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-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.

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.

10A NCAC 15 .0103 INTENTIONAL EXPOSURE

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.

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

10A NCAC 15 .0104 DEFINITIONS

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

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

(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 3.7×10^{10} disintegrations per second = 3.7×10^{10} becquerels = 2.22×10^{12} 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" (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm^2).

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

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

(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/cm^2).

(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 Equivalent[a]
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

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

If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, one rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the rules of this Chapter, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body.
If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from the following table to convert a measured tissue dose in rads to dose equivalent in rems:

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

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

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

(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 2.58×10^{-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" (H_S), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

(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:

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

(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 A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Rule .0113 of this Section or may be determined by procedures described in 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", w_T, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

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

[a] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.
[b] For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $w_T = 1.0$, has been specified.

(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.

History Note: *Authority G.S. 104E-7(a)(2); 10 CFR 20.1003;*
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.

10A NCAC 15 .0105 OTHER DEFINITIONS

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 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.

10A NCAC 15 .0106 EXEMPTIONS

(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.

History Note: *Authority G.S. 104E-2; 104E-7; 104E-15;*
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.

10A NCAC 15 .0107 INSPECTIONS

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

History Note: *Authority G.S. 104E-7; 104E-11(a);*
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'
Transferred and Recodified from 15A NCAC 11 .0107 Eff. February 1, 2015.

10A NCAC 15 .0108 ADDITIONAL REQUIREMENTS

(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.

History Note: *Authority G.S. 104E-7; 104E-18; 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;*
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.

10A NCAC 15 .0109 IMPOUNDING

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

History Note: *Authority G.S. 104E-14;*
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.

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.

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

10A NCAC 15 .0111 COMMUNICATIONS

(a) Except as provided in Paragraph (b) of this Rule, all communications and reports concerning these Rules and applications filed thereunder shall be mailed to the agency at Radiation Protection Section, 1645 Mail Service Center, Raleigh, North Carolina 27699-1600 or delivered to the agency at its office located at 5505 Creedmoor Road, Suite 100, Raleigh, North Carolina 27612.
(b) Except as specifically instructed otherwise by the agency, immediate telephone notification and reports required by the rules in this Chapter shall be directed to (919) 814-2250 from 8:00 a.m. to 5:30 p.m. on business days.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2212 Eff. January 4, 1990;
Amended Eff. August 1, 2002; April 1, 1999; May 1, 1993; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0805 Eff. February 1, 2015;
Amended Eff. January 1, 2016;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .0112 DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENCY

(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.

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

10A NCAC 15 .0113 CLASSIFICATION OF RADIOACTIVE MATERIAL

History Note: *Authority G.S. 104E-15;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2214 Eff. January 4, 1990;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0113 Eff. February 1, 2015;
Repealed Eff. May 1, 2023.

10A NCAC 15 .0114 TESTS FOR SPECIAL FORM

Special form radioactive material as defined in Rule .0104 of this Section must satisfactorily pass the following tests:

(1) a free drop through a distance of 30 feet onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage;

(2) impact of the flat circular end of a one-inch diameter steel rod weighing three pounds, dropped through a distance on a sheet of lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than one inch thick supported by a smooth essentially unyielding surface;
(3) heating in air to a temperature of 1,475 F. and remaining at that temperature for a period of ten minutes;
(4) immersion for 24 hours in water at room temperature at pH 6 to pH 8, with a maximum conductivity of ten micromhos per centimeter.

History Note: *Authority G.S. 104E-15;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2215 Eff. January 4, 1990;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0114 Eff. February 1, 2015.

10A NCAC 15 .0115 RECORDS

Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these Rules.

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2216 Eff. January 4, 1990;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0115 Eff. February 1, 2015.

10A NCAC 15 .0116 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 including, but not limited to, tests of:
(1) sources of radiation;
(2) facilities wherein sources of radiation are used or stored;
(3) radiation detection and monitoring instruments; and
(4) other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

History Note: *Authority G.S. 104E-7; 104E-7(2); 104E-11(a);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2217 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0116 Eff. February 1, 2015.

10A NCAC 15 .0117 INCORPORATION BY REFERENCE

(a) For the purpose of the rules in this Chapter, the following rules, standards and other requirements are hereby incorporated by reference including any subsequent amendments and editions:
(1) Appendix A, Appendix B, Appendix C, and Appendix G to 10 CFR Parts 20.1001 - 20.2401;
(2) The following parts of 10 CFR:
(A) Part 21;
(B) Parts 30.1, 30.4 and 30.10;
(C) Part 31, except 31.5;
(D) Parts 32.2, 32.13, 32.24, 32.110, 32.201, 32.210;
(E) Subpart J of 10 CFR Part 35, Parts 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, Subpart H of 10 CFR Part 35, 35.1000;
(F) Part 36;
(G) Part 40, except 40.12(b), 40.23, 40.27, 40.28, 40.31 (j through m), 40.32(d) and portions of (e) pertaining to uranium enrichment, and 40.32(g), 40.33, 40.38, 40.41(d), 40.41(e)(1), 40.41(e)(3), 40.41(g), 40.41(h), 40.51(b)(6), 40.64, 40.66, 40.67;
(H) Part 61 except 61.16, 61.23(i) and (j);

(I) Part 70, except 70.1 (c), (d), (e), 70.13, 70.14, 70.20(a), (b), 70.21(a)(1), (c), (f through h), 70.22(b), (c), (f through n), 70.23 (a)(6 through 12), (b), 70.23a, 70.24, 70.25(a)(1), 70.31(c through e), 70.32(a)(1), (a)(4 through 7), (b)(1), (b)(3), (b)(4)(c through k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), 70.52, 70.55(c), 70.59-62, 70.64, 70.65, 70.66, 70.72, 70.73, 70.74, 70.76, 70.82;

(J) Parts 71.0, 71.1, 71.2, 71.3, 71.13, 71.4, 71.5, 71.8, 71.14(a), 71.15, 71.17(a) through (e), 71.20, 71.21, 71.22, 71.23, 71.47, Subpart G of 10 CFR Part 71, 10 CFR 71.101(a) through (c)(1), 71.101(f), 71.101(g), 71.103, 71.105, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, Appendix A to 10 CFR Part 71; and

(K) Part 150 except 150.3 Definition: Foreign Obligations, 150.7, 150.10, 150.14, 150.15, 150.15a, 150.16-17, 150.17a, 150.19, 150.21.

(3) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040;

(4) 39 CFR Part 14 and 39 CFR Part 15;

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

(6) 40 CFR Part 261;

(7) 49 CFR Parts 100-189;

(8) "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;

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

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

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

(12) "10 CFR, Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 FR 7540"; and

(13) American National Standard N43.9 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography".

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

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

(2) Sixty-Seven dollars ($67.00) for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts 1-50;

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

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

(5) Forty-Seven dollars ($47.00) for the regulations listed in Subparagraph (a)(5) of this Rule in a volume containing 39 CFR;

(6) Thirty-six dollars ($36.00) for the manual listed in Subparagraph (a)(6) of this Rule; http://pe.usps.gov/text/dmm300/dmm300_landing.htm;

(7) Fifty-Six dollars ($56.00) for the regulations listed in Subparagraph (a)(7) of this Rule in a volume containing 40 CFR Parts 260-299;

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

(A) Seventy dollars ($70.00) for a volume containing 49 CFR Parts 100-177; and

(B) Seventy dollars ($70.00) for a volume containing 49 CFR Parts 178-199;

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

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

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

(12) Two Hundred Eighteen dollars ($218.00) for the ICRP Publication No. 23 in Subparagraph (a)(12) of this Rule, available from Pergamon Press, Inc., Maxwell House, Fairview Park, Elmsford, NY 10523;

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

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

(15) The Code of Federal Regulations is available free of charge on the internet at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

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

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

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

Any licensee or registrant may choose to implement the rules in Section .1600 of this Chapter prior to the January 1, 1994 effective date of that Section, in lieu of the rules in Section .0400 of this Chapter, provided such licensee or registrant shall:

(1) implement all rules in Section .1600 of this Chapter, except as exempted by the provisions of Rule .1602(c) of this Chapter;

(2) comply with the rules in Section .1600 of this Chapter in lieu of any rule in Section .0400 of this Chapter that is cited in license or registration conditions, except as otherwise provided in Rule .1602 of this Chapter; and

(3) provide written notification of implementation to the agency at the address in Rule .0111 of this Section.

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.

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, radiation machine facilities and persons who provide 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.

(c) In addition to the requirements of this Section, all registrants are subject to the provisions of the other sections of this Chapter.

(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.

(e) In addition to the requirements of this Section, all registrants are subject to the annual fee provisions contained in Section .1100 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.

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 square centimeters does not exceed 0.5 mrem per hour at five centimeters from any accessible surface of the equipment when any external shielding is removed. The production, testing, or factory servicing of such equipment are not exempt.

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

(c) Domestic television receivers are exempt from the requirements of this Section.

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

10A NCAC 15 .0203 APPLICATION: REGISTRATION: RADIATION MACHINES: FACILITIES

(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.

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

10A NCAC 15 .0204 PROHIBITED SERVICES AND INSTALLATION

(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.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0204 Eff. February 1, 2015.

10A NCAC 15 .0205 APPLICATION FOR REGISTRATION OF SERVICES

(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) of this Rule in this state, to any agency licensee or registrant, shall apply for registration of such services with the agency prior to furnishing or offering to furnish any of these services.
(b) Application for registration shall be completed on appropriate form(s) provided by the agency and shall 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 Paragraph (a) of this Rule shall certify that he has read and understands the requirements of the rules in this Chapter.
(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.

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

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

10A NCAC 15 .0206 REPORTS OF INSTALLATION

(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.

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

10A NCAC 15 .0207 ISSUANCE OF NOTICE OF REGISTRATION

(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.

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.

10A NCAC 15 .0208 PRIOR NOTIFICATION OF TRANSFER

(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.

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.

10A NCAC 15 .0209 REPORT OF CHANGES

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.

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.

10A NCAC 15 .0210 OTHER PROHIBITED ACTIVITIES

(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.

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

Transferred and Recodified from 15A NCAC 11 .0210 Eff. February 1, 2015.

10A NCAC 15 .0211 OUT-OF-STATE RADIATION MACHINES

(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.

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.

10A NCAC 15 .0212 MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRANTS

(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.

History Note: *Authority G.S. 104E-7; 104E-13;*
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.

10A NCAC 15 .0213 ADDITIONAL REQUIREMENTS: REGISTERED SERVICES

(a) An applicant for registration of diagnostic area radiation survey, diagnostic radiation output measurements or therapeutic calibration services pursuant to Rule .0205 of this Section shall meet the following additional requirements:

(1) The applicant shall have adequate 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 persons 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 for therapy calibration, provided the applicant satisfies the agency that the proposed frequency and procedures will provide equivalent or better assurance of proper calibration.

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

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

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

(C) the 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 calibration reports.

(b) An applicant for registration of services pursuant to Rule .0205 of this Section who proposes to provide 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 clients.

(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 which will be used.

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

History Note: *Authority G.S. 104E-7;*
Eff. June 1, 1989;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0213 Eff. February 1, 2015.

10A NCAC 15 .0214 TRAINING AND EDUCATIONAL REQUIREMENTS FOR EQUIPMENT SERVICES

(a) Each person registered 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 minimum qualifications for specific types of services:

(1) Class I - sales of radiation machines and machine components to end users: The applicant must certify knowledge of familiarity with the rules which govern the possession, installation and use of radiation machines in North Carolina.

(2) Class II - installation and service of radiation machines and machine components including the making of diagnostic radiation output measurements to verify performance associated with the installation or service:

(A) manufacturer's equipment school for service, maintenance and installation for the type of machine use (e.g. dental intraoral, medical diagnostic or medical fluoroscopic) or equivalent training;

(B) training in principles of radiation protection; and

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

(3) Class III - diagnostic radiographic facility and shielding design:

(A) training in principles of radiation protection;

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

(4) Class IV - diagnostic fluoroscopic facility and shielding design:
(A) training in principles of radiation protection;
(B) training in shielding design; and
(C) one year of experience in diagnostic fluoroscopic facility and shielding design for the specific type of machine application.

(5) Class V - diagnostic area radiation survey, e.g., shielding evaluation:
(A) training in basic radiological health;
(B) training in shielding evaluation; and
(C) one year of experience performing area radiation surveys.

(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 calibration:
(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; or certification by the American Board of Medical Physics; or
(B) having the following minimum training and experience:
(i) a master's degree in physics, biophysics, radiological physics or health physics;
(ii) one year of full-time training in therapeutic radiological physics
(iii) one year of full-time experience in a therapeutic facility including personal calibration and spot-check of at least one machine;
(C) shall 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;
(D) shall submit a copy of all forms, reports and documents that will be supplied to customers; and
(E) shall submit one sample of each specific type, e.g., teletherapy, accelerator.

(8) Class VIII - personnel dosimetry service: 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 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:
(A) baccalaureate degree in a physical science (e.g. physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics; graduate training in medical or health physics may be substituted on a year for year basis; or
(B) 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; certification by the American Board of Health Physics in health physics or certification by the American Board of Medical Physics.

(b) Any person not meeting the requirements in Paragraph (a) of this Rule may apply to the agency for registration, provided such person demonstrates education, training and experience which is equivalent to that required in Paragraph (a) of this Rule.

(c) Any person registered prior to the effective date of this Rule to provide equipment services pursuant to Rule .0205 of this Section shall meet the education, training and experience requirements in Paragraph (a) or (b) of this Rule no later than 24 months after the effective date of this Rule.

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

History Note: *Authority G.S. 104E-7; 104E-13;*
Eff. June 1, 1989;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0214 Eff. February 1, 2015.

SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL

Codifier's Note: 10 NCAC 03G .2400 was transferred to 15A NCAC 11 .0300 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0301 GENERAL RULES APPLICABLE TO THE SPECIFIC LICENSING OF BYPRODUCT MATERIAL

(a) All persons using byproduct material shall comply with the provisions of 10 CFR 30, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) 10 CFR 30.1, "Scope;"
(2) 10 CFR 30.2, "Resolution of conflict;"
(3) 10 CFR 30.3(a), (c), and (d), "Activities requiring license," except that references to 10 CFR 30.3(b)(1), (b)(2), and (b)(3) shall not apply;
(4) 10 CFR 30.4, "Definitions," except that references in the definitions to common defense and security shall not apply. The term "temporary jobsite" shall mean a location where byproduct materials are used and stored other than those location(s) of use authorized on the license;
(5) 10 CFR 30.6, "Communications," except that notices and reports required by this Rule shall be made to the agency at the address shown in Rule .0111 of this Chapter in lieu of the United States Nuclear Regulatory Commission (NRC);
(6) 10 CFR 30.9, "Completeness and accuracy of information;"
(7) 10 CFR 30.10, "Deliberate misconduct;"
(8) 10 CFR 30.11, "Specific exemptions;"
(9) 10 CFR 30.12, "Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts;"
(10) 10 CFR 30.13, "Carriers;"
(11) 10 CFR 30.14, "Exempt concentration;"
(12) 10 CFR 30.15, "Certain items containing byproduct material;"
(13) 10 CFR 30.18, "Exempt quantities;"
(14) 10 CFR 30.19, "Self-luminous products containing tritium, krypton-85, or promethium-147;"
(15) 10 CFR 30.20, "Gas and aerosol detectors containing byproduct material;"
(16) 10 CFR 30.21(a), (b), and (d), "Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans;"
(17) 10 CFR 30.22, "Certain industrial devices;"
(18) 10 CFR 30.31, "Types of licenses;"
(19) 10 CFR 30.32(a) – (d) and (f) – (j), "Application for specific licenses," except that the requirements of Paragraph (b) of this Rule shall be met.
(20) 10 CFR 30.33, "General requirements for issuance of specific licenses," except the agency shall issue a "Radioactive Materials License." In the event an "environmental document," as defined by G.S. 113A-9.(2), has been prepared in accordance with 15A NCAC 01C .0206, the agency may base the issuance of a specific license on information and evaluations made in that environmental document;
(21) 10 CFR 30.34(a) – (c), (e)(2), (e)(4), (f) – (k), "Terms and conditions of licenses;"
(22) 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning," the initials "DCE" shall mean "detailed cost estimate;"
(23) 10 CFR 30.36, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas;"
(24) 10 CFR 30.37, "Application for renewal of licenses;"
(25) 10 CFR 30.38, "Application for amendment of licenses and registration certificates." Licensees shall submit an application for amendment to the agency to add temporary jobsites to the license as authorized places of use if the duration of use or storage at the temporary jobsite exceeds 180 days in any calendar year;
(26) 10 CFR 30.39, "Commission action on applications to renew or amend;"
(27) 10 CFR 30.41(a), (b)(1) – (b)(5), (b)(7), (c), (d), "Transfer of byproduct material;"
(28) 10 CFR 30.50, "Reporting requirements;"
(29) 10 CFR 30.51, "Records;"
(30) 10 CFR 30.52, "Inspections;"
(31) 10 CFR 30.53, "Tests;"

(32) 10 CFR 30.61, "Modification and revocation of licenses and registration certificates;"
(33) 10 CFR 30.62, "Right to cause the withholding or recall of byproduct material;"
(34) 10 CFR 30.70, "Schedule A – Exempt concentrations;"
(35) 10 CFR 30.71, "Schedule B." This schedule shall also be known as the "exempt quantity table;"
(36) 10 CFR 30.72, "Schedule C – Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release;"
(37) Appendix A to Part 30, "Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning;"
(38) Appendix B to Part 30, "Quantities of Licensed Material Requiring Labeling;"
(39) Appendix C to Part 30, "Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning;"
(40) Appendix D to Part 30 "Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds;" and
(41) Appendix E to Part 30, "Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals."

(b) Applications shall be made on forms provided by the agency. One copy of the application 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 shall 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 shall 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/.

History Note: *Authority G.S. 104E-7; 104E-9(8); 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; August 1, 1998; January 1, 1994; May 1, 1992; June 1, 1989; July 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0301 Eff. February 1, 2015;
Readopted Eff. May 1. 2024.

10A NCAC 15 .0302 GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

(a) Persons possessing generally licensed items, manufactured or initially transferred pursuant to Subpart B of 10 CFR 32, shall comply with the provisions of 10 CFR 31, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) Reports, notifications, and responses to agency requests for information required by this Rule shall be made to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the agency;
(2) 10 CFR 31.1, "Purpose and scope;"
(3) 10 CFR 31.2, "Terms and conditions;"
(4) 10 CFR 31.5, "Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere," except that the fee required by 10 CFR 170.31 shall not apply. Persons using devices described in 31.5(a) shall be registered with the agency. Device registration shall be made in accordance with Paragraph (b) of this Rule and shall contain the information required by 31.5(c)(13)(iii);
(5) 10 CFR 31.6, "General license to install devices generally licensed in 10 CFR 31.5;"
(6) 10 CFR 31.7, "Luminous safety devices in aircraft;"
(7) 10 CFR 31.8, "Americium-241 and radium-226 in the form of calibration or reference sources;"
(8) 10 CFR 31.9, "General license to own byproduct material;"
(9) 10 CFR 31.10, "General license for strontium 90 in ice detection devices;"
(10) 10 CFR 31.11, "General license for use of byproduct material for certain in vitro clinical or laboratory testing," except that persons required by 31.11(b) to register devices with the agency shall comply with the provisions of Paragraph (b) of this Rule;
(11) 10 CFR 31.12, "General license for certain items and self-luminous products containing radium-226;" and
(12) 10 CFR 31.21, "Maintenance of records;"

(b) Persons registering devices shall use General License Application for Registration forms provided by the agency. These forms are available free of charge at: https://radiation.ncdhhs.gov/rms/rmsgenlicforms.htm. 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 United States Nuclear Regulatory Commission. The following information shall appear on the application:

(1) facility name, mailing address, physical address if different from the mailing address, and the name of the county where the facility is located;
(2) type of device;
(3) device manufacturer;
(4) device model numbers and serial numbers;
(5) number of devices being registered, isotopes, and activity;
(6) indicate if the devices have been leak tested by checking the corresponding check box;
(7) if the devices have been leak tested, write down the frequency that leak tests are required;
(8) the name of the person or company performing the leak test;
(9) describe the method of device disposal; and
(10) the signature, printed name, title, date the form is signed and telephone number of the contact person.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part031/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1989; October 1, 1984; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0302 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0303 EXEMPT CONCENTRATIONS: OTHER THAN SOURCE MATERIAL

History Note: *Authority G.S. 104E-7; 104E-10; 104E-20; 10 C.F.R. 30.70;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0303 Eff. February 1, 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0304 SPECIFIC LICENSES: MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

(a) All persons manufacturing or initially transferring items or devices containing exempt quantities or exempt concentrations of byproduct material, as described in Rule .0301(a)(11) and .0301(a)(13) of this Chapter, generally licensed and specifically licensed items or devices containing byproduct material, items or devices containing byproduct material for medical use in humans, and persons requesting safety evaluations of sealed sources or devices for registration with the national Sealed Source and Device Registry shall comply with the following requirements of 10 CFR 32:

(1) 10 CFR 32.1(a), (b), and (c)(2), "Purpose and scope;"
(2) 10 CFR 32.2, "Definitions," the term "initially transfer" shall mean the "initial commercial transfer of items and devices to an end user or a commercial or retail reseller;"
(3) 10 CFR 32.3, "Maintenance of records."

(b) All Persons manufacturing or initially transferring items or devices containing exempt quantities of byproduct material shall comply with the following requirements of Subpart A – Exempt Concentrations and Items:

(1) 10 CFR 32.13, "Same: Prohibition of introduction;"
(2) 10 CFR 32.24, "Same: Table of organ doses;" and
(3) applications to manufacture, process, produce, prepare, package, re-package, or initially transfer items or devices for commercial distribution containing exempt concentrations or exempt quantities of byproduct material shall be made to the United States Nuclear Regulatory Commission (NRC) in lieu of the agency.

(c) All persons manufacturing or initially transferring generally licensed devices containing byproduct material shall comply with Paragraph (g) of this Rule and the following requirements of Subpart B – Generally Licensed Items:

(1) 10 CFR 32.51, "Byproduct material contained in devices for use under 10 CFR 31.5; requirements for license to manufacture, or initially transfer;"
(2) 10 CFR 32.51a, "Same: Conditions of licenses;"
(3) 10 CFR 32.52, "Same: Material transfer reports and records;"
(4) 10 CFR 32.53, "Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer;"
(5) 10 CFR 32.54, "Same: Labeling of devices;"
(6) 10 CFR 32.55, "Same: Quality assurance; prohibition of transfer;"
(7) 10 CFR 32.56, "Same: Material transfer reports;"
(8) 10 CFR 32.57, "Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer;"
(9) 10 CFR 32.58, "Same: Labeling of devices;"
(10) 10 CFR 32.59, "Same: Leak testing of each source;"
(11) 10 CFR 32.61, "Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer;"
(12) 10 CFR 32.62, "Same: Quality assurance; prohibition of transfer;" and

(13) 10 CFR 32.71, "Manufacture and distribution of byproduct material in certain in vitro clinical or laboratory testing under general license."

(d) All persons manufacturing or initially transferring items or devices containing byproduct material for medical use in humans shall comply with Paragraph (g) of this Rule and the following requirements of Subpart C – Specifically Licensed Items:

(1) 10 CFR 32.72, "Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35;" and

(2) 10 CFR 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use."

(e) All persons manufacturing sealed sources containing byproduct material in quantities equal to or greater than the quantities listed in Appendix E of 10 CFR 20 shall comply with Paragraph (g) of this Rule and the requirements of 10 CFR 32.201.

(f) All persons manufacturing or initially transferring sealed sources or devices containing byproduct material under this Rule for commercial distribution and persons requesting safety evaluations of sealed sources or devices for registration with the national Sealed Source and Device Registry shall comply with the following requirements of Subpart D – Sealed Source and Device Registration:

(1) 10 CFR 32.210, "Registration of product information;"

(2) 10 CFR 32.211, "Inactivation of certificates of registration of sealed sources and devices;" and

(3) requests for safety evaluations and registration of product information under this Paragraph and inactivation of certificates of registration of sealed sources and devices issued by the agency 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.

(g) Applications shall be made on forms provided by the agency. One copy of the application 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 shall 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 shall 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(h) The regulations cited in this Rule from 10 CFR Part 32 are hereby incorporated by reference, including subsequent amendments and editions. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part032/.

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20; 10 CFR 30.71;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0304 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0305 SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

(a) Persons who have established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations in compliance with the rules of this Chapter shall comply with the provisions of 10 CFR 33, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) 10 CFR 33.1, "Purpose and scope;"

(2) 10 CFR 33.11(a), "Types of specific licenses of broad scope;"

(3) 10 CFR 33.12, "Applications for specific licenses of broad scope," except that the requirements of Paragraph (b) of this Rule shall be met;

(4) 10 CFR 33.13, "Requirements for the issuance of a Type A specific license of broad scope;"

(5) 10 CFR 33.16, "Application for other specific licenses;" and

(6) 10 CFR 33.17(a), (b), "Conditions of specific licenses of broad scope."

(b) Applications shall be made on forms provided by the agency. One copy of the application 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 United States Nuclear Regulatory Commission:

(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 instructions for completing the application printed on the application form shall be followed. 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 shall 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 instructions for completing the application printed on the application form shall be followed. 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 shall 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part033/.

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; April 1, 1999; June 1, 1993; October 1, 1982; September 1, 1981;
Transferred and Recodified from 15A NCAC 11 .0305 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0306 TYPES OF LICENSES: GENERAL AND SPECIFIC

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

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.

10A NCAC 15 .0307 MEDICAL USE OF BYPRODUCT MATERIAL IN HUMANS

(a) All persons using radioactive materials for medical use in humans shall comply with the general information requirements of Subpart A to 10 CFR 35, as follows:
(1) 10 CFR 35.1, "Purpose and scope;"
(2) 10 CFR 35.2, "Definitions;"
(3) 10 CFR 35.5, "Maintenance of records;"
(4) 10 CFR 35.6, "Provisions for the protection of human research subjects;"
(5) 10 CFR 35.7, "FDA, other Federal, and State requirements;"
(6) 10 CFR 35.10, "Implementation;"
(7) 10 CFR 35.11, "License required," except that 35.11(c)(1) shall not apply;

(8) 10 CFR 35.12, "Application for license, amendment, or renewal," except that the requirements in Paragraph (m) of this Rule shall be met;
(9) 10 CFR 35.13, "License amendments," except that 35.13(a)(1) shall not apply;
(10) 10 CFR 35.14, "Notifications," except that notifications required by this rule shall be submitted to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the agency;
(11) 10 CFR 35.15, "Exemptions regarding Type A specific licenses of broad scope;"
(12) 10 CFR 35.18, "License issuance," except 35.18(a)(2) shall not apply; and
(13) 10 CFR 35.19, "Specific exemptions."

(b) All persons using radioactive materials for medical use in humans shall comply with the general administrative requirements of Subpart B to 10 CFR 35, as follows:

(1) 10 CFR 35.24, "Authority and responsibilities for the radiation safety program;"
(2) 10 CFR 35.26, "Radiation protection program changes;"
(3) 10 CFR 35.27, "Supervision." Persons using instrumentation for the collection of data to be used by a physician shall hold active nuclear medicine technology (N) certification issued by the American Registry of Radiographic Technologists (ARRT) or hold active certification issued by the Nuclear Medicine Technologist Certification Board (NMTCB) within three (3) years of the effective date of this readopted Rule, or shall be in training and under the supervision of an individual holding active ARRT(N) or NMTCB certification or an authorized user;
(4) 10 CFR 35.40, "Written Directives;"
(5) 10 CFR 35.41, "Procedures for administrations requiring a written directive;"
(6) 10 CFR 35.49, "Suppliers for sealed source and devices for medical use;"
(7) 10 CFR 35.50, "Training for Radiation Safety Officer and Associate Radiation Safety Officer;"
(8) 10 CFR 35.51, "Training for an authorized medical physicist;"
(9) 10 CFR 35.55, "Training for an authorized nuclear pharmacist;"
(10) 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist;"
(11) 10 CFR 35.59, "Recentness of training;" and
(12) licensees administering radioactive materials to patients shall have a physician, a nurse practitioner, or a physicians' assistant available to provide emergency life-saving assistance in the event of a medical emergency. These individuals are not required to be users of radioactive materials.

(c) All persons administering radioactive materials to humans not requiring a written directive shall develop, document, maintain, and require the use of, a clinical procedures manual. A copy of this manual shall be provided to the agency with each application for a new license or each application for renewal of an existing license. This manual shall be approved in writing by an authorized user, and shall include, for each nuclear medicine procedure not requiring a written directive performed at the facility:

(1) the range of radiopharmaceutical dosages;
(2) the method used to determine the dosage;
(3) the route of administration;
(4) provision of job-specific training and assistance to medical personnel in the administration of radioactive material for purposes including, but not limited to, the evaluation of cardiac ischemia in the emergent setting and localization of seizure foci as an adjunct to epilepsy monitoring; and
(5) any other information the licensee determines to be useful for patient care, and to prevent the occurrence of medical events.

(d) All persons using radioactive materials for medical use in humans shall comply with the general technical requirements of Subpart C to 10 CFR 35, as follows:

(1) 10 CFR 35.60, "Possession, use, and calibration of instruments used to measure the activity of byproduct material;"
(2) 10 CFR 35.61, "Calibration of survey instruments;"
(3) 10 CFR 35.63, "Determination of dosages of unsealed byproduct material for medical use," except that the determination of dosages of unsealed photon emitting byproduct material shall be made only by direct measurement of radioactivity. If direct measurement of the dosage is not feasible because of the nature of the radiopharmaceutical, the manufacturer's recommendations for determining the dosage shall be used;
(4) 10 CFR 35.65, "Authorization for calibration, transmission, and reference sources;"
(5) 10 CFR 35.67, "Requirements for possession of sealed sources and brachytherapy sources," except that sealed sources and brachytherapy sources placed in storage may be decayed-in-storage as permitted by

Subparagraph (d)(10) of this Paragraph. Brachytherapy sources placed into decay-in-storage shall be exempt from leak testing and the semi-annual inventory requirements of this Subparagraph;

(6) 10 CFR 35.69, "Labeling of vials and syringes," except that syringe shields and dose carriers used to shield or transport syringes labeled in accordance with this Rule shall not be required to be labeled when under the continuous direct control of the individual measuring the dose in accordance with Subparagraph (d)(3) of this Rule and administering the dose to the patient;

(7) 10 CFR 35.70, "Surveys of ambient radiation exposure rate;"

(8) 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material;"

(9) 10 CFR 35.80, "Provision of mobile medical service;" and

(10) 10 CFR 35.92, "Decay-in-storage," except that licensees may hold byproduct material with a half-life of less than or equal to 275 days for decay-in-storage.

(e) Persons using unsealed radioactive material for medical use not requiring a written directive shall comply with the requirements of Subpart D to 10 CFR 35, as follows:

(1) 10 CFR 35.100, "Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required;"

(2) 10 CFR 35.190, "Training for uptake, dilution, and excretion studies;"

(3) 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required;"

(4) 10 CFR 35.204, "Permissible molybdenum-99, strontium-82, and strontium-85 concentrations;" and

(5) 10 CFR 35.290, "Training for imaging and localization studies."

(f) Persons using unsealed radioactive material for medical use requiring a written directive shall comply with the requirements of Subpart E to 10 CFR 35, as follows:

(1) 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required;"

(2) 10 CFR 35.310, "Safety instruction;"

(3) 10 CFR 35.315, "Safety precautions;" except that patient's or human research subject's personal items that cannot be effectively decontaminated to a level indistinguishable from the natural background may be released to them upon discharge, provided that the patient or human research subject is instructed not to share such items with others;

(4) 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required;"

(5) 10 CFR 35.392, "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries);"

(6) 10 CFR 35.394, "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries);" and

(7) 10 CFR 35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive."

(g) Persons using sealed source radioactive material for medical use in manual brachytherapy shall comply with the requirements of Subpart F to 10 CFR 35, as follows:

(1) 10 CFR 35.400, "Use of sources for manual brachytherapy;"

(2) 10 CFR 35.404, "Surveys after source implant and removal;"

(3) 10 CFR 35.406, "Brachytherapy sources accountability;"

(4) 10 CFR 35.410, "Safety instructions;"

(5) 10 CFR 35.415, "Safety precautions;"

(6) 10 CFR 35.432, "Calibration measurements of brachytherapy sources;"

(7) 10 CFR 35.433, "Strontium-90 sources for ophthalmic treatments;"

(8) 10 CFR 35.457, "Therapy-related computer systems;"

(9) 10 CFR 35.490, "Training for use of manual brachytherapy sources;"

(10) 10 CFR 35.491, "Training for ophthalmic use of strontium-90;" and

(11) activities listed in Subparagraphs (g)(6) and (g)(7) of this Rule shall be approved by an Authorized Medical Physicist.

(h) Persons using sealed source radioactive material for medical diagnosis shall comply with the requirements of Subpart G to 10 CFR 35, as follows:

(1) 10 CFR 35.500, "Use of sealed sources and medical devices for diagnosis;" and

(2) 10 CFR 35.590, "Training for use of sealed sources and medical devices for diagnosis."

(i) Persons using sealed source radioactive material for medical use in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall comply with the requirements of Subpart H to 10 CFR 35, as follows:

(1) 10 CFR 35.600, "Use of a sealed source in a remote afterloading unit, teletherapy unit, or gamma stereotactic radiosurgery unit;"
(2) 10 CFR 35.604, "Surveys of patients and human research subjects treated with a remote afterloader unit;"
(3) 10 CFR 35. 605, "Installation, maintenance, and repair;"
(4) 10 CFR 35.610, "Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"
(5) 10 CFR 35.615, "Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"
(6) 10 CFR 35.630, "Dosimetry equipment;"
(7) 10 CFR 35.632, "Full calibration measurements on teletherapy units;"
(8) 10 CFR 35.633, "Full calibration measurements on remote afterloader units;"
(9) 10 CFR 35.635, "Full calibration measurements on stereotactic radiosurgery units;"
(10) 10 CFR 35.642, "Periodic spot-checks for teletherapy units;"
(11) 10 CFR 35.643, "Periodic spot-checks for remote afterloader units;"
(12) 10 CFR 35.645, "Periodic spot-checks for on stereotactic radiosurgery units;"
(13) 10 CFR 35.647, "Additional technical requirements for mobile remote afterloader units;"
(14) 10 CFR 35.652, "Radiation surveys;"
(15) 10 CFR 35.655, "Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units;"
(16) 10 CFR 35.657, "Therapy-related computer systems;" and
(17) 10 CFR 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units."

(j) Persons using radioactive material for medical use, or radiation from radioactive material for medical use, that are not specifically addressed in Paragraphs (e) through (i) of this Rule shall comply with requirements of Subpart K to 10 CFR 35.

(k) All persons licensed by the agency for the medical use of radioactive material shall maintain records required by Subpart L to 10 CFR 35, as follows:

(1) 10 CFR 35.2024, "Records of authority and responsibilities for radiation protection programs;"
(2) 10 CFR 35.2026, "Records of radiation protection program changes;"
(3) 10 CFR 35.2040, "Records of written directives;"
(4) 10 CFR 35.2041, "Records of procedures for administrations requiring a written directive;"
(5) 10 CFR 35.2060, "Records of calibrations of instruments used to measure the activity of unsealed byproduct materials;"
(6) 10 CFR 35.2061, "Records of radiation survey instrument calibrations;"
(7) 10 CFR 35.2063, "Records of dosages of unsealed byproduct material for medical use;"
(8) 10 CFR 35.2067, "Records of leak tests of sealed sources and brachytherapy sources;"
(9) 10 CFR 35.2070, "Records of surveys for ambient radiation exposure rate;"
(10) 10 CFR 35.2075, "Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material;"
(11) 10 CFR 35.2080, "Records of mobile medical services;"
(12) 10 CFR 35.2092, "Records of decay-in-storage;"
(13) 10 CFR 35.2204, "Records of molybdemum-99, strontium-82, and strontium-85 concentrations;"
(14) 10 CFR 35.2310, "Records of safety instruction;"
(15) 10 CFR 35.2404, "Records of surveys after source implant and removal;"
(16) 10 CFR 35.2406, "Records of brachytherapy source accountability;"
(17) 10 CFR 35.2432, "Records of calibration measurements of brachytherapy sources;"
(18) 10 CFR 35.2433, "Records of decay of strontium-90 sources for ophthalmic treatments;"
(19) 10 CFR 35.2605, "Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"
(20) 10 CFR 35.2610, "Records of safety procedures;"
(21) 10 CFR 35.2630, "Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"
(22) 10 CFR 35.2632, "Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations;"

(23) 10 CFR 35.2642, "Records of periodic spot-checks for teletherapy units;"
(24) 10 CFR 35.2643, "Records of periodic spot-checks for remote afterloader units;"
(25) 10 CFR 35.2645, "Records of periodic spot-checks for gamma stereotactic radiosurgery units;"
(26) 10 CFR 35.2647, "Records of additional technical requirements for mobile remote afterloader units;"
(27) 10 CFR 35.2652, "Records of surveys of therapeutic treatment units;" and
(28) 10 CFR 35.2655, "Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units."

(l) All persons licensed by the agency for the medical use of radioactive material shall make, or cause to be made, the reports required by Subpart M to 10 CFR Part 35. Notifications made by telephone shall be made to the agency in lieu of the United States Nuclear Regulatory Commission (NRC) Operations Center. Written reports and correspondence required by this Rule shall be submitted to the agency at the address shown in Rule .0111 of this Chapter unless otherwise directed by the agency, in lieu of the NRC Regional Office:

(1) 10 CFR 35.3045, "Report and notification of a medical event;"
(2) 10 CFR 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child;"
(3) 10 CFR 35.3067, "Report of a leaking source;" and
(4) 10 CFR 35.3204, "Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations."

(m) Applications shall be made on forms provided by the agency. One copy of the application 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 shall 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 shall 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 free of charge at: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(n) The regulations cited in this Rule from 10 CFR 35 are hereby incorporated by reference, including subsequent amendments and editions. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0307 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0308 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

(a) Persons irradiating objects or materials using sealed sources containing radioactive materials shall comply with the provisions of 10 CFR 36, which are hereby incorporated by reference including subsequent amendments and editions, except that the requirements of 10 CFR 170 shall not apply, as follows:

(1) 10 CFR 36.1, "Purpose and scope;"
(2) 10 CFR 36.2, "Definitions," except that references to common defense and security shall not apply;
(3) 10 CFR 36.11, "Application for a specific license," except that the requirements of Paragraph (b) of this Rule shall be met;
(4) 10 CFR 36.13, "Specific licenses for irradiators;"
(5) 10 CFR 36.15, "Commencement of construction;"
(6) 10 CFR 36.17, "Applications for exemptions;"
(7) 10 CFR 36.19, "Requests for written statements;"
(8) 10 CFR 36.21, "Performance criteria for sealed sources;"
(9) 10 CFR 36.23, "Access control;"
(10) 10 CFR 36.25, "Shielding;"
(11) 10 CFR 36.27, "Fire protection;"
(12) 10 CFR 36.29, "Radiation monitors;"
(13) 10 CGR 36.31, "Control of source movement;"
(14) 10 CFR 36.33, "Irradiator pools;"
(15) 10 CFR 36.35, "Source rack protection;"
(16) 10 CFR 36.37, "Power failures;"
(17) 10 CFR 36.39, "Design requirements;"
(18) 10 CFR 36.41, "Construction monitoring and acceptance testing;"
(19) 10 CFR 36.51, "Training;"
(20) 10 CFR 36.53, "Operating and emergency procedures;"
(21) 10 CFR 36.55, "Personnel monitoring;"
(22) 10 CFR 36.57, "Radiation surveys;"
(23) 10 CFR 36.59, "Detection of leaking sources;"
(24) 10 CFR 36.61, "Inspection and maintenance;"
(25) 10 CFR 36.63, "Pool water quality;"
(26) 10 CFR 36.65, "Attendance during operations;"
(27) 10 CFR 36.67, "Entering and leaving the radiation room;"
(28) 10 CFR 36.69, "Irradiation of explosive or flammable materials;"
(29) 10 CFR 36.81, "Records and retention periods;" and
(30) 10 CFR 36.83, "Reports," except that reports required by this Rule shall be made to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the agency, in lieu of the United States Nuclear Regulatory Commission (NRC).

(b) Applications shall be made on forms provided by the agency. One copy of the application 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 shall 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 shall 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part036/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
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Transferred and Recodified from 15A NCAC 11 .0308 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0309 DOMESTIC LICENSING OF SOURCE MATERIAL

(a) Persons using source material and byproduct material as defined in this Rule shall comply with the provisions of 10 CFR 40, which are hereby incorporated by reference including subsequent amendments and editions, except that references to importation and exportation of radioactive material and references to and requirements of 10 CFR 70.22(b), (c), (f) – (n), and 10 CFR 110 shall not apply, as follows:

(1) 10 CFR 40.1, "Purpose;"

(2) 10 CFR 40.2, "Scope;"

(3) 10 CFR 40.2a, "Coverage of inactive tailings sites;"
(4) 10 CFR 40.3, "Licensing requirements;"
(5) 10 CFR 40.4, "Definitions," except that the definition of "foreign obligations," "reconciliation," and references in the definitions to common defense and security shall not apply;
(6) 10 CFR 40.5, "Communications," except that notices and reports shall be made to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the agency or specified otherwise in this Rule, in lieu of the United States Nuclear Regulatory Commission (NRC);
(7) 10 CFR 40.9, "Completeness and accuracy of information;"
(8) 10 CFR 40.10, "Deliberate misconduct;"
(9) 10 CFR 40.11, "Persons using source material under certain Department of Energy and Nuclear Regulatory Commission contracts;"
(10) 10 CFR 40.12(a), "Carriers;"
(11) 10 CFR 40.13, "Unimportant quantities of source material," except 10 CFR 40.13(c)(5)(iv);
(12) 10 CFR 40.14, "Specific Exemptions;"
(13) 10 CFR 40.20, "Types of licenses;"
(14) 10 CFR 40.21, "General license to receive title to source or byproduct material;"
(15) 10 CFR 40.22, "Small quantities of source material;"
(16) 10 CFR 40.25, "General license for use of certain industrial products or devices;"
(17) 10 CFR 40.26, "General license for possession and storage of byproduct material as defined in this part;"
(18) 10 CFR 40.31(a), (b), (d), (f) – (i), "Application for specific licenses," except that the requirements of Paragraph (b) of this Rule shall be met, and reports required by 10 CFR 40.31(g) shall be submitted to the NRC in lieu of the agency. In the event an "environmental document," as defined by G.S. 113-9.(2), has been prepared in accordance with 15A NCAC 01C .0206, the agency may base the issuance of a specific license on information and evaluations made in that environmental document;
(19) 10 CFR 40.32, "General requirements for issuance of specific licenses," except that 10 CFR 40.32(d), (g), and references to and requirements for uranium enrichment and uranium hexafluoride facilities shall not apply. In the event an "environmental document," as defined by G.S. 113A-9.(2), has been prepared in accordance with 15A NCAC 01C .0206, the agency may base the issuance of a specific license on information and evaluations made in that environmental document;
(20) 10 CFR 40.34, "Special requirements for issuance of specific licenses;"
(21) 10 CFR 40.35, "Conditions of specific licenses issued pursuant to 10 CFR 40.34;"
(22) 10 CFR 40.36, "Financial assurance and recordkeeping for decommissioning," the initials "DCE" shall mean "detailed cost estimate;"
(23) 10 CFR 40.41(a) – (c), (e)(2), (e)(4), (f), "Terms and conditions of licenses;"
(24) 10 CFR 40.42, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas;"
(25) 10 CFR 40.43, "Renewal of licenses;"
(26) 10 CFR 40.44, "Amendment of licenses at request of licensee;"
(27) 10 CFR 40.45, "Commission action on application to renew or amend;"
(28) 10 CFR 40.46, "Inalienability of licenses;"
(29) 10 CFR 40.51(a), (b)(1) – (b)(5), (b)(7), (c), (d), "Transfer of source or byproduct material;"
(30) 10 CFR 40.54, "Requirements for license to initially transfer source material for use under the 'small quantities of source material' general license;"
(31) 10 CFR 40.55, "Conditions of licenses to initially transfer source material for use under the 'small quantities of source material' general license: Quality control, labeling, safety instructions, and records and reports;"
(32) 10 CFR 40.60, "Reporting requirements;"
(33) 10 CFR 40.61, "Records;"
(34) 10 CFR 40.62, "Inspections;"
(35) 10 CFR 40.63, "Tests;"
(36) 10 CFR 40.65, "Effluent monitoring reporting requirements;"
(37) 10 CFR 40.71, "Modification and revocation of licenses," and
(38) Appendix A to Part 40, "Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores

Processed Primarily for Their Source Material Content," except Criterion 11A - F and 12 shall not apply.

(b) Applications shall be made on forms provided by the agency. One copy of the application 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 shall 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 shall 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part040/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; January 1, 2005; January 1, 1994; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0309 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0310 DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

(a) Persons using special nuclear material as defined in this Rule shall comply with the provisions of 10 CFR 70, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) 10 CFR 70.1(a) and (b), "Purpose;"
(2) 10 CFR 70.2, "Scope;"
(3) 10 CFR 70.3, "License requirements;"
(4) 10 CFR 70.4, "Definitions," except that references in the definitions to common defense and security shall not apply;
(5) 10 CFR 70.5, "Communications," except that notices and reports shall be made to the agency at the address shown in Rule .0111 of this Chapter in lieu of the United States Nuclear Regulatory Commission (NRC) unless otherwise specified by the agency;
(6) 10 CFR 70.9, "Completeness and accuracy of information;"
(7) 10 CFR 70.10, "Deliberate misconduct;"
(8) 10 CFR 70.11, "Persons using special nuclear material under certain DOE and NRC contracts;"
(9) 10 CFR 70.12, "Carriers;"
(10) 10 CFR 70.17, "Specific exemption;"
(11) 10 CFR 70.18, "Types of licenses;"
(12) 10 CFR 70.19, "General license for calibration and reference sources;"
(13) 10 CFR 70.20, "General license to own special nuclear material;"
(14) 10 CFR 70.21(a)(2), (a)(3), (b), "Filing," except that the requirements of Paragraph (b) of this Rule shall be met;
(15) 10 CFR 70.22(a), (d), and (e), "Contents of application;"
(16) 10 CFR 70.23(a)(1) – (5), "Requirements for the approval of applications;"
(17) 10 CFR 70.25(a)(2), (b) – (h), "Financial assurance and recordkeeping for decommissioning," the initials "DCE" shall mean "detailed cost estimate;"
(18) 10 CFR 70.31(a) and (b), "Issuance of license;"
(19) 10 CFR 70.32(a)(2), (a)(3), (a)(8), (a)(9), (b)(2), and (b)(5), "Conditions of licenses;"
(20) 10 CFR 70.33, "Applications for renewal of licenses;"
(21) 10 CFR 70.34, "Amendment of licenses;"
(22) 10 CFR 70.35, "Commission action on applications to renew or amend;"
(23) 10 CFR 70.36, "Inalienability of licenses;"
(24) 10 CFR 70.38, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor structures;"
(25) 10 CFR 70.39, "Specific licenses for the manufacture or initial transfer of calibration sources;"
(26) 10 CFR 70.41, "Authorized use of special nuclear material;"
(27) 10 CFR 70.42(a), (b)(1) – (b)(5), (b)(7), (c), (d), "Transfer of special nuclear material;"
(28) 10 CFR 70.50, "Reporting requirements;"
(29) 10 CFR 70.51, "Records requirements;"
(30) 10 CFR 70.55(a) and (b), "Inspections;"
(31) 10 CFR 70.56, "Tests;" and
(32) 10 CFR 70.81, "Modification and revocation of licenses."

(b) Applications shall be made on forms provided by the agency. One copy of the application 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 shall 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 shall 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part070/.

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 .0310 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0311 GENERAL LICENSES: LUMINOUS SAFETY DEVICES

(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.

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.

10A NCAC 15 .0312 GENERAL LICENSES: CALIBRATION AND REFERENCE

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 .0312 Eff. February 1, 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0313 OWNERSHIP OF RADIOACTIVE MATERIAL

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.

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.

10A NCAC 15 .0314 GENERAL LICENSES: IN VITRO CLINICAL OR LABORATORY TESTING
10A NCAC 15 .0315 GENERAL LICENSES: ICE DETECTION DEVICES

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 .0314 - .0315 Eff. February 1, 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0316 GENERAL LICENSES: TRANSPORTATION

(a) Any person transporting or storing byproduct material for transportation shall be exempt as authorized by 10 CFR 30.13.

(b) Any person transporting or storing source material for transportation shall be exempt as authorized by 10 CFR 40.12. Any person not exempt under 10 CFR 40.12 shall be issued a general license in accordance with Rule .0306(a) of this Section.

(c) Any person transporting or storing special nuclear material for transportation shall be exempt as authorized by 10 CFR 70.12. Any person not exempt shall be issued a general license in accordance with Rule .0306(a) of this Section.

(d) Any person preparing radioactive material for shipment or transporting radioactive material shall be subject to the provisions of 10 CFR Part 71 as applicable to the shipment and mode of transportation. Notwithstanding Rule .0117(a)(2)(J) of this Chapter, 10 CFR 71.85(a) through (c), and 71.91(b) are excluded from incorporation by reference for the purposes of this Rule.

(e) Notifications required by 10 CFR 71.97 and 10 CFR 73.37(b)(2) shall be made to the Governor's designee as follows:

(1) designee: N.C. Highway Patrol Headquarters, Operations Officer;
(2) mailing address: P.O. Box 27687, Raleigh, North Carolina 27611-7687;
(3) 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.

(f) Transportation of special nuclear material by aircraft shall be prohibited in accordance with 10 CFR 150.21.

(g) Notifications of incidents, accidents, or the loss of control of radioactive material while in transit or while being stored for transportation shall be made to the agency in accordance with Rule .0357 of this Section. Notification of the theft, or loss of radioactive material while in transit, or while being stored for transportation shall be made to the agency in accordance with Rule .1645 of this Chapter.

(h) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are

available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

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.

10A NCAC 15 .0317 SPECIFIC LICENSES: FILING APPLICATION AND GENERAL REQUIREMENT
10A NCAC 15 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE
10A NCAC 15 .0319 SPECIFIC LICENSES: HUMAN USE IN HOSPITALS
10A NCAC 15 .0320 SPECIFIC LICENSES: HUMAN USE BY INDIVIDUAL PHYSICIANS
10A NCAC 15 .0321 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE OF UNSEALED RADIOACTIVE MATERIALS
10A NCAC 15 .0322 SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES

History Note: *Authority G.S. 104E-7; 104E-7(2); 104E-10(b); 10 CFR 35.2;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; November 1, 2007; August 1, 2002; April 1, 1999; May 1, 1993; May 1, 1992; November 1, 1989; October 1, 1984;
Transferred and Recodified from 15A NCAC 11 .0317 - .0322 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. May 1, 2024.

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

(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 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 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. April 1, 1999; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0323 Eff. February 1, 2015;
Readopted Eff. May 1, 2023.

10A NCAC 15 .0324 SPECIFIC LICENSES: BROAD SCOPE

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0324 Eff. February 1, 2015;
Repealed Eff May 1, 2024.

10A NCAC 15 .0325 SPECIFIC LICENSES: PRODUCTS WITH EXEMPT CONCENTRATIONS
10A NCAC 15 .0326 SPECIFIC LICENSES: EXEMPT DISTRIBUTION

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1993;
Repealed Eff. October 1, 2013;
Transferred and Recodified from 15A NCAC 11 .0325 and 15A NCAC .0326 Eff. February 1, 2015.

10A NCAC 15 .0327 SPECIFIC LICENSES: EXEMPT GAS AND AEROSOL DETECTORS
10A NCAC 15 .0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED
10A NCAC 15 .0329 SPECIFIC LICENSES: LUMINOUS SAFETY DEVICES IN AIRCRAFT
10A NCAC 15 .0330 SPECIFIC LICENSES: MANUFACTURE OF CALIBRATION SOURCES
10A NCAC 15 .0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS
10A NCAC 15 .0332 SPECIFIC LICENSES: MANUFACTURE OF ICE DETECTION DEVICES
10A NCAC 15 .0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS

10A NCAC 15 .0334 SPECIFIC LICENSES: GENERATORS AND REAGENT KITS
10A NCAC 15 .0335 SPECIFIC LICENSES: PRODUCTS CONTAINING DEPLETED URANIUM

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; November 1, 2007; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0327 - .0335 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0336 COPIES OF APPLICABLE FEDERAL REGULATIONS

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Repealed Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0336 Eff. February 1, 2015.

10A NCAC 15 .0337 ISSUANCE OF SPECIFIC LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES
10A NCAC 15 .0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES
10A NCAC 15 .0339 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING
10A NCAC 15 .0340 RENEWAL OF LICENSES
10A NCAC 15 .0341 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE
10A NCAC 15 .0342 AGENCY ACTION ON APPLICATIONS TO RENEW OR AMEND
10A NCAC 15 .0343 TRANSFER OF MATERIAL
10A NCAC 15 .0344 MODIFICATION: REVOCATION: AND TERMINATION OF LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-13; 104E-18;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1993; May 1, 1992; June 1, 1989;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. October 1, 2013; April 1, 1999; August 1, 1998; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0337 - .0344 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0337 ISSUANCE OF SPECIFIC LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES

(a) An application for a specific license shall be approved, and a specific license issued, or amended by the agency if the agency determines that the applicant satisfies the provisions of 10 CFR 30.33(a)(1) through (4), 30.39, 40.32(a) through (f), and 70.23(a)(1) through (6) as applicable to the licensed activities, and any additional requirements in:

(1) 10 CFR 32.11, 32.14, 32.18, 32.21, 32.22, 32.26, and 32.30 as applicable to the manufacture of exempt concentrations of byproduct material, and items containing exempt concentrations of byproduct material listed in 10 CFR Part 32, Subpart A;
(2) 10 CFR 32.51, 32.53, 32.57, 32.61, and 32.71 as applicable to the manufacturing and distribution of generally licensed items and devices listed in 10 CFR Part 32, Subpart B;
(3) 10 CFR 32.72 and 32.74 as applicable to the manufacturing and distribution of radioactive drugs, sources, or devices listed in 10 CFR Part 32, Subpart C;
(4) 10 CFR 33.13 through 33.15, and 33.17 as applicable to activities of broad scope;
(5) 10 CFR 34.13 for industrial radiography;
(6) 10 CFR 35.18 for the medical use of radioactive materials;
(7) 10 CFR 36.13 for the use of sealed sources to irradiate materials;
(8) 10 CFR 39.13, 39.15, and 39.17 for the use of radioactive materials in well logging;

(9) 10 CFR 40.34 for the use of source material in the manufacture and initial transfer of devices containing depleted uranium to a person generally licensed under Rule .0307(b) of this Section;
(10) 10 CFR 40.52 for the use of source material in the manufacture of exempt devices listed in Rule .0305 of this Section;
(11) 10 CFR 40.54 for the initial transfer of source material to a person generally licensed under Rule .0307(a) of this Section;
(12) 10 CFR 61.23(a) through (h), and (k), and Section .1200 of this Chapter for the receipt, possession, transfer, or disposal of radioactive waste received from another person; and
(13) 10 CFR 70.31(a) and (b) for the use of special nuclear material.

(b) An application for a new or amended Sealed Source and Device Registration certificate shall be approved by the agency, and a new or amended Sealed Source and Device Registration certificate issued in accordance with 10 CFR 32.210(d) and (e).

(c) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0337 Eff. February 1, 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES

(a) All licenses issued by the agency for activities authorized under the rules of this Section are subject to the terms and conditions listed in 10 CFR 30.34(a) through (d), and 30.34(e)(2) through (j)(4). In addition to these terms and conditions, licenses of broad scope are subject to the terms and conditions listed in 10 CFR 33.17.

(b) All licenses issued by the agency authorizing the possession and use of source material are subject to the terms and conditions listed in 10 CFR 40.35, 40.41, 40.46, 40.53, 40.55, and 40.56.

(c) All licenses issued by the agency authorizing the receipt, possession, or disposal of radioactive waste received from another person are subject to the terms and conditions listed in 10 CFR 61.24, 61.25, and the Rules in Section .1200 of this Chapter.

(d) All licenses issued by the agency authorizing the possession and use of special nuclear material are subject to the terms and conditions of 10 CFR 70.32.

(e) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993; May 1, 1992; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0338 Eff. February 1, 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0339 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING

(a) Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal, as required in Rule .0340 of this Section, not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the agency, as provided for in Rule .0344 of this Section, expires at the end of the day on the date of the agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by agency order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of residual radioactive material present as contamination until the agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) limit actions involving radioactive material to those related to decommissioning; and

(2) continue to control entry to restricted areas until they are suitable for release for unrestricted use and the agency notifies the licensee in writing that the license is terminated.

(d) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Commission requirements, or submit within 12 months of notification a decommissioning plan, if required by Subparagraph (g)(1) of this Rule, and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to Paragraphs (a) or (b) of this Rule;

(2) The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Commission requirements;

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Commission requirements.

(e) Coincident with the notification requirements set forth in Paragraph (d) of this Rule, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to Rule .0353 of this Section in conjunction with a license issuance or renewal, or as required by this Rule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established in Paragraph (g) of this Rule.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this Rule becomes effective.

(2) Following agency approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the agency.

(f) The agency may grant a request to extend the time periods required in Paragraph (d) of this Rule if the agency determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request shall be submitted to the agency no later than 30 days before notification pursuant to Paragraph (d) of this Rule. The schedule for decommissioning set forth in Paragraph (d) of this Rule may not commence until the agency has made a determination on the licensee's request.

(g) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of following cases:

(1) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(2) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(3) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(4) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation. For the purpose of Subparagraphs (g)(2)-(4) of this Rule, significantly higher or significantly greater is defined as an increase likely to result in either an increase in radiation exposure to workers or the public in excess of one percent of their respective annual radiation exposure limit.

(h) The agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to Paragraph (d) of this Rule if the agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(i) Procedures such as those listed in Paragraph (g) of this Rule with potential health and safety impacts may not be carried out prior to agency approval of the decommissioning plan.

(j) The proposed decommissioning plan for the site or separate building or outdoor area shall include:

(1) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
(2) A description of planned decommissioning activities;
(3) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
(4) A description of the planned final radiation survey;
(5) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning; and
(6) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in Paragraph (m) of this Rule.

(k) The proposed decommissioning plan shall be approved by the agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be protected.

(l) Except as provided in Paragraph (m) of this Rule, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning. Except as provided in Paragraph (m) of this Rule, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(m) The agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 24 month period;
(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24 month period;
(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and
(5) Other site-specific factors which the agency may consider appropriate on a case-by-case basis, such as:
    (A) regulatory requirements of other government agencies;
    (B) lawsuits;
    (C) ground-water treatment activities;
    (D) monitored natural ground-water restoration;
    (E) actions that could result in more environmental harm than deferred cleanup; and
    (F) other factors beyond the control of the licensee.

(n) As the final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed "Certificate of Disposition"; and
(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:
    (A) Report levels of gamma radiation in units of microrem (millisieverts) per hour at one meter from surfaces;
    (B) Report levels of radioactivity, including alpha and beta, in units of microcuries per 100 square centimeters (or disintegrations per minute), removable and fixed, for surfaces; microcuries per milliliter for water; and picocuries per gram for solids such as soils or concrete; and
    (C) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(o) Specific licenses shall be terminated by written notice to the licensee when the agency determines that:

(1) radioactive material has been properly disposed;
(2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and
(3) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the requirements for decommissioning described in Rule .1653 of this Chapter, or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable

for release in accordance with the requirements for decommissioning described in Rule .1653 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-18;*
Eff. February 1, 1980;
Amended Eff. April 1, 1999; August 1, 1998; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0339 Eff. February 1, 2015.

10A NCAC 15 .0340 RENEWAL OF LICENSES
Applications for renewal of specific licenses shall be filed in accordance with Rule .0317 of this Section.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. August 1, 1998;
Transferred and Recodified from 15A NCAC 11 .0340 Eff. February 1, 2015.

10A NCAC 15 .0341 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE
Applications for amendment of a license shall be filed in accordance with Rule .0317 of this Section and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment. The applicant shall submit such other supporting information as required by the agency.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0341 Eff. February 1, 2015.

10A NCAC 15 .0342 AGENCY ACTION ON APPLICATIONS TO RENEW OR AMEND
In considering an application by a licensee to renew or amend his license, the agency shall apply the criteria set forth in the applicable rules of this Section.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0342 Eff. February 1, 2015.

10A NCAC 15 .0343 TRANSFER OF MATERIAL
(a) Any person licensed under the rules of this Section transferring byproduct material shall comply with the provisions of 10 CFR 30.41.
(b) Any person licensed under the rules of this Section transferring source material shall comply with the provisions of 10 CFR 40.51.
(c) Any person licensed under the rules of this Section transferring special nuclear material shall comply with the provisions of 10 CFR 70.42.
(d) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0343 Eff. February 1, 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0344 MODIFICATION: REVOCATION: AND TERMINATION OF LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES

(a) All licenses authorizing the receipt, possession, use, and transfer of byproduct material, and all sealed source and device registration certificates issued by the agency under the rules of this Section, are subject to modification by the agency in accordance with 10 CFR 30.61.
(b) All licenses issued by the agency for the receipt, possession, use, and transfer of source material under the rules of this Section, are subject to modification by the agency in accordance with 10 CFR 40.71.
(c) All licenses issued by the agency for the receipt, possession, transfer, or disposal of radioactive waste from another person are subject to modification by the agency in accordance with the provisions of 10 CFR 61.24.
(d) All licenses issued by the agency for the receipt, possession, use, and transfer of special nuclear material are subject to modification by the agency in accordance with 10 CFR 70.81.
(e) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-13;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0344 Eff. February 1, 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0345 RECIPROCAL RECOGNITION OF LICENSES

(a) Subject to these Rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that the following requirements are satisfied:

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(2) The out-of-state licensee notifies the agency in writing at least three days prior to engaging in such activity; such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document; if, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, including but not limited to adverse impact on the business of the licensee or his customer, he may upon application to the agency, obtain permission to proceed sooner; the agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this Rule if the agency determines that such written notifications are not necessary to ensure compliance with the rules in this Chapter or to protect the public;

(3) The out-of-state licensee complies with all applicable rules of the agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency;

(4) The out-of-state licensee supplies such other information as the agency may request; and

(5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this Rule except by transfer to a person:

(A) specifically licensed by the agency or by the U.S. Nuclear Regulatory Commission to receive the material, or

(B) exempt from the requirements for a license for the material under Rule .0303 of this Section.

(b) Additional reciprocity is provided in Rule .0310 of this Section.
(c) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that the action is necessary in order to prevent undue hazard to public health and safety or property.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0345 Eff. February 1, 2015.

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

(a) No licensee shall deliver any radioactive material to a carrier for transport, unless:

(1) The licensee complies with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the packing of radioactive material, and to the monitoring, marking and labeling of those packages;

(2) The licensee has established procedures for opening and closing packages in which radioactive material is transported to provide safety and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(3) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to, or have been available to the consignee.

(b) For the purpose of this Rule, a licensee who transports his own licensed material as a private carrier is considered to have delivered the material to a carrier for transport.

(c) In addition to the requirements of Paragraphs (a) and (b) of this Rule, prior to the transport of any nuclear waste, as defined in Part (d)(2)(A) of Rule .0316 of this Section, outside the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor's designee of each state through which the waste will be transported.

(d) Each advance notification required by Paragraph (c) of this Rule shall contain the following information:

(1) the name, address, and telephone number of the shipper, carrier and receiver of the shipment;

(2) a description of the nuclear waste contained in the shipment as required by the regulations of the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);

(3) the point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

(4) the seven-day period during which arrival of the shipment at state boundaries is estimated to occur;

(5) the destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

(6) a point of contact with a telephone number for current shipment information.

(e) The notification required by Paragraph (c) of this Rule shall be made in writing to the office of each appropriate governor or governor's designee. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor or governor's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for one year.

(f) The licensee shall notify each appropriate governor or governor's designee of any changes to schedule information provided pursuant to Paragraph (c) of this Rule. Such notification shall be by telephone to a responsible individual in the office of the governor or governor's designee of the appropriate state or states. The licensee shall maintain for one year a record of the name of the individual contacted.

(g) Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor or governor's designee of the appropriate state or states. A copy of the notice shall be retained by the licensee for one year.

(h) A list of governors or governors' designees for other states is available from the agency by contacting the North Carolina Division of Radiation Protection, P.O. Box 27687, Raleigh, North Carolina 27611-7687, Phone No. 919/571-4141 or facsimile number 919/571-4148. For the notification required in Paragraphs (c) through (g) of this Rule in North Carolina:

(1) governor's designee is the North Carolina Highway Patrol, Operations Office;

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

(3) telephone 919/733-4030 from 8 a.m. to 5 p.m. workdays, and 919/733-3861 all other times.

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

10A NCAC 15 .0347 SECURITY REQUIREMENTS

History Note: *Authority G.S. 104E-18;*

Eff. February 1, 1980;
Repealed Eff. May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0347 Eff. February 1, 2015.

10A NCAC 15 .0348 SPECIFIC LICENSES: CERTAIN INCINERATOR FACILITIES

History Note: *Authority G.S. 104E-7(2); 104E-7(a)(8); 104E-10(b);*
Eff. October 1, 1984;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0348 Eff. February 1, 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0349 EXEMPTIONS: WASTE MANAGEMENT BY GENERATORS

History Note: *Authority G.S. 104E-7(a)(10);*
Eff. June 1, 1989;
Amended Eff. January 1, 1994;
Filed as a Temporary Amendment Eff. November 22, 1995, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1996;
Transferred and Recodified from 15A NCAC 11 .0349 Eff. February 1, 2015;
Repealed Eff. May 1, 2023.

10A NCAC 15 .0350 RECORDS AND REPORTS OF MISADMINISTRATION

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. June 1, 1989;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995; May 1, 1992;
Repealed Eff. November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0350 Eff. February 1, 2015.

10A NCAC 15 .0351 SPECIFIC LICENSES: MOBILE NUCLEAR MEDICINE SERVICES

History Note: *Authority G.S. 104E-7(a)(2); 104E-10(b);*
Eff. June 1, 1989;
Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0351 Eff. February 1, 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0352 EMERGENCY PLANS
10A NCAC 15 .0353 FINANCIAL ASSURANCE AND RECORD-KEEPING FOR DECOMMISSIONING
10A NCAC 15 .0354 METHODS OF FINANCIAL ASSURANCE FOR DECOMMISSIONING
10A NCAC 15 .0355 FINANCIAL TESTS: SELF- AND PARENT CO. GUARANTEES: DECOMMISSIONING FUNDING

History Note: *Authority G.S. 104E-7; 104E-18; 10 CFR 30.72;*
Eff. May 1, 1992;
Amended Eff. October 1, 2013; May 1, 2006; April 1, 1999; August 1, 1998; January 1, 1994; May 1, 1993; October 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0352 - .0355 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0356 PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE
10A NCAC 15 .0357 REPORTING REQUIREMENTS

History Note: *Authority G.S. 104E-7; 104E-7(a)(2); 104E-10(b);*
Temporary Adoption Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0356 - .0357 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0356 PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

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

(1) The patient or human research subject's identity is verified before each administration; and
(2) Each administration is in accordance with the written directive.

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

(1) Verify the identity of the patient or human research subject;
(2) Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;
(3) Check both manual and computer-generated dose calculations; and
(4) Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

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

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

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

(1) if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose, or
(2) if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Temporary Adoption Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0356 Eff. February 1, 2015.

10A NCAC 15 .0357 REPORTING REQUIREMENTS

(a) All reports required by this Rule shall be made to the agency in accordance with Rule .0111 of this Chapter.

(b) Reports of incidents involving exposure, or incidents threatening to cause exposure to radiation in excess of the annual occupational limits of Rule .1604 of this Chapter, shall be made to the agency in accordance with the provisions of 10 CFR 20.2202.

(c) Reports of an event that prevents taking protective actions to avoid exposure to radiation or to radioactive material that could cause exposures in excess of the regulatory limits of this Chapter shall be made to the agency in accordance with the provisions of:

(1) 10 CFR 30.50 for licensees authorized for the possession and use of byproduct material;
(2) 10 CFR 40.60 for licensees authorized for the possession and use of source material; and
(3) 10 CFR 70.50 of this Chapter for licensees authorized for the possession and use of special nuclear material.

(d) Reports of exposure to radiation exceeding the exposure limits in Section .1600 of this Chapter, or to concentrations of radioactive material in any restricted or unrestricted area in excess of licensed or regulatory limits of 10 CFR 20.2203(a)(3) shall be made to the agency in accordance with 10 CFR 20.2203.

(e) Reports of incidents or events occurring at irradiation facilities licensed under the provisions of 10 CFR 36.1(b) shall be made to the agency in accordance with 10 CFR 36.83.

(f) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: *Authority G.S. 104E-7(a)(2); 104E-10(b);*
Temporary Adoption Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0357 Eff. February 1, 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0358 RELEASE OF PATIENTS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS

History Note: *Authority G.S. 104E-7(a)(8); 104E-12;*
Eff. August 1, 1998;
Amended Eff. October 1, 2013;
Transferred and Recodified from 15A NCAC 11 .0358 Eff. February 1, 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0359 MEASUREMENTS/DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE
10A NCAC 15 .0360 SURVEYS OF RADIOPHARMACEUTICAL AREAS FOR RADIATION EXPOSURE RATE
10A NCAC 15 .0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL
10A NCAC 15 .0362 DECAY-IN-STORAGE

History Note: *Authority G.S. 104E-7; 104E-7(a)(2); 104E-10(b); 104E-12;*
Eff. April 1, 1999;
Amended Eff. October 1, 2013; November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0359 - .0362 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0363 PROVISIONS FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS
10A NCAC 15 .0364 MEDICAL EVENTS
10A NCAC 15 .0365 REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD

History Note: *Authority G.S. 104E-7; 104E-7(a)(2); 104E-10(b); 104E-12;*
Eff. November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0363 - .0365 Eff. February 1, 2015;
Repealed Eff. May 1, 2024.

SECTION .0400 - STANDARDS FOR PROTECTION AGAINST RADIATION

Codifier's Note: 10 NCAC 03G .2500 was transferred to 15A NCAC 11 .0400 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0401 PURPOSE AND SCOPE
10A NCAC 15 .0402 RADIATION DOSE TO INDIVIDUALS IN RESTRICTED AREAS
10A NCAC 15 .0403 DETERMINATION OF PRIOR DOSE
10A NCAC 15 .0404 CONCENTRATIONS IN A RESTRICTED AREA
10A NCAC 15 .0405 EXPOSURE OF MINORS
10A NCAC 15 .0406 PERMISSIBLE LEVELS IN UNRESTRICTED AREAS
10A NCAC 15 .0407 CONCENTRATION IN EFFLUENTS TO UNRESTRICTED AREAS
10A NCAC 15 .0408 BIOASSAY SERVICES
10A NCAC 15 .0409 SURVEYS
10A NCAC 15 .0410 PERSONNEL MONITORING
10A NCAC 15 .0411 CAUTION SIGNS: LABELS: AND SIGNALS
10A NCAC 15 .0412 EXCEPTIONS FROM POSTING AND LABELING
10A NCAC 15 .0413 INSTRUCTION OF PERSONNEL
10A NCAC 15 .0414 STORAGE OF SOURCES OF RADIATION
10A NCAC 15 .0415 PICKING UP: RECEIVING: AND OPENING PACKAGES
10A NCAC 15 .0416 WASTE DISPOSAL
10A NCAC 15 .0417 RECORDS
10A NCAC 15 .0418 REPORTS OF THEFT OR LOSS
10A NCAC 15 .0419 NOTIFICATION OF INCIDENTS
10A NCAC 15 .0420 OVEREXPOSURES AND EXCESSIVE LEVELS AND CONCENTRATIONS
10A NCAC 15 .0421 VACATING PREMISES
10A NCAC 15 .0422 NOTIFICATION AND REPORTS TO INDIVIDUALS
10A NCAC 15 .0423 REFERENCE CONCENTRATIONS IN AIR AND WATER
10A NCAC 15 .0424 REFERENCE FOR LABELING AND DISPOSAL REQUIREMENTS

History Note: *Authority G.S. 104E-7; 104E-7(2),(5); 104E-12(a); 104E-12(a)(1),(2); 104E-12(b);*
Eff. February 1, 1980;
Amended Eff. May 1, 1992; June 1, 1989; October 1, 1984; September 1, 1981;
October 1, 1980;
Repealed Eff. August 1, 1998;
Transferred and Recodified from 15A NCAC 11 .0401-.0424 Eff. February 1, 2015.

10A NCAC 15 .0425 CLASSIFICATION/RADIOACTIVE WASTE FOR NEAR-SURFACE DISPOSAL
10A NCAC 15 .0426 RADIOACTIVE WASTE CHARACTERISTICS
10A NCAC 15 .0427 LABELING
10A NCAC 15 .0428 TRANSFER OF RADIOACTIVE WASTE FOR DISPOSAL AND MANIFESTS

History Note: *Authority G.S. 104E-7(2),(3); 104E-12(a);*
Eff. October 1, 1984;
Amended Eff. June 1, 1989;
Repealed Eff. August 1, 1998;
Transferred and Recodified from 15A NCAC 11 .0425-.0428 Eff. February 1, 2015.

SECTION .0500 - INDUSTRIAL RADIOGRAPHY X-RAY MACHINES

Codifier's Note: 10 NCAC 03G .2600 was transferred to 15A NCAC 11 .0500 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0501 INDUSTRIAL RADIOGRAPHIC OPERATIONS OF ELECTRONIC RADIATION MACHINES FOR NON-HUMAN USE

(a) Persons conducting industrial radiographic operations using radiation machines shall comply with the following provisions of 10 CFR 34, which are hereby incorporated by reference including subsequent amendments and editions, except references to and the requirements of 10 CFR 30, 37, 71, 150 and 171 contained therein shall not apply:

(1) 10 CFR 34.1, "Purpose and Scope;"

(2) 10 CFR 34.3, "Definitions;" except that the definition of becquerel, control (drive) cable, control drive mechanism, control tube, exposure head, field station, guide tube (projection sheath), S-tube, source assembly, source changer, and storage container, shall not apply. Prior to using industrial radiography all persons shall be registered in accordance with rules in Section .0200 of this Chapter. The following terms apply:

(A) "agreement state" shall have the same meaning as "agency" as defined in G.S 104E-5(2);

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

(C) "licensed" shall have the same meaning as "registered" pursuant to the rules in Section .0200 of this Chapter;

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

(E) "radiation source" shall have the same meaning as "radiation machine" in G.S. 104E-5(13);

(F) "radiographic exposure device" shall have the same meaning as "radiation machine" in G.S 104E-5(13); and

(G) "sealed source" shall have the same meaning as "radiation machine" in G.S 104E-5(13).

(3) 10 CFR 34.25, "Radiation survey instruments." The term "radioactive material" used in 10 CFR 34.25 shall have the same meaning as "radiation machine" in G.S. 104E-5(13);

(4) 10 CFR 34.31(a), (b)(1), and (c), "Inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments;"

(5) 10 CFR 34.33, "Permanent radiographic installations." The term "radioactive source" used in 10 CFR 34.33 shall have the same meaning as "radiation machine" in G.S. 104E-5(13);

(6) 10 CFR 34.35(c), "Labeling, storage, and transportation;"

(7) 10 CFR 34.41, "Conducting industrial radiographic operations;"

(8) 10 CFR 34.42, "Radiation Safety Officer for industrial radiograph;"

(9) 10 CFR 34.43, "Training;"

(10) 10 CFR 34.45(a)(1) through (a)(3), (a)(5), (a)(7) through (a)(11), (a)(13), and (b), "Operating and emergency procedure;"

(11) 10 CFR 34.46, "Supervision of radiographers' assistants;"

(12) 10 CFR 34.47, "Personnel monitoring;"

(13) 10 CFR 34.49, "Radiation surveys;"

(14) 10 CFR 34.51, "Surveillance;"

(15) 10 CFR 34.53, "Posting;"

(16) 10 CFR 34.61, "Records of the specific license for industrial radiography;"

(17) 10 CFR 34.65, "Records of radiation survey instrument;"

(18) 10 CFR 34.71, "Utilization logs;"

(19) 10 CFR 34.73, "Records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments;"

(20) 10 CFR 34.75, "Record of alarm system and entrance control checks at permanent radiographic installations;"

(21) 10 CFR 34.79, "Records of training and certification;"

(22) 10 CFR 34.81, "Copies of operating and emergency procedures;"

(23) 10 CFR 34.83, "Records of personnel monitoring procedures;"

(24) 10 CFR 34.85, "Records of radiation surveys;"

(25) 10 CFR 34.87, "Form of records;"

(26) 10 CFR 34.89(a), (b)(1 through 10), "Location of documents and records;" and

(27) Appendix A to 10 CFR 34-Radiographer Certification.

(b) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part034/index.html.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;

Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0501 Eff. February 1,2015;
Pursuant to G.S.150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. May 1, 2024.

10A NCAC 15 .0502 DEFINITIONS
10A NCAC 15 .0503 EQUIPMENT RADIATION LEVEL LIMITS
10A NCAC 15 .0504 RADIOGRAPHIC EXPOSURE DEVICES AND STORAGE CONTAINERS
10A NCAC 15 .0505 STORAGE, LABELS AND TRANSPORTATION PRECAUTIONS
10A NCAC 15 .0506 SURVEY INSTRUMENTS
10A NCAC 15 .0507 LEAK TESTING AND REPLACEMENT OF SEALED SOURCES
10A NCAC 15 .0508 QUARTERLY INVENTORY

History Note: *Authority G.S. 104E-7; 104E-12(a)(1); 10 CFR 34.3;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1993; May 1, 1992; June 1, 1989;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0502 - .0508 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0509 UTILIZATION LOGS
10A NCAC 15 .0510 LIMITATIONS
10A NCAC 15 .0511 INSPECTION AND MAINTENANCE
10A NCAC 15 .0512 PERSONNEL MONITORING
10A NCAC 15 .0513 OPERATING AND EMERGENCY PROCEDURES
10A NCAC 15 .0514 SECURITY
10A NCAC 15 .0515 RADIATION SURVEYS AND SURVEY RECORDS
10A NCAC 15 .0516 POSTING
10A NCAC 15 .0517 SUPERVISION OF RADIOGRAPHERS' ASSISTANTS

History Note: *Authority G.S. 104E-7;104E 12(a)(1); 104E-12(a)(2); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540; 10 C.F.R. 34.43; 10 C.F.R. Appendix A;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1993; June 1, 1989; October 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. January 1, 2005; April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0509 - .0517 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0518 RADIATION MACHINES

History Note: *Authority G.S. 104E-7; 104E-12(a)(1);*
Eff. February 1, 1980;
Amended 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. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0518 Eff. February 1, 2015;
Repealed Eff. October 1, 2015.

10A NCAC 15 .0519 SUBJECTS TO BE COVERED DURING INSTRUCTION OF RADIOGRAPHERS

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0519 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0520 PERMANENT RADIOGRAPHIC INSTALLATIONS

History Note: *Authority G.S. 104E-7; 104E-12(a)(1);*
Eff. October 1, 1980;
Amended Eff. January 1, 1994;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0520 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0521 PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT

History Note: *Authority G.S. 104E-7;*
Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0521 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0522 REPORTING REQUIREMENTS
10A NCAC 15 .0523 RECORDS OF INDUSTRIAL RADIOGRAPHY

History Note: *Authority G.S. 104E-7;*
Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. January 1, 2005; April 1, 1999;
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Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
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10A NCAC 15 .0524 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY
10A NCAC 15 .0525 RADIOGRAPHER CERTIFICATION

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SECTION .0600 - X-RAYS IN THE HEALING ARTS

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10A NCAC 15 .0601 PURPOSE AND SCOPE

This Section establishes requirements for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Section are in addition to, and not in substitution for, the provisions of Sections .0100, .0200, .0900, .1000, and .1600 of this Chapter.

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10A NCAC 15 .0602 DEFINITIONS

(a) As used in this Section, the following definitions shall apply:

(1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
(2) "Added filter" means the filter added to the inherent filtration.
(3) "Aluminum equivalent" means the thickness of aluminum, type 1100 alloy, affording the same attenuation, under specified conditions, as the material in question. The nominal composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum and 0.12 percent copper.
(4) "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.
(5) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation. Phototimer is described separately.
(6) "Beam axis" means a line from the source of x-rays through the centers of the x-ray fields.
(7) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.
(8) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
(9) "Changeable filters" means any added filter which can be removed from the useful x-ray beam through any electronic, mechanical or physical process.
(10) "Contact therapy system" means that the x-ray tube target is put within five centimeters of the surface being treated.
(11) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.
(12) "Cooling curve" means the graphical relationship between heat units stored and cooling time.
(13) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
(14) "Diagnostic source assembly" means the tube housing assembly with a device attached.
(15) "Diagnostic-type protective tube housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 mR in one hour when the tube is operated at its leakage technique factors.
(16) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.
(17) "Direct scattered radiation" means that radiation which has been deviated in direction by materials irradiated by the useful beam.(See also scattered radiation).
(18) "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.
(19) "Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons, negatrons and positrons, liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special unit of exposure is the roentgen.

(20) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(21) "Filter" means material placed in the useful beam to preferentially attenuate selected radiations.

(22) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks and structural material providing linkage between the image receptor and the diagnostic source assembly.

(23) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(24) "Gonad shield" means a protective barrier used to reduce exposure to the testes or ovaries.

(25) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(26) "Healing arts mass screening" means the examination of human beings using x-rays for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts who is legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. It does not include the use of x-ray tests as a requirement for hospital admission or as a condition of employment.

(27) "Image intensifier" means a device, including housing, which converts an x-ray pattern into a corresponding light image of higher energy density.

(28) "Image receptor" means any device, such as fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

(29) "Inherent filtration" means the filtration permanently in the useful beam; it includes the window of the x-ray tube and any permanent tube or source enclosure.

(30) "Installation" means the act of physical movement of a radiographic system from one location to another in conjunction with a change of ownership.

(31) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(32) "Leakage radiation" means radiation emanating from a diagnostic or therapeutic source assembly except for:

(A) the useful beam and

(B) radiation produced when the exposure switch or timer is not activated.

(33) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly (i.e., tube housing and beam limiting device) which are used in measuring leakage radiation. They are defined as follows:

(A) for diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mC) or the minimum obtainable from the unit, whichever is larger;

(B) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential; and

(C) for all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.

(34) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

(35) "Maximum line current" means the rms (root-mean-square) current in the supply line of an x-ray machine operating at its maximum rating.

(36) "Mobile equipment" (see x-ray equipment).

(37) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(38) "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").

(39) "Portable equipment" (see x-ray equipment).

(40) "Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.

(41) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for radiation protection purposes, to reduce the radiation exposure.

(42) "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.

(43) "Protective barrier" means a barrier of radiation attenuating material(s) used to reduce radiation exposure. Types of protective barriers are defined in other items of this Rule.

(44) "Protective glove" means a glove made of radiation attenuating materials used to reduce radiation exposure.

(45) "Qualified expert" means an individual who is registered pursuant to Rule .0205 of this Chapter.

(46) "Radiograph" means an image receptor on which the image has been created directly or indirectly by an x-ray pattern and results in a permanent record.

(47) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

(48) "Rating" means the operating limits as specified by the component manufacturer.

(49) "Recording" means producing a permanent form of an image resulting from x-ray photons such as film and video tape.

(50) "Registrant", as used in this Section, means any person who owns or possesses and administratively controls an x-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by the provisions contained in Sections .0100 and .0200 of this Chapter to register with the agency.

(51) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid-scale reading.

(52) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (See also "direct scattered radiation".)

(53) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

(54) "SID" means source-image receptor distance.

(55) "Source" means the focal spot of the x-ray tube.

(56) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

(57) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

(58) "Stationary equipment" (see x-ray equipment).

(59) "Stray radiation" means the sum of leakage and scattered radiation.

(60) "Technique factors" means the conditions of operation. They are specified as follows:

- (A) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
- (B) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
- (C) for all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(61) "Therapeutic-type protective tube housing" means the tube housing with tube installed, and it includes high voltage and filament transformers and other appropriate elements when they are contained within that housing.

(62) "Transportation equipment" means x-ray equipment which is installed in a vehicle or trailer.

(63) "Tube" means an x-ray tube, unless otherwise specified.

(64) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements when they are contained within the tube housing.

(65) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(66) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

(67) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at the given SID.

(68) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

(69) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices which control the technique factors of an x-ray exposure.

(70) "X-ray equipment" means an x-ray system, subsystem or component thereof.

(A) "Mobile equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(B) "Portable equipment" means x-ray equipment designed to be hand-carried.

(C) "Stationary equipment" means x-ray equipment which is installed in a fixed location.

(71) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(72) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.

(73) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

(74) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this Section.

(75) "X-ray tube" means an electron tube which is designed for the conversion of electrical energy into x-ray energy.

(b) Other definitions applicable to this Section may be found in Sections .0100 and .0200 of this Chapter.

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10A NCAC 15 .0603 GENERAL REQUIREMENTS

(a) Administrative controls

(1) The registrant shall be responsible for directing the operation of the x-ray machines which he has registered with the agency. He or his agent shall assure that the following provisions are met in the operation of the x-ray machine(s):

(A) An x-ray machine which does not meet the provisions of these Rules shall not be operated for diagnostic or therapeutic purposes, if so ordered by the agency in accordance with Rules .0109 and .0110 of this Chapter.

(B) Individuals who will be operating the x-ray equipment shall be instructed in the safe operating procedures and use of the equipment and demonstrate an understanding thereof to the registrant.

(C) In the vicinity of each diagnostic x-ray system's control panel, a chart shall be provided, which specifies for all usual examinations and associated projections which are performed by that system, a listing of information including patient's anatomical size versus technique factors to be utilized at a given source to image receptor distance. The chart shall also provide:

(i) type and size of the film or film-screen combination to be used,
(ii) type and ratio of grid to be used, if any, and focal spot to film distance,
(iii) type and placement of gonad shielding to be used.

(D) Written safety procedures and rules shall be established and made available to each individual operating x-ray equipment under his control. The operator shall be familiar with these rules.

(E) Only the professional staff and ancillary personnel required for the medical procedure or for training shall be in the room during the radiographic exposure. Other than the patient being examined:

(i) All individuals shall be positioned such that no part of the body including the extremities which is not protected by 0.5 mm lead equivalent will be exposed to the useful beam.

(ii) Professional staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.

(iii) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least six feet from both the tube head and the nearest edge of the image receptor.

(iv) When a portion of the body of a non- occupationally exposed professional staff or ancillary personnel is potentially subjected to stray radiation which would result in that individual receiving one-fourth of the maximum permissible dose as defined in Rule .1604 of this Chapter, additional protective measures shall be employed.

(v) Upon written application to the agency, the agency may waive the requirements in Subparts (a)(1)(E)(ii) and (a)(1)(E)(iii) of this Rule if the registrant demonstrates that such waiver is necessary for best management of patients and will not result in violation of the public and occupational dose limits established in the rules in this Chapter.

(F) Gonad shielding of not less than 0.5 mm lead equivalent shall be used for potentially procreative patients during radiographic procedures in which the gonads are in the direct, or useful beam, except for cases in which this would interfere with the diagnostic procedures.

(G) Individuals shall not be exposed to the useful beam except for healing arts purposes. Such exposures shall have been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other nonhealing arts purposes.

(H) When a patient or film must be provided with auxiliary support during a radiographic exposure:

(i) Mechanical holding devices shall be used whenever medical circumstances permit. Written safety procedures, as required in Part (a)(1)(D) of this Rule shall indicate the requirements for selecting a holder;

(ii) If a human holder is required, written safety procedures as required in Part (a)(1)(D) of this Rule, shall indicate the instructions provided to the holder;

(iii) The human holder shall be protected as required in Part (a)(1)(E) of this Rule;

(iv) No individual shall be used routinely to hold patients or film.

(I) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This includes, but is not limited to, the following requirements:

(i) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

(ii) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(iii) Portable or mobile equipment shall be used only for examinations where it is impractical for medical reasons to transfer the patient to a stationary radiographic installation.

(J) All persons who are associated with the operation of an x-ray system are subject to the occupational exposure limits as defined in Rules .1604 and .1638 of this Chapter, and personnel monitoring procedures in Rule .1614 of this Chapter. In addition, when protective

clothing or equipment is worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(i) When an apron is worn the monitoring device shall be worn at the collar outside the apron.

(ii) The dose to the whole body shall be recorded in the reports required in Rule .1640 of this Chapter. If more than one device is used, each dose shall be identified with the area where the device was worn on the body.

(2) The registrant shall maintain at least the following information for each x-ray machine:

(A) current registration information and other correspondence with the agency regarding that machine;

(B) records of surveys and calibrations;

(C) records of maintenance or modifications which affect the useful beam after the effective date of these Rules, along with the names of persons who performed the service.

(b) Plans Review. Prior to construction or structural modification, the floor plans and equipment arrangement of all installations utilizing x-rays for diagnostic or therapeutic purposes shall be reviewed by a qualified expert. The registrant shall submit recommendations of the expert to the agency.

(c) Radiation Survey

(1) For installations of x-ray equipment after the effective date of this Rule, an area radiation survey shall be performed within 30 days following initial operation of each radiation machine to show compliance with Rule .0604(b) of this Section. This survey shall include:

(A) a drawing of the room in which a stationary x-ray system is located and radiation levels in adjacent areas; and

(B) the name of the person approved by the agency performing the survey and the date the survey was performed.

(2) Any modification to the x-ray room or adjacent areas which could increase the radiation dosage to any individual shall require a new survey.

(3) Records of this survey shall be maintained in accordance with Subparagraph (a)(2) of this Rule.

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10A NCAC 15 .0604 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC SYSTEMS

(a) In addition to other requirements of this Section, all diagnostic x-ray systems shall meet the following requirements:

(1) The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operation instructions are observed."

(2) Equivalent wording may be used on battery-powered generators; visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(3) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 millirem in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(4) The radiation emitted by a component other than the diagnostic source assembly shall not exceed two millirem in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) Beam Quality

(A) Half-Value Layer

(i) The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in the following table. "Specified Dental System" is any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980. "Other X-Ray Systems" shall be all other x-ray systems subject to this Section.

X-Ray Tube Voltage	(kilovolt peak)	Minimum HVL (millimeters of Aluminum)	Minimum HVL (millimeters of Aluminum)
Designed operating range	Measured Operating Potential	Specified Dental Systems	Other X-ray Systems
Below 50----------	30	1.5	0.3
	40	1.5	0.4
	49	1.5	0.5
50 to 70----------	50	1.5	1.2
	60	1.5	1.2
	70	1.5	1.5
Above 70----------	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in the table, linear interpolation or extrapolation may be made. Positive means shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

(ii) The requirements of Subpart (a)(5)(A)(i) of this Rule shall be considered to be met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table:

Filtration Required versus Operating Voltage

Operating Voltage (kVp)	Minimum total filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 - 70	1.5 millimeters
Above 70	2.5 millimeters

(iii) Notwithstanding the requirements of Subpart (a)(5)(A)(ii) of this Rule, all intraoral dental systems manufactured after December 1, 1980, shall have a minimum of 1.5 mm aluminum equivalent filtration permanently installed in the useful beam.

(iv) Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

(v) For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

(vi) The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the focal spot of the

tube and the patient, such as a tabletop when the tube is mounted under the table and inherent filtration of the tube.

(B) For new x-ray systems installed after the effective date of these Rules and which have variable kVp and selectable filtration for the useful beam, a device shall link the kVp selector with the filter(s), so that the minimum filtration is always present for the kVp selected.

(6) Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected and their location shall be clearly indicated on the master control panel prior to initiation of the exposure.

(7) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a design function of the x-ray system.

(8) The location of the focal spot may be indicated on a readily visible area of the x-ray source housing in the plane parallel to the image receptor when the image receptor is perpendicular to the beam axis.

(9) Technique Indicators

(A) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

(B) Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(C) On equipment having fixed technique factors, the recommendation in Part (a)(9)(A) of this Rule may be met by permanent markings.

(b) Structural Shielding

(1) For stationary diagnostic systems, except for intraoral dental systems which shall meet the requirements of Rule .0607(j) of this Section, structural shielding shall be provided to assure compliance with Rules .1604 and .1611 of this Chapter. The following shall be provided:

(A) All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of 84 inches above the floor;

(B) Secondary barriers in the wall, floor and ceiling areas not having a primary barrier or where the primary barrier requirements are lower than the secondary barrier requirements; and

(C) A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposures.

(2) When a mobile system is used routinely in one location, the structural shielding in that location shall meet the requirements for stationary diagnostic systems in Subparagraph (b)(1) of this Rule.

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10A NCAC 15 .0605 FLUOROSCOPIC X-RAY SYSTEMS

All fluoroscopic x-ray systems shall meet the following requirements:

(1) Limitation of useful beam

(a) The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam at all times.

(b) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID.

(c) Limitation to the Imaging Surface

(i) The x-ray field produced by fluoroscopic equipment without image intensification shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot-filming procedures.

(ii) Image-intensified fluoroscopy and spot-filming shall comply with the following:

(A) During fluoroscopic or spot-filming procedures, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than three percent of the SID.

The sum of the excess length and the excess width shall be no greater than four percent of the SID.

(B) Compliance shall be determined with the beam axis perpendicular to the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(iii) In addition to other requirements of this Rule, equipment manufactured after the effective date of these Rules shall comply with the following:

(A) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. This adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.

(B) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID, shall be equal to or less than five centimeters by five centimeters.

(C) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID.

(2) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) Entrance exposure rates shall be limited as required in the following:

(a) Fluoroscopic equipment shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of ten roentgens per minute at the point where the center of the useful beam enters the patient, except:

(i) during recording of fluoroscopic images; or

(ii) when provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) In addition to the other requirements of this Rule equipment manufactured after August, 1974, which does not incorporate an automatic exposure control (e.g., automatic brightness control or ionization chamber control) shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the useful beam enters the patient except during the recording of fluoroscopic images or when provided with an optional high level control.

(c) Compliance with the provisions of Item (3) of this Rule shall be determined as follows:

(i) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(ii) If the source is below the table, the exposure rate shall be measured one centimeter above the tabletop or cradle.

(iii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iv) In a C-arm type fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(d) Periodic measurement of entrance exposure rate limits shall comply with the following:

(i) Such measurements shall be made every two years or after any maintenance of the system which might affect the exposure rate.

(ii) Results of these measurements shall be available or posted where any fluoroscopist may have ready access to them and shall be in the record required in Rule .0603(a)(2)(B) of this Section. Results of the measurements shall include the exposure rate, as well as the physical factors used to determine all data; the name of the person approved by the agency performing the measurements and the date the measurements were performed.

(iii) Entrance exposure rate shall be determined with the attenuation block in Rule .0602(a) in the primary beam.

(4) Radiation transmitted through the primary protective barrier of the fluoroscopic imaging assembly shall comply with the following requirements:

(a) The exposure rate resulting from transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgens per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(b) Measurements to determine compliance with Sub-item (4)(a) of this Rule shall be in accordance with the following:

(i) The exposure rate resulting from transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters;

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly, positioned 30 centimeters above the tabletop.

(iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters;

(iv) Movable grids and compression devices shall be removed from the useful beam during the measurement;

(v) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(5) During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.

(6) The source-skin distance shall not be less than:

(a) 38 centimeters on stationary fluoroscopes,

(b) 30 centimeters on all mobile fluoroscopes, or

(c) 20 centimeters for image intensified fluoroscopes during surgical application.

(7) Fluoroscopic timers shall meet the following requirements:

(a) Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(8) Mobile fluoroscopes, in addition to the other requirements of this Rule, shall provide image intensification.

(9) Scattered radiation shall be controlled in accordance with the following requirements:

(a) A shielding device of at least 0.25 mm lead equivalent for covering the Bucky slot during fluoroscopy shall be provided.

(b) A shield of at least 0.25 mm lead equivalent, such as overlapping protective drapes or hinged or sliding panels, shall be provided to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.

(c) Upon application to the agency with adequate justification, exceptions from Sub-items (9)(a) or (9)(b) of this Rule may be made in some special procedures where a sterile field will not

permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures.

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10A NCAC 15 .0606 SYSTEMS OTHER THAN FLUOROSCOPIC AND DENTAL INTRAORAL

(a) Unless specifically provided otherwise by the rules in this Chapter, the requirements in this Rule shall apply to all x-ray systems, except for fluoroscopic and dental intraoral x-ray systems. The useful beam of x-ray systems subject to provisions of this Rule shall be limited to the area of clinical interest or the image receptor, whichever is smaller.

(1) General purpose stationary and mobile x-ray systems shall meet the following special requirements:
  (A) There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.
  (B) Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
  (C) Notwithstanding Parts (a)(1)(A) and (B) of this Rule, equipment manufactured before August 1, 1974 may employ fixed cones and diaphragms or variable collimators without beam defining lights.

(2) In addition to the requirements of Subparagraph (a)(1) of this Rule, all stationary x-ray systems, except equipment originally manufactured before the effective date of this Rule, shall meet the following requirements:
  (A) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;
  (B) The beam limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;
  (C) Indication of field size dimensions and SID's shall be specified in inches or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.

(3) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.

(4) Special purpose x-ray systems shall meet the following requirements:
  (A) These systems shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
  (B) Such systems shall also be provided with means to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.
  (C) The requirements in Parts (a)(4)(A) and (B) of this Rule may be met with a system that meets the requirements for a general purpose x-ray system as specified in Subparagraph (a)(1) of this Rule or, when alignment means are also provided, as follows:
    (i) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where each device has clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which each aperture is designated and indicating which aperture is in position for use.

(b) Radiation exposure control devices shall meet the following requirements:

(1) Means shall be provided to terminate the exposure after a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:

(A) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero except during serial radiography, and

(B) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided.

(2) Control over x-ray exposures shall be in accordance with the following requirements:

(A) A control shall be incorporated into each x-ray system such that the operator can terminate an exposure at any time except for serial radiography where means may be provided to permit completion of any single exposure of the series in process.

(B) Each x-ray control shall be located in such a way as to meet the following criteria.

(i) For stationary x-ray systems, the control shall be permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(ii) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, except for equipment originally manufactured before the effective date of this Rule, a signal audible to the operator shall indicate that the exposure has terminated.

(3) When an automatic exposure control (e.g., phototimer) is provided the following requirements shall be met, except equipment originally manufactured before the effective date of this Rule:

(A) Indication shall be made on the control panel when this mode of operation is selected;

(B) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(C) The minimum exposure time for all equipment other than that specified in Part (b)(3)(B) of this Rule shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater;

(D) Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(E) A visible signal shall indicate when an exposure has been terminated at the limits described in Part (b)(3)(D) of this Rule and manual resetting shall be required before further automatically timed exposures can be made.

(4) When four timer tests are performed at identical timer setting equal to 5.0 seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period (Tmax) and the minimum period (Tmin) in accordance with the formula:

$$T > 5(Tmax-Tmin)$$

(c) Source-skin or source-image receptor distance shall meet the following requirement:

All radiographic systems shall be provided with a durable, securely fastened means to limit the source-skin distance to at least 30 centimeters. This is considered to be met when the collimator or cone provides the required limits.

(d) The exposure produced shall be reproducible to within the following criteria:

When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E)is greater

than five times the difference between the maximum exposure (Emax) and the minimum exposure (Emin) in accordance with the formula:

$$E > 5(Emax-Emin)$$

(e) Standby radiation from capacitor energy storage equipment, when the exposure switch or timer is not activated, shall not exceed a rate of two milliroentgens per hour at five centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

(f) Linearity

(1) When the equipment allows a choice of x-ray tube current settings, the average ratios of exposure to the indicated milliampere-seconds product, i.e., mR/mAs, obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, i.e., /mean of x1- x2/ < minus 0.10 mean of (x1+ x2), where the mean of x1 and x2 are the average mR/mAs values obtained at each of two consecutive tube current settings.

(2) Compliance shall be determined at the most commonly used mA stations by measuring mR/mAs at those stations and at one adjacent station to each.

(g) Timer accuracy

(1) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.

(2) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.

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10A NCAC 15 .0607 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS

(a) In addition to the provisions of Rules .0603 and .0605 of this Section, the requirements of this Rule apply to x-ray equipment and associated facilities used for dental radiography. Criteria for extraoral dental radiographic systems are covered in Rule .0606 of this Section.

(b) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-skin distance to not less than:

(1) 18 centimeters, if operated above 50 kilovolts peak; or

(2) ten centimeters, if operated at or below 50 kilovolts peak.

(c) The size of the direct radiation beam shall be limited in accordance with the following rules:

(1) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(A) If the source-skin distance (SSD) is 18 centimeters or more, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than seven centimeters; and

(B) If the SSD is less than 18 centimeters, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than six centimeters.

(2) Effective February 1, 1981, equipment manufactured prior to August 1974 shall be equipped with a lead line open position indicating device with at least 0.79 mm lead.

(d) The timing device shall comply with the following requirements:

(1) Termination of the exposure after a preset interval;

(2) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;

(3) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided; and

(4) When four timer tests are performed at identical timer settings equal to five seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period (Tmax) and the minimum period (Tmin) in accordance with the formula:

$$T > 5(Tmax- Tmin)$$

(5) Effective February 1, 1983, intraoral dental radiographic systems shall be equipped with an electronic timer.

(6) Timer accuracy

(A) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.

(B) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.

(e) The exposure switch shall comply with the following requirements:

(1) A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half second or less.

(2) Each x-ray control shall be located in such a way as to meet the following criteria:

(A) For stationary x-ray systems installed after the effective date of this Rule, the exposure switch shall be permanently mounted in a protected area (e.g., corridor outside the room) so that the operator is required to remain in that protected area during the entire exposure.

(B) For stationary x-ray systems without a protected area and installed before the effective date of this Rule, the exposure switch shall be such that the operator shall stand at least six feet away from the tube and out of the direct beam.

(C) For mobile and portable x-ray systems the switch shall meet the requirements of Part (e)(2)(B) of this Rule.

(3) For equipment manufactured after August 1, 1974, the x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(f) The exposure produced shall be reproducible to within the following criteria:

When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E) is greater than five times the difference between the maximum exposure (Emax) and the minimum exposure (Emin) in accordance with the formula:

$$E > 5(Emax - Emin)$$

(g) Patient and film holding devices shall be used when the techniques permit.

(h) Neither the tube housing nor the position indicating device shall be hand-held during an exposure.

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

(j) Structural shielding

(1) All wall, floor and ceiling areas shall have protective barriers sufficient to meet the requirements of Rules .1604 and .1611 of this Chapter.

(2) When intraoral x-ray systems are installed in adjacent rooms or areas, protective barriers as specified in Subparagraph (j)(1) of this Rule shall be provided between the rooms or areas.

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10A NCAC 15 .0608 THERAPEUTIC X-RAY INSTALLATIONS: LESS THAN ONE MEV

(a) Unless specifically provided otherwise by the rules in this Chapter, the requirements in this Rule shall apply only to therapeutic x-ray installations which are not capable of operating at or above one MeV. Therapeutic x-ray equipment subject to the provisions of this Rule shall comply with the following requirements:

(1) When the tube is operated at its leakage technique factors, the leakage radiation in any direction shall not exceed the value specified at the distance specified for the classification of that x-ray system.

(A) For contact therapy systems, the leakage radiation shall not exceed 100 mR/hr at five centimeters from the tube housing.

(B) Systems operating from zero to 150 kVp which are manufactured or installed prior to the effective date of this Rule shall have a leakage radiation which does not exceed one R in one hour at one meter from the source.

(C) Systems operating from zero to 150 kVp which are manufactured on or after the effective date of this Rule shall have a leakage radiation which does not exceed 100 mR in one hour at one meter from the source.

(D) Systems operating from 151 to 999 kVp shall have leakage radiation which does not exceed one R in one hour at one meter from the source, except systems which operate in excess of 500 kVp may have a leakage radiation in one hour at one meter from the source equivalent to 0.1 percent of the exposure in the useful beam in one hour at a distance of one meter from the source.

(2) Permanent beam limiting devices used for collimating the useful beam shall provide the same or higher degree of protection as that required by the tube housing assembly.

(3) Adjustable or removable beam limiting devices shall transmit not more than five percent of the useful beam as determined at the maximum tube potential and maximum treatment filter.

(4) The filter system shall be so designed that:

(A) Filters cannot be accidentally displaced from the useful beam at any tube orientation;

(B) Each filter is marked as to its material of construction and its thickness or wedge angle for wedges;

(C) It shall be possible for the operator to determine the presence of and identify each filter and the orientation of each wedge filter in the useful beam when the operator is positioned at the control panel either by display at the control panel or by direct observation;

(D) The filters and filter insertion slot opening shall be so designed that the radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens per hour under all operating conditions; and

(E) Each machine equipped with a beryllium or other low filtration window shall be clearly labeled as such upon the tube head housing and upon the control panel.

(5) The tube housing assembly shall be immobilized during stationary treatments.

(6) The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters and such marking shall be readily accessible.

(7) Equipment of greater than 150 kVp installed after the effective date of this Rule shall be provided with a beam monitor system.

(8) The exposure timer shall meet the following requirements:

(A) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and shall terminate irradiation when a preselected time has elapsed.

(B) The timer shall switch on and off with the radiation and retain its reading after irradiation is interrupted or terminated.

(9) The control panel shall have:

(A) an indication of whether electrical power is present and activation of the x-ray tube is possible;

(B) an indication of whether x-rays are being produced;

(C) the means for indicating kVp and x-ray tube current;

(D) the means for terminating an exposure at any time;

(E) a locking device which will prevent unauthorized use of the x-ray system and, for systems not having a lock at the control panel, an alternate method of preventing unauthorized use, shall be provided;

(F) for equipment manufactured after the effective date of this Rule, a positive display of specific filter(s) in the beam.

(10) When a control panel may energize more than one x-ray tube:

(A) It shall be possible to activate only one x-ray tube during any one time interval;

(B) There shall be an indication at the control panel identifying which x-ray tube can be energized; and

(C) There shall be an indication at the x-ray tube if that tubehead can be energized.

(11) There shall be means of determining the target to patient distance to within one centimeter.

(12) If exposures are controlled by a timer, that timer:

(A) shall permit the setting of exposure times at least as short as one second, and

(B) shall not permit an exposure if set at zero or "off".

(13) Unless it is possible to bring the x-ray exposure rate to its prescribed value within five seconds of actuating the x-ray "on" control, the tube housing shall be fitted with a shutter operable only from the control panel, and of lead equivalent not less than that of the tube housing. In addition:
  (A) The status of the shutter "Beam On", "Beam Off" or "Shutter Open", "Shutter Closed" or equivalent description, shall be indicated at the control panel.
  (B) It shall not be possible to initiate an exposure sequence unless the shutter has first been placed in the "Beam Off" or "Shutter Closed" position.
  (C) The shutter shall automatically go to the "Beam Off" or "Shutter Closed" position if the exposure is terminated by:
    (i) the operation of the timer,
    (ii) the dose monitoring system, if provided,
    (iii) the operation of a safety interlock, or
    (iv) a power failure.

(b) In addition to shielding adequate to meet requirements of Section .1600 of this Chapter, the following treatment room design requirements shall be met:
(1) Treatment room entrances shall be provided with warning lights in a readily observable position, which will indicate when the useful beam is "on".
(2) Provision shall be made for two-way communication with the patient from the control room.
(3) A system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position.
(4) Facilities which contain an x-ray system which may be operated above 150 kVp shall:
  (A) have all necessary shielding, except for any beam interceptor, provided by fixed barriers;
  (B) have the control panel in a protected area which is outside the treatment room;
  (C) have all entrance doors to the treatment room electrically connected such that the x-ray production cannot be initiated unless all doors are closed and shall cease if any door is opened during x-ray production;
  (D) if the radiation output of the x-ray tube is affected by any door opening, be so designed that it is possible to initiate x-ray production only by:
    (i) closing all doors and, subsequently,
    (ii) reinitiating the exposure by manual action at the control panel.

(c) Operating procedures, surveys, and calibration shall comply with the following requirements:
(1) All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the facility which might produce a radiation hazard. The expert shall report his findings in writing to the person in charge of the facility, and a copy of this report shall be transmitted by the registrant to the agency at the address in Rule .0111 of this Chapter.
(2) The radiation output of each therapeutic x-ray machine shall be calibrated by, or under the direction of a qualified expert who is physically present at the facility during the calibration procedure. The calibration shall be repeated after any change, in or replacement of, components of the x-ray generating equipment which could cause a change in x-ray output. Calibration of the therapy beam shall be performed with a measurement instrument, the calibration of which is traceable to national standards for exposure or absorbed dose, and which shall have been calibrated within the preceding 12 months. Records of radiation outputs shall be provided to and maintained by the registrant.
(3) Each therapeutic x-ray machine shall be calibrated as described in Subparagraph (c)(2) of this Rule at time intervals not exceeding one year. The calibration shall include at least the following determinations:
  (A) the accurate determination of the air exposure rate or the dose rate at a reference point within a suitable phantom, as appropriate;
  (B) the congruence between the radiation field and light localizer, when such is used;
  (C) the half-value layer for every combination of kVp and filter used for radiation therapy.
(4) Therapeutic x-ray systems capable of operation at greater than 150 kVp, in addition to the annual calibration required in Subparagraphs (c)(2) and (3) of this Rule, shall have spot checks performed.
  (A) The spot check methods and frequency shall be designed and in writing by a qualified expert. Spot checks shall include verification of continued congruency between the radiation field and the localizing device where an optical field illuminator is used.

(B) Whenever a spot check indicates a significant change in the operating characteristics of a machine, as specified in the qualified expert's spot check design, the machine shall be recalibrated as required.

(C) A log shall be kept of all spot check measurements.

(5) Therapeutic x-ray machines shall not be left unattended unless the locking device required by Part (a)(10)(E) of this Rule is set to prevent activation of the useful beam.

(6) Except as provided in Rule .0603(a)(1)(H) of this Section, no individual other than the patient shall be in the treatment room during exposures unless he is protected by a barrier sufficient to meet the requirements of Rule .1604 of this Chapter, and no individual other than the patient shall be in the treatment room when the kVp exceeds 150 during exposures.

(7) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

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10A NCAC 15 .0609 X-RAY AND ELECTRON THERAPY INSTALLATIONS ONE MEV AND ABOVE

(a) The requirements in Paragraphs (b) to (e) of this Rule shall apply only to medical facilities using medical x-ray and electron therapy equipment with energies one MeV and above. In addition, such medical facilities shall also comply with the requirements in Section .0900 of this Chapter.

(b) Equipment requirements are as follows:

(1) For existing equipment and new equipment manufactured or installed after the effective date of these Rules:

(A) The leakage radiation, excluding neutrons, at a distance of one meter from the source shall not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.

(B) Within one year after the effective date of these Rules the registrant shall determine or obtain from the manufacturer for each machine the leakage radiation specifications for electrons, x-rays and neutrons existing at the points specified in Part (b)(1)(A) of this Rule for specified operating conditions. Records on radiation leakage shall be maintained at the installation.

(C) For equipment from which neutron leakage may be a hazard, a qualified expert shall specify such additional requirements as may be necessary to protect health or minimize danger to life or property. The adequacy of these additional requirements shall be confirmed by a survey. Survey records shall be maintained by the registrant.

(2) Adjustable or interchangeable beam limiting devices shall be provided and shall meet the following requirements:

(A) For existing equipment and new equipment manufactured or installed after the effective date of these Rules:

(i) Adjustable or interchangeable beam limiting devices shall attenuate the radiation incident on the beam limiting devices such that the dose equivalent in rems at any distance from the source does not exceed two percent of the maximum dose equivalent in the useful beam measured at an equal distance from the radiation source.

(ii) If the beam limiting device does not meet the specifications in Subpart (b)(2)(A)(i) of this Rule, the agency may accept auxiliary equipment or methods for accomplishing attenuation.

(B) Dose equivalent measurements may be averaged over an area up to but not exceeding 100 square centimeters at a distance of one meter from the target.

(3) In equipment which uses a system of wedge filters, interchangeable field flattening filters or beam scattering devices:

(A) Irradiation shall not be possible until a selection of filter has been made at the treatment control panel;

(B) An interlock system shall be provided to prevent irradiation if the filter is not in the correct position;

(C) An indication of the orientation of the wedge filter with respect to the treatment field shall be provided when wedge filters are used; and

(D) A display shall be provided at the treatment control panel showing the filter(s) in use, including an indication of "no filters".

(4) Equipment installed after the effective date of these Rules shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system.

(A) Each primary system shall have a detector which is a transmission detector and is a full beam detector and is placed on the patient side of any fixed added filters other than a wedge filter;

(B) The detector(s) shall be removable only with tools or shall be interlocked to prevent incorrect positioning.

(C) Each detector shall be capable of independently monitoring and turning "off" the useful beam.

(D) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

(E) Each dose monitoring system shall have a legible display at the treatment control panel which shall:

(i) maintain a reading until intentionally reset;

(ii) in the event of power failure, have the capability of retrieving the information displayed at the time of failure.

(5) Selection and display of dose monitor units shall comply with the following requirements:

(A) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

(B) After useful beam termination, it shall be necessary to reset the preselected dose monitor units before treatment can be reinitiated.

(C) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset for the next irradiation.

(6) Automatic termination of irradiation by the dose monitoring system shall comply with the following requirements:

(A) Each of the monitoring systems shall be capable of independently terminating irradiation. Provisions shall be made to test the correct operation of each system.

(B) Each primary system shall terminate irradiation when the preselected number of dose monitor units have been reached, and each secondary system shall be used as a backup.

(7) It shall be possible to terminate irradiation and equipment movements or to go from an interruption condition to termination conditions at any time from the treatment control panel.

(8) It shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.

(9) A timer shall be provided and shall meet the following requirements:

(A) The timer shall have a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

(B) The timer shall be a cumulative timer which switches "on" and "off" with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero the elapsed time indicator and the preset time selector after irradiation is terminated, before reactivation is possible.

(C) To guard against failure of the dose monitoring systems, the timer shall terminate irradiation when a preselected time has elapsed.

(10) In equipment capable of both x-ray therapy and electron therapy:

(A) Irradiation shall not be possible until a selection of radiation type, x-rays or electrons, has been made at the treatment control panel;

(B) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;

(C) An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when x-ray wedge filters are fitted; and

(D) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

(11) In equipment capable of generating radiation beams of different energies:

(A) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

(B) An interlock system shall be provided to insure that the equipment emits primarily the energy of radiation which has been selected;

(C) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel; and

(D) The energy selected shall be displayed at the treatment control panel before and during irradiation.

(12) In equipment capable of both stationary-beam therapy and moving-beam therapy:

(A) Irradiation shall not be possible until a selection of stationary-beam therapy or moving-beam therapy has been made at the treatment control panel;

(B) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;

(C) An interlock system shall be provided to terminate irradiation if the movement stops during moving-beam therapy;

(D) Moving-beam therapy shall be so controlled that the required dose monitor units per degree of rotation is obtained; and

(E) The mode of operation shall be displayed at the treatment control panel.

(13) The registrant shall determine or obtain from the manufacturer the location with reference to an accessible point on the radiation head of:

(A) the x-ray target and the virtual source of x-rays;

(B) the electron window or the scattering foil; and

(C) all possible orientations of the useful beam.

(14) Means shall be provided so that all radiation safety interlocks can be checked. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel selection at one location shall not give a display at the other location until the requisite selection operations in both locations have been completed.

(c) Facility shielding shall be adequate to meet the requirements of Section .1600 of this Chapter.

(d) Facility design shall meet the following requirements:

(1) Except for entrance doors, all required barriers shall be fixed barriers.

(2) The control panel shall be located outside the treatment room. The door must be closed during radiation production.

(3) A viewing system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position. When the viewing system is by electronic means (e.g., television), an alternate viewing system shall be available.

(4) Provision shall be made for two-way aural communication with the patient from the control room, however, where excessive noise levels make aural communication impractical, other methods of communication shall be used.

(5) Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, in a readily observable position near the outside of all access doors, preferably at eye level, which will indicate when the useful beam is "on".

(6) Have all entrance doors to the treatment room electrically connected such that the x-ray production cannot be initiated unless all doors are closed and shall cease if any door is opened during x-ray production.

(e) The operating procedures which follow are in addition to those in Rule .0908 of this Chapter.

(1) Radiation protection surveys shall comply with the following requirements:

(A) All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by, or under the direction of, a qualified expert. This shall also be

done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(B) The expert shall report his findings in writing to the person in charge of the facility, and a copy of the report shall be transmitted by the registrant to the agency at the address in Rule .0111 of this Chapter.

(2) No person other than the patient shall be in the treatment room during treatment. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(3) The output of each therapeutic x-ray machine shall be calibrated by, or under the direct supervision of a qualified expert, before it is first used for medical purposes. Calibrations shall be repeated at least once every 12 months and after any change which might significantly increase radiation hazards. Calibration of the therapy beam shall be performed with measurement instruments, the calibration of which is traceable to national standards for exposure or absorbed dose and which shall have been calibrated within the preceding 12 months. Records of calibrations shall be provided to and maintained by the registrant. The calibration shall include at least the following determinations:

(A) the exposure rate or dose rate as appropriate for the field sizes used and for each effective energy and for each treatment distance used for radiation therapy;

(B) the beam quality (e.g., half-value layer when appropriate) for every proposed combination of operating conditions used for radiation therapy;

(C) the congruence between the radiation field and the field indicated by the localized device when used;

(D) verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and backpointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system and beam flatness and symmetry in air or at the specified depths in a water phantom.

(4) Spot checks shall be performed monthly.

(A) The spot check methods shall be in writing and shall be designed by a qualified expert.

(B) Whenever a spot check indicates a significant change (as specified in the qualified expert's spot check design) in the operating characteristics of a machine, the machine shall be recalibrated as required in Subparagraph (e)(3) of this Rule.

(C) A log shall be kept of all spot check measurements.

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0609 Eff. February 1, 2015.

10A NCAC 15 .0610 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

(a) The provisions of this Rule shall apply only to veterinary medicine radiographic installations. Radiographic equipment used in veterinary medicine radiographic installations shall meet the following requirements:

(1) The protective tube housing shall be of the diagnostic type.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of the image receptor and shall provide the same degree of protection as is required in the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50-70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(4) A device shall be provided to terminate the exposure after a preset time or exposure.

(5) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures or behind a protective barrier adequate to assure compliance with Rules .1604 and .1611 of this Chapter.

(b) All wall, ceiling and floor areas shall be equivalent to or provided with primary and secondary protective barriers necessary to comply with Rules .1604 and .1611 of this Chapter.

(c) Operating procedures shall meet the following requirements:

(1) The operator shall stand well away from the useful beam and the animal during radiographic exposures.

(2) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be used; except if the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the individual's body will be struck by the useful beam. The exposure of any professional staff or ancillary personnel used for this purpose shall be monitored and permanently recorded. Exposures shall comply with Rules .1604 and .1609 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0610 Eff. February 1, 2015.

10A NCAC 15 .0611 COMPUTED TOMOGRAPHY (CT) X-RAY SYSTEMS

(a) This Rule provides special requirements for human diagnostic use of computed tomography (CT) x-ray equipment. The uses of Cone Beam CT, Veterinary CT, CT Simulation, and CT attenuation correction shall be exempt from this Rule. The provisions of this Rule are in addition to, and not in substitution for, the Rules in Sections .0100, .0200, .0600, .0900, .1000, and .1600 of this Chapter.

(b) The following definitions shall apply to this Rule:

(1) "CT qualified expert (CT QE)" means an individual who is registered or is providing service for a registered facility where they are employed, as required by Section .0200 of this Chapter. The individual shall have the following education and experience:

(A) a master's or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from a college or university accredited by an agency recognized by the U.S. Department of Education, and three years work experience in a clinical CT environment. The work experience shall be supervised and documented by a medical physicist certified in the specialty area of diagnostic medical physics by the American Board of Radiology, the Canadian College of Physicists in Medicine, or the American Board of Medical Physics; or

(B) certification in the specialty area of diagnostic medical physics by the American Board of Radiology, the Canadian College of Physicists in Medicine, or the American Board of Medical Physics and shall abide by the certifying body's requirements for continuing education.

(2) "general supervision" means the activity is performed under the qualified supervisor's overall direction and control but the qualified supervisor's physical presence shall not be required during the activity.

(3) "personal supervision" means overall direction, control, and training of an individual by a qualified supervisor who shall be physically present during the activities performed by the supervised individual.

(c) Equipment and Installation Requirements

(1) CT x-ray systems shall meet the requirements of 21 CFR 1020.33 as incorporated by reference in Rule .0117(a)(3) of this Chapter.

(2) The operator of a CT scanner shall be able to maintain aural communication with the patient from a shielded position at the control panel.

(d) Personnel Requirements. Individuals who operate CT x-ray systems shall be specifically trained on the operational features of the unit and:

(1) hold (CT) registration with the American Registry of Radiologic Technologists (ARRT); or

(2) be a Registered Technologist (R.T.) by the ARRT with registration in radiography (R) or a Certified Nuclear Medicine Technologist by the Nuclear Medicine Technology Certification Board; these individuals shall document training and experience that is equivalent to that required to attain (CT) registration with the ARRT; or

(3) be in training under the personal supervision of an individual that meets the requirements of Subparagraph (d)(1) or (d)(2) of this Rule.

(e) System Performance Evaluations

(1) Performance evaluations of the CT x-ray system shall be performed by, or under the general supervision of, a CT QE who assumes the responsibility for the evaluation.

(2) The performance evaluation of a CT x-ray system shall be performed within 30 days of installation and at least every 14 months.

(3) Performance evaluation standards and tolerances shall meet manufacturer's specifications or standards and tolerances for the CT x-ray system from the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM) incorporated herein by reference including subsequent amendments and editions. These standards and tolerances may be found at no charge on the ACR website at https://www.acr.org and the AAPM website at www.aapm.org.

(4) The performance evaluation shall include the following as applicable to the design of the scanner:
- (A) geometric factors and alignment including alignment light accuracy, and table increment accuracy;
- (B) image localization from a scanned projection radiograph (localization image);
- (C) radiation beam width;
- (D) image quality including high-contrast (spatial) resolution, low-contrast resolution, image uniformity, noise, and artifact evaluation;
- (E) CT number accuracy;
- (F) image quality for acquisition workstation display devices; and
- (G) a review of the results of the routine QC, as set forth in Paragraph (f) of this Rule;

(5) The performance evaluation shall also include the evaluation of radiation output and patient dose indices for the following clinical protocols if performed:
- (A) pediatric head;
- (B) pediatric abdomen;
- (C) adult head;
- (D) adult abdomen; and
- (E) brain perfusion.

(6) Evaluation of radiation output shall be performed with a dosimetry system that is calibrated. The dosimetry system shall have been calibrated within the preceding two years by persons registered to provide such services pursuant to Rule .0205 of this Chapter.

(7) The performance evaluation shall be documented and maintained for inspection by the Agency. The documentation shall include the name of the CT QE performing or supervising the evaluation, as well as any other individuals participating in the evaluation under the general supervision of the CT QE. The documentation shall be retained for 14 months.

(f) Routine Quality Control (QC)

(1) A routine QC program for the CT system shall be developed by or have written approval by a CT QE and include:
- (A) instructions for the routine QC;
- (B) intervals for QC testing;
- (C) acceptable tolerances for the QC tests;
- (D) use of a water equivalent phantom to evaluate each day of clinical use: noise, CT number accuracy, and artifacts; and
- (E) routine QC tests that may be performed in place of system performance evaluations after equipment repairs or maintenance. This shall include the process for obtaining approval from the CT QE prior to conducting testing.

(2) The duties in the routine QC program, as described in Subparagraph (f)(1) of this Rule, shall be conducted by individuals that meet the requirements of Parargraph (d) of this Rule or individuals approved by the CT QE.

(3) The routine QC shall be documented and maintained for inspection by the Agency. The records shall be retained for 14 months.

(g) Operating Requirements. The following information shall be accessible to the CT operator during use of the machine and while performing routine QC:

(1) instructions on performing routine QC;

(2) a schedule of routine QC;

(3) any allowable variations set by the CT QE for the indicated parameters;

(4) the results of the most recent routine QC completed on the system; and

(5) established scanning protocols.

History Note: *Authority G.S. 104E-7; 104E-11; 104E-12;*

Eff. October 1, 2017.

SECTION .0700 - USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

Codifier's Note: 10 NCAC 03G .2800 was transferred to 15A NCAC 11 .0700 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0701 SCOPE
10A NCAC 15 .0702 MANUAL BRACHYTHERAPY

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. November 1, 2007; January 1, 2005; April 1, 1999; January 1, 1994; May 1, 1993; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0701 - .0702 Eff. February 1, 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0703 TELETHERAPY

History Note: *Authority G.S. 104E-7(a)(2); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;*
Eff. February 1, 1980;
Amended Eff. April 1, 1999; June 1, 1993; May 1, 1992; October 1, 1984; October 1, 1980;
Repealed Eff. November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0703 Eff. February 1, 2015.

SECTION .0800 - REQUIREMENTS FOR NON-HUMAN USE OF RADIATION GENERATING DEVICES

10A NCAC 15 .0801 PURPOSE AND SCOPE
(a) This Section provides special requirements for use of ionizing radiation generating devices (RGDs) operating above five thousand electron volts (5 keV), but below one million electron volts (1 MeV) that are in addition to requirements in the other sections of this Chapter.
(b) This Section does not pertain to radiation safety requirements for x-ray equipment that is covered in other sections of this Chapter (e.g., x-rays in the healing arts in Section .0600 of this Chapter, and particle accelerators in Section .0900 of this Chapter).

History Note: *Authority G.S. 104E-7;*
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Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .0802 DEFINITIONS
In addition to terms found in Rule .0104 of this Chapter the following definitions shall apply to this Section:

(1) "Accredited bomb squad" means a law enforcement agency utilizing certified bomb technicians.
(2) "Analytical RGD equipment" means equipment that uses electronic means to generate ionizing radiation for the purpose of examining the microstructure of materials, i.e. x-ray diffraction and x-ray spectroscopy.
(3) "Analytical RGD system" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.
(4) "Bomb detection RGDs" means RGDs used for the sole purpose of remotely detecting explosive devices.
(5) "Certified bomb technician" means a member of an accredited bomb squad who has completed the FBI Hazardous Devices School. Information pertaining to this program can be found on the school website at http://www.fbi.gov/about-us/cirg/hazardous-devices.

(6) "Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to meet the certification requirements specified in 21 CFR 1020.40 as incorporated by reference in Rule .0117 of this Chapter.

(7) "Certified cabinet x-ray system" means an RGD utilized in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed. These systems shall be certified in accordance with 21 CFR 1010.2 as incorporated by reference in Rule .0117 of this Chapter, as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40 as incorporated by reference in Rule .0117 of this Chapter.

(8) "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

(9) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

(10) "Electron Beam Device" means any device using electrons below 1MeV to heat, join, or otherwise irradiate materials.

(11) "Enclosed beam RGD" means an RGD with all possible x-ray beam paths contained in a chamber, coupled chambers, or other beam-path-confinement devices to prevent any part of the body from intercepting the beam during normal operations. Normal access to the primary beam path, such as a sample chamber door, shall be interlocked with the high voltage of the x-ray tube or the shutter for the beam to be considered "enclosed." An open-beam device placed in an interlocked enclosure is considered an "enclosed beam" unless there are provisions for routine bypassing of the interlocks.

(12) "Fail-safe characteristics" means a design feature that causes the radiation beam to terminate, port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device. For example, if an "X-ray On" light indicator or shutter indicator or interlock fails, the radiation beam shall terminate.

(13) "Hand-held x-ray system" means any device or equipment that is portable and used for similar purposes as analytical RGD equipment.

(14) "Hybrid gauge" means an x-ray gauge device utilizing both x-ray and radioactive sources.

(15) "Industrial radiography" means RGDs used to make radiographic images to examine the structure of materials by nondestructive methods. These RGDs shall not be contained in a cabinet and are not permanent installations.

(16) "Ion implantation equipment, low-energy" means any closed device operating below 1MeV used to accelerate elemental ions and implant them in other materials.

(17) "Leakage radiation" means radiation emanating from the source assembly housing except for:

(A) the primary beam;

(B) scatter radiation emanating from other components (e.g., shutter or collimator); and

(C) radiation produced when the beam on switch or timer is not activated.

(18) "Local components" means part of an RGD x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

(19) "Mobile RGD" means RGD equipment mounted on a permanent base with wheels or casters for moving while assembled.

(20) "Normal operating procedures" means step-by-step instructions necessary to accomplish a task. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures that are related to radiation safety.

(21) "Open-beam RGD" means a device or system designed in such a way that the primary beam is not completely enclosed during normal operation and used for analysis, gauging, or imaging in which an individual could accidentally place some part of their body in the primary beam or stray radiation path during normal operation.

(22) "Permanent radiographic installation" means an RGD utilized in an enclosed shielded room, cell, or vault that allows entry when the RGD is not energized.

(23) "Portable RGD" means RGD equipment designed to be carried.

(24) "Primary beam" means radiation that passes through an aperture of the source assembly housing by a direct path from the radiation source.

(25) "Radiation generating device (RGD)" means any system, device, subsystem, or machine component that may generate by electronic means x-rays or particle radiation above 5 keV, but below 1 MeV, and not used for healing arts on humans or animals. Examples of RGDs are the following:

(A) analytical RGD equipment;
(B) certified and certifiable cabinet x-ray systems;
(C) gauging devices using x-ray sources;
(D) hybrid gauging devices;
(E) e-beam welders;
(F) baggage scanners;
(G) industrial radiography RGDs; and
(H) permanent radiographic installations.

(26) "Remote components" means parts of an RGD x-ray system that are not struck by x-rays such as power supplies, transformers, amplifiers, readout devices, and control panels.

(27) "Scattered radiation" means radiation, other than leakage radiation, that during passage through matter, has been deviated in direction or has been modified by a decrease in energy.

(28) "Shutter" means an adjustable device, generally made of lead or other high atomic number material, fixed to a source assembly housing to intercept, block, or collimate the primary beam.

(29) "Source" means the point of origin of the radiation, such as the focal spot of an x-ray tube.

(30) "Stationary RGD" means RGD equipment that is installed or placed in a fixed location.

(31) "Stray radiation" means the sum of leakage and scatter radiation emanating from the source assembly or other components except for the primary beam, and radiation produced when the beam on switch or timer is not activated.

(32) "X-ray generator" means the part of an x-ray system that provides the accelerating (high) voltage and current for the x-ray tube.

(33) "X-ray gauge" means an x-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, or interface location of manufactured products.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
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Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .0803 EQUIPMENT REQUIREMENTS

(a) Certified cabinet x-ray systems shall meet the requirements of 21 CFR 1020.40 as incorporated by reference in Rule .0117(a)(3) of this Chapter.

(b) All certified and certifiable cabinet x-ray systems shall:

(1) be constructed so that, the radiation emitted from the system shall not exceed an exposure of 0.5 milliroentgen (mR) in one hour at any point five centimeters outside the external surface; and

(2) have a fail-safe interlock that prevents irradiation when the cabinet, chamber, or coupled chambers are open.

(c) Open-beam analytical RGD systems shall be equipped with a safety device that prevents the entry of any portion of an individual's body into the primary x-ray beam path that causes the beam to be shut off upon entry into its path.

(d) Open-beam analytical RGDs shall be provided with a visible and legible indication of:

(1) x-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; or

(2) shutter status (OPEN-CLOSED) or beam status (ON-OFF) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(e) Warning devices on open-beam analytical RGDs shall be labeled so that their purpose is identified. On open-beam analytical RGDs installed after February 1, 1980, warning devices and lights shall have fail-safe characteristics.

(f) Unused ports on radiation source housings for open-beam RGDs shall be secured in the closed position in a manner that will prevent unintended opening.

(g) Each port on the radiation source housing on open-beam analytical RGDs installed after February 1, 1980 and designed to accommodate interchangeable components shall be equipped with a shutter that cannot be opened unless a collimator or a component coupling is connected to the port.

(h) Portable open-beam analytical RGDs that shall be manufactured to be used hand-held without safety devices are exempt from the requirements of Paragraph (c) of this Rule and shall be constructed according to International Standard IEC 62495 that is incorporated by reference and includes subsequent amendments. This standard can be downloaded for

one hundred twenty-one dollars ($121.00) at the following website: http://webstore.ansi.org/FindStandards.aspx?SearchString=IEC+62495+Ed.+1.0+en%3a2011&SearchOption=0&PageNum=0&SearchTermsArray=null%7cIEC+62495+Ed.+1.0+en%3a2011%7cnull.

(i) A registrant may apply to the agency, as defined in Rule .0104 of this Chapter, for an exemption from the requirement of a safety device. This request shall include:

(1) a description of the safety devices;

(2) the reason safety devices cannot be used; and

(3) a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(j) Analytical RGDs shall be provided with a visible and legible label(s) bearing the radiation symbol and the words:

(1) "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar meaning, near the exit port to identify the location of the beam; and

(2) "CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar meaning, near any switch that energizes an x-ray tube, if the radiation source is an x-ray tube.

(k) Warning lights labeled with the words "X-RAYS ON," or other words having similar meaning, shall be located:

(1) near any switch that activates the high voltage to energize an x-ray tube; or

(2) in a conspicuous location near the radiation source housing and radiation beam(s) and visible from all instrument access areas.

(l) Warning lights shall activate when the x-ray tube is energized.

(m) Each x-ray tube housing shall be:

(1) constructed that when all shutters are closed the leakage radiation measured at a distance of five centimeters from its surface is not capable of producing an exposure in excess of 2.5 millirem (mrem)/(25 microsieverts µSv) in one hour; and

(2) if the tube housing is the primary shielding for the x-ray tube, does not produce x-rays when the housing is opened or disassembled.

(n) Each x-ray generator shall be supplied with a protection cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing an exposure in excess of 0.25 mrem/2.5µSv in one hour.

(o) Permanent radiographic installations and industrial radiography RGDs shall comply with the requirements of Rule .0807 of this Section.

History Note: *Authority G.S. 104E-7;*
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Amended Eff. October 1, 2015;
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10A NCAC 15 .0804 AREA REQUIREMENTS

(a) The local components of RGDs shall be located and arranged to include sufficient shielding or access control to ensure no radiation levels exist in any area surrounding the local components that could result in a dose to an individual present in excess of the dose limits given in Rule .1611(a) of this Chapter.

(b) Survey Requirements

(1) Radiation surveys, as set forth in Rule .1613(a) and (b) of this Chapter, of all RGDs sufficient to show compliance with Paragraph (a) of this Rule, shall be performed:

(A) within 30 days after initial operation of the device;

(B) prior to use following any change in the initial arrangement, including the number or type of local components in the system; and

(C) prior to use following any maintenance requiring the disassembly or removal of a local component in the system that could affect the radiation exposure to personnel.

(2) A registrant may apply to the agency for approval of procedures differing from those in Subparagraph (b)(1) of this Rule, provided that the registrant demonstrates satisfactory compliance with Paragraph (a) of this Rule.

(3) Surveys shall be performed with a radiation survey instrument capable of the following:

(A) measuring the radiation energies of the system surveyed;

(B) confirming that the radiation limits of this Section are met; and
(C) calibrated according to the manufacture's recommended frequency or at least annually when a frequency is not recommended.

(c) Each area of use or room containing RGDs shall be conspicuously posted with caution signs in accordance with the requirements of Rule .1623 of this Chapter, bearing the radiation caution symbol and the words "CAUTION - X-RAY EQUIPMENT," or words having a similar meaning.

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0804 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .0805 OPERATING REQUIREMENTS

(a) RGDs shall be operated by individuals that have completed the training requirements of Rule .0806 of this Section.
(b) Normal operating procedures shall be written and available to all RGD operators and support staff.
(c) No individual shall be permitted to operate RGDs in any manner other than that specified in the operating procedures unless the person has obtained written approval of the individual responsible for radiation or the Radiation Safety Officer (RSO) as defined in Rule .0104 of this Chapter.
(d) No individual shall bypass a safety device unless the person has obtained the approval of the person responsible for radiation safety or the RSO. This process shall be incorporated into the radiation protection program by the RSO, as set forth in Rule .1603(a), and the operating procedures as set forth in Rule .0603(a)(1)(B). The written approval, as granted by the RSO, shall include an expiration date. When a safety device has been bypassed, a legible sign bearing the words "SAFETY DEVICE NOT WORKING" or words having a similar meaning shall be placed on the radiation source housing and the control panel during the bypassing period.
(e) Prior to an individual modifying the:
(1) x-ray tube system, resulting in the removal of tube housings, covers, or shielding materials;
(2) shutters;
(3) collimators; or
(4) beam stops
the individual shall determine the tube is off and will remain off until safe conditions have been restored.
(f) Safety devices including interlocks, shutters, and warning lights shall be tested once annually for proper operation on all RGDs in operation. Records of the testing shall be retained by the registrant for three years.
(g) No individual shall hold a sample or object while it is being irradiated.

History Note: *Authority G.S. 104E-7; 104E-12;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0805 Eff. February 1, 2015;
Amended Eff. January 1, 2016; October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .0806 PERSONNEL REQUIREMENTS

(a) Personnel operating or maintaining RGDs shall comply with the following:
(1) No person shall be permitted to operate or maintain RGDs unless the person has received instruction in the operating and emergency procedures for the RGD and instruction that is in accordance with Rule .1003 of this Chapter.
(2) Each registrant operating or maintaining RGDs shall maintain, for inspection by the agency, records of training that demonstrate the requirements of this Rule have been satisfied.
(b) The registrant shall provide ring or wrist personnel monitoring equipment to:
(1) individuals using open-beam RGDs not equipped with a safety device; and
(2) individuals maintaining RGDs if the maintenance procedures require the presence of a primary x-ray beam when any local component in the RGD is disassembled or removed.

History Note: *Authority G.S. 104E-7; 104E-11; 104E-12;*
Eff. February 1, 1980;

Transferred and Recodified from 15A NCAC 11 .0806 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .0807 PERMANENT RADIOGRAPHIC INSTALLATIONS AND INDUSTRIAL RADIOGRAPHY RGDS

(a) Permanent radiographic installations and industrial radiography RGDs are exempt from the requirements of the rules of this Section except Rule .0802 and Rule .0804(a), (b)(1)(A), (b)(1)(C), (b)(2), and (b)(3).

(b) Permanent radiographic installations and industrial radiography RGDs shall comply with the following rules of this Chapter:

(1) .0501;
(2) .0502;
(3) .0506;
(4) .0509-.0520;
(5) .0522;
(6) .0523(a)(1);
(7) .0523(a)(3);
(8) .0523(a)(6) -.0523(a)(15);
(9) .0523(b)(1) -.0523(b)(4);
(10) .0523(b)(6) -.0523(b)(7);
(11) .0523(b)(9) -.0523(b)(12);
(12) .0523(c); and
(13) .0525.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2015.

10A NCAC 15 .0808 APPLICABLE RULES FOR BOMB DETECTION RGDS

Bomb detection RGDs utilized by accredited bomb squads and certified bomb technicians shall comply with the following rules of this Chapter:

(1) .0501;
(2) .0502;
(3) .0509;
(4) .0511-.0520 except for the requirements for a direct reading pocket dosimeter and operating alarm ratemeter in .0512(a);
(5) .0522;
(6) .0523(a)(1);
(7) .0523(a)(3);
(8) .0523(a)(6) -.0523(a)(15);
(9) .0523(b)(1) -.0523(b)(4);
(10) .0523(b)(6) -.0523(b)(7);
(11) .0523(b)(9) -.0523(b)(12);
(12) .0523(c); and
(13) .0525.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2015.

SECTION .0900 - REQUIREMENTS FOR PARTICLE ACCELERATORS

Codifier's Note: 10 NCAC 03G .3000 was transferred to 15A NCAC 11 .0900 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0901 PURPOSE AND SCOPE

(a) This Section establishes procedures for the licensing and the use of particle accelerators.

(b) In addition to the requirements of this Section, all licensees are subject to the requirements of Sections .0100, .0200, .1000, and .1600 of this Chapter. Licensees engaged in industrial radiographic operations are subject to the requirements of Section .0500 of this Chapter, and licensees engaged in the healing arts are subject to Rule .0350 of this Chapter and the applicable requirements of Section .0600 of this Chapter. Licensees engaged in the production of radioactive material or possessing radioactive material incidental to an accelerator are subject to the requirements of Section .0300 of this Chapter.
(c) In addition to the requirements of this Section, all particle accelerator licensees are subject to the annual fee provisions contained in Section .1100 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-9(a)(8); 104E-19(a);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1989; July 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0901 Eff. February 1, 2015.

10A NCAC 15 .0902 LICENSING REQUIREMENTS

No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a license issued pursuant to these Rules or as otherwise provided for in these Rules. The general procedures for licensing of particle accelerator facilities are included in Section .0903 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0902 Eff. February 1, 2015.

10A NCAC 15 .0903 REQUIREMENTS FOR ISSUANCE OF A LICENSE FOR ACCELERATORS

Application for use of a particle accelerator will be approved only if the agency determines that:

(1) The applicant and his operators are qualified by reason of training and experience to use the accelerator in such a manner as to minimize danger to public health and safety or property;
(2) The applicant's proposed equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;
(3) The applicant has appointed a radiation safety officer;
(4) The applicant has established a radiation safety committee to approve that the operation of the particle accelerator is in accordance with applicable radiation protection Sections of this Chapter; and
(5) The applicant for the use of a particle accelerator in the healing arts shall be a physician licensed to practice medicine in the state of North Carolina. The individuals designated on the application as users shall have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0903 Eff. February 1, 2015.

10A NCAC 15 .0904 LIMITATIONS

(a) No licensee shall permit any person to act as a particle accelerator operator until such person:

(1) has been instructed in radiation safety and shall have demonstrated an understanding thereof;
(2) has received copies of, and instruction in, this Section and the applicable requirements of this Chapter, pertinent licensing conditions and the licensee's operating and emergency procedures; and
(3) has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment.

(b) Either the radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if this action is deemed necessary to minimize danger to public health and safety or property.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0904 Eff. February 1, 2015.

10A NCAC 15 .0905 SHIELDING AND SAFETY DESIGN

(a) A qualified expert registered by the agency pursuant to Rule .0205 of this Chapter, shall be consulted in the design of a particle accelerator installation. A qualified expert shall perform a radiation survey when the accelerator is first capable of producing radiation to verify that radiation levels and shielding effectiveness meet the applicable requirements in this Chapter. A copy of the survey shall be submitted to the agency by the licensee prior to its use for its licensed purpose.

(b) Plans for construction of accelerator installations shall be submitted to the agency.

(c) Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with Rules .1604 and .1611 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0905 Eff. February 1, 2015.

10A NCAC 15 .0906 CONTROLS AND INTERLOCK SYSTEMS

(a) Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(b) All entrances into a target room or other high radiation area shall conform to the requirements of Rule .1615 of this Chapter.

(c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped and, subsequently at the main control console.

(d) Each safety interlock shall operate independently of all other safety interlocks.

(e) All safety interlocks shall be fail-safe, i.e., designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

(f) A "Scram button" or other emergency power cut-off switch shall be located and easily identifiable in all high radiation areas and at the control console. Such a cut-off switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without first manually resetting the cut-off switch.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0906 Eff. February 1, 2015.

10A NCAC 15 .0907 WARNING DEVICES

(a) All locations designated as high radiation areas, and entrances to such locations shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. This warning device shall be clearly discernible in all high radiation areas and all radiation areas.

(c) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with Rule .1624 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0907 Eff. February 1, 2015.

10A NCAC 15 .0908 OPERATING PROCEDURES

(a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam "on" and "off". The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

(c) All safety and warning devices, including interlocks shall be checked for proper operability at least every six months unless more frequent checks are required by the agency. Results of such tests shall be maintained for two years at the accelerator facility for inspection by the agency.
(d) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the agency.
(e) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:
(1) authorized by the radiation safety officer;
(2) recorded in a permanent log and a notice posted at the accelerator control console and at the location of the bypassed interlock; and
(3) terminated as soon as possible.
(f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0908 Eff. February 1, 2015.

10A NCAC 15 .0909 RADIATION MONITORING REQUIREMENTS
(a) Portable monitoring equipment shall be available at each particle accelerator facility. Such equipment shall be tested for proper operation monthly and calibrated at intervals not to exceed one year, and after each servicing and repair.
(b) A radiation protection survey shall be performed and documented by a qualified expert registered by the agency pursuant to Rule .0205 of this Chapter, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas. The licensee shall submit the report of the qualified expert to the agency at the address found in Rule .0111 of this Chapter.
(c) Except for facilities designed for human exposure, radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems and capable of providing a remote and local readout with visual or audible alarms at the control panel and other appropriate locations.
(d) All area monitors shall be tested for proper operation at least every six months unless more frequent checks are required by the agency.
(e) Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.
(f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.
(g) All area surveys shall be made in accordance with the written procedures established by a qualified expert registered by the agency pursuant to Rule .0205 of this Chapter, or the radiation safety officer of the particle accelerator facility.
(h) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility for two years for inspection by the agency.

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0909 Eff. February 1, 2015.

10A NCAC 15 .0910 VENTILATION SYSTEMS
(a) Adequate ventilation shall be provided in areas where airborne radioactivity may be produced to comply with Rule .1604 of this Chapter.
(b) The licensee shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area in excess of the limits specified in Rule .1611 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0910 Eff. February 1, 2015.

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) of this Chapter;

(B) "licensed" means registered pursuant to the rules in Section .0200 of this Chapter;

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

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

(E) "NRC-licensed" means registered pursuant to the rules in Section .0200 of this Chapter; and

(F) "radioactive material" shall have the same meaning as "radiation machine" as defined in Rule .0104(122) 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 .1002 POSTING OF NOTICES TO WORKERS
10A NCAC 15 .1003 INSTRUCTIONS TO WORKERS

History Note: *Authority G.S. 104E-7; 104E-10; 104E-12;*
Eff. February 1, 1980;
Amended Eff. April 1, 1999; January 1, 1994; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .1002 and .1003, Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Repealed Eff. October 1, 2023.

10A NCAC 15 .1004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-12;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .1004 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. October 1, 2023.

10A NCAC 15 .1005 PRESENCE OF REPRESENTATIVES DURING INSPECTIONS
10A NCAC 15 .1006 CONSULTATION WITH WORKERS

History Note: *Authority G.S. 104E-7; 104E-10; 104E-11;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1005 and .1006 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Repealed Eff. October 1, 2023.

10A NCAC 15 .1007 REQUESTS FOR INSPECTIONS
10A NCAC 15 .1008 INSPECTIONS NOT WARRANTED

History Note: *Authority G.S. 104E-7; 104E-10;*
Eff. February 1, 1980;
Amended Eff. May 1, 1992; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1007 – .1008 Eff. February 1, 2015;
Repealed Eff. October 1, 2023.

SECTION .1100 - FEES

Codifier's Note: 10 NCAC 03G .3200 was transferred to 15A NCAC 11 .1100 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .1101 PURPOSE AND SCOPE

(a) This Section establishes annual fees to cover the anticipated costs of inspection, educational and training activities of the agency.

(b) The fees are imposed on persons registered pursuant to provisions of Section .0200 of this Chapter, on persons licensed pursuant to provisions of Sections .0300 and .0900 of this Chapter, and on certain persons applying for out-of-state reciprocal recognition.

(c) Notwithstanding Paragraph (b) of this Rule, no fee shall be imposed on any person in conjunction with the person's possession and use of any luminous safety device or luminous gunsight pursuant to the general licenses in Rules .0309 and .0311 of this Chapter. For purposes of this Section, "luminous safety device" means an exit marker, hazard warning sign, safety related marker, or other safety equipment containing one or more radioactive material powered light sources for the purpose of improving legibility or visibility.

History Note: *Authority G.S. 104E-9(8); 104E-19(a);*
Eff. July 1, 1982;
Amended Eff. July 1, 1989; May 1, 1983;
Transferred and Recodified from 15A NCAC 11 .1101 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1102 PAYMENT DUE

(a) All fees established in this Section shall be due on the first day of July of each year.

(b) Notwithstanding Paragraph (a) of this Rule, when a new license or registration is issued by the agency or after the first day of July of any subsequent year, the initial fee shall be due on the date of issuance of the license or registration.

(c) The initial fee in Paragraph (b) of this Rule shall be computed as follows:

(1) When any new license or registration is issued before the first day of January of any year, the initial fee shall be the full amount specified in Rule .1105 or .1106 of this Section; and

(2) When any new license or registration is issued on or after the first day of January of any year, the initial fee shall be one-half of the amount specified in Rule .1105 or .1106 of this Section.

(d) All fees received by the agency pursuant to provisions of this Section shall be nonrefundable.

(e) Each licensee or registrant shall pay all fees online at https://www.thepayplace.com/northcarolinadhhs/dhsr/ncrpsfees/challenge.aspx, or by check or money order made payable to "Radiation Protection Section" and mail such payment to: Radiation Protection Section, Division of Health Service Regulation, Department of Health and Human Services to the address shown on the facility invoice.

History Note: *Authority G.S. 104E-9(a)(8); 104E-19(a);*
Eff. July 1, 1982;
Amended Eff. May 1, 1993; May 1, 1992; July 1, 1989;
Temporary Amendment Eff. June 30, 2002;
Temporary Amendment Expired on March 28, 2003;
Findings of need for Emergency Rule disapproved by Codifier on June 8, 2007;
Emergency Amendment Eff. June 19, 2007 pursuant to G.S. 150B-21.1A(b);
Amended Eff. August 1, 2007;
Transferred and Recodified from 15A NCAC 11 .1102 Eff. February 1, 2015;
Readopted Eff. July 1, 2020.

10A NCAC 15 .1103 NOTICES OF PAYMENT DUE

Within five days after the due dates established in Paragraphs (a) and (b) of Rule .1102 of this Section, the agency shall mail to each licensee and registrant, who has not already submitted payment, a notice which indicates the due date, delinquent date and the amount of fees due.

History Note: *Authority G.S. 104E-9(8); 104E-19(a);*
Eff. July 1, 1982;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1103 Eff. February 1, 2015;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1104 DELINQUENT AND UNCOLLECTIBLE FEES

(a) Payment of fees established in this Section shall be delinquent, if not received by the agency within 60 days after the due date specified in Paragraphs (a) and (b) of Rule .1102 of this Section.

(b) If a licensee or registrant remits a fee in the form of a check or other instrument which is uncollectible from the paying institution, the agency shall notify the licensee or registrant by certified mail and allow the licensee or registrant 15 days to correct the matter, which includes payment of any fee charged to the agency by a banking institution.

(c) If payment of fees is uncollectible from the paying institution or not submitted to the agency by the delinquent date, the agency may institute legal action to collect.

History Note: *Authority G.S. 104E-9(8); 104E-19(a);*
Eff. July 1, 1982;
Amended Eff. August 1, 2007; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1104 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1105 X-RAY FEE AMOUNTS

(a) Annual fees for persons registered pursuant to provisions of Section .0200 of this Chapter are as listed in the following table:

Type of Registered Facility	Letters Appearing in Registration Number	Facility Plus First X-ray Tube	Each Additional X-ray Tube
Chiropractors	C	$ 180.00	$ 24.00
Dentists	D	$ 180.00	$ 24.00
Educational	E	$ 130.00	$ 22.00
Government	G	$ 130.00	$ 22.00
Podiatrists	H	$ 180.00	$ 24.00
Industrial	I	$ 180.00	$ 24.00
Industrial Medical	IM	$ 260.00	$ 33.00
Health Departments	L	$ 260.00	$ 33.00
Hospitals	M	$ 390.00	$ 44.00
Physicians	P	$ 180.00	$ 24.00
Industrial Radiography	R	$ 380.00	$ 44.00
Services	S	$ 260.00	$ 0.00
Therapy	T	$ 400.00	$ 50.00
Veterinarians	V	$ 130.00	$ 22.00
Other	Z	$ 180.00	$ 24.00

(b) Annual fees for out-of-state persons granted permission to use sources of radiation in this state pursuant to provisions of Rule .0211 of this Chapter are the same as that provided for in the applicable category specified in Paragraph (a) of this Rule.

History Note: *Authority G.S. 104E-9(a)(8); 104E-19(a);*
Eff. July 1, 1982;
Amended Eff. July 1, 2011; August 1, 2007; August 1, 2002; July 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1105 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1106 RADIOACTIVE MATERIALS AND ACCELERATOR FEE AMOUNTS

(a) Annual fees for persons licensed pursuant to the provisions of Section .0300 of this Chapter shall be:

Type of Radioactive Material License	Annual Fee
Specific license of broad scope including:	
-academic or research and development (R&D)	$ 5,180.00
-manufacture or distribution	$ 6,100.00
-medical	$ 6,760.00
Specific license including:	
-educational institutions, R&D laboratories	$ 2,960.00
-industrial radiography	$ 5,400.00
-irradiator >10,000Ci	$ 19,140.00
-irradiator ≤10,000Ci	$ 2,160.00
-manufacture or distribution	$ 2,320.00
-medical (human use), diagnostic	$ 2,940.00
-medical (human use), therapeutic	$ 4,760.00
-services, consultants, gauges (all types), or not specified above	$ 1,860.00
-well logging, subsurface tracer studies	$ 3,200.00
General license including:	
-not subject to annual registration requirements	$ 200.00
-subject to annual registration requirements	$ 325.00
-possession of self-luminous devices under Rule .0309 of this Chapter	no fee
-possession of source material from water remediation activities under Rule .0307 of this Chapter	no fee

(b) Annual fees for persons licensed pursuant to the provisions of Section .0900 of this Chapter shall be four thousand seven hundred sixty dollars ($4,760.00).

(c) Fees for out-of-state persons granted permission to use sources of radiation in this State pursuant to Rule .0345 of this Chapter are the same as that provided for in the applicable category specified in Paragraphs (a) and (b) of this Rule. The fees shall be due when the application for reciprocal recognition of out-of-state license is made.

(d) Each location listed on a license issued by the Agency that is not part of a contiguous property controlled by the licensee shall require an additional fee equal to the amount specified in Paragraphs (a) and (b) of this Rule. Fees for client locations listed on mobile medical licenses shall be one-half of the amount specified in Paragraphs (a) or (b) of this Rule for each client site.

(e) Persons licensed to conduct activities subject to multiple categories of fees under Paragraph (a) of this Rule shall be required to pay only the highest fee category.

(f) Persons possessing Sealed Source and Device Registration (SS&D) certificates shall pay an annual fee of one thousand four hundred eighty dollars ($1,480.00) per active SS&D certificate issued by the Agency, in addition to any amounts specified in Paragraph (a) of this Rule.

(g) Notwithstanding Paragraph (a) of this Rule, persons licensed to conduct activities under a specific license with annual receipts of less than two hundred fifty thousand dollars ($250,000) may pay a reduced license fee of one-half of the amount shown in Paragraph (a) of this Rule, provided:

(1) payment of fees is made in accordance with Rule .1102 of this Section;

(2) an affidavit is submitted to the agency every year that reduced fees are paid, no later than the date that payment of license fees are due, stating that annual receipts for all business activities are less than the amount shown in this Paragraph during the consecutive 12 month period preceding the date license fees are due. This affidavit shall be signed by the individual authorized to sign license amendments and this signature shall be witnessed and notarized;

(3) records of annual receipts of all business activities shall be made available to the agency for inspection in accordance with Rule .0107 of this Chapter. These records shall include municipal, county, and State tax records; and

(4) a copy of the affidavit and records of annual receipts shall be maintained for five years after the date the affidavit is notarized.

History Note: Authority G.S. 104E-9(a)(8); 104E-19(a);

Eff. August 1, 2007;
Amended Eff. July 1, 2011;
Transferred and Recodified from 15A NCAC 11 .1106 Eff. February 1, 2015;
Amended Eff. May 1, 2019;
Readopted Eff. July 1, 2020.

SECTION .1200 - LAND DISPOSAL OF RADIOACTIVE WASTE

10A NCAC 15 .1201 PURPOSE AND SCOPE
10A NCAC 15 .1202 DEFINITIONS

History Note: *Authority G.S. 104E-2; 104E-3; 104E-5; 104E-7; 104E-10; 104E-10.1; 104E-10.2; 104E-25; 104E-26;*
Eff. December 1, 1987;
Amended Eff. January 1, 1994; May 1, 1993; May 1, 1992; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1201 - .1202 Eff. February 1, 2015;
Repealed Eff. May 1, 2023.

10A NCAC 15 .1203 LICENSE REQUIRED: LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE

(a) This Rule establishes the procedures, standards, criteria, and terms and conditions upon which the Department issues licenses authorizing land disposal of low-level radioactive waste received from other persons for disposal.

(1) No person may receive, possess, and dispose of low-level radioactive waste at a land disposal facility located in North Carolina unless authorized by a license issued by the Department pursuant to this Rule.

(2) No low-level radioactive waste shall be received from any source not licensed by the agency except as may be specifically authorized in writing by the agency.

(3) The regulations in 10 CFR 61 which are hereby incorporated by reference, including subsequent amendments and editions, except that 10 CFR 61.5, 61.8, 61.16, 61.23(i) and (j), 61.83, and 61.84 are not incorporated by reference. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part061/. Communications, records, reports, and notifications required by 10 CFR 61.4 and 61.80 shall be submitted to the agency at the address shown in Rule .0111 of this Chapter in lieu of the NRC.

(4) The requirements found in G.S. 104E-6.1, 104E-10.1(a), (a1), and (b), 104E-10.2, 104E-25(a), (c) through (h), and (j) shall be met.

(5) In addition to the definitions found in 10 CFR 61.2, the definitions in G.S. 104E-5 shall apply.

(6) The agency may access and inspect any licensed low-level radioactive waste disposal facility on a temporary or emergency basis to determine compliance with the rules in this Chapter or to respond to any emergency which involves possible or actual release of radioactive material.

(b) This Rule establishes the procedures, criteria, and terms and conditions upon which the agency issues licenses authorizing access to low-level radioactive waste land disposal facilities licensed under Paragraph (a) of this Rule.

(1) No person shall transport or transfer waste to a low-level radioactive waste land disposal facility licensed under Paragraph (a) of this Rule unless licensed by the agency or otherwise specifically authorized in writing by the agency.

(2) The definitions of terms in G.S. 104E-5 shall apply.

(3) Generators, waste brokers, and waste processors of low-level radioactive waste shall develop procedures and implement practices to prevent, minimize, and reduce the generation of low-level radioactive waste, including segregating radioactive waste by half-life and holding low-level radioactive waste for decay in storage.

(4) Upon receipt of an application for a license authorizing access to low-level radioactive waste land disposal facilities licensed under Paragraph (a) of this Rule, the agency shall review the contents of the application and determine if the applicant's facilities, staffing, equipment, and procedures are adequate to protect the health and safety of the public and occupationally exposed workers, and if the requirements in Subparagraph (b)(3) of this Rule are met. If the agency determines that the applicant's facilities, staffing, equipment, and procedures are adequate to protect the health and safety of the public and occupationally exposed workers, and that the applicant's procedures and practices prevent,

minimize and reduce the generation of low-level radioactive waste, the agency shall issue a license as described in this Rule.

(5) Licenses issued under this Rule are subject to suspension or revocation for failure to comply with the rules of this Chapter or in accordance with 10 CFR 61.9b(a) and (c).

(6) Facilities licensed by the agency and licensed activities may be inspected by authorized representatives of the Department as permitted by G.S. 104E-11(a). For licenses issued to licensees located outside of the jurisdiction of the Department, the Department may delegate this authority to individuals representing the radiation control programs within those jurisdictions.

(c) Applications required by this Rule shall be made on forms provided by the agency, and the payment of fees required by 10 CFR 61.20(c) shall not apply. 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) Application forms specified in this Rule shall be made available by the agency on the agency's public website.

(d) Nothing in this Rule shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.

History Note: *Authority G.S. 104E-5; 104E-6.1; 104E-7; 104E-10(b); 104E-10.1; 104E-10.2; 104E-10.3; 104E-11; 104E-18; 104E-25; 104E-26; 104E-27;*
Eff. December 1, 1987;

Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1203 Eff. February 1, 2015;
Readopted Eff. May 1, 2023.

10A NCAC 15 .1204 CONTENT OF APPLICATION
10A NCAC 15 .1205 GENERAL INFORMATION
10A NCAC 15 .1206 SPECIFIC TECHNICAL INFORMATION
10A NCAC 15 .1207 ENVIRONMENTAL INFORMATION
10A NCAC 15 .1208 TECHNICAL AND ENVIRONMENTAL ANALYSES
10A NCAC 15 .1209 INSTITUTIONAL INFORMATION
10A NCAC 15 .1210 FINANCIAL INFORMATION
10A NCAC 15 .1211 FILING AND DISTRIBUTION OF APPLICATION
10A NCAC 15 .1212 ELIMINATION OF REPETITION
10A NCAC 15 .1213 UPDATING OF APPLICATION
10A NCAC 15 .1214 STANDARDS FOR ISSUANCE OF A LICENSE
10A NCAC 15 .1215 CONDITIONS OF LICENSE
10A NCAC 15 .1216 AMENDMENT OF LICENSE
10A NCAC 15 .1217 APPLICATION FOR RENEWAL OR CLOSURE
10A NCAC 15 .1218 CONTENTS OF APPLICATION FOR CLOSURE
10A NCAC 15 .1219 POSTCLOSURE OBSERVATION AND MAINTENANCE
10A NCAC 15 .1220 TRANSFER OF LICENSE
10A NCAC 15 .1221 TERMINATION OF LICENSE
10A NCAC 15 .1222 PERFORMANCE OBJECTIVES: GENERAL REQUIREMENT
10A NCAC 15 .1223 PROTECTION OF POPULATION FROM RELEASES OF RADIOACTIVITY
10A NCAC 15 .1224 PROTECTION OF INDIVIDUALS FROM INADVERTENT INTRUSION
10A NCAC 15 .1225 PROTECTION OF INDIVIDUALS DURING OPERATIONS
10A NCAC 15 .1226 STABILITY OF THE DISPOSAL SITE AFTER CLOSURE
10A NCAC 15 .1227 TECHNICAL REQUIREMENTS FOR LAND DISPOSAL FACILITIES
10A NCAC 15 .1228 DISPOSAL SITE SUITABILITY REQUIREMENTS
10A NCAC 15 .1229 SITE DESIGN FOR LAND DISPOSAL
10A NCAC 15 .1230 FACILITY OPERATION AND DISPOSAL SITE CLOSURE
10A NCAC 15 .1231 ENVIRONMENTAL MONITORING

History Note: *Authority G.S. 104E-5; 104E-6.1; 104E-7; 104E-9(3); 104E-9(a)(3); 104E-10; 104E-10(b); 104E-10.1; 104E-10.2; 104E-12; 104E-13(a); 104E-15; 104E-16; 104E-18; 104E-25; 104E-26; 104G-13; 104G-14; 150B-19(6); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;*
Eff. December 1, 1987;
Amended Eff. January 1, 1994; June 1, 1993; May 1, 1993; May 1, 1992; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1204 - .1231 Eff. February 1, 2015;
Repealed Eff. May 1, 2023.

10A NCAC 15 .1232 VARIANCE

History Note: *Authority G.S. 104E-7; 104E-9(3); 104E-10(b); 104E-25; 104E-26;*
Eff. December 1, 1987;
Repealed Eff. July 1, 1990 in accordance with G.S. 150B-59(c);
Transferred and Recodified from 15A NCAC 11 .1232 Eff. February 1, 2015.

10A NCAC 15 .1233 WASTE CLASSIFICATION AND CHARACTERISTICS
10A NCAC 15 .1234 INSTITUTIONAL REQUIREMENTS
10A NCAC 15 .1235 APPLICANT QUALIFICATIONS AND ASSURANCES
10A NCAC 15 .1236 FUNDING OF CLOSURE: STABILIZATION: INSTITUTIONAL CONTROLS
10A NCAC 15 .1237 RECORDS: REPORTS: TESTS: AND INSPECTIONS
10A NCAC 15 .1238 MAINTENANCE OF RECORDS: REPORTS AND TRANSFERS
10A NCAC 15 .1239 TESTS AT LAND DISPOSAL FACILITIES

10A NCAC 15 .1240 AGENCY INSPECTIONS OF LAND DISPOSAL FACILITIES
10A NCAC 15 .1241 INSPECTION
10A NCAC 15 .1242 NOTIFICATIONS AND REPORTS

History Note: *Authority G.S. 104E-6.1; 104E-7; 104E-9(3); 104E-9(a)(3); 104E-10(b); 104E-10.1; 104E-10.2; 104E-11; 104E-12; 104E-15; 104E-16; 104E-17; 104E-18; 104E-19(b); 104E-25; 104E-26;*
Eff. December 1, 1987;
Amended Eff. January 1, 1994; May 1, 1993;
Transferred and Recodified from 15A NCAC 11.1233 - .1242 Eff. February 1, 2015;
Repealed Eff. May 1, 2023.

SECTION .1300 - REQUIREMENTS FOR WIRELINE-SERVICE OPERATORS AND SUBSURFACE-TRACER STUDIES

Codifier's Note: 10 NCAC 03G .3400 was transferred to 15A NCAC 11 .1300 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .1301 WELL LOGGING, WIRELINE-SERVICE OPERATIONS, AND SUBSURFACE TRACER STUDIES: REQUIREMENTS FOR LICENSEES

(a) Persons using sources of radiation for well logging, wireline-service operations, mineral logging, radioactive markers, or subsurface tracer studies shall comply with the provisions of 10 CFR Part 39, except that 10 CFR 39.5, 39.8, 39.101, and 39.103 shall not apply.

(b) In addition to the terms defined in 10 CFR 39.2, the following definitions shall also apply to this Section:

(1) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas;

(2) "Well-bore" means a drilled hole in which wireline-service operations and subsurface-tracer studies are performed;

(3) "Wireline" means a cable containing one or more electrical conductors that is used to lower and raise logging tools in the well-bore; and

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

(c) Applications required by 10 CFR 39.11 shall be made on forms provided by the agency, and the payment of fees required by 10 CFR Part 170 shall not apply. One copy of the application 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. Items one through five on the application form shall be completed by the applicant, using additional sheets as necessary. 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. Items one through seven on the application form shall be completed by the applicant, using additional sheets as necessary. 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 free of charge at: www.ncradiation.net/rms/rmsforms2.htm(Rev01).htm.

(d) Persons conducting subsurface tracer studies using unsealed sources of radiation shall obtain agency approval prior to injecting licensed material into the subsurface. Agency approval shall be obtained by submitting a license application to the agency in accordance with Paragraph (c) of this Rule.

(e) Notifications, authorization requests, and reports required by 10 CFR 39.77 shall be made to the agency at the address shown in Rule .0111 of this Chapter in lieu of the NRC.

(f) Applications for exemptions to this Rule shall be submitted to the agency at the address shown in Rule .0111 of this Chapter in lieu of the NRC.

(g) The regulations cited in this Rule from 10 CFR Part 39 are hereby incorporated by reference, including subsequent amendments and editions. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part039/.

History Note: *Authority G.S. 104E-3; 104E-7;*
Eff. June 1, 1989;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .1301 Eff. February 1, 2015;
Readopted Eff. October 1, 2022.

10A NCAC 15 .1302 DEFINITIONS
10A NCAC 15 .1303 WRITTEN AGREEMENTS REQUIRED
10A NCAC 15 .1304 LIMITS ON LEVELS OF RADIATION
10A NCAC 15 .1305 STORAGE PRECAUTIONS
10A NCAC 15 .1306 TRANSPORT PRECAUTIONS
10A NCAC 15 .1307 RADIATION SURVEY INSTRUMENTS
10A NCAC 15 .1308 LEAK TESTING OF SEALED SOURCES
10A NCAC 15 .1309 QUARTERLY INVENTORY
10A NCAC 15 .1310 UTILIZATION RECORDS
10A NCAC 15 .1311 DESIGN: PERFORMANCE: AND CERTIFICATION CRITERIA
10A NCAC 15 .1312 LABELING
10A NCAC 15 .1313 INSPECTION AND MAINTENANCE
10A NCAC 15 .1314 TRAINING REQUIREMENTS
10A NCAC 15 .1315 OPERATING AND EMERGENCY PROCEDURES
10A NCAC 15 .1316 PERSONNEL MONITORING
10A NCAC 15 .1317 SECURITY
10A NCAC 15 .1318 HANDLING TOOLS
10A NCAC 15 .1319 SUBSURFACE-TRACER STUDIES

10A NCAC 15 .1320 PARTICLE ACCELERATORS
10A NCAC 15 .1321 RADIATION SURVEYS
10A NCAC 15 .1322 DOCUMENTS AND RECORDS REQUIRED AT FIELD STATIONS
10A NCAC 15 .1323 DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOBSITES
10A NCAC 15 .1324 NOTIFICATION OF INCIDENTS: ABANDONMENT: AND LOST SOURCES
10A NCAC 15 .1325 SUBJECTS IN TRAINING COURSES FOR LOGGING SUPERVISORS

History Note: *Authority G.S. 20-167.1; 104E-7; 104E-10(b); 104E-12(a); 104E-12(a)(1); 104E-12(a)(2); 104E-15(a); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;*
Eff. June 1, 1989;
Amended Eff. January 1, 2005; January 1, 1994; May 1, 1993; May 1, 1992; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1302 - .1325 Eff. February 1, 2015;
Repealed Eff. October 1, 2022.

10A NCAC 15 .1326 ENERGY COMPENSATION SOURCES
10A NCAC 15 .1327 TRITIUM NEUTRON GENERATOR TARGET SOURCES

History Note: *Authority G.S. 104E-7;*
Eff. January 1, 2005;
Transferred and Recodified from 15A NCAC 11 .1326 - .1327 Eff. February 1, 2015;
Repealed Eff. October 1, 2022.

SECTION .1400 - TANNING FACILITIES

Codifier's Note: 10 NCAC 03G .3500 was transferred to 15A NCAC 11 .1400 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .1401 PURPOSE AND SCOPE
(a) This Section provides for the registration and regulation of facilities and equipment which employ ultraviolet and other lamps for the purpose of tanning the skin of the living human body through the application of ultraviolet radiation.
(b) Except as otherwise provided in this Section, tanning facilities are exempt from the Rules in Sections .0100 through .1300 of this Chapter to the extent that such facilities do not receive, own, possess or use radioactive material or other sources of ionizing radiation as defined in G.S. 104E-5.
(c) Nothing in this Section shall be interpreted as limiting the intentional exposure of patients to ultraviolet radiation for the purpose of treatment or therapy other than skin tanning, provided such treatment or therapy is supervised by a licensed practitioner of the healing arts in the lawful practice of their profession, in accordance with the requirements of their professional licensing board to prescribe and supervise such treatment.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1401 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1402 COMPLIANCE WITH OTHER LAWS
Nothing in this Section shall relieve any person of responsibility for complying with other pertinent North Carolina laws and regulations.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1402 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1403 DEFINITIONS
As used in this Section, the following definitions shall apply:

(1) "Agency" means the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.
(2) "Consumer" means any individual who is provided access to a tanning facility that is required to be registered pursuant to provisions of this Section.
(3) "Formal Operator Training" is a course of study approved by this agency as meeting the requirements in Paragraph (i) of Rule .1418 in this Section.
(4) "Individual" means any human being.
(5) "Inspection" means an official examination or observation to determine compliance with the rules in this Section, and orders, requirements, and conditions of the agency.
(6) "Minor" means any individual less than 18 years of age.
(7) "Medical Lamps" means any lamp that is designed or labeled for medical use only.
(8) "Operator" means any individual designated by the registrant to operate or to assist and instruct the consumer in the operation and use of the tanning facility or tanning equipment. Under this definition, the term "operator," includes any individual who conducts one or more of the following activities:
    (a) determining consumer's skin type;
    (b) determining the suitability of prospective consumers for tanning equipment use;
    (c) informing the consumer of dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing agents;
    (d) assuring that the consumer reads and signs all forms as required by the rules in this Section;
    (e) maintaining required consumer exposure records;
    (f) recognizing and reporting consumer injuries or alleged injuries to the registrant;
    (g) determining the consumer's exposure schedule;
    (h) setting timers which control the duration of exposure; and
    (i) instructing the consumer in the proper use of protective eyewear.
(9) "Person," as defined in G.S. 104E-5(11), means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of these entities.
(10) "Registrant" means any person who is registered with the agency as required by provisions of this Section.
(11) "Registration" means registration with the agency in accordance with provisions of this Section.
(12) "Tanning components" means any constituent tanning equipment part, to include ballasts, starters, lamps, reflectors, acrylic shields, timers, and airflow cooling systems.
(13) "Tanning equipment" means ultraviolet or other lamps and equipment containing such lamps intended to induce skin tanning through the irradiation of any part of the living human body with ultraviolet radiation, e.g., beds, booths, facials, and wands.
(14) "Tanning equipment services" means the installation, sales and servicing of tanning equipment and associated tanning components; calibration of equipment used in surveys to measure radiation and timer accuracy; tanning health physics consulting, e.g. radiation output measurements, design of safety programs, and training seminars for tanning operators and service personnel.
(15) "Tanning facility" means any location, place, area, structure or business that provides consumers access to tanning equipment. For the purpose of this definition, tanning equipment registered to different persons at the same location and tanning equipment registered to the same person, but at separate locations, shall constitute separate tanning facilities.
(16) "Ultraviolet radiation" means electromagnetic radiation with wavelengths in air between 200 nanometers and 400 nanometers.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Amended Eff. August 1, 2002; May 1, 1993; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .1403 Eff. February 1, 2015;
Amended Eff. May 1, 2016;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1404 EXEMPTIONS

(a) Any person is exempt from the provisions of this Section to the extent that such person:

(1) uses equipment which emits ultraviolet radiation incidental to its proper operation, and
(2) does not use the equipment in Subparagraph (a)(1) of this Rule to deliberately expose parts of the living human body to ultraviolet radiation for the purpose of skin tanning.

(b) Any individual is exempt from the provisions of this Section to the extent that such individual owns tanning equipment exclusively for personal use.

(c) Tanning equipment while in transit or storage incidental thereto is exempt from the provisions of this Section.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Amended Eff. November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1404 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1405 APPLICATION FOR REGISTRATION OF TANNING FACILITIES

(a) Each person having a tanning facility on the effective date of this Rule shall apply for registration of such facility no later than 60 days following the effective date of this Rule.

(b) Each person acquiring or establishing a tanning facility after the effective date of this Rule shall have a certificate of registration issued by the agency for such facility prior to beginning operation.

(c) The application required in Paragraphs (a) and (b) of this Rule shall be completed on forms provided by the agency.

(d) The agency shall require at least the following information on the forms provided for applying for registration of tanning facilities:

(1) name, physical address, mail address and telephone number of the tanning facility;
(2) name(s), mail address(es) and telephone number(s) of the owner(s) of the tanning facility;
(3) each facility shall submit a copy of the tanning operator training certificate for each of the tanning facility operator(s) with the initial application in accordance with the provisions of the rules of this Section;
(4) the manufacturer(s), model number(s) and type(s) of ultraviolet lamp(s) or tanning equipment located at the tanning facility;
(5) name(s) of the tanning equipment supplier(s), installer(s) and service agent(s);
(6) certification that the applicant has read and understands the requirements of the rules in this Section, such certification to be signed and dated by the manager and the owner of the tanning facility; and
(7) certification that each person operating a tanning facility shall not allow any individual under 18 years of age to be the operator of tanning equipment.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Amended Eff. August 1, 2002; June 1, 1993; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .1405 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1406 ISSUANCE OF CERTIFICATE OF REGISTRATION

(a) Upon determination that an application meets the requirements of this Section, the agency will issue a certificate of registration.

(b) The agency may incorporate in the certificate of registration, at the time of issuance or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of tanning equipment and tanning facilities as the agency deems appropriate or necessary.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1406 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1407 EXPIRATION OF CERTIFICATE OF REGISTRATION

Except as provided in Rule .1408(b) of this Section, each certificate of registration shall expire at midnight on the expiration date stated therein.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1407 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1408 RENEWAL OF CERTIFICATE OF REGISTRATION

(a) The registrant shall file applications for renewal in accordance with Rule .1405 of this Section.

(b) Provided that a registrant files with the agency an application for renewal in proper form for renewal by August 29 of each calendar year, such certificate of registration shall not expire pending final action on the application by the agency.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Amended Eff. August 1, 2002;
Transferred and Recodified from 15A NCAC 11 .1408 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1409 REPORT OF CHANGES

The registrant shall notify the agency in writing within 30 calendar days after making any change which would render the information contained in the application for registration or the certificate of registration no longer accurate.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Amended Eff. August 1, 2002;
Transferred and Recodified from 15A NCAC 11 .1409 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1410 TRANSFER OF CERTIFICATE OF REGISTRATION

No certificate of registration may be transferred from one person to another person or from one tanning facility to another tanning facility.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1410 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1411 APPROVAL NOT IMPLIED

No person, in any advertisement, shall refer to the fact that such person or such person's facility is registered with the agency pursuant to the provisions of this Section, and no person shall state or imply that any activity under such registration has been approved by the agency.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Amended Eff. November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1411 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1412 DENIAL: REVOCATION: TERMINATION OF REGISTRATION

(a) The agency may deny, suspend or revoke a certificate of registration applied for or issued pursuant to this Section:

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

(2) because of conditions revealed by the application or any report, record, inspection or other means which would warrant the agency to refuse to grant a certificate of registration on an original application;

(3) for operation of the tanning facility in a manner that causes or threatens to cause hazard to the public health or safety;

(4) for failure to allow authorized representatives of the agency to enter the tanning facility at reasonable times for the purpose of determining compliance with the provisions of this Section, conditions of the certificate of registration or an order of the agency;
(5) for violation of or failure to observe any of the terms and conditions of the certificate of registration, the rules in this Section, or an order of the agency; or
(6) for failure to pay a fee within 15 days of becoming delinquent as described in Paragraph (h) of Rule .1423 or for failure to correct payment of a fee in the form of a check or other instrument which is uncollectible from the paying institution within the timeframe specified in accordance with the provisions of the rules of this Section.

(b) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for suspension or revocation of a certificate of registration, the agency shall:
(1) call to the attention of the registrant, in writing, the facts or conduct which may warrant such actions, and
(2) provide reasonable opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

(c) Any person aggrieved by a decision by the agency to deny a certificate of registration or to suspend or revoke a certificate of registration after issuance may request a hearing under provisions of G.S. 150B, Article 3.
(d) The agency may terminate a certificate of registration upon receipt of a written request for termination from the registrant.

History Note: *Authority G.S. 104E-7(a)(7); 104E-11(a);*
Eff. June 1, 1989;
Amended Eff. August 1, 2002; June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1412 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1413 CONSTRUCTION AND OPERATION OF TANNING EQUIPMENT

Except as otherwise ordered or approved by the agency, each tanning facility shall be constructed, operated and maintained in accordance with the requirements in Rules .1414 to .1418 of this Section.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1413 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1414 WARNING SIGNS REQUIRED

(a) The registrant shall post the warning sign described in Paragraph (b) of this Rule within one meter of each tanning station and in such a manner that the sign is clearly visible to consumers; not obstructed by any barrier, equipment, or other object; and may be easily viewed by the consumer before the tanning equipment is energized.
(b) The warning sign in Paragraph (a) of this Rule shall use upper and lower case letters that are at least seven millimeters and three and one-half millimeters in height, respectively, and shall state:

DANGER - ULTRAVIOLET RADIATION
UV – emitting tanning devices have been classified as "carcinogenic to humans. "
ATTENTION: THIS DEVICE SHALL NOT BE USED BY PERSONS UNDER 18 YEARS OF AGE.

- Follow instruction.
- Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. REPEATED EXPOSURE MAY CAUSE PREMATURE AGING OF THE SKIN AND SKIN CANCER.
- Wear protective eyewear.

FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Contraindications: This sunlamp product must not be used if skin lesions or open wounds are present.

Warning: This sunlamp product should not be used on individuals who have had skin cancer or have a family history of skin cancer.
Warning: Persons repeatedly exposed to ultraviolet sunlamp products should be regularly evaluated for skin cancer.

- Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using sunlamp or tanning equipment if you are using medication or have a history of skin problems or believe yourself to be especially sensitive to sunlight. Consult your certified tanning operator for a list of cosmetics and products known to create sensitivity to light.

- If you do not tan in the sun, you are unlikely to tan from the use of this product.

- Consumers should report to the agency any injury for which medical attention is sought or obtained resulting from the use of registered tanning equipment. This report should be made within five working days after the occurrence.

(c) Warning signs shall include the current address and telephone number of the agency: Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section, 1645 Mail Service Center, Raleigh, NC 27699-1600, (919) 814-2250.

History Note: *Authority G.S. 104E-7(a)(7); 104E-9.1;*
Eff. June 1, 1989;
Amended Eff. August 1, 2002; June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1403 Eff. February 1, 2015;
Amended Eff. May 1, 2016;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1415 EQUIPMENT AND CONSTRUCTION REQUIREMENTS

(a) The registrant shall use only tanning equipment manufactured in accordance with the specifications set forth in 21 Code of Federal Regulations (CFR) Part 1040, Section 1040.20, and with 21 CFR Part 878.4635, which is herein incorporated by reference, including subsequent amendments and editions and may be accessed at http://www.ecfr.gov/cgi-bin/ECFR?page=browse. The standard of compliance shall be the standards in effect at the time of manufacture as shown on the equipment identification label required by 21 CFR Part 1010, Section 1010.3. The registrant shall place an additional label on the bed that states "North Carolina state law prohibits the use of this device by persons under 18 years of age."

(b) Each assembly of tanning equipment shall be designed for use by only one consumer at a time.

(c) Each assembly of tanning equipment shall be equipped with a timer that complies with the requirements of 21 CFR Part 1040, Section 1040.20(c)(2). The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time. No timer interval shall have an error exceeding plus or minus 10 percent of the maximum timer interval for the product.

(d) Tanning equipment shall include physical barriers to protect consumers from injury induced by touching or breaking the lamps.

(e) All tanning equipment labeling required in Paragraph (a) of this Rule shall be easily read by the consumer while in the proximity of the tanning bed.

(f) The timer intervals shall be numerically indicated on the face of the timer.

(g) The timer shall not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle when emission from the tanning device has been interrupted.

(h) Each assembly of tanning equipment shall be provided with a control on the equipment to enable the consumer to manually terminate radiation emission from the equipment at any time without disconnecting the electrical plug or removing any ultraviolet lamp.

(i) The timer for the tanning devices shall be remotely located outside the room where the tanning equipment is located. The remote timer shall be set by a certified tanning operator.

(j) The registrant shall ensure that timer tests are performed annually on each assembly of tanning equipment and documented in writing for agency review during inspections to ensure the timer is accurate to within 10 percent as specified in Paragraph (c) of this Rule and the consumer is able to terminate the radiation manually in accordance with Paragraph (h) of this Rule.

(k) Medical lamps shall not be used for commercial cosmetic tanning purposes.

History Note: *Authority G.S. 104E-7(a)(7); 104E-9.1;*
Eff. June 1, 1989;
Amended Eff. August 1, 2002; June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1415 Eff. February 1, 2015;
Amended Eff. May 1, 2016;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1416 ADDITIONAL REQUIREMENTS FOR STAND-UP BOOTHS

Tanning booths designed for stand-up use shall also comply with the following additional requirements:

(1) Booths shall have physical barriers or other means, such as handrails or floor markings, to indicate the proper exposure distance between ultraviolet lamps and the consumer's skin.
(2) Booths shall be constructed with sufficient strength and rigidity to withstand the stress of use and the impact of a falling person.
(3) Access to booths shall be of rigid construction with doors which are non-latching and open outwardly.
(4) Booths shall be equipped with handrails and non-slip floors.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1416 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1417 PROTECTIVE EYEWEAR REQUIRED

(a) The registrant shall provide protective eyewear to each consumer for use during any use of tanning equipment.
(b) The protective eyewear in Paragraph (a) of this Rule shall meet the requirements of 21 CFR Part 1040, Section 1040.20(c)(4).
(c) Tanning facility operators shall instruct the consumer in the proper utilization of the protective eyewear required by this Rule.
(d) The registrant shall ensure that the protective eyewear required by this Rule is sanitized before each use and shall not rely upon exposure to the ultraviolet radiation produced by the tanning equipment itself to provide such sanitizing.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Amended Eff. August 1, 2002; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1417 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1418 RECORDS: REPORTS AND OPERATING REQUIREMENTS

(a) Prior to initial exposure, the registrant shall provide each consumer the opportunity to read a copy of the warning specified in Rule .1414(b) of this Section and have the consumer sign a statement that the information has been read and understood. For illiterate or visually impaired persons unable to read, the warning statement shall be read aloud by the operator to that individual, in the presence of a witness, and the witness and the operator shall sign the statement.
(b) The registrant shall maintain a record of each consumer's total number of tanning visits, including dates and durations of tanning exposures.
(c) The registrant shall determine each consumer's skin type using a method that distinguishes between six skin types and record the skin type on the client tan record.
(d) The registrant shall submit a written report of injury for which medical attention was sought or obtained from the use of registered tanning equipment to the Radiation Protection Section within five business days after occurrence. The report shall include:

(1) the name of the affected individual;
(2) the name and location of the tanning facility involved;
(3) the nature of the actual or alleged injury; and
(4) any other information relevant to the actual or alleged injury, including the date and duration of exposure and any documentation of medical attention sought or obtained.

(e) The registrant shall not allow individuals under the age of 18 to use tanning equipment.

(f) The registrant shall verify by checking legal identification that includes a driver's license, a passport, or military identification, each consumer is 18 years of age or older.
(g) The registrant shall not allow minors to remain in the tanning room while the tanning equipment is in operation.
(h) The registrant shall replace defective or burned out lamps, bulbs, or filters with a type intended for use in the affected tanning equipment as specified by the manufacturer's product label and having the same spectral distribution (certified equivalent lamp).
(i) The registrant shall replace ultraviolet lamps and bulbs that are not otherwise defective or damaged at such frequency or after such duration of use as is recommended by the manufacturer of such lamps and bulbs.
(j) The registrant shall maintain a record for inspection by authorized representatives of the agency of the number of hours that ultraviolet lamps and bulbs are used.
(k) The registrant shall certify that all tanning equipment operators are trained in the following:

(1) the requirements of this Section;
(2) procedures for correct operation of the tanning facility and tanning equipment;
(3) recognition of injury or overexposure to ultraviolet radiation;
(4) the tanning equipment manufacturer's procedures for operation and maintenance of the tanning equipment;
(5) the determination of skin type of customers and determination of duration of exposure to registered tanning equipment; and
(6) emergency procedures to be followed in case of injury.

(l) The registrant shall allow operation of tanning equipment only by and in the physical presence of persons who have completed formal training courses that meet the requirements of Paragraph (k) of this Rule.
(m) The registrant shall maintain a record of operator training required in Paragraph (k) of this Rule for inspection by authorized representatives of the agency.
(n) No registrant shall possess, use, operate, or transfer tanning equipment or his or her ultraviolet radiation sources in such a manner as to cause any individual under 18 years of age to be exposed to radiation emissions from such equipment.
(o) Each registrant shall make available to all employees current copies of the following documents:

(1) the facility's certificate of registration with the Radiation Protection Section; and
(2) conditions or documents incorporated into the registration by reference and amendments thereto.

History Note: *Authority G.S. 104E-7(a)(7); 104E-9; 104E-9.1; 104E-12;*
Eff. June 1, 1989;
Amended Eff. August 1, 2002; May 1, 1993; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .1418 Eff. February 1, 2015;
Amended Eff. May 1, 2016;
Readopted Eff. October 1, 2020.

10A NCAC 15 .1419 COMMUNICATIONS WITH THE AGENCY: AGENCY ADDRESS

Applications for registration, reports, notifications, and other communications required by this Section shall be mailed to the Radiation Protection Section,1645 Mail Service Center, Raleigh, North Carolina 27699-1600 or delivered to the agency at its office located at 5505 Creedmoor Road, Suite 100, Raleigh, North Carolina 27612.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1989;
Amended Eff. August 1, 2002; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .1419 Eff. February 1, 2015;
Amended Eff. May 1, 2016;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1420 PROPOSED SERVICING

Effective August 1, 1993, each person registered pursuant to Rule .1405 of this Section shall prohibit any person from furnishing tanning equipment services to their tanning equipment or facility until such person provides evidence that they are registered with the agency as a provider of services in accordance with the provisions of Rule .1421 of this Section.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. May 1, 1993;

Transferred and Recodified from 15A NCAC 11 .1420 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1421 APPLICATION FOR REGISTRATION OF SERVICING OR SERVICES

(a) Each person who offers tanning equipment services to any agency registrant, shall apply for registration of such services with the agency within 60 days following the effective date of this Rule or, thereafter, prior to furnishing or offering to furnish any of these services.

(b) The application for registration required in Paragraph (a) of this Rule shall be completed on an approved agency form.

(c) Persons applying for registration under Paragraph (a) of this Rule shall certify that they have read and understand the requirements of the rules in this Section.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1421 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1422 REPORTS AND INSTALLATION

(a) Persons registered pursuant to Rule .1421 of this Section, who sell, lease, transfer, lend, dispose of, assemble or install tanning equipment in this state shall, within 30 days after each calendar quarter, notify the agency at the address in Rule .1419 of this Section, of:

(1) whether any tanning equipment was installed, transferred, or disposed of during the calendar quarter;
(2) the name and address of persons who receive tanning equipment during the calendar quarter;
(3) the manufacturer, model and serial number of tanning equipment transferred or otherwise disposed of; and
(4) the date of transfer of any tanning equipment.

(b) No person shall make, sell, lease, transfer, lend, repair, assemble, or install tanning equipment or the supplies used in connection with such equipment unless such supplies and equipment when properly placed in operation and used shall meet the requirements of the rules in this Section and the regulations of 21 CFR 1040.20.

History Note: *Authority G.S. 104E-7(a)(7);*
Eff. May 1, 1993;
Amended Eff. August 1, 2002;
Transferred and Recodified from 15A NCAC 11 .1422 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1423 FEES AND PAYMENT

(a) Annual fees established in this Rule shall be due on the first day of July of each year.

(b) Notwithstanding Paragraph (a) of this Rule, when a new registration is issued by the agency after the first day of July of any year, the initial fee is due on the date of issuance of the registration.

(c) The initial fee in Paragraph (b) of this Rule shall be computed as follows:

(1) When any new registration is issued before the first day of January of any year, the initial fee is the full amount specified in this Rule; and
(2) When any new registration is issued on or after the first day of January of any year, the initial fee is one-half of the amount specified in this Rule.

(d) Each registrant may pay all fees by cash, check, or money order as follows:

(1) Checks or money orders shall be made payable to "Radiation Protection Section," and mailed to 1645 Mail Service Center, Raleigh, NC 27699-1600 or delivered to the agency office at 5505 Creedmoor Road, Suite 100, Raleigh, NC 27612; and
(2) Cash payments shall be made only by appointment by calling the agency at 919/814-2250 and delivered to the agency office at 5505 Creedmoor Road, Suite 100, Raleigh, NC 27612.

(e) Within five days after the due dates established in Paragraphs (a) and (b) of this Rule, the agency shall mail to each registrant who has not already submitted payment a notice that indicates the due date, the amount of fees due, and the delinquent date.

(f) Payment of fees established in this Rule shall be delinquent if not received by the agency within 60 days after the due date specified in Paragraphs (a) and (b) of this Rule.

(g) If a registrant remits a fee in the form of a check or other instrument that is uncollectible from the paying institution, the agency shall notify the registrant by certified mail and allow the registrant 15 days to correct the matter, including payment of any fee charged to the agency by a banking institution.
(h) If payment of fees is uncollectible from the paying institution or not submitted to the agency by the delinquent date, the agency shall institute legal action to collect.
(i) Annual fees for persons registered pursuant to provisions of this Section are as listed in the following table:

Type of registered facility	Letters appearing in registration number	Facility plus first piece of tanning equipment	Each additional piece of tanning equipment
Tanning Facility	B	$200.00	$30.00

History Note: *Authority G.S. 104E-9(a)(8); 104E-19(a);*
Eff. July 1, 1994;
Amended Eff. July 1, 2011; August 1, 2007; August 1, 2002;
Transferred and Recodified from 15A NCAC 11 .1423 Eff. February 1, 2015;
Amended Eff. May 1, 2016;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

SECTION .1500 - LICENSES FOR DISPOSAL SITE ACCESS

10A NCAC 15 .1501 PURPOSE AND SCOPE
10A NCAC 15 .1502 DEFINITIONS
10A NCAC 15 .1503 LICENSE REQUIRED
10A NCAC 15 .1504 APPLICATION FOR SITE ACCESS LICENSE: GENERAL REQUIREMENTS
10A NCAC 15 .1505 APPLICATION FOR SITE ACCESS LICENSE - WASTE GENERATORS
10A NCAC 15 .1506 CONTENT OF APPLICATION FOR WASTE COLLECTORS
10A NCAC 15 .1507 CONTENT OF APPLICATION FOR WASTE PROCESSORS
10A NCAC 15 .1508 CERTIFICATION OF COMPLIANCE WITH APPLICABLE REQUIREMENTS
10A NCAC 15 .1509 PRIOR NOTIFICATION FOR WASTE SHIPMENTS
10A NCAC 15 .1510 RADIOACTIVE SHIPMENT MANIFEST
10A NCAC 15 .1511 FINANCIAL QUALIFICATIONS AND REQUIREMENTS
10A NCAC 15 .1512 WASTE MANAGEMENT AND REDUCTION REQUIREMENTS
10A NCAC 15 .1513 ISSUANCE AND EXPIRATION OF SITE ACCESS LICENSES
10A NCAC 15 .1514 SITE ACCESS LICENSE RENEWAL
10A NCAC 15 .1515 SITE ACCESS LICENSE AMENDMENT
10A NCAC 15 .1516 MODIFICATION, REVOCATION, AND TERMINATION OF LICENSES
10A NCAC 15 .1517 TEMPORARY OR EMERGENCY ACCESS

History Note: *Authority G.S. 104E-5; 104E-7; 104E-10.3; 104E-18; 104E-27; 104E-29; 132-1.2;*
Eff. January 1, 1995;
Transferred and Recodified from 15A NCAC 11 .1501 - .1517 Eff. February 1, 2015;
Repealed Eff. May 1, 2023.

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) of this Chapter;
  (B) "licensed" means registered pursuant to the rules in Section .0200 of this Chapter;
  (C) "licensed material" shall have the same meaning as "radiation machine" as defined in Rule .0104(122) of this Chapter, and
  (D) "licensee" shall have the same meaning as "registrant" as defined in Rule .0104(130) 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.

10A NCAC 15 .1602	**IMPLEMENTATION**
10A NCAC 15 .1603	**RADIATION PROTECTION PROGRAMS**
10A NCAC 15 .1604	**OCCUPATIONAL DOSE LIMITS FOR ADULTS**
10A NCAC 15 .1605	**REQUIREMENTS FOR SUMMATION OF EXTERNAL, INTERNAL DOSES**
10A NCAC 15 .1606	**EXTERNAL DOSE FROM AIRBORNE RADIOACTIVE MATERIAL**
10A NCAC 15 .1607	**DETERMINATION OF INTERNAL EXPOSURE**
10A NCAC 15 .1608	**PLANNED SPECIAL EXPOSURES**
10A NCAC 15 .1609	**OCCUPATIONAL DOSE LIMITS FOR MINORS**
10A NCAC 15 .1610	**DOSE EQUIVALENT TO AN EMBRYO/FETUS**
10A NCAC 15 .1611	**DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC**
10A NCAC 15 .1612	**COMPLIANCE WITH DOSE LIMITS FOR MEMBERS OF THE PUBLIC**
10A NCAC 15 .1613	**SURVEYS**
10A NCAC 15 .1614	**MONITORING OF EXTERNAL AND INTERNAL OCCUPATIONAL DOSE**
10A NCAC 15 .1615	**CONTROL OF ACCESS TO HIGH RADIATION AREAS**
10A NCAC 15 .1616	**CONTROL OF ACCESS TO VERY HIGH RADIATION AREAS**
10A NCAC 15 .1617	**ACCESS TO VERY HIGH RADIATION AREAS: IRRADIATORS**
10A NCAC 15 .1618	**USE OF PROCESS OR OTHER ENGINEERING CONTROLS**
10A NCAC 15 .1619	**USE OF OTHER CONTROLS TO RESTRICT INTERNAL EXPOSURE**
10A NCAC 15 .1620	**USE OF INDIVIDUAL RESPIRATORY PROTECTION EQUIPMENT**
10A NCAC 15 .1621	**RESTRICTIONS ON THE USE OF RESPIRATORY PROTECTION EQUIPMENT**
10A NCAC 15 .1622	**SECURITY OF SOURCES OF RADIATION**
10A NCAC 15 .1623	**CAUTION SIGNS**
10A NCAC 15 .1624	**POSTING REQUIREMENTS**
10A NCAC 15 .1625	**EXCEPTIONS TO POSTING REQUIREMENTS**
10A NCAC 15 .1626	**LABELING REQUIREMENTS AND EXEMPTIONS**
10A NCAC 15 .1627	**PROCEDURES FOR RECEIVING AND OPENING PACKAGES**
10A NCAC 15 .1628	**GENERAL REQUIREMENTS FOR WASTE DISPOSAL**
10A NCAC 15 .1629	**METHOD FOR OBTAINING APPROVAL OF DISPOSAL PROCEDURES**
10A NCAC 15 .1630	**DISPOSAL BY RELEASE INTO SANITARY SEWERAGE**
10A NCAC 15 .1631	**TREATMENT OR DISPOSAL BY INCINERATION**
10A NCAC 15 .1632	**DISPOSAL OF SPECIFIC WASTES**
10A NCAC 15 .1633	**TRANSFER FOR DISPOSAL AND MANIFESTS**
10A NCAC 15 .1634	**COMPLIANCE WITH ENV. AND HEALTH PROTECTION REGULATIONS**
10A NCAC 15 .1635	**GENERAL PROVISIONS FOR RECORDS**
10A NCAC 15 .1636	**RECORDS OF RADIATION PROTECTION PROGRAMS**
10A NCAC 15 .1637	**RECORDS OF SURVEYS**
10A NCAC 15 .1638	**DETERMINATION OF PRIOR OCCUPATIONAL DOSE**
10A NCAC 15 .1639	**RECORDS OF PLANNED EXPOSURES**
10A NCAC 15 .1640	**RECORDS OF INDIVIDUAL MONITORING RESULTS**
10A NCAC 15 .1641	**RECORDS OF DOSE TO INDIVIDUAL MEMBERS OF THE PUBLIC**
10A NCAC 15 .1642	**RECORDS OF WASTE DISPOSAL**
10A NCAC 15 .1643	**RECORDS OF TESTING ENTRY CONTROL DEVICES**
10A NCAC 15 .1644	**FORM OF RECORDS**
10A NCAC 15 .1645	**REPORTS OF THEFT OR LOSS OF LICENSED RADIOACTIVE MATERIAL**
10A NCAC 15 .1646	**NOTIFICATION OF INCIDENTS**
10A NCAC 15 .1647	**REPORTS OF RADIATION EXCEEDING THE LIMITS**
10A NCAC 15 .1648	**REPORTS OF PLANNED SPECIAL EXPOSURES**
10A NCAC 15 .1649	**REPORTS OF INDIVIDUAL MONITORING**

History Note: *Authority G.S. 104E-7(a)(2); 104E-7(a)(3); 104E-7(a)(5); 104E-12; 104E-12(a); 104E-15; 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R 7540;*
Eff. January 1, 1994;

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 .1602 - .1649 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. October 1, 2023.

10A NCAC 15 .1650 CLASSIFICATION/RADIOACTIVE WASTE FOR NEAR-SURFACE DISPOSAL
10A NCAC 15 .1651 RADIOACTIVE WASTE CHARACTERISTICS
10A NCAC 15 .1652 LABELING

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .1650 - .1652 Eff. February 1, 2015;
Repealed Eff. May 1, 2023.

10A NCAC 15 .1653 RADIOLOGICAL REQUIREMENTS FOR LICENSE TERMINATION

History Note: *Authority G.S. 104E-7(a)(2); 104E-10(b);*
Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .1653 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Repealed Eff. October 1, 2023.

SECTION .1700 – PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

10A NCAC 15 .1701 ADDITIONAL REQUIREMENTS FOR LICENSEES POSSESSING CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

(a) Licensees possessing an aggregate category 1 or category 2 quantity of radioactive material, as defined in 10 CFR 37.5, shall comply with the requirements for the physical protection program listed in 10 CFR Part 37, which is hereby incorporated by reference, including any subsequent amendments and editions, except the following regulations are not incorporated:

(1) 10 CFR 37.1;
(2) 10 CFR 37.3;
(3) 10 CFR 37.7;
(4) 10 CFR 37.9;
(5) 10 CFR 37.11(a) and (b);
(6) 10 CFR 37.13;
(7) 10 CFR 37.105;
(8) 10 CFR 37.107; and
(9) 10 CFR 37.109.

(b) Licensee required reports of events or notifications in 10 CFR 37.23(b)(2), 37.41, 37.45, 37.57, 37.77(a) through (d), and 37.81 shall use the Agency contact information in Rule .0111 of this Chapter.

(c) The Code of Federal Regulations incorporated by this Rule are available free of charge at https://www.ecfr.gov/current/title-10/chapter-I/part-37.

History Note: *Authority G.S. 104E-7;*
Eff. June 1, 2016;
Amended Eff. May 1, 2023.

SECTION .1800 – STANDARDS FOR RADON PROFICIENCY PROGRAM APPROVAL

10A NCAC 15 .1801 REQUIREMENTS FOR REGISTRATION OF RADON PROFICIENCY PROGRAMS

(a) In addition to the definitions found in Rule .0104 of this Chapter, the following definition shall apply to this Rule: "Radon proficiency program" means an organization that provides training, competency testing, and certification to an individual as a radon professional.

(b) Persons seeking initial registration, to amend a registration, or to renew a registration as a radon proficiency program shall:

(1) submit an application for registration to the agency at the addresses shown in Rule .0111(a) of this Chapter or as otherwise instructed by the agency. Applications for initial registration and applications to renew a registration shall be submitted with supporting information demonstrating that the requirements of Paragraph (c) of this Rule and S.L. 2023-91, s. 2 are met. Applications to amend a registration shall be submitted with an attachment explaining the items to be amended; and

(2) comply with the provisions of Paragraph (h) of this Rule.

(c) The Department shall approve an application for initial registration or to renew a registration as a radon proficiency program that meets the criteria set out in S.L. 2023-91, s. 2.

(d) Radon proficiency program registrations issued by the Department shall expire at midnight on the expiration date stated on the radon proficiency program registration. The Department shall not issue an initial or renewed registration expiring less than one year from the date of issuance.

(e) The Department shall deny an application for initial registration or to renew a registration as a radon proficiency program if the application fails to demonstrate compliance with Paragraph (c) of this Rule and S.L. 2023-91, s. 2.

(f) Persons whose radon proficiency program registrations are revoked or expired may apply for registration in accordance with Paragraph (b) of this Rule and S.L. 2023-91, s. 2.

(g) Each registrant shall, upon notice of at least 48 hours, make available to the Department for inspection records maintained pursuant to this Rule.

(h) Applications submitted to the Department for registration as a radon proficiency program shall contain the following information:

(1) Box 1, check the box next to the type of registration requested;

(2) Box 2, business physical address:

(A) name of the radiation proficiency program;

(B) phone number at the physical location;

(C) website associated with the radiation proficiency program;

(D) physical address of the business, including the street address, city, county, state, and zip code. The five digit zip code may be used if the nine digit zip code is not known;

(E) mailing address if different from Box 1. If the physical and mailing addresses are the same, the mailing address may be left blank: Mailing address of the business, including city, state, and zip code. The five digit zip code may be used if the nine digit zip code is not known; and

(F) name, phone number and email for the individual completing the form.

(3) Box 3, authorizing signature of individual responsible for the radon proficiency program:

(A) name of company or corporate office;

(B) full legal name. Middle initials may be used in lieu of the full middle name; and

(C) signature of the individual registering the radiation proficiency program on behalf of the business; and

(4) Additional Attachments to include with application:

(A) documents establishing compliance and periodic reaccreditation with the international program approval standard through accreditation by a recognized accreditation body or demonstration of current approval by the United States Environmental Protection Agency as a radon proficiency; program; or

(B) list of a board members from various private and public sector stakeholders to make decisions regarding curriculum, testing, instructor qualifications, quality assurance and control, continuing education requirements, and procedures for the handling of complaints;

(C) minimum training requirements for radon professionals for each type of certification offered;

(D) examination requirements for each type of certification;

(E) continuing education requirements for each type of certification; and

(F) instructor names and qualifications demonstrating relevant knowledge and experience.

(5) copies of the registration form are available free of charge by emailing the contacts listed at https://www.ncdhhs.gov/divisions/health-service-regulation/north-carolina-radon-program/contacts.

History Note: *Authority S.L. 2023-91, s. 2;*

Temporary Adoption Eff. February 14, 2024.