) be set to give an alarm signal at a preset rate not to exceed 500 mR/hr or 5 mSv/hr;

(3) require special means to change the preset alarm function;

(4) alarm within plus or minus 20 percent of the true radiation rate;

(5) be calibrated at periods not to exceed one year for correct response to radiation.

(g) Records of daily dosimeter readings, determination of exposure as a result of a lost or damaged ~~film badge or TLD~~ personnel dosimeter, 12 month response checks on dosimeters and results from the ~~film badge or TLD~~ accredited NVLAP personnel dosimeter processor shall be maintained in accordance with Rule .0523 of this Section.

(h) Notwithstanding the requirements of Paragraph (a) of this Rule, the agency may approve a higher pocket dosimeter range upon written request by the licensee or registrant if the agency determines that the requested range will afford the protection required by the rules in this Chapter.

History Note: *Filed as a Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
Authority G.S. 104E-7; 104E-12(a)(2);
Eff. February 1, 1980;
Amended Eff. August 1, 2004; April 1, 1999; May 1, 1995.

15A NCAC 11.0523 is proposed to be amended as follows:

15A NCAC 11 .0523 RECORDS OF INDUSTRIAL RADIOGRAPHY

(a) Each licensee or registrant shall maintain, for a period of three years after the record is made, the following records for inspection by the agency:

(1) copies of the following documents:

(A) radioactive materials license or registration issued by the agency;

(B) the complete application submitted for the license or registration that includes all amendments; and

(C) current operating and emergency procedures;

(2) records showing the receipt and transfer of all sealed sources and devices using depleted uranium (DU) for shielding that include:

(A) date;

(B) individual making the record;

(C) radionuclide;

(D) activity in curies or becquerel or mass for depleted uranium; and

(E) make, model and serial number of each sealed source and device;

(3) records of the calibrations of radiation detection instrumentation;

(4) records of leak tests for sealed sources and devices containing depleted uranium in units of microcuries or becquerel;

(5) records of quarterly inventories that include:

(A) radionuclide;

(B) activity in curies or becquerel;

(C) specific information on each sealed source and the radiographic exposure device, storage container or source changer which contains the sealed source to include:

(i) model numbers;

(ii) serial numbers; and

(iii) manufacturers names;

(D) location of sealed sources;

(E) name of the individual conducting the inventory; and

(F) the date of the inventory;

(6) records of utilization logs showing the following information:

(A) a description of each radiographic exposure device, radiation machine or transport or storage container in which the sealed source is located that includes:

(i) make;

(ii) model number; and

(iii) serial number;

(B) the identity and signature of the radiographer to whom assigned; and

(C) the plant or site where used; and

(D) dates of use that includes the dates removed and returned to storage;

(7) records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers and radiation machines. The record shall include:

(A) date of the check;

(B) name of the individual performing the check;

(C) equipment involved;

(D) any problems found in daily checks and quarterly inspections; and

(E) any repairs or maintenance made and name of individual or company performing the repair;

(8) records of alarm system tests for permanent radiographic installations;

(9) records of the training and certification of each radiographer and radiographer's assistant as follows:

(A) radiographer certification documents and verification of certification status;

(B) for initial training, copies of written tests, dates and results of oral tests and field examinations; and names of individuals conducting and receiving the oral test or field examination;

(C) for periodic training and semi-annual inspections of job performance, list of topics discussed, date(s) of the review, names of the instructors and the attendees; and

(D) for inspections of job performance, the records shall also include a list showing the items checked and any noncompliance observed by the Radiation Safety Officer.

(10) records for pocket dosimeters to include daily exposure readings and yearly operability checks;

(11) records of reports received from the ~~film badge or TLD~~ personnel dosimetry processor. These records shall be maintained until the agency terminates the license or registration or until authorized by the agency;

(12) records of exposure device surveys performed at the end of the work day and prior to placing the device in storage;

(13) records of area surveys required by Rule .0515 of this Section;

(14) copy of current operating and emergency procedures until the agency terminates the license or registration and copies of superseded material shall be retained for three years after the change is made; and

(15) evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters or electronic personal dosimeters.

(b) Each licensee or registrant conducting operations at temporary jobsites shall maintain copies of the following documents and records at the temporary jobsite until the radiographic operation is completed:

(1) operating and emergency procedures required by Rule .0513 of this Section;

(2) radioactive materials license or registration;

(3) evidence of training of the radiographers and radiographer's assistants. The individuals shall either be listed on the radioactive materials license or registration and offer identification or shall have certification of his training and offer identification;

(4) evidence of the latest calibration of the radiation detection instrumentation in use at the site as required by Rule .0506 of this Section;

(5) evidence of the latest leak test of the sealed source required by Rule .0507 of this Section;

(6) records of the latest surveys required by Rule .0515 of this Section;

(7) records of current direct reading dosimeters such as pocket dosimeter or electronic personal dosimeter readings;

(8) shipping papers for the transportation of radioactive materials required by 10 CFR Part 71.5; and

(9) records of area surveys required by Rule .0515 of this Section;

(10) a copy of Section .0500 of this Chapter;

(11) utilization records for each radiographic exposure device dispatched from that location as required by Subparagraph (a) of Rule .0523 of this Section;

(12) records of equipment problems identified in daily checks of equipment; and

(13) when operating under reciprocity, a copy of the Nuclear Regulatory Commission or agreement state license authorizing the use of radioactive material.

(c) Each record required by this Rule shall be legible throughout the specified retention period. The record may be an original, a reproduced copy or microform provided that the copy or microform is authenticated by the licensee and the microform is capable of reproducing a clear copy throughout the required record retention period. The record may also be stored in electronic media with the capability for producing legible, accurate and complete records during the required record retention period. Records, such as letters, drawings and specifications shall include all pertinent information, such as stamps, initials and signatures. The licensee or registrant shall maintain safeguards against tampering with and loss of records.

History Note: *Filed as a Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
Authority G.S. 104E-7;
Eff. May 1, 1995;
Amended Eff. August 1, 2004; April 1, 1999.

15A NCAC 11 .0702 is proposed to be amended as follows:

15A NCAC 11 .0702 INTERSTITIAL: INTRACAVITARY AND SUPERFICIAL APPLICATIONS

(a) Accountability, storage and transit

(1) Each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources. A physical inventory shall be made at least every six months and a written record of the inventory maintained.

(2) When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as necessary to assure compliance with the provisions of Rules .1604, .1609 and .1611 of this Chapter.

(b) Testing sealed sources for leakage and contamination

(1) All sealed sources with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and contamination prior to initial use and at intervals not to exceed six months. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.

(2) Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample, or in the case of radium, the escape of radon at rate of 0.001 microcurie per 24 hours. Any test conducted pursuant to Subparagraph (b)(1) of this Rule which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of Section .1600 of this Chapter. A report describing the sealed sources involved, the test results and the corrective action taken shall be submitted in writing to the agency at the address stated in Rule .0111 of this Chapter within five days after the test.

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

(c) Radiation surveys

(1) The maximum radiation level at a distance of one meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation. This radiation level shall be entered on the patient's chart and other signs as required in Paragraph (d) of this Rule.

(2) The radiation surveying in Paragraph (c) of this Rule or a special survey shall be performed and shall include measurements necessary to comply with the following requirements:

(A) The therapeutic use of sealed sources shall not create radiation levels in areas occupied by patients not undergoing radiation therapy which would result in an accumulated dose in excess of ~~125~~ 100 millirem if a patient were continuously present during the entire treatment period.

(B) The licensee shall maintain a record of this survey and the calculation which demonstrates compliance with Subparagraph (c)(1) of this Rule.

(C) The licensee shall select rooms for hospitalization of these sealed source therapy patients in a manner so as to minimize radiation exposure of other patients, hospital staff, visitors and the public, especially those who are under 18 years of age or who are pregnant females.

(D) This Rule does not relieve the licensee of responsibility to monitor or limit occupational radiation exposure for the licensee's staff as provided in Section .1600 of this Chapter.

(3) Immediately after implanting sources in an individual the licensee shall make a radiation survey of the individual and the area of use to confirm that no source has been misplaced. The licensee shall make a record of each survey.

(4) Immediately after removing the last temporary implant source from an individual, the licensee shall make a radiation survey of the individual with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care an individual treated by temporary implant until all sources have been removed.

(d) A licensee shall maintain accountability for all brachytherapy sources in storage or in use. After removing sources from an individual, a licensee shall return brachytherapy sources to the storage area. A licensee shall ensure that all sources taken from the storage area have been returned, and shall make a record of the source accountability and retain the record for three years.

(e) For temporary implants, the record shall include:

(1) the number and activity of sources removed from storage;

(2) the date the sources were removed from storage;

(3) the number and activity of sources returned to storage; and

(4) the date the sources were returned to storage.

(f) For permanent implants, the record shall include:

(1) the number and activity of sources removed from storage;

(2) the date the sources were removed from storage;

(3) the number and activity of sources returned to storage;

(4) the date the sources were returned to storage; and

(5) the number and activity of sources permanently implanted in the individual.

(g) Signs and records

(1) In addition to the requirements of Rule .1624 of this Chapter, the bed, cubicle, or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, activity, date, and the individual(s) to contact for radiation safety instructions. The sign is not required provided the exception in Rule .1625 of this Chapter is satisfied.

(2) The following information shall be included in the patient's chart:

(A) the radionuclide administered, number of sources, activity in millicuries and time and date of administration;

(B) the exposure rate at one meter, the time the determination was made, and by whom;

(C) the radiation symbol; and

(D) the precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted in Paragraph (c) of this Rule.

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. August 1, 2004; April 1, 1999; January 1, 1994; October 1, 1980.

15A NCAC 11 .1302 DEFINITIONS

As used in this Section, the following definitions apply:

(1) "Energy compensation sources (ECS)" means a small sealed source, with an activity not exceeding 100 microcuries (3.7 MBq), used within a logging tool or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

~~(1)~~(2) "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

~~(2)~~(3) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

~~(3)~~(4) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.

~~(4)~~(5) "Logging tool" means a device used subsurface to perform well-logging.

~~(5)~~(6) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

~~(6)~~(7) "Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

~~(7)~~(8) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

~~(8)~~(9) "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

~~(9)~~(10) "Subsurface-tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

~~(10)~~(11) "Temporary jobsite" means a location to which radioactive materials have been dispatched to perform wireline-service operations or subsurface-tracer studies.

(12) "Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

~~(11)~~(13) "Well-bore" means a drilled hole in which wireline-service operations and subsurface-tracer studies are performed.

~~(12)~~(14) "Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

~~(13)~~(15) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

~~(14)~~(16) "Wireline-service operations" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

History Note: *Authority G.S. 104E-7;*
Eff. June 1, 1989;
Amended Eff. August 1, 2004.

15A NCAC 11 .1307 is proposed to be amended as follows:

15A NCAC 11 .1307 RADIATION SURVEY INSTRUMENTS

(a) The licensee shall maintain sufficient calibrated and operable radiation survey instruments at each field station and temporary jobsite to make physical radiation surveys as required by this Section and by Section .1600 of this Chapter. Instrumentation shall be capable of measuring beta and gamma radiation from 0.1 milliroentgen per hour through at least 50 milliroentgens per hour.

(b) Each radiation survey instrument shall be calibrated:

(1) at intervals not to exceed six months and after each instrument servicing;

(2) at energies and radiation levels appropriate for use; and

(3) so that accuracy within plus or minus 20 percent of the true radiation level can be demonstrated on each scale.

(c) Calibration records shall be maintained for a period of three years for inspection by the agency.

History Note: *Authority G.S. 104E-7; 104E-12(a)(1);*
Eff. June 1, 1989;
Amended Eff. August 1, 2004; January 1, 1994.

15A NCAC 11 .1308 is proposed to be amended as follows:

15A NCAC 11 .1308 LEAK TESTING OF SEALED SOURCES

(a) Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the agency for six months after the next required leak test is performed or until transfer or disposal of the sealed source.

(b) Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample.

(c) Each sealed source of radioactive material, with the exception of energy compensation sources (ECSs), shall be tested at intervals not to exceed six months. Each ECS source that is not exempted from leak testing pursuant to Paragraph (e) of this Rule shall be tested at intervals not to exceed 3 years. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(d) If the test reveals the presence of 0.005 microcurie or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these Rules. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the agency.

(e) The following sources are exempt from the periodic leak test and notification requirements of this Rule:

(1) hydrogen-3 (tritium) sources;

(2) sources of radioactive material with a half-life of 30 days or less;

(3) sealed sources of radioactive material in gaseous form;

(4) sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries or less; and

(5) sources of alpha-emitting radioactive material with an activity of ten microcuries or less.

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. June 1, 1989;
Amended Eff. August 1, 2004; May 1, 1993.

15 A NCAC 11 .1311 is proposed to be amended as follows:

15A NCAC 11 .1311 DESIGN: PERFORMANCE: AND CERTIFICATION CRITERIA

(a) ~~Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured after October 1, 1989, shall be certified by the manufacturer, or other testing organization acceptable to the agency, to meet the following minimum criteria:~~ Each sealed source used in downhole operations, except those containing radioactive material in gaseous form, shall meet the following minimum criteria:

(1) be of doubly encapsulated construction;

(2) contain radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical; and

(3) ~~individually pressure tested to at least 24,656 pounds per square inch absolute without failure.~~ meets the requirements in paragraphs (b), (c) and (d) of this Rule.

(b) ~~For sealed sources, except those containing radioactive material in gaseous form, acquired after October 1, 1989, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of this Rule, the sealed source shall not be put into use until such determinations and testing have been performed.~~ For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source for downhole operations if it meets the requirements of USASU N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in paragraphs (c) and (d) of this Rule.

(c) ~~Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after October 1, 1989, shall be certified by the manufacturer, or other testing organization acceptable to the agency, as meeting the sealed source performance requirements for oil well logging as contained in the American National Standard N542, "Sealed Radioactive Sources, Classification" adopted November 1, 1977, and effective on October 1, 1989.~~ For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for downhole operations if it meets the oil-well logging requirements of ANSI/HPS N43.6-1977, "Sealed Radioactive Sources, Classification."

(d) ~~Certification documents shall be maintained for inspection by the agency for a period of two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the agency authorizes disposition.~~ For a sealed source manufactured after July 14, 1989, a licensee may use the source for downhole operations if the sealed source's prototype has been tested and found to maintain its integrity after being subjected to each of the following tests:

(1) The test source shall be held at -40° C for 20 minutes, 600° C for one hour, and then be subjected to a thermal shock test with a temperature drop from 600° C to 20° C within 15 seconds;

(2) A 5 kg steel hammer, 2.5 cm in diameter, shall be dropped from a height of 1 meter onto the test source;

(3) The test source shall be subjected to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes;

(4) A 1 gram hammer and pin, 0.3 cm pin diameter, shall be dropped from a height of 1 m onto the test source; and

(5) The test source shall be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals).

(e) The requirements of paragraphs (a) through (d) of this Rule do not apply to energy compensation sources (ECSs).

History Note: *Authority G.S. 104E-7;*
Eff. June 1, 1989;
Amended Eff. August 1, 2004.

15A NCAC 11 .1312 is proposed to be amended as follows:

15A NCAC 11 .1312 LABELING

(a) General requirements are as follows:

(1) Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

CAUTION
RADIOACTIVE MATERIAL

(2) The marking or labeling required in Subparagraph (a)(1) of this Rule shall be on the smallest component transported as a separate piece of equipment.

(3) Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

CAUTION
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

(4) Each uranium sinker bar used by the licensee in downhole operations shall be legibly impressed with the following wording:

CAUTION
RADIOACTIVE DEPLETED URANIUM
NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

(b) The word "danger" may be substituted for the word "caution" in the signs described in this Rule.

History Note: *Authority G.S. 104E-7; 104E-12(a)(1);*
Eff. June 1, 1989;
Amended Eff. August 1, 2004.

15A NCAC 11 .1614 is proposed to be amended as follows:

15A NCAC 11 .1614 MONITORING OF EXTERNAL AND INTERNAL OCCUPATIONAL DOSE

Each licensee or registrant shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this Section. As a minimum:

(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

(a) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in Rule .1604(a) of this Section;

(b) minors likely to receive, in one year, from sources of radiation, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent in excess of 0.5 rem (5 mSv);

(c) declared pregnant women likely to receive, during the entire pregnancy, from sources of radiation external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and

(d) individuals entering a high or very high radiation area.

(2) Each licensee shall monitor the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(a) adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1, Columns 1 and 2, of Appendix B to 10 CFR 20.1001 - 20.2402; and

(b) minors ~~and declared pregnant women~~ likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 rem ~~(1mSv).~~ (1mSv); and

(c) declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1mSv).

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994;
Amended Eff. August 1, 2004; August 1, 2002.

15A NCAC 11 .1316 is proposed to be amended as follows:

15A NCAC 11 .1316 PERSONNEL MONITORING

(a) No licensee shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears ~~either a film badge or a thermoluminescent dosimeter (TLD).~~ personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.

(b) Each ~~film badge or TLD~~ personnel dosimeter required in Paragraph (a) of this Rule shall be assigned to and worn by only one individual.

(c) Each film badge shall be replaced at least monthly and other personnel dosimeters shall be replaced at least quarterly.

~~(c)~~ (d) The licensee shall maintain personnel monitoring records for inspection until the agency authorizes disposal.

History Note: *Authority G.S. 104E-7; 104E-12(a)(2);*
Eff. June 1, 1989;
Amended Eff. August 1, 2004.

15A NCAC 11 .1618 is proposed to be amended as follows:

15A NCAC 11 .1618 USE OF PROCESS OR OTHER ENGINEERING CONTROLS

The licensee shall use, to the extent practicable, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentrations of radioactive material in air.

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994;
Amended Eff. August 1, 2004.

15A NCAC 11 .1619 is proposed to be amended as follows:

15A NCAC 11 .1619 USE OF OTHER CONTROLS TO RESTRICT INTERNAL EXPOSURE

~~When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes of radionuclides by one or more of the following means:~~

~~(1) the control of access to the area;~~

~~(2) the limitation of exposure times of personnel in the area;~~

~~(3) the use of respiratory protection equipment; or~~

~~(4) other controls.~~

(a) When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes of radionuclides by one or more of the following means:

(1) the control of access to the area;

(2) the limitation of exposure times of personnel in the area;

(3) the use of respiratory protection equipment; or

(4) other controls.

(b) If the licensee performs ALARA analyses to determine whether or not respirators are to be used, the licensee may consider safety factors other than radiological factors. The licensee shall also consider the impact of respirator use on workers' industrial health and safety.

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994
Amended Eff. August 1, 2004.

15A NCAC 11 .1620 is proposed to be amended as follows:

15A NCAC 11 .1620 USE OF INDIVIDUAL RESPIRATORY PROTECTION EQUIPMENT

(a) If the licensee uses respiratory protection equipment to limit ~~intakes pursuant to Rule .1619 of this Section~~ intakes, the licensee shall:

(1) use only respiratory protection equipment that is tested and certified ~~or had certification extended~~ by the National Institute for Occupational Safety and Health~~/Mine Safety and Health Administration~~ (NIOSH~~/MSHA~~);

(2) if the licensee wishes to use equipment that has not been tested or certified by ~~NIOSH/MSHA, has not had certification extended by~~ NIOSH~~/MSHA~~, or for which there is no schedule for testing or certification, submit an application to the Agency for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use;

(3) implement and maintain a respiratory protection program that includes:

(A) air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures;

(B) surveys and bioassays, as appropriate, to evaluate actual intakes;

(C) testing of respirators for operability immediately prior to each use;

(D) written procedures ~~regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and record keeping;~~ regarding: monitoring, including air sampling and bioassays; supervision and training of respirator users; fit testing; respirator selection; breathing air quality; inventory and control; storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment; recordkeeping; and limitations on periods of respirator use and relief from respirator use; and

(E) determination by a physician prior to initial fitting of ~~respirators~~ of a face sealing respirator, prior to the first field use of a non-face sealing respirator, and at least every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is physically able to use the respiratory protection equipment; and

(F) Fit testing, with fit factor ≥ 10 times the APF for negative pressure devices, and a fit factor ≥ 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

~~(4) issue a written policy statement on respirator usage covering:~~

~~(A) the use of process or other engineering controls, instead of respirators;~~

~~(B) the routine, non-routine, and emergency use of respirators; and~~

~~(C) the periods of respirator use and relief from respirator use.~~

~~(5)~~(4) advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief; and

~~(6)~~(5) use equipment within limitations for type and mode of use and shall provide ~~proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.~~ for vision correction, effective communication, low temperature work environments, the concurrent use of other safety or radiological protection equipment, and assurance that other such equipment will be used in such a way as not to interfere with proper operation of the respirator.

(6) proved standby rescue personnel whenever one-piece atmosphere-supplying suits, or any combination of suppied air respiratory protection devices and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby rescue personnel shall:

(A) be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards identified by the licensee;

(B) observe or otherwise maintain continuous communication with the workers through visual, voice, signal line, telephone, radio, or other means suitable for the environment;

(C) be immediately available to assist workers in the event of a failure of the air supply or for any other reason that requires relief from distress;

(D) immediately available in sufficient number to assist all users of this type of equipment and to provide effective emergency rescue, if needed.

(7) provide Atmosphere-supplying respirators with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in Title 29 CFR 1910.134(i)(1)(ii)(A) – (E) of the Occupational Safety and Health Administration. Grade D quality air criteria include:

(A) Oxygen content of 19.5% - 23.5%;

(B) condensed Hydrocarbon content of 5 milligrams per cubic meter of air or less;

(C) Carbon Monoxide (CO) content of 1,000ppm or less; and

(D) lack of noticable odor.

(8) ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face-to-facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

~~(b) In estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to Rule .1619 of this Section, provided that the following conditions, in addition to those in Paragraph (a) of this Rule, are satisfied:~~

~~(1) The licensee selects respiratory protection equipment that provides a protection factor, as specified in Appendix A to 10 CFR §§ 20.1001 - 20.2401, greater than the multiple by which peak concentrations of~~

~~airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B to 10 CFR §§ 20.1001—20.2401, Table 1, Column 3. If the selection of a respiratory protection device with a protection factor greater than the peak concentration is inconsistent with the goal specified in Rule .1619 of this Section of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than estimated, the corrected value shall be used. If the exposure is later found to be less than estimated, the corrected value may be used.~~

~~(2) The licensee shall obtain authorization from the agency before assigning respiratory protection factors in excess of those specified in Appendix A to 10 CFR §§ 20.1001—20.2401. The agency may authorize a licensee to use higher protection factors on receipt of an application that:~~

~~(A) describes the situation for which a need exists for higher protection factors, and~~

~~(B) demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.~~

(b) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in aire without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

~~(c) The licensee shall use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.~~

(c) The licensee shall obtain authorization, in writing, from the agency before using assigned portection factors in excess of those specified in Appendix A to 10 CFR Part 20. The agency may authorize the use of higher assigned protection factors upon receipt of an application that:

(1) describes the situation for which a need exists for higher protection factors; and

(2) demonstrates that the respiratory equipment provides the higher protection factors under the proposed conditions of use.

~~(d) The licensee shall notify the agency, in writing, at least 30 days before the date that respiratory protection equipment is first used under the provisions of either Paragraph (a) or (b) of this Rule.~~

History Note: *Authority G.S. 104E-7(a)(2); 104E-12(a);*
Eff. January 1, 1994;
Amended Eff. August 1, 2004; August 1, 1998.

15A NCAC 11 .1621 is proposed to be amended as follows:

15A NCAC 11 .1621 RESTRICTIONS ON THE USE OF RESPIRATORY PROTECTION EQUIPMENT

The agency may impose restrictions in addition to those in Rules .1619 and .1620 of this Section, and Appendix A to 10 CFR §§ 20.1001 - 20.2401 when the agency determines that such requirements are necessary to:

(1) ensure that the respiratory protection program of the licensee is adequate to limit exposures of individuals to airborne radioactive materials to ~~the~~ levels ~~prescribed in this Section;~~ that are ALARA; and

(2) limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls when process or other engineering controls are appropriate to limit exposures of individuals to airborne radioactive materials to the levels prescribed in this Section.

History Note: *Authority G.S. 104E-7(a)(2); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;*
Eff. January 1, 1994;
Amended Eff. August 1, 2004.

15A NCAC 11 .1324 is proposed to be amended as follows:

15A NCAC 11 .1324 NOTIFICATION OF INCIDENTS: ABANDONMENT: AND LOST SOURCES

(a) The licensee shall comply with the applicable notification requirements in Section .1600 of this Chapter for incidents and sources lost in other than downhole logging operations.

(b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

(1) monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and

(2) notify the agency immediately by telephone if radioactive contamination is detected at the surface or if the source appears to be damaged.

(c) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

(1) advise the well-operator of the rules of the appropriate state agency with jurisdiction over abandonment and appropriate method of abandonment, which shall include:

(A) the immobilization and sealing in place of the radioactive source with a concrete plug;

(B) ~~the setting of a whipstock or other deflection device; and~~ a means of preventing inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

(C) the mounting of a permanent identification plaque, at the surface of the well, containing the ~~appropriate~~ information required by Paragraph (d) of this Rule;

(2) notify the agency by telephone, giving the circumstances of the loss and requesting approval of the proposed abandonment procedures; and

(3) file a written report with the agency within 30 days of the abandonment, setting forth the following information:

(A) date of occurrence and a brief description of attempts to recover the source; and

(B) a description of the radioactive source involved, including radionuclide, quantity, and chemical and physical form;

(i) surface location and identification of well,

(ii) results of efforts to immobilize and set the source in place,

(iii) depth of the radioactive source,

(iv) depth of the top of the cement plug,

(v) depth of the well, and

(vi) information contained on the permanent identification plaque.

(d) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque for posting the well or well-bore. This plaque shall:

(1) be constructed of long-lasting material, such as stainless ~~steel or monel, and~~ steel, brass, bronze, or monel;

(2) be at least 7 inches (17 cm) square and 1/8 inch (3mm) thick; and

~~(2)~~(3) contain the following information engraved on its face;

(A) the word "CAUTION";

(B) the radiation symbol without the conventional color requirement;

(C) the date of abandonment;

(D) the name of the well-operator or well owner;

(E) the well name and well identification number(s) or other designation;

(F) the sealed source(s) by radionuclide and quantity of activity;

(G) the source depth and the depth to the top of the plug; and

(H) an appropriate warning, depending on the specific circumstances of each abandonment, which may include:

(i) "Do not drill below plug back depth",

(ii) "Do not enlarge casing", or

(iii) "Do not re-enter the hole" before contacting the ~~Division of Radiation Protection~~ agency at the address in Rule .0111 of this Chapter.

(e) The licensee shall immediately notify the agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate the consequences.

History Note: *Authority G.S. 104E-7;*
Eff. June 1, 1989;
Amended Eff. August 1, 2004; January 1, 1994; May 1, 1992.

15A NCAC 11 .1326 is proposed to be added as follows:

15A NCAC 11 .1326 ENERGY COMPENSATION SOURCES

The licensee shall use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).

(1) For downhole operations utilizing a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of Rules .1308, .1309, .1310, and .1323 of this Section.

(2) For downhole operations without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of Rules .1303, .1308, .1309, .1310, .1323, and .1324 of this Section.

History Note: *Authority G.S. 104E-7;*
Eff. August 1, 2004.

15A NCAC 11 .1327 is proposed to be added as follows:

15A NCAC 11 .1327 TRITIUM NEUTRON GENERATOR TARGET SOURCES

(a) The use of a tritium neutron generator target source, containing quantities not exceeding 30 Curies (1,110 MBq) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this Rule with the exception of Rules .1303, .1311, and .1324 of this Section.

(b) The use of a tritium neutron generator target source, containing quantities exceeding 30 Curies (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this Rule with the exception of Rule .1311 of this Section.

History Note: *Authority G.S. 104E-7;*
Eff. August 1, 2004.