10A NCAC 15 .0101 is readopted as published in 39:05 NCR 187-208 as follows:

CHAPTER 15 – RADIATION PROTECTION

SECTION .0100 – GENERAL PROVISIONS

10A NCAC 15 .0101 SCOPE

(a) Except as otherwise specifically provided these Rules apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation within the State of North Carolina.

(b) Nothing in these Rules shall apply to any person to the extent any person is subject to regulation by the United States Nuclear Regulatory Commission.

(c) Regulation by the State of North Carolina of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended" under provisions of Public Law 86-373, as amended, and 10 CFR Part 150.

History Note: *Authority G.S. 104E-2; ~~104E-7, 104E-10104E-7(a)(2);~~ 104E-7; 104E-10; 104E-12(a);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2201 Eff. January 4, 1990;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0101 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0102 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0102 COMPLIANCE WITH LAWS

Nothing in these Rules shall relieve any person of responsibility for complying with other pertinent North Carolina laws and rules.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2202 Eff. January 4, 1990;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0102 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0103 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0103 ~~INTENTIONAL EXPOSURE~~ DEFINITIONS

~~Nothing in Sections .0100 to .1000 of this Chapter shall be interpreted as limiting the intentional exposure of patients to radiation for the purposes of medical diagnosis and therapy.~~

(a) As used in the Rules of this Chapter, persons registered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed under the rules in Sections .0300, .0900, .1200, and 1300 of this Chapter, the following definitions apply:

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

(2) "Agency" means the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.

(3) "Authorized representative" means an employee of the agency.

(4) "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).

(5) “Calendar month” means January, February, March, April, May, June, July, August, September, October, November, or December.

(6) “Calendar year” means the period of time between 12:00:00 am January 1 to 11:59:59 pm December 31.

(7) “Calibration” means the determination of the reading or response of an instrument to known radiation values over the range of the instrument, or the strength of a source of radiation relative to a standard.

(8) “CFR” means Code of Federal Regulations.

(9) "Commission" has the meaning as defined in G.S. 104E-5(5), except as stated in Paragraph (c) of this Rule.

(10) "Department" has the meaning as defined in G.S. 104E-5(6) except as stated in Paragraph (c) of this Rule.

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

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

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

(14) “Monthly” means once every calendar month.

(15) “Natural radioactivity" means radioactivity of naturally occurring nuclides.

(16) “Person” has the same meaning as defined in G.S. 104E-5(11).

(17) "Quarterly" means four time per calendar year, and:

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

(B) once per month during the months of January, April, July, and October; or

(C) once per month during the months of February, May, August, and November; or

(D) once per month during the months of March, June, September, and December.

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

(19) "Radiation dose" means dose.

(20) "Semiannually" means twice per calendar year at six month intervals.

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

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

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

(24) "These Rules" means Chapter 10 of this Title.

(b) As used in the Rules of this Chapter, persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following definitions shall apply:

(1) “Clinical study” means human use of a radiation machine for research and development. The terms “clinical investigation”, “clinical research”, “research”, and “study” also means “clinical study”.

(2) “Consulting” means providing professional technical advice on radiological matters by an expert registered with the agency in accordance with Rule .0205 of this Chapter.

(3) “Facility” means the location at which one or more radiation machines or sources of radiation are installed or located within one building, at one address or vehicle, and are under the same administrative control.

(4) “Healing arts” means the art or science of diagnostic examination using a source of radiation in the diagnosis or treatment of human or animal diseases.

(5) “Individual responsible for radiation protection” means a person who has the knowledge and responsibility to apply appropriate radiation protection rules, for persons registered with the agency in accordance with Section .0200 of this Chapter, commensurate with the scope of the activities authorized by the registrant.

(6) “Install or installation” means the assembly, placement, initial calibration, operational testing, or other actions that allow a radiation machine to be used in a new location or after being moved from one location to another.

(7) “Licensed practitioner” means a person authorized to order diagnostic exams that use radiation machines for diagnosing or treatment of human or animal diseases. The person shall be:

(A) a physician in accordance with Subparagraph (8) of this Paragraph; or

(B) licensed by the appropriate licensing board in North Carolina pursuant to G.S. Chapter 90 to provide professional services in chiropractic, dentistry, podiatry, and veterinary medicine.

(8) "Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 1.

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

(10) "Registrant" means any person who is registered with the agency, after completing the registration process, in accordance with Rule .0203 of this Chapter.

(11) "Registration" means the process of registration, with the agency, by completing and submitting agency forms in accordance with Rules .0203 and .0205 of this Chapter.

(12) "Registered" means a facility or service provider that has completed the registration process in accordance with Rules .0203 and .0205 of this Chapter and has been issued a Notice of Registration in accordance with Rule .0207 of this Chapter.

(13) "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.

(14) "Service" means calibration, conversion, repair, routine maintenance, or other testing performed on a radiation machine, x-ray system or subsystem, or source of radiation, other than those actions taken during installation.

(15) "Service Provider" means any person engaged in equipment services included in Rule .0205(d) of this Chapter.

(c) Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600, .0800, .1000, .1200, .1300, .1400, .1600, and .1700 of this Chapter.

(d) To reconcile differences between the Rules of this Chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations:

(1) With the exception of 10 CFR 30.4 and in the definition of Special Nuclear Material, a reference to ''NRC'' or ''Commission'' means the "Agency.

(2) A reference to ''NRC or agreement state" means the "Agency or agreement state.

(3) In 10 CFR 40.4 and 70.4, in the definition of "Special Nuclear Material", the sentence "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material", remains preserved as implemented by G.S. 104E-5.(16).

(4) In 10 CFR 30.18(d), 30.32(g), 31.5(b)(1)(ii), 31.5(c)(3)(ii), 31.5(c)(8)(i), 31.6, 31.7(a), 31.10(a), 1.10(b)(1), 31.12(c)(4), 32.13, 32.51(a), 32.51(c), 32.56, 32.59, 32.72(b)(5)(ii), 40.13(c)(10),

40.22(e), 40.25(b), 40.25(d)(3), 40.54, 40.55(c), (c)(1), (d)(1)(ii), (d)(2) and (d)(3), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC".

(5) In 10 CFR 31.6 where the words "any non-agreement state" or "offshore waters" are used, substitute the words "State of North Carolina,".

(6) In 10 CFR 70.19(a)(1) and 70.19(c)(3), the term "Commission or the Atomic Energy Commission" remains and does not mean the Agency or have the same definition shown in G.S. 104E-5(5). In 10 CFR 70.42(b)(1) the word "Department" means the "U.S. Department of Energy".

(7) "Written directive," except as defined in Rule .0307 of this Chapter, 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 radiation therapy through the use of a licensed accelerator that contains the patient or human research subject's name and the following information:

(A) total dose;

(B) dose per fraction;

(C) treatment site, and

(D) number of fractions.

History Note: *Authority G.S. 104E-7; 104E-7(a); 10 CFR 20.1003;*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2203 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0103 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0104 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0104 ~~DEFINITIONS~~ INCORPORATION BY REFERENCE

~~As used in these Rules, the following definitions 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 Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.~~

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

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

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

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

~~(a) in excess of the derived air concentrations 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 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. The 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 and self-contained breathing apparatus units.

(16) "Authorized representative" means an employee of the agency, or an individual outside the agency when the individual is 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 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) "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.

(22) "Brachytherapy source" means a radioactive source or a manufacturer assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(23) "Byproduct material" has the meaning as defined in G.S. 104E-5(4), and in addition includes:

(a) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface

wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

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

(c) Any material that:

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

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

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

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

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

(24) "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

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

(26) "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.

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

(28) "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.

(29) "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 = ΣwTHT,50).

(30) "Consortium" means an association of medical use licensees and a PET radionuclide production facility that jointly own or share in the operation and maintenance costs of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The consortium's PET radionuclide production facility must be located at an educational institution, federal or medical facility.

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

(32) "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.

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

(34) "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.

(35) "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.

(36) "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.

(37) "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).

(38) "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.

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

(40) "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.

(41) "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).

(42) "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).

(43) "Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

(44) "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).

(45) "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.

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

(47) "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).

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

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

(50) "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 = ΣwTHT).

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

(52) "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.

(53) "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.

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

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

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

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

(58) "Eye dose equivalent" (See "Lens dose equivalent" as defined in this Rule).

(59) "Filtering facepiece" or "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.

(60) "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.

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

(62) "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. 2011 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.

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

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

(65) "High dose rate remote afterloader" (HDR) 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.

(66) "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.

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

(68) "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.

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

(70) "Individual" means any human being.

(71) "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 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.

(72) "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.

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

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

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

(76) "Lens dose equivalent" (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).

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

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

(79) "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 includes licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).

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

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

(82) "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.

(83) "Low dose rate remote afterloader" (LDR) 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.

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

(85) "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy 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.

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

(87) "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.

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

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

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

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

(92) "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.

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

(94) "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.

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

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

(97) "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 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, from voluntary participation in medical research programs, or as a member of the public.

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

(99) "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.

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

(101) "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 of radiation received by the individual.

(102) "Pharmacist" means a person licensed to practice pharmacy in North Carolina pursuant to G.S. Chapter 90, Article 4A.

(103) "Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 1.

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

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

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

(107) "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.

(108) "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.

(109) "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.

(110) "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.

(111) "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 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.

(112) "Pulsed dose rate remote 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:

(a) Is approximately one tenth of the activity of typical high dose rate remote afterloader sources; and

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

(113) "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.

(114) "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.

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

(116) "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.

(117) "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.

(118) "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).

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

(120) "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.

(121) "Radiation dose" means dose.

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

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

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

(125) "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.

(126) "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.

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

(128) "Radiobioassay" means bioassay.

(129) "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.

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

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

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

(133) "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 Equivalenta

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 x 10-8	2	980 x 106
1 x 10-7	2	980 x 106
1 x 10-6	2	810 x 106
1 x 10-5	2	810 x 106
1 x 10-4	2	840 x 106
1 x 10-3	2	980 x 106
1 x 10-2	2.5	1010 x 106
1 x 10-1	7.5	170 x 106
5 x 10-1	11	39 x 106
1	11	27 x 106
2.5	9	29 x 106
5	8	23 x 106

7	7	24 x 106
10	6.5	24 x 106
14	7.5	17 x 106
20	8	16 x 106
40	7	14 x 106
60	5.5	16 x 106
1 x 102	4	20 x 106
2 x 102	3.5	19 x 106
3 x 102	3.5	16 x 106
4 x 102	3.5	14 x 106

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.

(134) "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.

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

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

(137) "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.

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

(139) "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.

(140) "Sealed source" means radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(141) "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.

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

(143) "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).

(144) "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).

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

(146) "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).

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

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

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

(150) "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.

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

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

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

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

(154) "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.

(155) "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.

(156) "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.

(157) "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.

(158) "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.

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

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

(161) "To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable effort, taking into account the state of technology, the economics of improvements in

relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

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

(163) "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).

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

(165) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A1 for special form radioactive material or A2 for normal form radioactive material, where A1 and A2 are given in Rule .0113 of this Section or may be determined by procedures described in that Rule. All quantities of radioactive material greater than a Type A quantity are Type B.

(166) "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.

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

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

(169) "User seal check" or "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.

(170) "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).

(171) "Waste" means low level radioactive waste as defined in G.S. 104E-5(9a) and includes those low-level radioactive wastes containing source, special nuclear, or radioactive material that are acceptable for disposal in a land disposal facility. For purposes of this definition, low level waste means radioactive waste not classified as high level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in this Rule, and licensed naturally occurring and accelerator produced radioactive material which is not subject to regulation by the U.S. Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended, except as defined differently in Rule .1202 of this Chapter.

(172) "Week" means seven consecutive days.

(173) "Weighting factor", wT, 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 wT 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, wT = 1.0, has been specified.

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

(175) "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.

(176) "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.

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

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

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

~~(b) for the therapeutic administration of a radiopharmaceutical other than sodium iodide I-131:~~

~~(i) radionuclide;~~

~~(ii) dosage; and~~

~~(iii) route of administration;~~

~~(c) for teletherapy or accelerator radiation therapy:~~

~~(i) total dose;~~

~~(ii) dose per fraction;~~

~~(iii) treatment site; and~~

~~(iv) number of fractions;~~

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

~~(i) radionuclide;~~

~~(ii) treatment site;~~

~~(iii) dose per fraction~~

~~(iv) number of fractions; and~~

~~(v) total dose;~~

~~(e) for all other brachytherapy:~~

~~(i) prior to implantation:~~

~~(A) radionuclide;~~

~~(B) treatment site; and~~

~~(C) dose; and~~

~~(ii) after implantation:~~

~~(A) radionuclide;~~

~~(B) treatment site;~~

~~(C) number of sources;~~

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

~~(E) total dose; and~~

~~(f) for gamma stereotactic radiosurgery:~~

~~(i) the total dose;~~

~~(ii) treatment site; and~~

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

~~(179) "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.~~

(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) The following parts of 21 CFR Subchapter J:

(A) Part 1000, “General;”

(B) Subpart A 1000.1, “General Provisions - General;”

(C) Subpart A 1000.3(a) through (j),(k),(1), and (n) through (t), “Definitions;”

(D) Subpart A 1000.15, “Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968;”

(E) Part 1002, “Records and Reports;”

(F) Subpart A 1002.1(a) and (c)(4), “Applicability;”

(G) Subpart D 1002.31, “Preservation and inspection of records;”

(H) Part 1003, “Notification of Defects of Failures to Comply;”

(I) Subpart A 1003.1, “Applicability;”

(J) Subpart A 1003.2, “Defect in an electronic product;”

(K) Subpart C 1003.21, “Notification by the manufacturer to affected persons;”

(L) Part 1010, “Performance Standards for Electronic Products - General;”

(M) Subpart A 1010.1, “Scope;”

(N) Subpart A 1010.2(a),(b), and (d), “Certification;”

(O) Subpart A 1010.3, “Identification;”

(P) Subpart A 1010.4(a) and (d), “Variances;”

(Q) Part 1020, “Performance Standards for Ionizing Radiation Emitting Products;”

(R) Section 1020.20, “Cold-cathode gas discharge tubes;”

(S) Section 1020.30, “Diagnostic x-ray systems and their main components;”

(T) Section 1020.31, “Radiographic equipment;”

(U) Section 1020.32, “Fluoroscopic equipment;” and

(V) Section 1020.33, “Computed tomography (CT) equipment.”

(2) "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.

(b) The rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule are available free of charge at:

(1) https://www.ecfr.gov/current/title-21/chapter-I/subchapter-J for Part (a)(1)(A) through (a)(1)(V) of this Rule, and

(2) https://www.nrc.gov/cdn/nmss/pdf/ncagreements.pdf for the agreement between the NRC and the State of North Carolina.

History Note: *Authority G.S. 104E-7(a)(2); ~~10 CFR 20.1003;~~104E-15(a); 104E-25(b); 150B-19(5)(b); 150B-21.6;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989; June 1, 1989; October 1, 1984;
Transferred and Recodified from 10 NCAC 03G .2204 Eff. January 4, 1990;
Amended Eff. January 1, 1994; May 1, 1992;
Temporary Amendment Eff. August 20, 1994, for a Period of 180 Days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. October 1, 2013; November 1, 2007; May 1, 2006; January 1, 2005; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0104 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0105 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0105 ~~OTHER DEFINITIONS~~DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENECY

~~Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600, .0800, .1200, .1300, .1400, and .1500 of this Chapter. Waste class is defined in Rule .1650 of this Chapter.~~

(a) When an employee of the agency is qualified and is specifically designated by the agency, the employee shall be an authorized representative of the agency to conduct inspections, tests, or surveys.

(b) When a public employee is determined by the agency to be qualified, the agency may designate the employee to conduct tests or surveys with an authorized representative of the agency.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 03G .2205 Eff. January 4, 1990;
Amended Eff. October 1, 2013; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0105 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0106 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0106 ~~EXEMPTIONS~~INSPECTIONS AND TESTS

~~(a) The agency may, upon application therefore, grant individual exemptions or exceptions from the requirements of these Rules if it will not result in radiation dose or contamination in excess of the limits prescribed in these Rules for the protection of public health, safety or property.~~

~~(b) Except as otherwise provided in this Rule, common and contract or other carriers, freight forwarders, and warehousemen, who are subject to the regulations of the U.S. Postal Service (39 CFR Parts 14 and 15), are exempt from these Rules to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto. Common, contract, or other carriers who are not exempt pursuant to this Rule are subject to the provisions of Rule .0316 of this Chapter. Notwithstanding these exemptions, common, contract or other carriers are required to comply with the provisions of Rule .0316(c) of this Chapter to the extent that these carriers are transporting spent nuclear fuel, as defined in Rule .0316(c) of this Chapter, upon the highways of North Carolina.~~

~~(c) Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these Rules to the extent that the contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:~~

~~(1) prime contractors performing work for the U.S. Department of Energy at U.S. government owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;~~

~~(2) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;~~

~~(3) prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States government owned vehicle or vessel; and~~

~~(4) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the agency and the U.S. Nuclear Regulatory Commission jointly determine that:~~

~~(A) the exemption of the prime contractor or subcontractor in Subparagraph (c)(4) of this Rule is authorized by law, and~~

~~(B) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.~~

(a) Inspections. At all reasonable times during hours of operation, each licensee and registrant shall:

(1) allow authorized representatives of the agency the opportunity to inspect any radiation machine or source of radiation and the facility or premises where any radiation machine or source of radiation is used or stored; and

(2) make available to the agency for inspection, upon reasonable notice, records maintained pursuant to the Rules in this Chapter.

(b) Tests. Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary of any:

(1) radiation machine or source of radiation;

(2) facility wherein any radiation machine or source of radiation is used or stored;

(3) radiation detection and monitoring instruments; and

(4) other equipment and devices used in connection with utilization or storage of any radiation machine or source of radiation.

History Note: *Authority G.S. ~~104E-2;~~ 104E-7; ~~104E-15;~~104E-7(2); 104E-11(a);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2206 Eff. January 4, 1990;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0106 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0107 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0107 ~~INSPECTIONS~~ IMPOUNDING

~~Each licensee and registrant shall, upon reasonable notice, make available to the agency for inspection records maintained pursuant to provisions of these Rules.~~

Radiation machines and sources of radiation are subject to impounding by authorized representatives of the agency pursuant to the provisions of the Act.

History Note: *Authority G.S. ~~104E-7; 104E-11(a);~~104E-14;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2207 Eff. January 4, 1990;
Amended Eff. May 1, ~~1993~~'1993;
Transferred and Recodified from 15A NCAC 11 .0107 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0108 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0108 ~~ADDITIONAL REQUIREMENTS~~ ENFORCEMENT

~~(a) The agency may, by license condition, registration condition, or order, when not in conflict with any law, waive any requirement in these Rules or impose additional requirements in accordance with 46 FR 7540 as it deems appropriate or necessary to minimize danger to public health, safety or property. Such additional requirements are subject to appeal procedures contained in Section 15A NCAC 1B .0200.~~

~~(b) The Commission may by rule require radioactive material licensees to procure and file with the department such bond, insurance or other security as the Commission deems necessary to protect the state from costs for emergency response and perpetual maintenance.~~

Any person is subject to administrative penalties pursuant to provisions of the Act for the following:

(1) failing to comply with provisions of this Chapter; or

(2) refusal of an inspection in accordance with Rule .0106(a) of this Section or impounding in accordance with Rule .0107 of this Section.

History Note: *Authority G.S. 104E-2; 104E-7; ~~104E-18;~~104E-11; 104E-14;~~10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;~~ 104E-(24);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2208 Eff. January 4, 1990;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0108 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0109 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0109 ~~IMPOUNDING~~ RECORDS

~~Sources of radiation are subject to impounding by authorized representatives of the agency pursuant to provisions of the Act.~~

(a) Each registrant shall maintain records:

(1) showing the receipt, transfer, and disposal of all radiation machines and sources of radiation;

(2) documenting operator training; and

(3) additional record requirements specified elsewhere in the Rules of this Chapter.

(b) These records shall be available for agency review during inspection or upon agency request.

History Note: *Authority G.S. 104E-7; ~~104E-14;~~104E-12(a);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2210 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0109 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0110 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0110 PROHIBITED USES

~~(a) Hand-held fluoroscopic screens shall not be used.~~

~~(b) Shoe-fitting fluoroscopic devices shall not be used.~~

~~(c) Effective February 1, 1981, plastic-pointed position-indicating devices on intraoral dental systems shall not be used.~~

~~(d) Effective February 1, 1983, mechanical timers on intraoral dental machines shall not be used.~~

~~(e) Dental fluoroscopy without image intensification shall not be used.~~

~~(f) Non-intensified photofluorographic equipment shall not be used.~~

The agency prohibits the use of the following:

(1) demonstration or training of radiation machines or sources of radiation without providing engineered or administrative protective controls to ensure exposure to radiation does not exceed dose limits in Rule .1601(a) of this Chapter;

(2) hand-held radiation machines used for diagnostic exams, ordered by a licensed practitioner as defined in Rule .0103(7) of this Section in the diagnosing or treatment of human or animal diseases, except for dental hand-held equipment authorized for use by the agency;

(3) hand-held fluoroscopic screens;

(4) shoe-fitting fluoroscopic devices;

(5) dental fluoroscopy without image intensification; and

(6) non-intensified photofluorographic equipment.

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2211 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0110 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0112 is amended as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0112 ~~DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENCY~~ PETITIONING FOR RULEMAKING

~~(a) When an employee of the agency is qualified and is specifically designated by the agency, the employee shall be an authorized representative of the agency to conduct inspections, or tests, or surveys.~~

~~(b) When a public employee of other than the agency is determined by the agency to be qualified, the agency may designate the employee as an authorized representative of the agency to conduct specified inspections, or tests, or surveys.~~

(a) Except for petitions regarding the Rules in Section .1100 of this Chapter, any person wishing to submit a petition for rulemaking requesting the adoption, amendment, or repeal of a Rule in this Chapter shall address the petition to the Radiation Protection Commission care of the Radiation Protection Section and submit the petition to one of the addresses shown in Rule .0111(a) of this Chapter. A petition for adoption, amendment, or repeal of a Rule in Section .1100 of this Chapter shall be addressed to the Department of Health and Human Services care of the Radiation Protection Section and submitted to one of the addresses shown in Rule .0111(a) of this Chapter.

(b) Petitions to adopt a new Rule, or to amend or repeal an existing Rule shall contain the following information:

(1) the proposed text of the new Rule or the proposed text amending a Rule. If the petition is for the repeal of a Rule the petitioner shall not be required to submit proposed Rule text;

(2) statutory authority supporting the new Rule, or amending or repealing a Rule;

(3) reason for the proposed rulemaking action;

(4) effect of the proposed rule change on existing rules;

(5) effect of the proposed rule change on existing practices;

(6) information supporting the proposed rulemaking;

(7) effect of the proposed rule change on the regulated community and the public; and

(8) name and contact information of the petitioner.

(c) The agency shall determine if the petitioned rule change is authorized under G.S. 104E. The agency shall maintain a record of this review.

(d) Petitions failing to contain the information required by Subparagraphs (b)(1) through (b)(7) of this Rule and petitions for rulemaking activities that are not authorized by G.S. 104E as determined by the agency under Paragraph (c) of this Rule shall be denied and the petitioner shall be notified by the agency of this decision and the reason for this decision if the information required by Subparagraph (b)(8) of this Rule is provided in the petition. Denial of a petition for failing to contain the information required by Paragraph (b) of this Rule shall not preclude resubmitting a corrected petition.

(e) Except for petitions denied in accordance with Paragraph (d) of this Rule, the agency shall send the petition to the Department of Health and Human Services (department). The department shall provide copies of the documents required by G.S 150B-20(a) to the Office of Administrative Hearings.

(f) Except for petitions denied in accordance with Paragraph (d) of this Rule and petitions for changes to the Rules in Section .1100 of this Chapter, the agency shall submit the rulemaking petition to the Radiation Protection Commission

(commission). The agency may include written recommendations to the commission endorsing or not endorsing the petition for rulemaking when it submits the petition to the commission.

(g) The commission shall grant or deny a rulemaking petition within the time requirements of G.S. 150B20.(b). The commission shall grant or deny a rulemaking petition based on the requirements of G.S. 104E-7(a). The petitioner shall be notified in writing of this decision and the reason for this decision if the information required by Subparagraph (b)(8) of this Rule is provided in the petition. If the commission grants the rulemaking petition the commission shall initiate rulemaking proceedings.

(h) Except for petitions denied in accordance with Paragraph (d) of this Rule, the agency shall submit petitions for changes to the Rules in Section .1100 of this Chapter to the department. The agency may include written recommendations to the department endorsing or not endorsing the petition for rulemaking when it submits the petition to the department.

(i) The department shall grant or deny a rulemaking petition regarding the Rules in Section .1100 of this Chapter within the time requirements of G.S. 150B-20.(b). The department shall grant or deny a rulemaking petition regarding the Rules in Section .1100 of this Chapter based on the requirements of G.S. 104E-19. The petitioner shall be notified in writing of this decision and the reason for this decision if the information required by Subparagraph (b)(8) of this Rule is provided in the petition. If the department grants the rulemaking petition the department shall initiate rulemaking proceedings.

(j) Failure of the commission or the department to grant or deny a rulemaking petition within the time limit set in this Rule is a denial of the petition for rulemaking.

(k) Denial of a rulemaking petition is a final agency action and is subject to judicial review as specified by G.S. 150B-20.(d).

History Note: *Authority G.S. ~~104E-7~~; 104E-15;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2213 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0112 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~2019;
Amended Eff. May 1, 2025.

10A NCAC 15 .0114 - .0116 are repealed through readoption as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0114 TESTS FOR SPECIAL FORM

10A NCAC 15 .0115 RECORDS

10A NCAC 15 .0116 TESTS

History Note: *Authority G.S. 104E-7; 104E-7(2); 104E-11(a); 104E-12(a); 104E-15;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2215 - 2217 Eff. January 4, 1990;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0114 - .0116 Eff. February 1, ~~2015.~~2015;
Repealed Eff. May 1, 2025.

10A NCAC 15 .0117 is repealed through readoption as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0117 INCORPORATION BY REFERENCE

History Note: *Authority G.S. 104E-7; 104E-15(a); 104E-25(b); 150B-19(5)(b); 150B-21.6;*
Eff. June 1, 1993;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. October 1, 2013; November 1, 2007; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0117 Eff. February 1, ~~2015~~2015;
Repealed Eff. May 1, 2025.

10A NCAC 15 .0118 is repealed through readoption as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0118 OPTIONAL EARLY COMPLIANCE WITH SECTION .1600

History Note: *Authority G.S. 104E-7(a)(2); 104E-12(a);*
Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0118 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2025.

10A NCAC 15 .0201 is amended as published in 39:10 NCR 629-642 as follows:

SECTION .0200 - REGISTRATION OF RADIATION MACHINES: FACILITIES AND SERVICES

Codifier's Note: 10 NCAC 03G .2300 was transferred to 15A NCAC 11 .0200 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0201 PURPOSE AND SCOPE

(a) This Section provides for the registration of radiation ~~machines,~~ machines, radiation generating devices, ~~radiation machine~~ facilities, and persons providing other radiological services.

(b) ~~For purposes of this Section, "facility" means the location at which one or more radiation machines are installed or located within one building, vehicle, or under one roof and are under the same administrative control~~. A person who acquires, owns, possesses, or receives a radiation machine or radiation generating device before receiving a notice of registration in accordance with Rule .0209 of this Section is subject to the requirements of this Chapter.

(c) In addition to the requirements of this Section, all registrants are subject to the provisions in ~~of the other sections~~ Sections .0100, .1000, .1100, and .1600 of this Chapter.

~~(e)~~(d) ~~Special requirements for registration of particle accelerators are provided in Section .0900 of this Chapter and are in addition to the requirements of this Section.~~ Service providers using radiation machines for demonstration purposes or that provide mobile leasing services are subject to the additional requirements of Rule .0205 of this Section. Service providers that provide those services by bringing radiation machines or radiation generating devices from out state are subject to the additional requirements of Rule .0208 of this Section.

~~(f)~~(e) Emerging technologies for radiation machines and radiation generating devices that do not meet the equipment requirements of this Chapter are subject to the additional requirements in Rule .0212 of this Section.

~~(h)~~(f) Registrants using industrial radiographic machines are subject to the additional requirements of Section .0500 of this Chapter.

~~(d)~~(g) ~~In addition to the requirements of this Section, all registrants are subject to the annual fee provisions contained in Section .1100 of this Chapter.~~ Registrants using radiation machines for human and veterinary use are subject to the additional requirements in Section .0600 of this Chapter.

~~(g)~~(h) Registrants using radiation machines for non-human use at educational facilities, for forensic medicine, or by service providers for demonstration purposes are subject to the additional requirements of Section .0600 of this Chapter.

(i) Registrants using ionizing radiation generating devices are subject to the requirements of Section .0800 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-9(8); 104E-19(a);*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; July 1, 1982;

Transferred and Recodified from 15A NCAC 11 .0201 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019. 2019;
Amended Eff. May 1, 2025.

10A NCAC 15 .0202 is readopted with changes as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0202 EXEMPTIONS

(a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Section provided that the dose equivalent rate average over an area of ~~ten~~ 10 square centimeters does not exceed 0.5 mrem per hour at ~~five~~ 5 centimeters from any accessible surface of the equipment when any external shielding is removed. The production, testing, or factory servicing of such equipment is not exempt.

(b) ~~Radiation machines while in transit or storage incident thereto are exempt from the requirements of this Section.~~ The following are exempt from the requirements of this Section:

(1) all radioactive materials; and

(2) radiation machines while in transit.

(c) ~~Domestic television receivers are exempt from the requirements of this Section.~~ ~~[The agency may, upon application, grant individual exemptions or exceptions from the requirements of these Rules if it will not result in a radiation dose that exceeds the limits prescribed in these Rules for the protection of public health, safety, or property.]~~

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0202 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0203 is readopted with changes as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0203 ~~APPLICATION: REGISTRATION: RADIATION MACHINES: FACILITIES~~ APPLICATION FOR REGISTRATION PROCESS: GENERAL REQUIREMENTS FOR ALL FACILITIES, RADIATION MACHINES, AND SERVICES PROVIDED

~~(a) Each person having an unregistered radiation machine or facility shall:~~

~~(1) apply for registration of such facility and each radiation machine within 30 days following initial operation of that facility and each radiation machine. Application for registration shall be completed on agency forms and shall contain all information required by the forms and accompanying instructions. The registration of the first radiation machine at a facility constitutes registration of the facility itself.~~

~~(2) designate on the application form an individual who shall be responsible for radiation protection.~~

~~(b) Agency forms described in Subparagraph (a)(1) of this Rule require the following and other information:~~

~~(1) name, address and telephone number of the radiation machine facility;~~

~~(2) name of the person responsible for radiation protection in the facility;~~

~~(3) name, training and experience of the person designated in Subparagraph (a)(2) of this Rule;~~

~~(4) the manufacturer, model number, serial number and type of each radiation machine located within the facility;~~

~~(5) the date of the application and the signatures of the persons specified in Subparagraphs (b)(2) and (3) of this Rule.~~

(a) A person with an unregistered facility, radiation machine, radiation generating device, or an unregistered service provider, shall apply for registration with the agency. After submitting the required application forms prescribed by the agency in this Rule, registration of the first radiation machine, radiation generating device, or registration of services provided, constitutes registration of the facility or service provider.

(b) All application forms in this Rule shall be completed by meeting the following requirements:

(1) [~~The~~] An individual with administrative control and representative of the organization, of a radiation ~~machine or~~ machine, radiation generating device, or who[~~that~~] is responsible for providing services, shall ensure application forms, required by the agency in this Rule, meet the following requirements:

(A) are accurate, complete, and contain all the information required by the application forms and accompanying instructions; and

(B) submitted to the agency at the e-mail address on the application for registration forms or mailed to the address in Rule .0111 of this Chapter.

(2) Incomplete application forms or application forms submitted without the requested documentation to provide services, will not be processed.

(3) The agency may require additional information at any time after submission of the application to determine if the notice of registration should be issued or denied.

(4) Application forms can be found at https://radiation.ncdhhs.gov/Xray/applic.htm.

(c) A Business Application form shall be submitted prior to the operation of a facility or providing services in this state and the following additional requirements shall be met:

(1) The application shall be submitted by any person:

(A) with one or more radiation machines at a facility; or

(B) that plans to engage in services listed in Paragraphs (f) and (g) of this Rule.

(2) The application form requires the following:

(A) indication if the application is for a new facility, a change of ownership, [~~when a facility moves~~] relocation of a facility, or to update information by marking the corresponding checkbox;

(B) the legal business name, facility physical address, phone number, type of business, days and hours of operation;

(C) the name, title, mailing address, phone, and e-mail address of business manager;

(D) the name of the individual on-site who is responsible for radiation protection. The training and experience qualifying him or her to perform the job duties and responsibilities in Rule .0211 of this Section, shall be documented on the application;

(E) the name, title, mailing address, phone, and e-mail address for the invoice contact;

(F) description of facility use;

(G) description of service provider equipment;

(H) dated and signed by the owner or the individual with administrative control; and

(I) identify equipment forms included with the application form by marking the corresponding checkbox.

(d) Equipment application forms shall be submitted in accordance with Rule .0204(c)(1) through (5) of this Section, for the type of radiation machine or radiation generating device owned by the registrant or potential registrant or the service provided. The following additional requirements shall be met:

(1) The application shall be submitted by any person:

(A) with one or more unregistered radiation machines or radiation generating devices at a facility; or

(B) that is engaged in leasing or performing demonstrations using an unregistered radiation machine or radiation generating device.

(2) The application requires the following information:

(A) registration number;

(B) equipment location;

(C) manufacturer, model, serial number, number of tubes, install date, modality, application, type, and use;

(D) location of equipment not in use;

(E) installer information; and

(F) shall be dated and signed by the individual with administrative control. The individual with administrative control can delegate a responsible person or persons within the organization to sign when amendments are made to this form by notifying the agency in writing.

(e) A Delete X-Ray Equipment form shall be submitted when a facility disposes of a radiation machine or radiation generating device. The agency form requires the following information:

(1) registration number, facility name, and physical address;

(2) identify if the application is for a new facility, for a change of ownership, a facility [~~moves~~] relocates, or to update information;

(3) equipment location; manufacturer, model, serial number;

(4) identify the reason for deleting the equipment;

(5) the recipient of the equipment, to the individual or business name, physical and e-mail address, and phone number; and

(6) dated and signed by the owner or the individual with administrative control of the radiation machine or radiation generating device.

(f) A Company Service application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (C) of this Paragraph and the following additional requirements shall be met:

(1) The application shall be submitted by any person engaged in:

(A) direct sales, demonstration, leasing, or transfer of radiation machines or radiation generating devices;

(B) providing individual monitoring devices; and

(C) radiation survey equipment ~~calibrations.~~ calibrations, except when calibrations are performed by the manufacturer of the equipment.

(2) The application requires the following information:

(A) registration number;

(B) business name, facility physical address;

(C) identify if the application is for a new service provider, for a change of ownership, [~~if a facility moves~~] relocation of the facility, or to update information;

(D) identify each class and modality of services requested to be provided in the state;

(E) submit the requirements listed on the agency form for each class and modality requesting to provide services in the state;

(F) list any class or modality not listed on this form;

(G) description of service provider equipment used for output measurements and surveys; and

(H) signature of the individual with administrative control.

(g) A Company Employee Services application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (H) of this Paragraph and the following additional requirements shall be met:

(1) The application shall be submitted by any person engaged in providing the following services:

(A) area radiation surveys for diagnostic radiographic and fluoroscopy facilities;

(B) equipment surveys and shielding designs for radiation generating devices;

(C) general health physics consulting services to perform dose estimates, radiation output measurements, radiation safety program development, and radiation safety program training;

(D) installation or service repair of radiation machines or radiation generating devices;

(E) qualified expert consulting services for CT and mammography radiation machines;

(F) radiation protection expert;

(G) shielding designs for diagnostic radiographic and fluoroscopy facilities; and

(H) therapeutic facility and shielding design, area radiation survey, or calibration.

(2) The application requires the following information:

(A) name of the employee to be registered;

(B) start date if the employee is being added and the stop date if the employee is being removed from the registration;

(C) business registration number, name, physical address, and contact e-mail;

(D) [~~identify class~~] class identification and modality of services to be provided;

(E) training and experience to submit for each class of services to be provided;

(F) [~~the~~] date and signature of the employee applying for registration;

(G) [~~the~~] date and signature of the individual with administrative control; and

(H) [~~any~~] additional information the agency determines is necessary for evaluating the application for registration.

(h) Owners of radiation imaging systems and in-house personnel employed by a facility or corporation shall be exempt from the registration requirements in this Rule to provide services in NC provided such personnel:

(1) meets the education, or is supervised by an individual that meets, training, and experience requirements of the Class for the services provided;

(2) provides services at one facility or corporation; and

(3) provides requirements in Subparagraph (1) of this Rule, for agency review during inspection.

~~(h)~~(i) The following general requirements apply to all facilities and services provided in North Carolina.

(1) The registrant shall notify the agency when any change will render the information in an application for registration or notice of registration no longer accurate.

(2) A registrant that terminates all activities of radiation machines, radiation generating devices, or providing services shall meet the following requirements within 30 days:

(A) request termination of the notice of registration in writing by the owner or the individual with administrative control;

(B) submit to the agency, a delete a radiation machine or radiation generation device form, in accordance with Paragraph(e) of this Rule; and

(C) pay any outstanding fees pursuant to Section .1100 of this Chapter.

(3) A registrant shall not transfer the registration as part of a change of ownership.

(4) A person who takes possession of a radiation machine or radiation generating device because of bankruptcy, foreclosure, or state auction may possess the machine or device when the following additional requirements are met:

(A) The machine or device shall be posted stating that the new owner is responsible for registering with the agency if used in this state.

(B) If the machine or device is energized, it shall only be energized by someone registered in accordance with this Section and only to demonstrate that it is operable for sale or transfer.

(5) No person shall in any advertisement refer to the fact that his or her facility is registered with the agency pursuant to the provisions of Rule .0204 or .0205 of this Section, and no person shall state or imply that under such registration any activities have been approved by the agency.

History Note: *Authority G.S. 104E-7; 104E-12; 104E-20;*
Eff. February 1, 1980;
Amended Eff. May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0203 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0204 is readopted with changes as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0204 ~~PROHIBITED SERVICES AND INSTALLATION~~ FACILITY RESPONSIBILITIES

~~(a) Except as provided in Paragraph (b) of this Rule or otherwise authorized in writing by the agency, each person registered pursuant to Rule .0203 of this Section shall prohibit any person from furnishing equipment services described in Rule .0205(d) of this Section to his facility until such person provides evidence that he is currently registered with the agency as a provider of such services in accordance with Rule .0205 of this Section.~~

~~(b) No person registered pursuant to the provisions of Rule .0203 of this Section shall perform any services listed in Rule .0205(d) of this Section in his facility unless such person satisfies the applicable requirements in Rules .0205, .0213, and .0214 of this Section and has received written authorization from the agency to perform such services.~~

(a) All forms in this Rule shall be completed in accordance with Rule .0203 of this Section and any accompanying instructions.

(b) Shielding design requirements:

(1) Prior to construction for all new installations of radiation machines for ~~human~~ human, non-human, or veterinary use and prior to structural modification of existing installations, an applicant, shall have the floor plans, shielding specifications, and equipment arrangement reviewed by a registered service provider.

(2) The registrant shall submit the shielding design and the agency ~~shielding design review form~~ Shielding Design Review Form to the agency for review. The agency form shall include the following information:

(A) facility and service provider name, registration number, e-mail and physical address, and phone number;

(B) equipment location, manufacturer, status, kVp, mA, mA min per week, facility type; and

(C) proposed date of installation.

(3) A radiation machine shall not be installed until the applicant has received acknowledgment of the shielding design from the agency.

(4) A radiation machine shall not be replaced until the existing shielding design, acknowledged previously by the agency, is reviewed by a registered service ~~provider.~~ provider in accordance with Rule .0205. The registrant shall have a service provider review the acknowledged shielding design for the proposed radiation machine replacement to assess if the existing shielding meets the requirements of this Chapter. The documentation provided to the registrant from the service provider shall be submitted to the agency and maintained for agency review during inspection.

(5) The acknowledgment of such plans shall not preclude the requirement for additional modifications should a subsequent analysis of operating conditions indicate the possibility of a dose that exceeds the limits in Rule .1601 of this Chapter.

(6) Shielding designs are not required to be submitted for the following radiation machines:

[~~(A) bonedensitometry;~~]

(A)(~~B~~) dental handheld;

(B) dual x-ray absorptiometry (DEXA);

(C) mammography; or

(D) mobile or portable radiographic and fluoroscopic machines used in more than two locations.

(c) Facility registration

(1) Mobile radiation machines located and used in this state that are fixed in a vehicle or trailer shall meet the following requirements prior to use:

(A) [~~submit~~]have a shielding ~~design,~~ design submitted in accordance with Paragraph (a) of this ~~Rule,~~ Rule;~~[out-of-state fixed radiation machines used in a vehicle or trailer shall submit a shielding design with the Equipment Form application in Part (B) of this Subparagraph and maintain documentation for agency review during inspection~~]

(B) [~~submit~~]have an Equipment Form application submitted in accordance with Rule .0203 (d) of this Section. Radiation machines leased or on loan from a registered service provider shall register the radiation machine if used for more than 30 days;

(C) [~~submit~~] have a copy of the operating and safety procedures to protect patients, operators, and the public from radiation ~~[that exceeds doses in Rule .1601 of this Chapter;]~~submitted to the agency;

(D) receive a notice of registration from the agency; and

(E) the individual with administrative control shall ensure that radiation machines are operated in accordance with [~~Part (c)(4)(B) or (c)(5)(B) of this Section; and~~] Section .0600 of this Chapter.

~~[(F) in addition to the requirements of this Rule, out-of-state mobile radiation machines shall have a notice submitted to the agency in accordance with Rule .0208 of this Section.]~~

(2) Mobile radiation machines located out-of-state and brought into this state for use that are fixed in a vehicle or trailer shall meet the following requirements prior to use:

(A) have the requirements in Parts (c)(1)(A) through (c)(1)(D) of this Rule submitted as a complete document for agency review; and

(B) have a notice in submitted accordance with Rule .0208 of this Section and maintained for agency review during inspection.

(3)(~~2~~) Radiation machines for ~~human~~ human, non-human, or veterinary use shall meet the following additional requirements:

(A) have a shielding design acknowledged by the agency in accordance with Paragraph (b) of this Rule; and

(B) submit an Equipment Form application in accordance with Rule .0203 (d) of this Section within 30 days of use.

~~[(3) Radiation machines for clinical studies, research, and screenings shall meet the following additional requirements prior to use:~~

~~(A) submit a request in accordance with Rule .0213 of this Section; and~~

~~(B) receive a notice of acknowledgment and conditions for use from the agency to conduct the study.]~~

(4) Radiation generating devices in Section .0800 of this Chapter shall meet the following additional requirements prior to use:

(A) submit an Equipment Form application in accordance with Rule .0203(d) of this Section; and

(B) the individual with administrative control shall ensure operators are qualified in accordance with Rule .0800 of this Chapter to use the radiation generating device indicated on the equipment application.

(5) Industrial radiography radiation machines in Section .0500 of this Chapter shall meet the following additional requirements prior to use:

(A) submit an Equipment Form application in accordance with Rule .0203(d) of this Section; and

(B) the individual with administrative control shall ensure operators are qualified in accordance with Section .0500 of this Chapter to use the machines indicated on the equipment application.

(d) Persons registered pursuant to Paragraph (c) of this Rule shall notify the agency, using the Delete Radiation Machine or Radiation Generating Devices form, prior to disposition or the transfer of a registered radiation machine or radiation generating device to another person required to be registered pursuant to Paragraph (c) of this Rule.

(e) Persons registered pursuant to Paragraph(c) of this Rule shall prohibit any person from furnishing services described in Rule .0205(d) of this Section, at his or her facility, until such person provides evidence they are currently registered with the agency as a provider of such services in accordance with Rule .0205 of this Section.

(f) No person registered pursuant to the provisions of Paragraph (c) of this Rule shall perform any services listed in Rule .0205(d) of this Section in his or her facility unless such person meets the requirements in Rules .0205 and .0206 of this Section and has received written authorization from the agency to perform such services.

History Note: *Authority G.S. 104E-7; 104E-9(a)(3); 104E-12;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0204 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0205 is readopted with changes as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0205 ~~APPLICATION FOR REGISTRATION OF SERVICES~~ SERVICE PROVIDER RESPONSIBILITIES

(a) Each person who is engaged in the business of ~~installing or offering to install radiation machines and machine components or is engaged in the business of~~ furnishing or offering to furnish any ~~equipment~~ services listed in Paragraph ~~(d)~~ (e) of this Rule in this ~~state, to any agency licensee or registrant,~~ state or any agency registrant shall apply for registration of such services with the agency prior to furnishing or offering to furnish any of these services.

(b) ~~Application~~ Applications for registration shall be completed ~~on appropriate form(s) provided by the agency~~ in accordance with Rule .0203 of this Section and contain all information required by the agency as indicated on the form and accompanying instructions. ~~This information shall include:~~

~~(1) the name, address and telephone number of:~~

~~(A) the individual or the company to be registered;~~

~~(B) the owner(s) of the company;~~

~~(2) the description of the services to be provided;~~

~~(3) the name, training and experience of each person who provides services specified in Paragraph (d) of this Rule;~~

~~(4) the date of the application and the signature of the person responsible for the company; and~~

~~(5) any additional information the agency determines to be necessary for evaluation of the application for registration.~~

(c) Each person applying for registration ~~under~~ pursuant to Paragraph (a) of this Rule shall ~~certify~~ attest that he or she has read and understands the requirements of the rules in this ~~Chapter.~~ Chapter by signing the [~~company or employee services application.~~] Company Employee Services Form or Company Services Form application.

~~(d) For the purpose of this Section, equipment services include:~~

~~(1) direct sale and transfer of radiation machines and machine components to end users;~~

~~(2) installation or servicing of radiation machines and associated radiation machine components;~~

~~(3) diagnostic radiographic facility and shielding design;~~

~~(4) diagnostic fluoroscopic facility and shielding design;~~

~~(5) diagnostic area radiation survey, e.g., shielding evaluation;~~

~~(6) radiation instrument calibration;~~

~~(7) therapeutic facility and shielding design, area radiation survey or calibration;~~

~~(8) personnel dosimetry services; and~~

~~(9) general health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, non-healing arts facility and shielding design and area radiation surveys.~~

(d) Applicants for registration of services are subject to the requirements of Rules .0206 and .0207 of this Section.

~~(e) Applicants for registration of services are subject to the applicable requirements of Rules .0213 and .0214 of this Section.~~

(e) For purposes of this Section, services include:

(1)~~(2)~~ Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of radiation machines or radiation generating devices;

(2)~~(4)~~ Class II - ~~installation or service repair~~ installation, repair, or service [~~to include~~] of the following:

(A) radiation machines and machine components, including the making of diagnostic radiation output ~~measurements;~~ measurements, and performance verification; or

(B) radiation generating devices to include equipment surveys.

(3)~~(9)~~ Class III - shielding designs for diagnostic radiographic facilities;

(4) Class IV - shielding designs for diagnostic fluoroscopy facilities;

(5)~~(1)~~ Class V - area radiation surveys and shielding evaluations for diagnostic radiographic and fluoroscopy facilities;

~~[(5) manufacturer training for the use of radiation machines or radiation generating devices;]~~

(6)~~(8)~~ Class VI - radiation survey equipment calibrations;

(7)~~(10)~~ Class VII - therapeutic facility and shielding design, area radiation survey, or ~~calibration.~~ verification;

(8)~~(6)~~ Class VIII - providing individual monitoring devices;

(9)~~(3)~~ Class IX - general health and medical physics consulting to include the following services:

(A) equipment surveys and shielding designs for radiation generating devices;

(B) dose estimates;

(C) radiation output measurements;

(D) radiation safety program development; and

(E) radiation safety program training.

(f) Persons registered pursuant to [~~Subparagraph(e)(7) of this Rule shall have all surveys, reports, or other work performed, reviewed and signed by a general health or medical physicist registered in accordance with this Rule.~~] Subparagraph (e)(1) as a Class I service provider to provide mobile radiation machines that are fixed in a vehicle or trailer for demonstration purposes or that provides leasing services shall meet the following requirements prior to ~~use in this state:~~ use:

(A) [~~submit a shielding design in accordance with Rule .0204(a) of this Section, except out-of-state fixed radiation machines used in a vehicle or trailer shall submit a shielding design with the Equipment Form application and maintain documentation for agency review during inspection;~~] mobile radiation machines located and used in this state meet the requirements of Rules .0204(c)(1)(A) through (E) of this Section; and

(B) [~~submit an Equipment Form application in accordance with Rule .0203 (d) of this Section;~~] mobile radiation machines located out of state and brought into this state for use shall meet the requirements of Rules .0204(c)(2)(A) and (B) of this Section.

~~[(C) submit a copy of the operating and safety procedures to protect patients, operators, and the public from radiation that exceeds doses in Rule .1601 of this Chapter;~~

~~(D) receive a notice of registration from the agency; and~~

~~(E) in addition to the requirements of this Rule, out-of-state mobile radiation machines shall have a notice submitted to the agency in accordance with Rule .0208 of this Section.]~~

(g) Report of installation

(1) Persons registered pursuant to Paragraph (a) of this Rule who sell, install, transfer, lease, lend, or dispose ~~of, or install~~ of radiation machines in this state shall, within 15 days after each calendar quarter, notify the agency at XrayNORS@dhhs.nc.gov or the address in accordance with Rule .0111 of this Chapter of the following:

(A) whether any radiation machines were directly sold, disposed of, installed, leased, loaned, or transferred during the calendar quarter;

(B) the name and address of persons who received radiation machines during the calendar quarter;

(C) the manufacturer, model, and serial number of each radiation machine [~~transferred or~~] directly sold, disposed of, installed, leased, loaned, or transferred during the calendar quarter; and

(D) the [~~transfer~~]date of disposition, installation, lease, loan, sale, or transfer of each radiation ~~machine.~~ machine during the calendar quarter.

(2) The information specified in Parts (g)(1)(A) through (D) of this Rule may be omitted from the quarterly reports when the following requirements are met:

(A) for any diagnostic x-ray system that contains certified components, when a copy of the assembler's report prepared in compliance with 21 CFR 1020.30(d) is submitted to the agency; or

(B) for radiation machines for nonhuman use and radiation generating devices, when a Report of Sale and Installation [~~pursuant to~~] form prepared in accordance with Paragraph (i) of this Rule is submitted to the agency.

(h) A Report of Sale and Installation ~~report of sale and installation of~~ for radiation machines for nonhuman use or radiation generating devices can be found at https://radiation.ncdhhs.gov/Xray/documents/rptofassembly.pdf and shall include the following information:

(1) facility registration number, street address, city, state, and telephone number;

(2) service provider registration number, company name, street address, city, state, and telephone number;

(3) identify if the radiation machine or the radiation generating device was sold or installed by checking the corresponding checkbox;

(4) identify the system type by checking the corresponding checkbox;

(5) room location, ~~date of sale or installation;~~

(6) date of sale or installation;

~~(6)~~(7) manufacturer, serial number, and control model number;

~~(7)~~(8) the seller's signature or signature of the individual responsible for installation; and

~~(8)~~(9) the date signed.

(i) No person registered pursuant to Paragraph (a) of this Rule for x-ray sales or installations shall not make, sell, assemble, install, lease, lend, [~~assemble~~] or transfer radiation machines, radiation machine components, or radiation generating devices unless such machines and devices when placed in operation shall meet the requirements of these Rules.

(j) No person registered pursuant to Rule .0205 of this Section shall install radiation machines that are subject to provisions of Section .0600 of this Chapter unless the registrant first determines that the agency has issued a written acknowledgment of a shielding design in accordance with Rule .0204(b) of this Section.

(k) Tests performed at the time of installation [~~for fluoroscopy machine output measurement and radiation generating devices equipment surveys,~~] demonstrating the requirements of these Rules are met, shall be provided to the registrant [~~at the time of installation.~~]for agency review during inspection for the following:

(1) fluoroscopy machine output measurement; and

(2) radiation generating devices equipment surveys.

(l) Records of any routine maintenance, repair, alterations, or reassembly of radiation machines or radiation generating devices shall:

(1) include the date that the service was performed and a legible signature of the person performing the service; and

(2) be provided to the registrant [~~when the service is provided.~~] for agency review during inspection.

History Note: *Authority G.S. 104E-7; 104E-12; 104E-20;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1992; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0205 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0206 is readopted with changes as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0206 ~~REPORTS OF INSTALLATION~~ TRAINING AND EDUCATIONAL REQUIREMENTS TO PROVIDE SERVICES

~~(a) Persons, registered pursuant to Rule .0205 of this Section, who sell, lease, transfer, lend, dispose of, assemble or install radiation machines in this state shall, within 30 days after each calendar quarter, notify the agency at the address in Rule .0111 of this Chapter, of:~~

~~(1) whether any radiation machines were installed, transferred, or disposed of during the calendar quarter;~~

~~(2) the name and address of persons who received radiation machines during the calendar quarter;~~

~~(3) the manufacturer, model and serial number of each radiation machine transferred or disposed of;~~

~~(4) the date of transfer of each radiation machine.~~

~~(b) The information specified in Subparagraphs (a)(2), (3) and (4) of this Rule may be omitted from the quarterly reports required in (a) of this Rule for any diagnostic x-ray system which contains certified components when a copy of the assembler's report prepared in compliance with 21 CFR 1020.30(d) is submitted to the agency.~~

(a) A person registered qualified to provide services pursuant to Rule .0205 of this Section shall be qualified by reason of education, training, and experience to provide the services for which registration is requested. The following are the minimum qualifications for ~~[specific types of services:]~~ each service class:

(1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of radiation machines or radiation generating devices: The applicant shall certify all persons providing services are knowledgeable, familiar, and comply with the rules which govern the possession, installation, and use of radiation machines in North Carolina.

(2) Class II - installation or service to verify performance associated with the installation or service:

(A) manufacturer's equipment school for service, maintenance, and installation for the type of radiation machine used for dental hand-held, intraoral, and extra-oral, medical diagnostic, or medical fluoroscopic or equivalent training;

(B) training in basic principles of radiation protection; and

(C) three months of experience in the installation and service of radiation machines and machine components services are required.

(3) Class III –shielding design for diagnostic radiographic facilities:

(A) training in basic principles of radiation protection;

(B) training in shielding design for each modality registering to provide services; and

(C) one year of experience in diagnostic radiographic facility and shielding for the specific type of machine application.

(4) Class IV - shielding design for diagnostic fluoroscopic facilities:

(A) training in basic principles of radiation protection;

(B) training in shielding design for each modality registering to provide services; and

(C) one year of experience in diagnostic fluoroscopic facility and shielding for ~~[the specific]~~ each type of machine application.

(5) Class V - area radiation surveys and shielding evaluation for diagnostic radiographic and fluoroscopy facilities:

(A) training in basic principles of radiation protection;

(B) training in shielding evaluation for each modality registering to provide services; and

(C) one year of experience performing area radiation surveys for ~~[the specific]~~ each type of machine application.

(6) Class VI - radiation instrument calibration: The applicant must possess a current radioactive materials license or registration authorizing radiation instrument calibration.

(7) Class VII - therapeutic facility and shielding design, area radiation survey, or verification:

(A) certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics;

(B) certification by the American Board of Medical Physics;

(C) doctorate degree in medical physics or related field; or

~~(C)~~(D) have a master's degree in physics, biophysics, radiological physics, nuclear engineering, or health physics, one year of full-time training in therapeutic radiological physics, one year of full-time experience in a therapeutic facility including personal calibration and spot-check of at least one machine, submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed, submit a copy of all forms, reports, and documents that will be supplied to customers; and submit one sample of each specific type of therapy modality service provided.

(8) Class VIII – providing individual monitoring dosimetry: The applicant must hold current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology or use NVLAP-accredited dosimetry.

(9) Class IX - general health or medical physics consulting shall be performed by a person meeting one of the following requirements:

(A) certified by the American Board of Health Physics in health physics in the appropriate field or specialties for services provided;

(B) certified by the American Board of Medical Physics;

(C) certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, x-ray and radium physics; or

(D) hold a master's or doctorate in physics, medical physics, other physical science, engineering, or applied mathematics, from an accredited college or university and have 40 hours of practical training or supervised experience in x-ray physics.

~~[(10) Class X - radiation protection expert:~~

~~(A) having education and experience equivalent to a graduate or a master's degree from an accredited college or university in radiation protection, radiation safety, biology, chemistry, engineering, physics, or a closely related physical or biological science; and~~

~~(B) acquired competence in radiation protection, by receiving special studies, training, and practical experience. Such special studies and training must have been sufficient in the above sciences to provide the understanding, ability, and competency.]~~

(b) Any person registered to provide Class IX services prior to the effective date of this rule and holding a baccalaureate degree in physical science of physics, chemistry, or radiologic science, engineering or related field, and having two years of progressive experience in medical or health physics or two years of graduate training in medical or health physics is exempt from the requirements in Parts (a)(9)(A) through (D) of this Rule, provided he or she is in good standing with the agency.

(c) The agency shall initiate action to terminate the registration of any person who fails to meet the requirements of this Rule.

History Note: *Authority G.S. 104E-7; ~~104E-12;~~ 104E-13;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0206 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0207 is readopted with changes as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0207 ~~ISSUANCE OF NOTICE OF REGISTRATION~~ ADDITIONAL REQUIREMENTS TO PROVIDE SERVICES

~~(a) The agency shall issue a notice of registration upon a determination that an applicant:~~

~~(1) is qualified by reason of education, training or experience in the use and hazards of radiation sources described in the application for registration;~~

~~(2) has facilities and equipment which meet the requirements in these Rules;~~

~~(3) has established a radiation protection program, appropriate to the registered activities, which assures compliance with radiation protection requirements in these Rules; and~~

~~(4) meets the applicable requirements in this Chapter.~~

~~(b) The agency may, by registration condition or order, when not in conflict with any law, waive any requirement in these Rules or impose requirements with respect to the registrant's receipt, possession, use and transfer of radiation machines as the agency deems appropriate or necessary for compliance with the rules in this Chapter. Such additional requirements are subject to appeal under 15A NCAC 1B .0200.~~

~~(c) The agency may refuse to grant a registration required in Rules .0203 and .0205 of this Section to any applicant who does not possess adequate qualifications or equipment or satisfy the applicable requirements in this Chapter; provided that, before any order is entered denying an application for registration, the agency shall give notice and grant a hearing as provided in G.S. 150B.~~

(a) A person applying for registration [~~of~~] to perform Class - II or Class - IX services for diagnostic radiation output measurements, Class - V area radiation surveys and shielding evaluations for diagnostic radiographic and fluoroscopy facilities, or Class -VII therapeutic area radiation survey or verification [~~calibration~~]services pursuant to Rule .0205 of this Section shall meet the following additional requirements:

(1) [~~The applicant shall~~] have radiation survey and radiation measurement equipment appropriate to the services requested for authorization;

(2) [~~The applicant shall~~] ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated [~~at least every 12 months by a person registered to provide such services pursuant to Rule .0205 of this Section, except as provided in Subparagraph (a)(3) of this Rule. The agency may approve less frequent calibration of equipment used, provided the applicant satisfies to the agency that the proposed frequency and procedures will provide equivalent or better assurance of proper calibration.~~] according to the manufacturer or the American Association of Physicists in Medicine (AAPM) standards;

~~[(3) The applicant may perform the equipment calibrations required in Subparagraph (a)(2) of this Rule provided that:~~

~~(A) such calibrations are current and traceable to the National Institute of Standards and Technology;~~

~~(B) calibration procedures are approved by the agency;~~

~~(C) radiation sources used for such calibration are licensed or registered as required by the rules in this Chapter; and~~

~~(D) the equipment is labeled to indicate the date of calibration and records of the calibration are maintained.~~

~~(4) The applicant shall submit:~~

~~(A) a description of the procedures that will be used in performing area radiation surveys including a list of all guides and references to the employed;~~

~~(B) a copy of all forms, reports, and documents that will be supplied to customers;~~

~~(C) samples of three different types of surveys;~~

~~(D) samples of three reports of diagnostic radiation output measurements; and~~

~~(E) samples of three therapeutic kV imaging calibration reports.~~

~~(b) A person applying for registration of diagnostic radiographic, fluoroscopic, and therapeutic facility and shielding design services shall meet the following additional requirements:~~

~~(1) The applicant shall submit examples of the facility and shielding design which will be provided to registrants.~~

~~(2) The applicant shall submit examples of the calculations, which will be performed as part of the facility and shielding design, along with any guides, occupancy factor rationales, and workload estimation rationales, that will be used.~~

~~(3) The applicant shall ensure that the facility and shielding design services provided to registrants of the agency meet the requirements in this Chapter.]~~

(3) submit the following for agency review prior to registration:

(1) a description of the procedures that will be used in performing area radiation surveys including a list of all guides and references to the employed;

(2) a copy of all forms, reports, and documents that will be supplied to registrants;

(3) samples of surveys for each modality requested for registration;

(4) samples of reports of diagnostic radiation output measurements for each modality requested for registration; and

(5) samples of calibration reports for each therapeutic and kV imaging modality requested for registration.

(b) A person applying for registration to perform Class -IX equipment calibrations shall meet the following requirements:

(1) ensure such calibrations are current and traceable to the National Institute of Standards and Technology;

(2) license or register radiation sources used for such calibration as required by the rules in this Chapter;

(3) label the equipment to indicate the date of calibration; and

(4) maintain records of the calibration.

(c) A person applying for registration to perform Class III - shielding designs for diagnostic radiographic facilities, Class IV - shielding designs for diagnostic fluoroscopy facilities, and Class -VII therapeutic facilities and shielding design services shall meet the following additional requirements:

(1) submit examples of the facility and shielding design which will be provided to registrants;

(2) submit any technical guides, methodology, occupancy factor rationales, and workload estimation rationales that will be used; and

(3) ensure that the facility and shielding design services provided to registrants meet the requirements in this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0207 Eff. February 1, 2015.
Readopted Eff. May 1, 2025.

10A NCAC 15 .0208 is amended as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0208 ~~PRIOR NOTIFICATION OF TRANSFER~~ OUT-OF-STATE RADIATION MACHINES AND RADIATION GENERATION DEVICES

~~(a) Persons registered pursuant to Rule .0203 of this Section shall notify the agency in writing prior to transfer of a registered radiation machine to another person required to be registered pursuant to Rule .0203(a) of this Section. This Rule does not prohibit transfer without prior notification to sales and service companies registered pursuant to Rule .0205 of this Section.~~

~~(b) The notification shall include:~~

~~(1) the name and address of the transferee, and~~

~~(2) the manufacturer, model number and serial number of the radiation machine to be transferred.~~

(a) No person shall bring any radiation machine or radiation generating device into the state, for any temporary use, unless such person has given a written notice to the agency at least five working days prior to use in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine or radiation generating device will be used. If, for a specific case, the five working day period would impose an undue hardship on the person, he or she may, upon application to the agency, obtain permission to proceed sooner.

(b) A person bringing a radiation machine or radiation generating device into this state, for any temporary use, shall meet the following requirements:

(1) complete the registration process in accordance with Rules .0203, .0204, and .0205 of this Section prior to beginning operations in this state;

(2) supply the agency with other information the agency may reasonably request; and

(3) comply with the Rules of this Chapter.

(c) The out of state registrant shall maintain with the radiation machine or radiation generating device, when located and used in this state, the following:

(1) the current notice of registration from this agency;

(2) a copy of the notice submitted to the agency in accordance with Paragraph (a) of the Rule;

(3) the shielding design, if required, in accordance with Rule .0204(c)(1)(A) of this Section; and

(4) a copy of the out of state registrant's operating and safety procedure.

(d) An inspection may be conducted by an authorized representative of the agency on any radiation machine or radiation generating device used in this state.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0208 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;

Amended Eff. May 1, 2025.

10A NCAC 15 .0209 is readopted as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0209 ~~REPORT OF CHANGES~~ ISSUANCE OF NOTICE OF REGISTRATION

~~Any registrant shall notify the agency in writing when any change will render the information contained in the application for registration or notice of registration no longer accurate.~~

(a) The agency shall issue a notice of registration upon a determination that an applicant:

(1) is qualified by reason of education, training, or experience in the use and hazards of radiation sources described in the application for registration;

(2) has facilities and equipment which meet the requirements in these Rules;

(3) has established a radiation protection program, appropriate to the registered activities, which assures compliance with radiation protection requirements in these Rules; and

(4) meets the applicable requirements in this Chapter.

(b) The agency may, by registration condition or order, when not in conflict with any law, waive any requirement in these Rules or impose requirements with respect to the registrant's receipt, possession, use, and transfer of radiation machines or radiation generating devices as the agency deems appropriate or necessary for compliance with the rules in this Chapter.

(c) The agency may refuse to grant a registration required in Rules .0203, .0204, and .0205 of this Section to any applicant who does not possess adequate qualifications or equipment or satisfy the applicable requirements in this Chapter; provided that, before any order is entered denying an application for registration, the agency shall give notice and grant a hearing as provided in G.S. 150B.

History Note: *Authority G.S. 104E-7; ~~104E-12;~~*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0209 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0210 is readopted as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0210 ~~OTHER PROHIBITED ACTIVITIES~~ MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRATIONS

~~(a) No person registered pursuant to Rule .0205 of this Section for x-ray sales or installations shall make, sell, lease, transfer, lend, assemble, or install radiation machines or equipment used in connection with such machines unless such machines and equipment when placed in operation shall meet the applicable requirements of these Rules.~~

~~(b) No person, in any advertisement, shall refer to the fact that he or his facility is registered with the agency pursuant to the provisions of Rule .0203 or .0205 of this Section and no person shall state or imply that any activity under such registration has been approved by the agency.~~

~~(c) No person registered pursuant to Rule .0205 of this Section shall install radiation machines which are subject to provisions of Section .0600 of this Chapter unless the registrant first determines that the agency has issued written acknowledgement of receipt of any facility and shielding design required in Rule .0603 of this Chapter.~~

(a) The terms and conditions of all registrations are subject to amendment, revision or modification and all registrations are subject to suspension or revocation by reason of:

(1) rules adopted pursuant to provisions of the Act; or

(2) orders issued by the agency pursuant to provisions of the Act and rules adopted pursuant to provisions of the Act.

(b) Any registration may be revoked, suspended, or modified in whole or in part:

(1) for any materially false statement in the application or in any statement of fact required by provisions of this Section;

(2) because of conditions that would warrant the agency to refuse to grant registration on the original application revealed by:

(A) the application;

(B) any statement of fact;

(C) any report, record, inspection, or other means; or

(3) for violations of, or failure to observe any of the terms and conditions of the Act, the registration, the rules of this Chapter, or the order of the agency.

(c) Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, prior to the institution of proceedings for modification, revocation, or suspension of a registrant, the agency shall:

(1) call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and

(2) provide an opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

(d) Before any order is entered suspending, revoking, or modifying a registration, the agency shall give notice and grant a hearing as provided in Chapter 150B of the North Carolina General Statutes.

(e) The agency may terminate a registration upon written request submitted by the registrant to the agency.

History Note: *Authority G.S. 104E-7; ~~104E-20;~~ 104E-13;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0210 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0211 is amended with changes as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0211 ~~OUT OF STATE RADIATION MACHINES~~ ~~REQUIREMENTS AND RESPONSIBILITIES FOR~~ THE INDIVIDUAL RESPONSIBLE FOR RADIATION PROTECTION REQUIREMENTS AND RESPONSIBILITIES

~~(a) No person shall bring any radiation machine into the state, for any temporary use, unless such person has given a written notice to the agency at least five working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine is to be used. If, for a specific case, the five working day period would impose an undue hardship on the person, he may, upon application to the agency, obtain permission to proceed sooner.~~

~~(b) The person in Paragraph (a) of this Rule shall:~~

~~(1) comply with all applicable rules in this Chapter, including registration pursuant to Rule .0203 of this Section; and~~

~~(2) supply the agency with such other information as the agency may reasonably request.~~

(a) A person applying for registration shall designate an individual responsible for radiation protection on the Business Application form pursuant to Rule .0203(c) of this Section. The qualified individual, ~~[shall be qualified]~~ which can be an actively registered radiologic technologist, shall be on site and be qualified by reason of education, training, and experience. ~~experience [commensurate with the registration requested.]~~ The following are the minimum qualifications that must be met to carry out the job duties:

(1) training in basic radiation protection principles;

(2) completed educational courses relating to ionizing radiation;

(3) know potential radiation hazards and emergency precautions; and

(4) training and experience in and knowing the proper use of the type of equipment used.

(b) The individual shall be responsible for the following:

(1) Establishing and overseeing operating and safety procedures:

(A) that maintain radiation exposures as low as reasonably achievable (ALARA); and

(B) to review the procedures annually, or when changes occur to ensure the procedures are current.

(2) Ensuring individual monitoring devices are used in accordance with these Rules by occupationally exposed personnel and records of monitoring results shall be:

(A) reviewed;

(B) maintained; and

(C) notifications are made in accordance with Rule .1601 of this Chapter.

(3) Ensuring that personnel are complying with:

(A) this Chapter;

(B) the conditions of the notice of registration; and

(C) the operating and safety procedures of the registrant.

(4) Knowing:

(A) the management policies and administrative procedures of the registrant; and

(B) keeping management informed of the registrant's radiation protection program.

~~[(5) Investigating and reporting to the agency:~~

~~(A) known or suspected radiation exposure to an individual; or~~

~~(B) radiation levels that exceed the limits in this Chapter.]~~

~~(6)~~(5) Assuming control and having the authority to carry out corrective actions including stopping operations in emergencies or unsafe conditions.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0211 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended Eff. May 1, 2025.

10A NCAC 15 .0212 is amended with changes as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0212 ~~**MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRANTS**~~ **EMERGING TECHNOLOGIES NOT MEETING EXISTING EQUIPMENT REQUIREMENTS**

~~(a) The terms and conditions of all registrations are subject to amendment, revision or modification and all registrations are subject to suspension or revocation by reason of:~~

~~(1) rules adopted pursuant to provisions of the Act; or~~

~~(2) orders issued by the agency pursuant to provisions of the Act and rules adopted pursuant to provisions of the Act.~~

~~(b) Any registration may be revoked, suspended or modified in whole or in part:~~

~~(1) for any material false statement in the application or in any statement of fact required by provisions of this Section;~~

~~(2) because of conditions which would warrant the agency to refuse to grant a registration on original application revealed by:~~

~~(A) the application;~~

~~(B) any statement of fact;~~

~~(C) any report, record, inspection or other means; or~~

~~(3) for violations of, or failure to observe any of the terms and conditions of the Act, the registration, the rules of this Chapter, or order of the agency.~~

~~(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for modification, revocation or suspension of a registrant, the agency shall:~~

~~(1) call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and~~

~~(2) provide an opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.~~

~~(d) Before any order is entered suspending, revoking or modifying a registration, the agency shall give notice and grant a hearing as provided in Chapter 150B of the North Carolina General Statutes.~~

~~(e) The agency may terminate a registration upon written request submitted by the registrant to the agency.~~

(a) Radiation machines or radiation generating devices that [~~are not able~~] do not meet the [~~equipment requirements of these Rules~~] radiation machine requirements Section .0600 of this Chapter or radiation generating devices in Rule .0807 of this Chapter shall not be sold, installed, or used prior to the agency completing a review of information regarding the radiation machine and determining if the use of the radiation machine is allowed. The user or manufacturer of the radiation machine shall submit the following to the agency for review:

(1) an equipment application form in accordance with Rule .0204(c) of this Section;

(2) the manufacturer manual;

(3) description of intended use;

(4) operator training provided to the end user;

(5) an independent equipment survey to include the following:

(A) all equipment settings available to the operator;

(B) output at the highest setting; and

(C) leakage radiation around the radiation machine.

(6) an area survey to include the following:

(A) radiation levels in adjacent areas, the operator location, and annual exposure to an operator;

(B) the survey instrument used; and

(C) the name and legible signature of the person who performed the ~~survey; and~~ survey.

(7) the hazard level associated with the use of the RGD.

(b) After receiving the information in Paragraph (a) of this Rule, the agency will respond to the applicant in writing within 90 days. Upon review, the agency may require additional information to determine if the radiation machine is allowed for use.

History Note: *Authority G.S. 104E-7; ~~104E-13;~~ 104E-20;*
Eff. June 1, 1989;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0212 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended Eff. May 1, 2025.

10A NCAC 15 .0306 is readopted as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0306 ~~**TYPES OF LICENSES: GENERAL AND SPECIFIC**~~ **SPECIFIC LICENSES: SEALED SOURCES IN INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS**

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

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

(a) Persons conducting industrial radiography using radioactive materials shall comply with the requirements of 10 CFR 34, which are hereby incorporated by reference including subsequent amendments and editions, except for: 10 CFR 34.5, 34.8, 34.121, and 34.123. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part034/.

(b) Applications required by 10 CFR 34 shall be made on forms provided by the agency. Applications and supporting material shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of this Chapter in lieu of the NRC:

(1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive materials licenses, shall submit an Application for Radioactive Materials License. The following information shall appear on the application:

(A) legal business name and mailing address;

(B) physical address(es) where radioactive material shall be used or possessed. The application shall indicate if radioactive materials shall be used at temporary jobsites;

(C) the name, telephone number, and e-mail address of the Radiation Safety Officer;

(D) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, the application may so state;

(E) the application shall indicate if the application is for a new license, or for the renewal of an existing license, by marking the corresponding check box;

(F) if the application is for the renewal of an existing license, the license number shall be provided on the application;

(G) applicants shall indicate the type and category of license as shown on the form by marking the corresponding check box; and

(H) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee, who is authorized by the licensee to sign license applications on behalf of the business or licensee.

(2) Persons applying for an amendment to an existing license shall submit an Application for Amendment of Radioactive Materials and Accelerator Licenses. The following information shall appear on the application:

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

(D) licensee name as it currently appears on the license;

(E) the name, telephone number, and e-mail address of the Radiation Safety Officer;

(F) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, item 5b on the application may be left blank;

(G) applicants shall provide a description of the action requested by marking the corresponding checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief description of the action requested in the space provided in item 6b;

(H) explanation of the action requested; and

(I) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee who is authorized by the licensee to sign license applications on behalf of the business or licensee.

(3) Applications specified in this Rule are available at: www.ncradiation.net/rms/rmsforms2.htm(Rev01).htm

(c) Reports of leaking sealed sources required by 10 CFR 34.27 shall be made to the agency at the address shown in Rule ~~.0111~~ .0111(a) of this Chapter in lieu of the NRC.

(d) Notifications required by 10 CFR 34.101, including notifications of source disconnects, shall be made to the agency at the address shown in Rule ~~.0111~~ .0111(a) of this Chapter in lieu of the NRC. In addition to the information required by 10 CFR 34.101(b), notifications of devices with failed or worn through S-tubes shall contain the serial number and storage location of the device, whether the device has been disposed of or returned to the manufacturer, and whether personnel contamination occurred.

(e) Requests for exemption under 10 CFR 34.111 shall be made to the agency as specified in Paragraph (b) of this Rule.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 2005;
Transferred and Recodified from 15A NCAC 11 .0306 Eff. February 1, ~~2015.~~ 2015;

Readopted Eff. May 1, 2025.

10A NCAC 15 .0311 is readopted with changes as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0311 ~~GENERAL LICENSES: LUMINOUS SAFETY DEVICES~~ PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

~~(a) A general license shall be issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:~~

~~(1) each device contains not more than ten curies of tritium or 300 millicuries of promethium-147; and~~

~~(2) each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.~~

~~(b) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in Paragraph (a) of this Rule are exempt from the requirements of Sections .1000 and .1600 of this Chapter except for Rules .1645 and .1646 of this Chapter.~~

~~(c) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.~~

~~(d) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.~~

~~(e) The general license provided in Paragraphs (a) and (b) of this Rule are subject to the provisions of Rules .0107 to .0111, .0303(a), .0338, .0343, .0344 and .0346 of this Chapter.~~

(a) All persons packaging, preparing for transport, or transporting radioactive materials shall comply with the provisions of 10 CFR 71, which are hereby incorporated by reference including subsequent amendments and editions, as follows;

(1) 10 CFR 71.0, "Purpose and scope;"

(2) 10 CFR 71.1, "Communications and records;" except that communications, notices, and reports required by this Rule shall be sent to the addresses shown in Rule .0111 of this Chapter unless directed otherwise by the agency, in lieu of the NRC;

(4) 10 CFR 71.3, "Requirement for license;"

(5) 10 CFR 71.4, "Definitions;"

(6) 10 CFR 71.5, "Transportation of licensed material;"

(7) 10 CFR 71.7(a), "Completeness and accuracy of information;"

(8) 10 CFR 71.8, "Deliberate misconduct;"

(9) 10 CFR 71.12, "Specific exemptions;"

(10) 10 CFR 71.13, "Exemption of Physicians;"

(11) 10 CFR 71.14(a), "Exemption for low-level materials;"

(12) 10 CFR 71.15, "Exemption from classification as fissile material;"

(13) 10 CFR 71.17, "General license: NRC-approved [~~package;"~~] package," except that quality assurance program approval required by 10 CFR 71.17(b) shall be issued by the agency in lieu of the NRC. Notifications required by 10 CFR 71.17(c) shall be made to the agency as required by Subparagraph (2) of this Paragraph and to the NRC in accordance with 71.17(c)(3);

(14) 10 CFR 71.21, "General license: Use of foreign approved package;"

(15) 10 CFR 71.22, "General license: Fissile material;"

(16) 10 CFR 71.23, "General license: Plutonium-beryllium special form material;"

(17) 10 CFR 71.47, "External radiation standards for all packages;"

(18) 10 CFR 71.81, "Applicability of operating controls and procedures;"

(19) 10 CFR 71.83, "Assumptions as to unknown properties;"

(20) 10 CFR 71.85(d), "Preliminary determinations;"

(21) 10 CFR 71.87, "Routine determinations;"

(22) 10 CFR 71.88, "Air transport of plutonium;"

(23) 10 CFR 71.89, "Opening instructions;"

(24) 10 CFR 71.91(a), (c) through (d), "Records;"

(25) 10 CFR 71.93, "Inspection and tests;"

(26) 10 CFR 71.95, "Reports;"

(27) 10 CFR 71.97, "Advance notification of shipment of irradiated reactor fuel and nuclear waste." Advanced notifications required by this Subparagraph shall be made [to the NRC as required by 10 CFR 71(c)(iii) and] to the Governor's designee [~~in lieu of the NRC~~] as follows:

(A) designee: N.C. Highway Patrol Headquarters, Operations Officer;

(B) mailing address: P.O. Box 27687, Raleigh, North Carolina 27611-7687;

(C) telephone: (919) 733-4030 from 8 a.m. to 5 p.m. Monday through Friday except State holidays, and (919) 733-3861 at all other times.

(28) 10 CFR 71.101(a) through (c)(1), (f), (g), "Quality assurance requirements." The quality assurance plan required by 10 CFR 71.101(c)(1) shall be submitted to the agency for review and approval in lieu of the NRC;

(29) 10 CFR 71.103, "Quality assurance organization," except that certificates of compliance shall be issued by the NRC in lieu of the agency;

(30) 10 CFR 71.105, "Quality assurance program;"

(31) 10 CFR 71.106, Changes to quality assurance program;"

(32) 10 CFR 71.127, "Handling, storage, and shipping control;"

(33) 10 CFR 71.129, "Inspection, test, and operating status;"

(34) 10 CFR 71.131, "Nonconforming materials, parts, or components;"

(35) 10 CFR 71.133, "Corrective action;"

(36) 10 CFR 71.135, "Quality assurance records;"

(37) 10 CFR 71.137, "Audits;"

(38) Appendix A to 10 CFR 71, "Determination of A_1 and A_2;"

(39) Table A-1 of Appendix A to 10 CFR 71, "A_1 and A_2 Values for Radionuclides;"

(40) Table A-2 of Appendix A to 10 CFR 71, "Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides," and

(41) Table A-3 of Appendix A to 10 CFR 71, "General Values for A_1 and A_2."

(b) Requests for a specific exemption from this Rule as permitted by 10 CFR 71.12 shall be made on the licensee's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:

(1) licensee name;

(2) license number;

(3) name of the individual requesting the exemption;

(4) contact information for the individual requesting the exemption;

(5) a description of the exemption being requested; and

(6) an explanation describing why the exemption is necessary.

(c) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part071/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0311 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0313 is readopted with changes as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0313 ~~OWNERSHIP OF RADIOACTIVE MATERIAL~~ EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

~~A general license shall be issued to own radioactive material without regard to quantity. This general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.~~

(a) All persons using byproduct material, source material, or special nuclear material shall comply with the provisions of 10 CFR 150, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) 10 CFR 150.1, "Purpose;"

(2) 10 CFR 150.2, "Scope;"

(3) 10 CFR 150.3, "Definitions," except that the [~~term~~] [terms] "foreign obligations" [and "reconciliation"] shall not apply;

(4) 10 CFR 150.4, "Communications," except that questions about this Rule and communications and reports required by this Rule shall be sent to the address shown in Rule .0111(a) of this Chapter unless directed otherwise by the agency, in lieu of the NRC;

(5) 10 CFR 150.11, "Critical Mass;"

(6) 10 CFR 150.20, "Recognition of Agreement State licenses;"

(7) 10 CFR 150.31, "Requirements for Agreement State regulation of byproduct material," and

(8) 10 CFR 150.32, "Funds for reclamation or maintenance of byproduct material;"

(b) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part150/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0313 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0316 is repealed through readoption as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0316 GENERAL LICENSES: TRANSPORTATION

History Note: *Authority G.S. 20-167.1; 104E-7; 104E-10(b); 104E-15(a);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992; October 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0316 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2025.

10A NCAC 15 .0323 is repealed as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0323 SPECIFIC LICENSES: SEALED SOURCES IN INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. April 1, 1999; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0323 Eff. February 1, 2015;
Readopted Eff. May 1, ~~2023.~~ 2023;
Repealed Eff. May 1, 2025.

10 NCAC 15 .0345 and .0346 are repealed through readoption as published in 39:05 NCR 187-208 as follows:

10A NCAC 15 .0345 RECIPROCAL RECOGNITION OF LICENSES

10A NCAC 15 .0346 PREPARATION OF RADIOACTIVE MATERIAL FOR TRANSPORT

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-15(a);*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1993; November 1, 1989; October 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0345, .0346 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2025.

Rule 10A NCAC 15 .1001 is amended as published in 39:05 NCR 187-208 as follows:

SECTION .1000 - NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS

Codifier's Note: 10A NCAC 03G .3100 was transferred to 15A NCAC 11 .1000 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .1001 NOTICES, INSTRUCTIONS, AND REPORTS TO EMPLOYEES

(a) Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed under the rules in Sections .0300, .0900, .1200, and .1300 of this Chapter shall comply with the provisions of 10 CFR 19 as follows, which are hereby incorporated by reference including subsequent amendments and editions, except that references to and requirements for 10 CFR 2, 50, 52, 54, 60, 63, 72, and 76 shall not apply:

(1) 10 CFR 19.1, "Purpose;"

(2) 10 CFR 19.2, "Scope;"

(3) 10 CFR 19.3, "Definitions," except that the definition of "regulated activities" and "regulated entities" shall not apply. For persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following terms used in 10 CFR 19 shall have the following substitutions:

(A) "license" shall have the same meaning as "registration" as defined in Rule ~~.0104(131)~~ .0103(b) of this Chapter;

(B) "licensed" means “registered” as defined in Rule ~~.0104(131)~~ .0103(b) of this Chapter;

(C) "licensee" shall have the same meaning as "registrant" as defined in Rule ~~.0104(130)~~ .0103(b) of this Chapter;

(D) "materials" shall have the same meaning as "radiation machine" as defined in Rule ~~.0104(122)~~ .0103(b) of this Chapter;

(E) "NRC-licensed" means “registered”; and

(F) "radioactive material" shall have the same meaning as "radiation machine" as defined in Rule ~~.0104(122)~~ .0103(b) of this Chapter.

(4) 10 CFR 19.5, "Communications," except that licensees and registrants shall address communications and reports to the agency as instructed by Rule .0111 of this Chapter in lieu of the NRC;

(5) 10 CFR 19.11, "Posting of notices to workers," except that 19.11(b) and (e) shall not apply;

(A) NRC Form 3 shall not be used in lieu of the Notice to Employees issued by the agency, except as authorized by the agency in writing;

(B) licensees and registrants shall not post other notices, postings, notes, or other materials over the Notice to Employees, nor shall equipment be placed in such a manner that the Notice to Employees is obscured or hidden by that equipment; and

(C) additional copies of the Notice to Employees may be obtained free of charge from the agency by contacting the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC, or online at https://radiation.ncdhhs.gov/;

(6) 10 CFR 19.12, "Instructions to workers;"

(7) 10 CFR 19.13, "Notifications and reports to individuals;"

(8) 10 CFR 19.14, "Presence of representatives of licensees and regulated entities, and workers during inspections," except that 19.14(a) shall not apply;

(9) 10 CFR 19.15, "Consultation with workers during inspections;"

(10) 10 CFR 19.16, "Requests by workers for inspections." Requests for inspections shall be mailed or delivered to the agency as instructed by Rule .0111(a) of this Chapter in lieu of the NRC;

(11) 10 CFR 19.17, "Inspections not warranted; informal review." Communications regarding the agency's decisions with respect to a request for inspection submitted to the agency under Subparagraph (a)(10) shall be mailed or delivered to the agency as instructed by Rule .0111(a) of this Chapter in lieu of the NRC;

(12) 10 CFR 19.18, "Sequestration of witnesses and exclusion of counsel in interviews conducted under subpoena;"

(13) 10 CFR 19.20, "Employee protection;"

(14) 10 CFR 19.31, "Application for exemptions," except that the request for exemption shall be made on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:

(A) licensee or registrant name;

(B) license or registration number;

(C) name of the individual requesting the exemption;

(D) contact information for the individual requesting the exemption;

(E) a description of the exemption being requested; and

(F) an explanation describing why the exemption is necessary.

(b) Notwithstanding Subparagraph (a)(5) of this Rule, registrants temporarily working in North Carolina and licensees working in North Carolina under reciprocity may post the Notice to Employees, NRC Form 3, or an equivalent form issued under the authority of the regulatory agency issuing the registration or license.

(c) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part019/.

History Note: *Authority G.S. 104E-7; 104E-12;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989;

Transferred and Recodified from 15A NCAC 11 .1001 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. October 1, 2023.

10A NCAC 15 .1601 is amended as published in 39:05 NCR 187-208 as follows:

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION

(a) Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed pursuant to the rules in Section .0300, .0900, .1200, or .1300 of this Chapter shall comply with the provisions of 10 CFR 20 as follows, which are hereby incorporated by reference including subsequent amendments and editions, except references to and requirements for 10 CFR 50, 52, 60, 63, 72, 73, and 76 shall not apply:

(1) 20.1001, "Purpose," except that non-ionizing radiation from radiation machines registered in accordance with the rules in Section .0200 of this Chapter shall also be regulated by this Rule;

(2) 20.1002, "Scope;"

(3) 20.1003, "Definitions," except that for persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following terms used in 10 CFR 20 shall have the following substitutions:

(A) "license" shall have the same meaning as "registration" as defined in Rule ~~.0104(131)~~ .0103(b) of this Chapter;

(B) "licensed" ~~means registered pursuant to the rules in Section .0200~~ shall have the same meaning as “registered” as defined in Rule .0103(b) of this Chapter;

(C) "licensed material" shall have the same meaning as "radiation machine" as defined in Rule ~~.0104(122)~~ .0103(b) of this Chapter, and

(D) "licensee" shall have the same meaning as "registrant" as defined in Rule ~~.0104(130)~~ .0103(b) of this Chapter;

(4) 20.1004, "Units of radiation dose;"

(5) 20.1005, "Units of radioactivity;"

(6) 20.1007, "Communications," except that licensees and registrants shall address communications regarding these rules, notifications, and reports to the agency as instructed by Rule .0111 of this Chapter in lieu of the NRC;

(7) 20.1101, "Radiation protection programs;"

(8) 20.1201, "Occupational dose limits for adults;"

(9) 20.1202, "Compliance with requirements for summation of external and internal doses;"

(10) 20.1203, "Determination of external dose from airborne radioactive material;"

(11) 20.1204, "Determination of internal exposure;"

(12) 20.1206, "Planned special exposures;"

(13) 20.1207, "Occupational dose limits for minors;"

(14) 20.1208, "Dose equivalent to an embryo/fetus;"

(15) 20.1301, "Dose limits for individual members of the public;"

(16) 20.1302, "Compliance with dose limits for individual members of the public;"

(17) 20.1401, "General provisions and scope;"

(18) 20.1402, "Radiological criteria for unrestricted use;"

(19) 20.1403, "Criteria for license termination under restricted conditions;"

(20) 20.1404, "Alternate criteria for license termination;"

(21) 20.1405, "Public notification and public participation," except the agency shall not publish a notice in the Federal Register;

(22) 20.1406, "Minimization of contamination," except that 20.1406(b) shall not apply;

(23) 20.1501, "General;"

(24) 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose;"

(25) 20.1601, "Control of access to high radiation areas;"

(26) 20.1602, "Control of access to very high radiation areas;"

(27) 20.1701, "Use of process or other engineering controls;"

(28) 20.1702, "Use of other controls;"

(29) 20.1703, "Use of individual respiratory protection equipment;"

(30) 20.1704, "Further restrictions on the use of respiratory equipment;"

(31) 20.1705, "Application for use of higher assigned protection factors;"

(32) 20.1801, "Security of stored material;"

(33) 20.1802, "Control of material not in storage;"

(34) 20.1901, "Caution signs;"

(35) 20.1902, "Posting requirements;"

(36) 20.1903, "Exceptions to posting requirements;"

(37) 20.1904, "Labeling containers;"

(38) 20.1905, "Exemptions to labeling requirements," except that 20.1905(g) shall not apply;

(39) 20.1906, "Procedures for receiving and opening packages;"

(40) 20.2001, "General requirements;"

(41) 20.2002, "Method for obtaining approval of proposed disposal procedures;"

(42) 20.2003, "Disposal by release to sanitary sewerage;"

(43) 20.2004, "Treatment or disposal by incineration;"

(44) 20.2005, "Disposal of specific wastes;"

(45) 20.2006, "Transfer for disposal and manifests;"

(46) 20.2007, "Compliance with environmental and health protection regulations;"

(47) 20.2008, "Disposal of certain byproduct material;"

(48) 20.2101, "General provisions;"

(49) 20.2102, "Records of radiation protection programs;"

(50) 20.2103, "Records of surveys;"

(51) 20.2104, "Determination of prior occupational dose;"

(52) 20.2105, "Records of planned special exposures;"

(53) 20.2106, "Records of individual monitoring results;"

(54) 20.2107, "Records of dose to individual members of the public;"

(55) 20.2108, "Records of waste disposal;"

(56) 20.2110, "Form of records;"

(57) 20.2201, "Reports of theft or loss of material." Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter shall make telephone reports of the theft or loss of radiation machines in accordance with 20.2201(a)(1)(i);

(58) 20.2202, "Notifications of incidents;"

(59) 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits," except that 20.2203(c) shall not apply;

(60) 20.2204, "Reports of planned special exposures;"

(61) 20.2205, "Reports to individuals exceeding dose limits;"

(62) 20.2206, "Reports of individual monitoring," except that 20.2206(a)(1), and 20.2206(a)(3) through (a)(5) shall not apply. The report required by 20.2206(b) shall be submitted upon request by the agency in lieu of the requirements of 20.2206(c);

(63) 20.2207, "Reports of transactions involving nationally tracked sources." Notwithstanding Subparagraph (a)(6) of this Rule, reports required by this Subparagraph shall be made in accordance with 20.2207(f) and (g);

(64) 20.2301, "Application for exemptions," except that the request for exemption shall be made on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:

(A) licensee or registrant name;

(B) license or registration number;

(C) name and contact information for the individual requesting the exemption;

(D) a description of the exemption being requested, and

(E) an explanation describing why the exemption is necessary;

(65) 20.2302, "Additional requirements;"

(66) Appendix A to Part 20, "Assigned Protection Factors for Respirators;"

(67) Appendix B to Part 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage;"

(68) Appendix C to Part 20, "Quantities of Radioactive Material Requiring Labeling;"

(69) Appendix E to Part 20, "Nationally Tracked Source Thresholds," and

(70) Appendix G to Part 20, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests."

(b) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(c) Licensees and registrants shall continue to perform all activities required by the rules of this Chapter, license or registration condition, and shall pay annual fees as instructed on an invoice issued by the agency until the license or registration is terminated. Registrants shall maintain registration of all radiation machines under their control until those units are disposed.

(d) Nothing in the rules of this Chapter shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.

(e) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/.

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994;
Amended Eff. August 1, 1998;
Transferred and Recodified from 15A NCAC 11 .1601 Eff. February 1, 2015;
Readopted Eff. October 1, ~~2023.~~ 2023;
Amended Eff. May 1, 2025.