North Carolina
Division of Environmental Health

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VIA ELECTRONIC MAIL (monica.orendi@nrc.gov)
& U.S. MAIL

May 29, 2008

Robert Lewis, Director
Office of Federal and State Materials and Environmental Management Programs
Division of Materials Safety and State Agreements
U.S. Nuclear Regulatory Commission
Mail Stop 8E24
Washington, DC 20555-0001

Dear Mr. Lewis:

We had previously transmitted via hardcopy, copies of recent changes to the North Carolina Regulations for Protection Against Radiation. The regulations were approved by the North Carolina Rules Review Commission and were codified on November 01, 2007. The regulations we have amended correspond to the following NRC rulemaking ID numbers:

RATS ID	Title	FR Notice	Corresponding N.C. Regulation
2002-2	Medical Use of Byproduct Material – Parts 20, 32, and 35	67 FR 20249	Multiple
2004-1	Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71	69 FR 3697	.0117
2005-2	Medical Use of Byproduct Material – Recognition of Specialty Boards – Part 35	70 FR 16336, 71 FR 1926	.0117

Mr. Eaddy of my staff gave the final version of the regulations to Ms. Orendi on May 17, 2008, but did not include a letter formally requesting review of the rules. Therefore, we hereby request NRC's review of our regulations.

We believe that the aforementioned documents will be sufficient to address the required elements and are consistent with FSME Procedure SA-200.

If you have any questions, please contact me at (919) 571-4141.

Sincerely,

/ W

W. Lee Cox, III, Manager
Radioactive Materials Branch

jme

enclosure (as stated)

15A NCAC 11 .0104 DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(13) "Annually" means either:

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

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

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

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

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

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

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

control of the licensee or registrant. "Background radiation" does not include sources of radiation regulated by the agency.

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

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

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

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

CLASSIFICATION OF INHALED MATERIAL

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

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

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

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

(26) "Committed effective dose equivalent" (HE,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 (HE,50 =Σ wTHT,50).

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

(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.

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

(30) "Curie" is the special unit of radioactivity. One curie is equal to 3.7 x 1010 disintegrations per second = 3.7 x 1010 becquerels = 2.22 x 1012 disintegrations per minute.

(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.

(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.

(33) "Deep-dose equivalent" (Hd), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm2).

(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.

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

(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.

(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).

(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).

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

(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).

(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.

(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.

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

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

(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.

(46) "Effective dose equivalent" (HE) is the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factors (wT) applicable to each of the body organs or tissues that are irradiated ($HE = \Sigma wTHT$).

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

(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.

(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.

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

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

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

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

(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.

(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.

(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.

(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 completely covers the head and neck and may also cover portions of the shoulders and torso.

(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.

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

(65) "Individual" means any human being.

(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.

(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.

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

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

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

(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/cm2).

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

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

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

(75) "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.

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

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

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

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

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

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

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

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

(85) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) In a written directive; or

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

(99) "Prescribed dose" means:

(a) for teletherapy or accelerator radiation:

(i) the total dose; and

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

(b) for brachytherapy:

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

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

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

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

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

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

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

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

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

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

(106) Quarterly" means either:

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

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

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

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

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

(110) "Radiation dose" means dose.

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

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

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

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

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

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

(117) "Radiobioassay" means bioassay.

(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.

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

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

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

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

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

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

(123) Research and development" means:

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

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

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

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

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

(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.

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

(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.

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

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

(132) "Semiannually" means either:

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

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

(133) "Shallow-dose equivalent" (Hs), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2).

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

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

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

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

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

(139) "Special form radioactive material" means radioactive material which satisfies the following conditions:

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

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

(c) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission, Subpart F of 10 CFR Part 71, and the tests prescribed in Rule .0114 of this Section. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory

Commission requirements, Subpart F of 10 CFR Part 71, in effect on June 30, 1984, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

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

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

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

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

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

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

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

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

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

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

(149) "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).

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

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

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

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

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

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

(156) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at one meter from a radiation source or from any surface that the radiation

penetrates. At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

(157) "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.

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

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

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

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

(162) "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	wT
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30a
Whole body	1.00b

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

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

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

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

(165) "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 x 105 MeV of potential alpha particle energy.

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

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

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

(b) for the therapeutic administration of a radiopharmaceutical other than sodium iodide I-131:
  (i) radionuclide;
  (ii) dosage; and
  (iii) route of administration;

(c) for teletherapy or accelerator radiation therapy:
  (i) total dose;
  (ii) dose per fraction;
  (iii) treatment site; and

(iv) number of fractions;

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

(i) radionuclide;

(ii) treatment site;

(iii) dose per fraction

(iv) number of fractions; and

(v) total dose;

(e) for all other brachytherapy:

(i) prior to implantation:

(A) radionuclide;

(B) treatment site; and

(C) dose; and

(ii) after implantation:

(A) radionuclide;

(B) treatment site;

(C) number of sources;

(D) total source strength and exposure time; and

(E) total dose;

(f) for gamma stereotactic radiosurgery:

(i) the total dose;

(ii) treatment site; and

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

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

15A NCAC 11 .0117 INCORPORATION BY REFERENCE

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

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

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

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

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

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

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

(7) 40 CFR Part 261;

(8) 49 CFR Parts 100-189;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Is identified as an authorized user on:

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

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

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

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

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

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

(f) For the purposes of this Rule "High dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(g) For the purposes of this Rule "Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(p) License required:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) measurement of radiopharmaceutical doses prior to administration;

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

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

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

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

(A) general characteristics of radiation and radioactive materials;

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

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

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

(E) principles and practices of radiation protection;

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

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

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

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

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

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

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

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

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

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

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medial uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, rules of this Chapter, and license conditions with respect to the medical use of radioactive material.

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

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

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

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

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

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

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

(1) identify radiation safety problems;

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

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

(4) verify implementation of corrective actions; and

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

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

(1) Patient or human research subject control;

(2) Visitor control, including

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

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

(3) Contamination control;

(4) Waste control;

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

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

(1) List of topics covered;

(2) The date of the instruction;

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

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

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

15A NCAC 11 .0320 SPECIFIC LICENSES: HUMAN USE BY INDIVIDUAL PHYSICIANS

(a) An application by an individual physician or a group of physicians for a specific license for human use of radioactive material shall be approved if:

(1) the applicant satisfies the general requirements in Rule .0318 of this Section;

(2) The application is for use in the applicant's practice in an office(s) outside a medical institution;

(3) the applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable;

(4) the applicant has experience, which meets the requirements of the applicable sections of 10 CFR Part 35, in the proposed use, the handling and administration of radioisotopes, and where applicable, the clinical management of radioactive patients; and

(5) the physician(s) furnishes suitable evidence of experience along with the application, except that a statement from the medical isotope committee in the hospital where the applicant acquired experience, indicating its amount and nature, may be submitted as evidence of experience. 10 CFR Part 35 provides the requirements that meet the test for suitable evidence of experience.

(b) The agency shall not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use radioactive material on the premises of a hospital unless:

(1) The use of radioactive material is limited to:

(A) the administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(B) the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(C) the performance of IN VITRO diagnostic studies; or

(D) the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation;

(2) The physician brings the radioactive material with him and removes the radioactive material when he departs;

(3) No radioactive material is received, possessed or stored in the hospital other than the amount of material remaining in the patient; and

(4) The hospital does not hold a radioactive material license under Rule .0319 of this Section.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. November 1, 2007; August 1, 2002; November 1, 1989.

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

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

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

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

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

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

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

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

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

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

(3) Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0,56 GBq);

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

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

(c) Any licensee who possesses sealed sources as calibration and reference sources pursuant to Paragraph (b) of this Rule shall test each source for leakage and contamination prior to initial use and at intervals not to exceed six months or at other intervals approved by the U.S. Nuclear Regulatory Commission or an Agreement State in the Sealed Source and Device Registry. If there is reason to suspect that a sealed source may have been damaged, or might be leaking, it shall be tested for leakage before further use.

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

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

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

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

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

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

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

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

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

(3) either monitor material or items removed from the individual's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation

detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste; and

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

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

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

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

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

(2) the applicant meets the applicable requirements in Section 32.72 of 10 CFR Part 32.

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

15A NCAC 11 .0350 RECORDS AND REPORTS OF MISADMINISTRATION

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. June 1, 1989;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995; May 1, 1992;
Repealed Eff. November 1, 2007.

15A NCAC 11 .0356 PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide that:

(1) The patient or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) The procedures required by Paragraph (a) of this Rule must address the following items that are applicable to the licensee's use of radioactive material:

(1) Verify the identity of the patient or human research subject;

(2) Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Check both manual and computer-generated dose calculations; and

(4) Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

(c) A licensee shall retain a copy of the procedures required under Paragraph (a) until the agency terminates the pertinent license.

(d) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(e) A revision to an existing written directive may be made:

(1) if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose, or

(2) if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(f) The licensee shall retain a record of the written directive and any revisions to the written directive for three years.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Temporary Adoption Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. November 1, 2007.

15A NCAC 11 .0359 MEASUREMENTS/DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE

(a) A licensee shall possess and use a dose calibrator to measure the radioactivity of dosages of photon-emitting radionuclides prior to administration to each individual. A licensee shall:

(1) develop, maintain, and implement written procedures for use of the dose calibrator;

(2) calibrate each dose calibrator in accordance with the requirements of 10 CFR 35.60(b).

(b) A licensee shall retain a record of each check, test, and calibration performed in accordance with this Rule for a period of three years following the test.

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

15A NCAC 11 .0360 SURVEYS OF RADIOPHARMACEUTICAL AREAS FOR RADIATION EXPOSURE RATE

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) A licensee shall conduct the survey required by Paragraph (a) of this Rule so as to be able to detect dose rates as low as 0.1 millirem (1 microsievert) per hour.

(c) A licensee shall establish radiation dose rate trigger levels for the surveys required by Paragraph (a) of this Rule. A licensee shall require the individual performing the survey to promptly notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(d) A licensee shall retain a record of the survey required by this Rule for three years. The record shall include:

(1) the date of the survey;
(2) a plan of each area surveyed;
(3) the trigger level established for each area;
(4) the detected dose rate at several points in each area surveyed expressed in millirem (or microsievert) per hour;
(5) the instrument used to make the survey; and
(6) the initials of the individual who performed the survey.

(e) Any licensee authorized by the rules of this Chapter to manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use shall have in its possession a calibrated portable radiation survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour (1 microsievert per hour) to 100 millirem per hour (.01 millisievert per hour), and a portable radiation survey instrument capable of measuring dose rates over the range of one millirem per hour (.01 millisievert per hour) to 1,000 millirem per hour (10 millisievert per hour). A licensee shall calibrate the survey instruments used to show compliance with this Section before first use, annually, and following repair. The licensee shall:

(1) calibrate all scales with readings up to 1,000 millirem (10 millisievert) per hour with a radiation source;
(2) calibrate two separated readings on each scale that must be calibrated; and
(3) conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(f) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent.

(g) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(h) A licensee shall retain a record of each survey instrument calibration for three years. The record must include:

(1) a description of the calibration procedure; and
(2) the date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the identity of the individual who performed the calibration.

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

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

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

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

(2) Prepared by:

(A) An authorized nuclear pharmacist;

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

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

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

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

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

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

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

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

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

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

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

15A NCAC 11 .0363 PROVISIONS FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS

(a) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Research Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board" as defined and prescribed in the Federal Policy; and

(2) Obtain "informed consent" as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board" as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as described in the Federal Policy, from the human research subject.

(d) Nothing in this Rule relieves licensees from complying with the other requirements in this Chapter or with any other applicable Rules and Laws in the State of North Carolina.

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-12;*
Eff. November 1, 2007.

15A NCAC 11 .0364 MEDICAL EVENTS

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sievert (Sv)) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and
   (A) The total dose delivered differs from the prescribed dose by 20 percent or more;
   (B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
   (C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:
   (A) An administration of a wrong radioactive drug containing radioactive material;
   (B) An administration of a radioactive drug containing radioactive material by the wrong route of administration;
   (C) An administration of a dose or dosage to a wrong individual or human research subject;
   (D) An administration of a dose or dosage delivered by the wrong mode of treatment; or
   (E) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licenses shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the agency no later than the next calendar day after discovery of the medical event.

(d) The licensee shall submit a written report to the agency at the address listed in Rule .0111 of this Chapter within 15 days of the discovery of the medical event. The written report must include:

(1) The licensee's name;
(2) The name of the prescribing physician;
(3) A brief description of the event;
(4) Why the event occurred;
(5) The effect, if any, on the individual(s) who received the administration;
(6) What actions, if any, have been taken or are planned to prevent recurrence; and
(7) Certification that the licensee notified the individual (or the individual's responsible relative or guardian) and if not, why not.

The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery unless the referring physician personally informs the licensee either that he or she will inform the individual or that based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this Paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

(1) Annotate a copy of the report provided to the agency with the:
   (A) Name of the individual who is the subject of the event; and
   (B) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event; and

(2) Provide a copy of the annotated report to the referring physician if other than the licensee, no later than 15 days after the discovery of the event.

History Note: *Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12;*
Eff. November 1, 2007.

15A NCAC 11 .0365 REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD

(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by that authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of administration of radioactive material to a breast-feeding individual, that:

(1) Is greater than 5 rem (50 mSv) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in Paragraphs (a) or (b) of this Rule.

(d) The licensee shall submit a written report to the agency at the address listed in Rule .0111 of this Chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in Paragraphs (a) or (b) in this Rule.

(1) The written report must include:

(A) The licensee's name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the embryo/fetus or the nursing child;

(F) What actions, if any, have been taken or are planned to prevent recurrence; and

(G) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under Paragraphs (a) or (b) of this Rule, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this Paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible guardian, that a written description of the event can be obtained from the licensee upon request, The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the agency with the:

(A) Name of the pregnant individual or the nursing child who is the subject of the event; and

(B) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-12;*
Eff. November 1, 2007.

15A NCAC 11 .0702 MANUAL BRACHYTHERAPY

(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 quarterly 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 or at other intervals approved by the U.S. Nuclear Regulatory Commission or an Agreement State in the Sealed Source and Device Registry. If there is reason 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) 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.

(2) 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 and time the sources were removed from storage;
(3) the name of the individual who removed the sources from storage;
(4) the location of use;
(5) the number and activity of sources returned to storage;
(6) the date and time the sources were returned to storage; and
(7) the name of the individual who returned the sources to storage.

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

(1) the number and activity of sources removed from storage;
(2) the date and time the sources were removed from storage;
(3) The name of the individual who removed the sources from storage;
(4) the number and activity of sources not implanted;
(5) the date the sources were returned to storage; and
(6) the name of the individual who returned the sources to storage.

(g) For each patient or human research subject who is receiving brachytherapy and cannot be released under Rule .0358 of this Section, a licensee shall:

(1) Not quarter the patient or human research subject in the same room as an individual who is not receiving brachytherapy;
(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and
(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(h) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source;
(1) Dislodged from the patient; or
(2) Lodged within the patient following removal of the source applicators.

(i) A licensee shall notify the Radiation Safety Officer or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. November 1, 2007; January 1, 2005; April 1, 1999; January 1, 1994; October 1, 1980.

15A NCAC 11 .0703 TELETHERAPY

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. February 1, 1980;
Amended Eff. April 1, 1999; June 1, 1993; May 1, 1992; October 1, 1984; October 1, 1980;
Repealed Eff. November 1, 2007.

15A NCAC 11 .1611 DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

(a) Each licensee or registrant shall conduct operations so that:

(1) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) in a year exclusive of the dose contribution from background radiation from the licensee's disposal of radioactive material into sanitary sewerage in accordance with Rule .1630 of this Section, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter and from voluntary participation in medical research programs; and

(2) The dose in any unrestricted area from external sources of radiation, exclusive of the dose contribution from patients administered radioactive material and released in accordance with Rule .0358 of this Chapter, does not exceed 0.002 rem (0.02 mSv) in any one hour.

(b) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(c) A licensee, registrant, license applicant or registration applicant may apply for and must receive agency authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee, registrant, license applicant or registration applicant shall include the following information in this application:

(1) demonstration of the need for and the expected duration of operations in excess of the limit in Paragraph (a) of this Rule;

(2) the licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(3) the procedures to be followed to maintain the dose as low as is reasonably achievable.

(d) The agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to maintain the collective dose as low as reasonably achievable.

(e) Notwithstanding Subparagraph (a)(1) of this Rule, a licensee may permit visitors to an individual who cannot be released in accordance with Rule .0358 of this Section to receive a dose in excess of 0.1 rem (1 mSv) if:

(1) The radiation dose received does not exceed 0.5 rem (5 mSv); and

(2) The authorized user, as defined in Section .0300 of this Chapter had determined before the visit that it is appropriate.

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994;
Amended Eff. November 1, 2007; August 1, 1998.