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-10; 104E-12(a);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 03G .2201 Eff. January 4, 1990;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0101 Eff. February 1, 2015;
Readopted Eff. May 1, 2025.

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;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0103 DEFINITIONS

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

(1) "Act" means North Carolina Radiation Protection Act as defined in G.S. 104E-1.
(2) "Agency" means the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.
(3) "Authorized representative of the agency" means an employee of the agency.
(4) "Annually" means either:
    (A) at intervals not to exceed 12 consecutive months; or
    (B) once per year at the same time each year (completed during the same month each year over a period of multiple years).
(5) "Calendar month" means January, February, March, April, May, June, July, August, September, October, November, or December.
(6) "Calendar year" means the period of time between 12:00:00 am January 1 to 11:59:59 pm December 31.
(7) "Calibration" means the determination of the reading or response of an instrument to known radiation values over the range of the instrument, or the strength of a source of radiation relative to a standard.
(8) "CFR" means Code of Federal Regulations.
(9) "Commission" has the meaning as defined in G.S. 104E-5(5), except as stated in Paragraph (c) of this Rule.

(10) "Department" has the meaning as defined in G.S. 104E-5(6) except as stated in Paragraph (c) of this Rule.
(11) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.
(12) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.
(13) "Inspection" means an examination or observation by an authorized representative of the agency to determine compliance with rules, orders, requirements, and conditions of the agency or the Commission.
(14) "Monthly" means once every calendar month.
(15) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
(16) "Person" has the same meaning as defined in G.S. 104E-5(11).
(17) "Quarterly" means four times per calendar year, and:
(A) at intervals not to exceed 13 weeks; or
(B) once per month during the months of January, April, July, and October; or
(C) once per month during the months of February, May, August, and November; or
(D) once per month during the months of March, June, September, and December.
(18) "Radiation" except as otherwise defined in Section .1400 of this Chapter, has the meaning as defined in G.S. 104E-5(12).
(19) "Semiannually" means twice per calendar year at six month intervals.
(20) "SI unit" means a unit of measure from the International System of Units as established by the General Conference of Weights and Measures.
(21) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.
(22) "State" means the State of North Carolina.
(23) "These Rules" means Chapter 10 of this Title.

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

(1) "Clinical study" means human use of a radiation machine for research and development. The terms "clinical investigation", "clinical research", "research", and "study" also mean "clinical study".
(2) "Consulting" means providing professional technical advice on radiological matters by an expert registered with the agency in accordance with Rule .0205 of this Chapter.
(3) "Facility" means the location at which one or more radiation machines or sources of radiation are installed or located within one building, at one address or vehicle, and are under the same administrative control.
(4) "Healing arts" means the art or science of diagnostic examination using a source of radiation in the diagnosis or treatment of human or animal diseases.
(5) "Individual responsible for radiation protection" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules, for persons registered with the agency in accordance with Section .0200 of this Chapter, commensurate with the scope of the activities authorized by the registrant.
(6) "Install or installation" means the assembly, placement, initial calibration, operational testing, or other actions that allow a radiation machine to be used in a new location or after being moved from one location to another.
(7) "Licensed practitioner" means a person authorized to order diagnostic exams that use radiation machines for diagnosing or treatment of human or animal diseases. The person shall be:
(A) a physician in accordance with Subparagraph (8) of this Paragraph; or
(B) licensed by the appropriate licensing board in North Carolina pursuant to G.S. Chapter 90 to provide professional services in chiropractic, dentistry, podiatry, and veterinary medicine.
(8) "Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 1.
(9) "Radiation machine" has the same meaning as defined in G.S. 104E-5(13).
(10) "Registrant" means any person who is registered with the agency, after completing the registration process, in accordance with Rule .0203 of this Chapter.

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

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

(13) "Research and development" means:

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

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

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

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

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

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

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

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

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

(4) In 10 CFR 30.18(d), 30.32(g), 31.5(b)(1)(ii), 31.5(c)(3)(ii), 31.5(c)(8)(i), 31.6, 31.7(a), 31.10(a), 1.10(b)(1), 31.12(c)(4), 32.13, 32.51(a), 32.51(c), 32.56, 32.59, 32.72(b)(5)(ii), 40.13(c)(10), 40.22(e), 40.25(b), 40.25(d)(3), 40.54, 40.55(c), (c)(1), (d)(1)(ii), (d)(2) and (d)(3), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC".

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

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

(7) "Written directive," except as defined in Rule .0307 of this Chapter, means an order in writing for a specific patient or human research subject dated and signed by an authorized user prior to the administration of radiation therapy through the use of a licensed accelerator that contains the patient or human research subject's name and the following information:

(A) total dose;

(B) dose per fraction;

(C) treatment site, and

(D) number of fractions.

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

10A NCAC 15 .0104 INCORPORATION BY REFERENCE

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

(1) The following parts of 21 CFR Subchapter J:
  (A) Part 1000, "General;"
  (B) Subpart A 1000.1, "General Provisions - General;"
  (C) Subpart A 1000.3(a) through (j),(k),(1), and (n) through (t), "Definitions;"
  (D) Subpart A 1000.15, "Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968;"
  (E) Part 1002, "Records and Reports;"
  (F) Subpart A 1002.1(a) and (c)(4), "Applicability;"
  (G) Subpart D 1002.31, "Preservation and inspection of records;"
  (H) Part 1003, "Notification of Defects of Failures to Comply;"
  (I) Subpart A 1003.1, "Applicability;"
  (J) Subpart A 1003.2, "Defect in an electronic product;"
  (K) Subpart C 1003.21, "Notification by the manufacturer to affected persons;"
  (L) Part 1010, "Performance Standards for Electronic Products - General;"
  (M) Subpart A 1010.1, "Scope;"
  (N) Subpart A 1010.2(a),(b), and (d), "Certification;"
  (O) Subpart A 1010.3, "Identification;"
  (P) Subpart A 1010.4(a) and (d), "Variances;"
  (Q) Part 1020, "Performance Standards for Ionizing Radiation Emitting Products;"
  (R) Section 1020.20, "Cold-cathode gas discharge tubes;"
  (S) Section 1020.30, "Diagnostic x-ray systems and their main components;"
  (T) Section 1020.31, "Radiographic equipment;"
  (U) Section 1020.32, "Fluoroscopic equipment;" and
  (V) Section 1020.33, "Computed tomography (CT) equipment."
(2) "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended," signed July 21, 1964.

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

(1) https://www.ecfr.gov/current/title-21/chapter-I/subchapter-J for Part (a)(1)(A) through (a)(1)(V) of this Rule, and
(2) https://www.nrc.gov/cdn/nmss/pdf/ncagreements.pdf for the agreement between the NRC and the State of North Carolina.

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

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

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

(b) The agency may designate an individual registered in accordance with Section .0200 of this Chapter to provide Class I through Class IX services, to conduct tests or surveys while being supervised by an authorized representative of the agency.

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

Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 03G .2205 Eff. January 4, 1990;
Amended Eff. October 1, 2013; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0105 Eff. February 1, 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0106 INSPECTIONS AND TESTS

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

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

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

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

(1) radiation machine or source of radiation;

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

(3) radiation detection and monitoring instruments; and

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

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

10A NCAC 15 .0107 IMPOUNDING

Radiation machines and sources of radiation are subject to impounding in the event of an emergency or by order of impounding of radiation machines and sources of radiation, in the possession of any person who fails to follow the rules of this Chapter, by an authorized representative of the agency.

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

10A NCAC 15 .0108 ENFORCEMENT

(a) Any person or entity is subject to administrative penalties each day of a continuing violation for the following:

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

(2) refusing to allow an inspection, in accordance with Rule .0106(a) of this Section, or impounding, in accordance with Rule .0107 of this Section.

(b) Each day of a continuing violation constitutes a separate violation and the penalty shall not exceed ten thousand dollars ($10,000) per day, pursuant to the provisions of the Act.

History Note: *Authority G.S. 104E-2; 104E-7; 104E-11; 104E-14; 104E-(24);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2208 Eff. January 4, 1990;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0108 Eff. February 1, 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0109 RECORDS

(a) Each registrant shall maintain records documenting:

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

(2) operator training; and

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

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

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

10A NCAC 15 .0110 PROHIBITED USES

The agency prohibits the use of the following:

(1) demonstration or training of radiation machines or sources of radiation without providing engineered protective barriers or implementing administrative protective controls to change work policies, practices, and procedures that will ensure exposure to radiation does not exceed dose limits in Rule .1601(a) of this Chapter;

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

(3) hand-held fluoroscopic screens;

(4) shoe-fitting fluoroscopic devices;

(5) dental fluoroscopy without image intensification; and

(6) non-intensified photofluorographic equipment.

History Note: *Authority G.S. 104E-7;*
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;
Readopted Eff. May 1, 2025.

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 PETITIONING FOR RULEMAKING

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

.1100 of this Chapter shall be addressed to the Department of Health and Human Services, care of the Radiation Protection Section, and submitted to one of the addresses shown in Rule .0111(a) of this Section.

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

(1) the proposed text of the new rule or the proposed text amending a rule. If the petition is for the repeal of a rule, the petitioner shall not be required to submit proposed rule text;
(2) statutory authority supporting the new rule, or amending or repealing a rule;
(3) reason for the proposed rulemaking action;
(4) effect of the proposed rule change on existing rules;
(5) effect of the proposed rule change on existing practices;
(6) information supporting the proposed rulemaking;
(7) effect of the proposed rule change on the regulated community and the public; and
(8) name and contact information of the petitioner.

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

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

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

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

(g) The Commission shall grant or deny a rulemaking petition within the time requirements of G.S. 150B-20(b). The Commission shall grant or deny a rulemaking petition based on the requirements of G.S. 104E-7(a). The petitioner shall be notified in writing of this decision and the reason for this decision if the information required by Subparagraph (b)(8) of this Rule is provided in the petition. If the Commission grants the rulemaking petition the Commission shall initiate rulemaking proceedings.

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

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

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

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

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

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
10A NCAC 15 .0115 RECORDS
10A NCAC 15 .0116 TESTS

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

10A NCAC 15 .0117 INCORPORATION BY REFERENCE

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

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

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

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 generating devices, facilities, and persons providing other radiological services.

(b) A person who acquires, owns, possesses, or receives a radiation machine or radiation generating device before receiving a notice of registration in accordance with Rule .0209 of this Section is subject to the requirements of this Chapter.

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

(d) Service providers using radiation machines for demonstration purposes or that provide mobile leasing services are subject to the additional requirements of Rule .0205 of this Section. Service providers that provide those services

by bringing radiation machines or radiation generating devices from out of state are subject to the additional requirements of Rule .0208 of this Section.
(e) Emerging technologies for radiation machines and radiation generating devices that do not meet the equipment requirements of this Chapter are subject to the additional requirements in Rule .0212 of this Section.
(f) Registrants using industrial radiographic machines are subject to the additional requirements of Section .0500 of this Chapter.
(g) Registrants using radiation machines for human and veterinary use are subject to the additional requirements in Section .0600 of this Chapter.
(h) Registrants using radiation machines for non-human use at educational facilities, for forensic medicine, or by service providers for demonstration purposes are subject to the additional requirements of Section .0600 of this Chapter.
(i) Registrants using ionizing radiation generating devices are subject to the requirements of Section .0800 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-9(8); 104E-19(a);*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; July 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0201 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. October 1, 2025.

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 10 square centimeters does not exceed 0.5 mrem per hour at 5 centimeters from any accessible surface of the equipment when any external shielding is removed. The production, testing, or factory servicing of such equipment is not exempt.
(b) The following are exempt from the requirements of this Section:
(1) all radioactive materials; and
(2) radiation machines while in transit.

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

10A NCAC 15 .0203 APPLICATION FOR REGISTRATION PROCESS: GENERAL REQUIREMENTS FOR ALL FACILITIES, RADIATION MACHINES, AND SERVICES PROVIDED
(a) A person with an unregistered facility, radiation machine, radiation generating device, or an unregistered service provider, shall apply for registration with the agency. After submitting the required application forms prescribed by the agency in this Rule, registration of the first radiation machine, radiation generating device, or registration of services provided, constitutes registration of the facility or service provider.
(b) All application forms in this Rule shall be completed by meeting the following requirements:
(1) An individual with administrative control and representative of the organization of a radiation machine, radiation generating device, or who is responsible for providing services, shall ensure application forms, required by the agency in this Rule, meet the following requirements:
(A) are accurate, complete, and contain all the information required by the application forms and accompanying instructions; and
(B) submitted to the agency at the e-mail address on the application for registration forms or mailed to the address in Rule .0111 of this Chapter.
(2) Incomplete application forms or application forms submitted without the requested documentation to provide services, will not be processed.
(3) The agency may require additional information at any time after submission of the application to determine if the notice of registration should be issued or denied.

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

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

(1) The application shall be submitted by any person:
  (A) with one or more radiation machines at a facility; or
  (B) that plans to engage in services listed in Paragraphs (f) and (g) of this Rule.

(2) The application form requires the following:
  (A) indication if the application is for a new facility, a change of ownership, relocation of a facility, or to update information by marking the corresponding checkbox;
  (B) the legal business name, facility physical address, phone number, type of business, days and hours of operation;
  (C) the name, title, mailing address, phone, and e-mail address of business manager;
  (D) the name of the individual on-site who is responsible for radiation protection. The training and experience qualifying him or her to perform the job duties and responsibilities in Rule .0211 of this Section, shall be documented on the application;
  (E) the name, title, mailing address, phone, and e-mail address for the invoice contact;
  (F) description of facility use;
  (G) description of service provider equipment;
  (H) dated and signed by the owner or the individual with administrative control; and
  (I) identify equipment forms included with the application form by marking the corresponding checkbox.

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

(1) The application shall be submitted by any person:
  (A) with one or more unregistered radiation machines or radiation generating devices at a facility; or
  (B) that is engaged in leasing or performing demonstrations using an unregistered radiation machine or radiation generating device.

(2) The application requires the following information:
  (A) registration number;
  (B) machine or device location;
  (C) manufacturer, model, serial number, number of tubes, install date, modality, application, type, and use;
  (D) location of machine or device not in use;
  (E) installer information; and
  (F) shall be dated and signed by the individual with administrative control. An individual with administrative control can delegate a responsible person or persons within the organization to sign when amendments are made to this form by notifying the agency in writing.

(e) A Disposal of a Radiation Machine or Radiation Generating Device Form shall be submitted when a facility disposes of a radiation machine or radiation generating device. The agency form requires the following information:

(1) registration number, facility name, and physical address;
(2) identify if the application is for a new facility, for a change of ownership, a facility relocates, or to update information;
(3) radiation machine or radiation generating device location; manufacturer, model, serial number;
(4) identify the reason for disposal of the radiation machine or radiation generating device;
(5) the recipient of the radiation machine or radiation generating device, to the individual or business name, physical and e-mail address, and phone number; and
(6) dated and signed by the owner or the individual with administrative control of the radiation machine or radiation generating device.

(f) A Company Service Application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (C) of Subparagraph (f)(1) and the following additional requirements shall be met:

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

(A) direct sales, demonstration, leasing, or transfer of radiation machines or radiation generating devices;
(B) providing individual monitoring devices; and
(C) radiation survey equipment calibrations, except when calibrations are performed by the manufacturer of the equipment.

(2) The application requires the following information:
(A) registration number;
(B) business name, facility physical address;
(C) identify if the application is for a new service provider, for a change of ownership, relocation of the facility, or to update information;
(D) identify each class and modality of services requested to be provided in the State;
(E) submit the requirements listed on the agency form for each class and modality requesting to provide services in the State;
(F) list any class or modality not listed on this form;
(G) description of service provider equipment used for output measurements and surveys; and
(H) signature of the individual with administrative control.

(g) A Company Employee Services Application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (H) of Subparagraph (g)(1) and the following additional requirements shall be met:

(1) The application shall be submitted by any person engaged in providing the following services:
(A) area radiation surveys for diagnostic radiographic and fluoroscopy facilities;
(B) equipment surveys and shielding designs for radiation generating devices;
(C) general health physics consulting services to perform dose estimates, radiation output measurements, radiation safety program development, and radiation safety program training;
(D) installation or service repair of radiation machines or radiation generating devices;
(E) qualified expert consulting services for CT and mammography radiation machines;
(F) radiation protection expert;
(G) shielding designs for diagnostic radiographic and fluoroscopy facilities; and
(H) therapeutic facility and shielding design, area radiation survey, or calibration.

(2) The application requires the following information:
(A) name of the employee to be registered;
(B) start date if the employee is being added and the stop date if the employee is being removed from the registration;
(C) business registration number, name, physical address, and contact e-mail;
(D) class identification and modality of services to be provided;
(E) training and experience to submit for each class of services to be provided;
(F) date and signature of the employee applying for registration;
(G) date and signature of the individual with administrative control; and
(H) additional information the agency determines is necessary for evaluating the application for registration.

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

(1) meets the education, or is supervised by an individual who meets the training and experience requirements of the Class for the services provided;
(2) provides services at one facility or corporation; and
(3) provides requirements in Subparagraph (1)(h) of this Rule for agency review during inspection.

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

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

(2) A registrant that terminates all activities of radiation machines, radiation generating devices, or providing services shall meet the following requirements within 30 days:
(A) request termination of the notice of registration in writing by the owner or the individual with administrative control;
(B) submit to the agency, a Disposal of a Radiation Machine or Radiation Generating Device Form in accordance with Paragraph (e) of this Rule; and
(C) pay any outstanding fees pursuant to Section .1100 of this Chapter.

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

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

(A) The machine or device shall be posted with a visible sign stating that the new owner is responsible for registering with the agency if used in this State; and

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

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

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

10A NCAC 15 .0204 FACILITY RESPONSIBILITIES

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

(b) Shielding design requirements:

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

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

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

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

(C) proposed date of installation.

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

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

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

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

(A) dental handheld;

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

(C) mammography; or

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

(c) Facility registration

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

(A) have a shielding design submitted in accordance with Paragraph (a) of this Rule;

(B) have a Radiation Machine Application or a Radiation Generating Devices Application form submitted in accordance with Rule .0203(d) of this Section. Radiation machines

leased or on loan from a registered service provider shall register the radiation machine if used for more than 30 days;

(C) have a copy of the operating and safety procedures to protect patients, operators, and the public from radiation submitted to the agency;

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

(E) an individual with administrative control shall ensure that radiation machines are operated in accordance with Section .0600 of this Chapter.

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

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

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

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

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

(B) submit a Radiation Machine Application form in accordance with Rule .0203 (d) of this Section within 30 days of use.

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

(A) submit a Radiation Generation Device Application in accordance with Rule .0203(d) of this Section; and

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

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

(A) submit a Radiation Generating Device Application in accordance with Rule .0203(d) of this Section; and

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

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

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

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

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

10A NCAC 15 .0205 SERVICE PROVIDER RESPONSIBILITIES

(a) Each person who is engaged in the business of furnishing or offering to furnish any services listed in Paragraph (e) of this Rule in this State, or any agency registrant, shall apply for registration of such services with the agency prior to furnishing or offering to furnish any of these services.

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

(c) Each person applying for registration pursuant to Paragraph (a) of this Rule shall certify that he or she has read and understands the requirements of the rules in this Chapter by signing the Company Employee Services Application or Company Services Application form.
(d) Applicants for registration of services are subject to the requirements of Rules .0206 and .0207 of this Section.
(e) For purposes of this Section, services include:
(1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of radiation machines or radiation generating devices;
(2) Class II - installation, repair, or service of the following:
(A) radiation machines and machine components, including the making of diagnostic radiation output measurements, and performance verification; or
(B) radiation generating devices to include equipment surveys.
(3) Class III - shielding designs for diagnostic radiographic facilities;
(4) Class IV - shielding designs for diagnostic fluoroscopy facilities;
(5) Class V - area radiation surveys and shielding evaluations for diagnostic radiographic and fluoroscopy facilities;
(6) Class VI - radiation survey equipment calibrations;
(7) Class VII - therapeutic facility and shielding design, area radiation survey, or verification;
(8) Class VIII - providing individual monitoring devices;
(9) Class IX - general health and medical physics consulting to include the following services:
(A) equipment surveys and shielding designs for radiation generating devices;
(B) dose estimates;
(C) radiation output measurements;
(D) radiation safety program development; and
(E) radiation safety program training.
(f) Persons registered pursuant to Subparagraph (e)(1) as a Class I service provider to provide mobile radiation machines that are fixed in a vehicle or trailer for demonstration purposes or that provides leasing services shall meet the following requirements prior to use:
(1) mobile radiation machines located and used in this State shall meet the requirements of Rules .0204(c)(1)(A) through (E) of this Section; and
(2) mobile radiation machines located out of state and brought into this State for use shall meet the requirements of Rules .0204(c)(2)(A) and (B) of this Section.
(g) Report of installation
(1) Persons registered pursuant to Paragraph (a) of this Rule who sell, install, transfer, lease, lend, or dispose of radiation machines in this State shall, within 15 days after each calendar quarter, notify the agency at XrayNORS@dhhs.nc.gov or the address, in accordance with Rule .0111 of this Chapter, of the following:
(A) whether any radiation machines were directly sold, disposed of, installed, leased, loaned, or transferred during the calendar quarter;
(B) the name and address of persons who received radiation machines during the calendar quarter;
(C) the manufacturer, model, and serial number of each radiation machine directly sold, disposed of, installed, leased, loaned, or transferred during the calendar quarter; and
(D) the date of disposition, installation, lease, loan, sale, or transfer of each radiation machine during the calendar quarter.
(2) The information specified in Parts (g)(1)(A) through (D) of this Rule may be omitted from the quarterly reports when either of the following requirements are met:
(A) for any diagnostic x-ray system that contains certified components, when a copy of the assembler's report prepared in compliance with 21 CFR 1020.30(d) is received by the agency; or
(B) for radiation machines for nonhuman use and radiation generating devices, when a Report of Sale and Installation Form prepared in accordance with Paragraph (i) of this Rule is received by the agency.
(h) A Report of Sale and Installation of radiation machines for nonhuman use or radiation generating devices can be found at https://radiation.ncdhhs.gov/Xray/documents/rptofassembly.pdf and shall include the following information:
(1) facility registration number, street address, city, state, and telephone number;

(2) service provider registration number, company name, street address, city, state, and telephone number;
(3) identify if the radiation machine or the radiation generating device was sold or installed by checking the corresponding checkbox;
(4) identify the system type by checking the corresponding checkbox;
(5) room location;
(6) date of sale or installation;
(7) manufacturer, serial number, and control model number;
(8) the seller's signature or signature of the individual responsible for installation; and
(9) the date signed.

(i) No person registered pursuant to Paragraph (a) of this Rule for x-ray sales or installations shall make, sell, lease, transfer, lend, assemble, or install radiation machines, radiation machine components, or radiation machine generating devices unless such machines and devices when placed in operation shall meet the requirements of these Rules.

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

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

(l) Records of any routine maintenance, repair, alterations, or reassembly of radiation machines or radiation generating devices shall:
(1) include the date that the service was performed and a legible signature of the person performing the service; and
(2) be provided to the registrant for agency review during inspection.

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

10A NCAC 15 .0206 TRAINING AND EDUCATIONAL REQUIREMENTS TO PROVIDE SERVICES

(a) A person registered to provide services pursuant to Rule .0205 of this Section shall be qualified by reason of education, training, and experience to provide the services for which registration is requested. The following are the minimum qualifications for each service class:
(1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of radiation machines or radiation generating devices: The applicant shall certify all persons providing services are knowledgeable, familiar, and comply with the rules which govern the possession, installation, and use of radiation machines in North Carolina.
(2) Class II - installation or service to verify performance associated with the installation or service:
(A) manufacturer's equipment school for service, maintenance, and installation for the type of radiation machine used for dental hand-held, intraoral, and extra-oral, medical diagnostic, or medical fluoroscopic, radiation generation devices, or equivalent training;
(B) training in basic principles of radiation protection; and
(C) three months of experience in the installation and service of radiation machines, radiation generating devices, and machine components services are required.
(3) Class III - shielding design for diagnostic radiographic facilities:
(A) training in basic principles of radiation protection;
(B) training in shielding design for each modality registering to provide services; and
(C) one year of experience in diagnostic radiographic facility and shielding for each type of machine application.
(4) Class IV - shielding design for diagnostic fluoroscopic facilities:
(A) training in basic principles of radiation protection;

(B) training in shielding design for each modality registering to provide services; and
(C) one year of experience in diagnostic fluoroscopic facility and shielding for each type of machine application.

(5) Class V - area radiation surveys and shielding evaluation for diagnostic radiographic and fluoroscopy facilities:
(A) training in basic principles of radiation protection;
(B) training in shielding evaluation for each modality registering to provide services; and
(C) one year of experience performing area radiation surveys for each type of machine application.

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

(7) Class VII - therapeutic facility and shielding design, area radiation survey, or verification:
(A) certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics;
(B) certification by the American Board of Medical Physics;
(C) doctorate degree in medical physics or related field; or
(D) have a master's degree in physics, biophysics, radiological physics, nuclear engineering, or health physics, one year of full-time training in therapeutic radiological physics, one year of full-time experience in a therapeutic facility including personal calibration and spot-check of at least one machine, submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed, submit a copy of all forms, reports, and documents that will be supplied to customers; and submit one sample of each type of therapy modality service provided.

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

(9) Class IX - general health or medical physics consulting shall be performed by a person meeting one of the following requirements:
(A) certified by the American Board of Health Physics in health physics in the appropriate field or specialties for services provided;
(B) certified by the American Board of Medical Physics;
(C) certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, x-ray and radium physics; or
(D) hold a master's or doctorate in physics, medical physics, other physical science, engineering, or applied mathematics, from an accredited college or university, and have 40 hours of practical training or supervised experience in x-ray physics.

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

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

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

10A NCAC 15 .0207 ADDITIONAL REQUIREMENTS TO PROVIDE SERVICES

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

(1) have radiation survey and radiation measurement equipment capable of measuring the radiation energies corresponding to the services requested for authorization;

(2) ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated annually when a frequency is not recommended by the manufacturer;
(3) submit the following for agency review prior to registration:
(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 registrants;
(C) samples of surveys for each modality requested for registration;
(D) samples of reports of diagnostic radiation output measurements for each modality requested for registration; and
(E) samples of calibration reports for each therapeutic and kV imaging modality requested for registration.

(b) A person applying for registration to perform Class VI equipment calibrations shall meet the following requirements:
(1) ensure such calibrations are current and traceable to the National Institute of Standards and Technology;
(2) license or register radiation sources used for such calibration as required by the rules in this Chapter;
(3) label the equipment to indicate the date of calibration; and
(4) maintain records of the calibration.

(c) A person applying for registration to perform Class III shielding designs for diagnostic radiographic facilities, Class IV shielding designs for diagnostic fluoroscopy facilities, and Class VII therapeutic facilities and shielding design services shall meet the following additional requirements:
(1) submit examples of the facility and shielding design which will be provided to registrants;
(2) submit any technical guides, methodology, occupancy factor rationales, and workload estimation rationales that will be used; and
(3) ensure that the facility and shielding design services provided to registrants meet the requirements in this Chapter.

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

10A NCAC 15 .0208 OUT-OF-STATE RADIATION MACHINES AND RADIATION GENERATION DEVICES

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

(b) A person bringing a radiation machine or radiation generating device into this State, for any temporary use, shall meet the following requirements:
(1) complete the registration process in accordance with Rules .0203, .0204, and .0205 of this Section prior to beginning operations in this State;
(2) supply the agency with other information the agency may request; and
(3) comply with the Rules of this Chapter.

(c) The out of state registrant shall maintain with the radiation machine or radiation generating device, when located and used in this State, the following:
(1) the current notice of registration from this agency;
(2) a copy of the written notice submitted to the agency in accordance with Paragraph (a) of the Rule;
(3) the shielding design, if required, in accordance with Rule .0204 (c)(1)(A) of this Section; and
(4) a copy of the out of state registrant's operating and safety procedures.

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0208 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. October 1, 2025.

10A NCAC 15 .0209 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 or radiation generating devices as the agency deems appropriate or necessary for compliance with the rules in this Chapter.

(c) The agency may refuse to grant a registration required in Rules .0203, .0204, and .0205 of this Section to any applicant who does not possess the 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 Chapter 150B of the North Carolina General Statutes.

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

10A NCAC 15 .0210 MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRATIONS

(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.

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

(1) for any materially false statement in the application or any false statement of fact required by provisions of this Section;
(2) because of a decision made by the agency to refuse to grant registration on the original application revealed by:
    (A) the application;
    (B) any statement of fact;
    (C) any report, record, inspection, or other means; or
(3) for violations of, or failure to follow any of the terms and conditions of the Act, the registration, the rules of this Chapter, or the order of the agency.

(c) In cases of knowingly and intentionally choosing not to follow the requirements of this Chapter or those in which the public health, interest, or safety requires otherwise, prior to modification, revocation, or suspension of a registrant, the agency shall:

(1) notify the registrant in writing of the facts or conduct which may warrant these actions, and
(2) provide an opportunity for the registrant to demonstrate or achieve compliance with the requirements of this Chapter.

(d) 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. February 1, 1980;

Amended Eff. May 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0210 Eff. February 1, 2015;
Readopted Eff. October 1, 2025.

10A NCAC 15 .0211 THE INDIVIDUAL RESPONSIBLE FOR RADIATION PROTECTION REQUIREMENTS AND RESPONSIBILITIES

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

(1) training in basic radiation protection principles;
(2) completed educational courses relating to ionizing radiation;
(3) know potential radiation hazards and emergency precautions; and
(4) training and experience in and knowing the proper use of the type of equipment used.

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

(1) Establishing and overseeing operating and safety procedures:
  (A) that maintain radiation exposures as low as reasonably achievable (ALARA); and
  (B) to review the procedures annually, or when changes occur to ensure the procedures are current.
(2) Ensuring individual monitoring devices are used in accordance with these Rules by occupationally exposed personnel and records of monitoring results shall be:
  (A) reviewed;
  (B) maintained; and
  (C) notifications made in accordance with Rule .1601 of this Chapter.
(3) Ensuring that personnel are complying with:
  (A) this Chapter;
  (B) the conditions of the notice of registration; and
  (C) the operating and safety procedures of the registrant.
(4) Knowing:
  (A) the management policies and administrative procedures of the registrant; and
  (B) keeping management informed of the registrant's radiation protection program.
(5) Assuming control and having the authority to carry out corrective actions including stopping operations in emergencies or unsafe conditions.

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

10A NCAC 15 .0212 EMERGING TECHNOLOGIES NOT MEETING EXISTING EQUIPMENT REQUIREMENTS

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

(1) an application form in accordance with Rule .0203(d) of this Section;
(2) the manufacturer manual;
(3) description of intended use;
(4) operator training provided to the end user;
(5) an independent equipment survey to include the following:
  (A) all equipment settings available to the operator;
  (B) output at the highest setting; and

(C) leakage radiation around the radiation machine.

(6) an area survey to include the following:

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

(B) the survey instrument used; and

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

(7) the hazard level associated with the use of the radiation machine.

(8) means to achieve radiation protection equivalent to the rules of this Section.

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

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

10A NCAC 15 .0213 ADDITIONAL REQUIREMENTS: REGISTERED SERVICES

History Note: *Authority G.S. 104E-7;*
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Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0213 Eff. February 1, 2015;
Repealed Eff. October 1, 2025.

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;
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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;*
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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 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 to Licensing.RAM@dhhs.nc.gov, or mailed to 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 the 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 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(a) of this Chapter in lieu of the NRC.

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

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 2005;
Transferred and Recodified from 15A NCAC 11 .0306 Eff. February 1, 2015;
Readopted Eff. May 1, 2025.

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/.

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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);*
Eff. February 1, 1980;
Amended Eff. January 1, 2005; January 1, 1994;
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 PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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

(1) 10 CFR 71.0, "Purpose and scope;"
(2) 10 CFR 71.1, "Communications and records;" except that communications, notices, and reports required by this Rule shall be sent to the addresses shown in Rule .0111 of this Chapter unless directed otherwise by the agency, in lieu of the NRC;
(3) 10 CFR 71.3, "Requirement for license;"
(4) 10 CFR 71.4, "Definitions;"
(5) 10 CFR 71.5, "Transportation of licensed material;"
(6) 10 CFR 71.7(a), "Completeness and accuracy of information;"
(7) 10 CFR 71.8, "Deliberate misconduct;"
(8) 10 CFR 71.12, "Specific exemptions;"

(9) 10 CFR 71.13, "Exemption of Physicians;"
(10) 10 CFR 71.14(a), "Exemption for low-level materials;"
(11) 10 CFR 71.15, "Exemption from classification as fissile material;"
(12) 10 CFR 71.17, "General license: NRC-approved package," except that quality assurance program approval required by 10 CFR 71.17(b) shall be issued by the agency in lieu of the NRC. Notifications required by 10 CFR 71.17(c) shall be made to the agency as required by Subparagraph (2) of this Paragraph and to the NRC in accordance with 71.17(c)(3);
(13) 10 CFR 71.21, "General license: Use of foreign approved package;"
(14) 10 CFR 71.22, "General license: Fissile material;"
(15) 10 CFR 71.23, "General license: Plutonium-beryllium special form material;"
(16) 10 CFR 71.47, "External radiation standards for all packages;"
(17) 10 CFR 71.81, "Applicability of operating controls and procedures;"
(18) 10 CFR 71.83, "Assumptions as to unknown properties;"
(19) 10 CFR 71.85(d), "Preliminary determinations;"
(20) 10 CFR 71.87, "Routine determinations;"
(21) 10 CFR 71.88, "Air transport of plutonium;"
(22) 10 CFR 71.89, "Opening instructions;"
(23) 10 CFR 71.91(a), (c) through (d), "Records;"
(24) 10 CFR 71.93, "Inspection and tests;"
(25) 10 CFR 71.95, "Reports;"
(26) 10 CFR 71.97, "Advance notification of shipment of irradiated reactor fuel and nuclear waste." Advanced notifications required by this Subparagraph shall be made to the NRC as required by 10 CFR 71(c)(iii) and to the Governor's designee as follows:
(A) designee: N.C. Highway Patrol Headquarters, Operations Officer;
(B) mailing address: P.O. Box 27687, Raleigh, North Carolina 27611-7687;
(C) telephone: (919) 733-4030 from 8 a.m. to 5 p.m. Monday through Friday except State holidays, and (919) 733-3861 at all other times.
(27) 10 CFR 71.101(a) through (c)(1), (f), (g), "Quality assurance requirements." The quality assurance plan required by 10 CFR 71.101(c)(1) shall be submitted to the agency for review and approval in lieu of the NRC;
(28) 10 CFR 71.103, "Quality assurance organization," except that certificates of compliance shall be issued by the NRC in lieu of the agency;
(29) 10 CFR 71.105, "Quality assurance program;"
(30) 10 CFR 71.106, "Changes to quality assurance program;"
(31) 10 CFR 71.127, "Handling, storage, and shipping control;"
(32) 10 CFR 71.129, "Inspection, test, and operating status;"
(33) 10 CFR 71.131, "Nonconforming materials, parts, or components;"
(34) 10 CFR 71.133, "Corrective action;"
(35) 10 CFR 71.135, "Quality assurance records;"
(36) 10 CFR 71.137, "Audits;"
(37) Appendix A to 10 CFR 71, "Determination of A_1 and A_2;"
(38) Table A-1 of Appendix A to 10 CFR 71, "A_1 and A_2 Values for Radionuclides;"
(39) Table A-2 of Appendix A to 10 CFR 71, "Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides," and
(40) Table A-3 of Appendix A to 10 CFR 71, "General Values for A_1 and A_2."

(b) Requests for a specific exemption from this Rule as permitted by 10 CFR 71.12 shall be made on the licensee's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter, in lieu of the NRC, or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:
(1) licensee name;
(2) license number;
(3) name of the individual requesting the exemption;
(4) contact information for the individual requesting the exemption;
(5) a description of the exemption being requested; and
(6) an explanation describing why the exemption is necessary.

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

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

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 EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

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

(1) 10 CFR 150.1, "Purpose;"
(2) 10 CFR 150.2, "Scope;"
(3) 10 CFR 150.3, "Definitions," except that the terms "foreign obligations" and "reconciliation" shall not apply;
(4) 10 CFR 150.4, "Communications," except that questions about this Rule and communications and reports required by this Rule shall be sent to the address shown in Rule .0111(a) of this Chapter unless directed otherwise by the agency, in lieu of the NRC;
(5) 10 CFR 150.11, "Critical Mass;"
(6) 10 CFR 150.20, "Recognition of Agreement State licenses;"
(7) 10 CFR 150.31, "Requirements for Agreement State regulation of byproduct material," and
(8) 10 CFR 150.32, "Funds for reclamation or maintenance of byproduct material;"

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

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

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

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;
Repealed Eff. May 1, 2025.

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

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;
Repealed Eff. May 1, 2025.

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 .0345 RECIPROCAL RECOGNITION OF LICENSES
10A NCAC 15 .0346 PREPARATION OF RADIOACTIVE MATERIAL FOR TRANSPORT

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

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 .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 .0103 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 .0103 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. October 1, 2025; 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;
Transferred and Recodified from 15A NCAC 11 .0522 - .0523 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 .0524 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY
10A NCAC 15 .0525 RADIOGRAPHER CERTIFICATION

History Note: *Authority G.S. 104E-7; 104E-10(b); 10 C.F.R. 34, Appendix A; 10 C.F.R. 34.43;*
Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0524, .0525 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.

SECTION .0600 - X-RAYS IN THE HEALING ARTS

Codifier's Note: 10 NCAC 03G .2700 was transferred to 15A NCAC 11 .0600 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

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.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0601 Eff. February 1, 2015.

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.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; November 1, 1989; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0606 Eff. February 1, 2015.

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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Eff. February 1, 1980;
Amended Eff. January 1, 1994; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0607 Eff. February 1, 2015.

10A NCAC 15 .0608 THERAPEUTIC X-RAY INSTALLATIONS: LESS THAN ONE MEV
10A NCAC 15 .0609 X-RAY AND ELECTRON THERAPY INSTALLATIONS ONE MEV AND ABOVE

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. January1, 1994; May 1, 1992; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0608 and .0609 Eff. February 1, 2015;
Repealed Eff. October 1, 2025.

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.

History Note: *Authority G.S. 104E-7; 104E-12(a);*
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Transferred and Recodified from 15A NCAC 11 .0608 Eff. February 1, 2015.

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.

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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.

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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 - RADIATION GENERATING DEVICES

10A NCAC 15 .0801 PURPOSE AND SCOPE

(a) This Section provides additional 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). The requirements of this Section are in addition to the provisions in Sections .0100, .0200, .1000, and .1600 of this Chapter.
(b) This Section does not pertain to radiation safety requirements for industrial radiographic machines for non-human use that are covered in Section .0500 of this Chapter, x-rays in the healing arts in Section .0600 of this Chapter, and particle accelerators in Section .0900 of this Chapter.
(c) RGDs used for the purpose of elemental analysis, microstructural analysis, quality assurance, quality control, research and development, gauging and measurement, or other nondestructive testing and evaluation in this Section includes:

(1) analytical RGDs;
(2) cabinet x-ray systems;
(3) electron beam devices operating below 1MeV;
(4) electron microscopes;
(5) ion implantation equipment, low energy;
(6) gauging devices;
(7) radiographic and radioscopic non-healing arts x-ray equipment; and
(8) security screening devices and systems for government use only.

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;
Amended Eff. November 1, 2024.

10A NCAC 15 .0802 DEFINITIONS

In addition to terms found in Rule .0103 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) "Accessible surface" means the external or outside surface of the enclosure or housing provided by the manufacturer or designer of the RGD. This includes the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware, and including the plane across the exterior edge of any opening.
(3) "Analytical RGD equipment" means equipment that uses electronic means to generate ionizing radiation for the purpose of examining the microstructure of materials using direct x-ray transmission, x-ray diffraction, x-ray fluorescence, and x-ray spectroscopy.
(4) "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.
(5) "Certified bomb technician" means a member of an accredited bomb squad who has successfully completed the FBI Hazardous Devices School. Information pertaining to this program can be found 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 C.F.R. 1020.40, as incorporated by reference in Rule .0104 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 .0104 of this Chapter, as being manufactured and assembled pursuant to the provisions of 21 C.F.R. 1020.40, as incorporated by reference in Rule .0104 of this Chapter.

(8) "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

(9) "Control panel" means the part of the x-ray control where the switches, knobs, pushbuttons, and other hardware are, located 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) "Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected radiation exposure of an individual exceeding administrative or regulatory limits found in Rule 10A NCAC 15 .1601(a)(8) and .1601(a)(15). This procedure shall include the names and telephone numbers of individuals to be contacted, as well as directives for processing individual monitoring devices.

(13) "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, shutter indicator, or interlock fails, the radiation beam shall terminate.

(14) "Gauging device" means a mechanism containing a source of ionizing radiation that is designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative composition of materials. It may include components such as radiation shields, useful-beam controls, and other safety features in order to meet the requirements or specifications of the device.

(15) "General-use system" means a security screening system that delivers an effective dose of 25 microrem (0.25 microSv) or less per screening.

(16) "Hand-held x-ray system" means any device or equipment that is portable and used for similar purposes as analytical RGD equipment.

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

(18) "Inspection Zone" means the area established for the purpose of controlling access where screening is performed. Areas controlled due to the presence of radiation shall include areas of ingress, egress, gates, portals, and traffic paths. The area outside of the inspection zone shall not exceed the limits of Rule .1601(a)(13) of this Chapter.

(19) "Interlock" means a feature designed to prevent access to an area of radiation hazard by preventing entry or by automatically removing the hazard.

(20) "Ion implantation equipment, low-energy" means any enclosed device operating below 1MeV used to accelerate elemental ions and implant them in other materials.

(21) "Leakage radiation" means radiation emanating from the source assembly housing except for:

(A) the primary beam;

(B) scatter radiation emanating from other components; and

(C) radiation produced when the "beam on" switch or timer is not activated.

(22) "Limited-use system" means a screening system that is capable of delivering an effective dose greater than 25 microrem (0.25 microSv) per screening, but shall not exceed an effective dose of 1 mrem (10 microSv) per screening,

(23) "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.

(24) "Mobile RGD" means RGD equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(25) "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.

(26) "Open-beam RGD" means a device or system designed in such a way that the primary beam is not completely enclosed during normal operation, when used for analysis, gauging, or imaging, an individual could accidentally place some part of their body in the primary beam or stray radiation path during normal operation.

(27) "Portable RGD" means RGD equipment designed to be carried by hand.

(28) "Primary beam" means radiation that passes through an aperture of the source assembly housing by a direct path from the radiation source.

(29) "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 parts on humans or animals. RGDs may be used as a:

(A) mobile RGD;

(B) portable RGD; or

(C) stationary RGD.

(30) "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.

(31) "Safety Device" means a device, interlock or system that prevents the entry of any portion of an individual's body into the primary x-ray beam or that will cause the beam to shut off upon entry into its path.

(32) "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.

(33) "Screening" means the sum of scans necessary for a security screening system to image concealed objects as intended by the system design under normal operating conditions.

(34) "Security screening device" means a non-human use open-beam device designed for the detection of contraband or weapons concealed in baggage, mail, packages, or other structures. These devices include bomb detection devices used for the sole purpose of detecting explosive devices.

(35) "Security screening system" means a system specifically designed to detect contraband and weapons concealed on a person and is used for the sole purpose of public safety and security evaluation by law enforcement.

(36) "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.

(37) "Source" means the point of origin of the radiation, such as the focal spot of an x-ray tube.

(38) "Stationary RGD" means RGD equipment that is installed or placed in a fixed location.

(39) "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.

(40) "Warning device" means an audible or visible signal that warns individuals of a potential radiation hazard.

(41) "X-ray generator" means the part of an x-ray system that provides the accelerating (high) voltage and current for the x-ray tube.

(42) "X-ray source housing" means the portion of an RGD system which contains the x-ray tube and emitting target. The housing often contains radiation shielding material or inherently provides shielding.

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;
Amended Eff. October 1, 2025; November 1, 2024.

10A NCAC 15 .0803 PERSONNEL REQUIREMENTS

(a) The registrant, as defined in 10A NCAC 15 .0103, shall document the scope of training and instruction required for the RGD in use.

(b) No individual shall be permitted to operate or maintain RGDs unless the individual has received instruction in the basic principles of radiation protection, training specific to the manufacturer's recommendations for safe operation and unique features of the RGD in use, and instruction in the operating and emergency procedures. Instruction and training shall include:

(1) Basic principles of radiation protection:
  (A) radiation fundamentals;
  (B) source and magnitude of common sources of radiation exposure;
  (C) units of radiation dose and measurements;
  (D) potential hazards, biological effects of ionizing radiation, and recognition of symptoms of an acute localized exposure;
  (E) ALARA (As Low As Reasonably Achievable) principles for radiation protection concepts of time, distance, and shielding to minimize radiation exposure;
  (F) declared pregnancy policy;
  (G) occupational, embryo/fetus, and public dose limits; and
  (H) proper use of individual monitoring devices and survey instruments.

(2) Device specific training for each RGD:
  (A) hands-on training for proper use;
  (B) radiation hazards associated with use;
  (C) precautions to take or measures required to minimize radiation exposure;
  (D) procedures to prevent unauthorized use; and
  (E) agency rules regarding use.

(3) Operating and emergency procedure requirements of Rule .0804 in this Section.

(c) Records of instruction and training for each individual operating RGDs, documenting that the requirements of this Rule have been met, shall be maintained and available for agency review during inspection.

(d) Persons who will be operating the RGD shall be able to demonstrate an understanding in safe operating procedures and use of the RGD according to the manufacturer's specifications and to an authorized representative of the Radiation Protection Section.

(e) Each registrant shall provide ring or wrist individual monitoring devices to individuals:

(1) operating open-beam RGDs; and

(2) performing maintenance on an RDG, 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;*
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10A NCAC 15 .0804 OPERATING REQUIREMENTS

(a) RGDs shall only be operated by individuals who have completed the requirements in Rule .0803 of this Section.

(b) No individual shall be permitted to operate an RGD in any manner other than that specified in the operating procedures, unless the individual has obtained written approval from the individual responsible for radiation protection as defined in 10A NCAC 15 .0802(17).

(c) Normal operating and emergency procedures from the manufacturer or supplier of the RGD shall be available to all operators and support staff for review during the use of an RGD.

(d) Normal operating and emergency procedures shall include the following:

(1) safe use of the RGD;

(2) protocols in the event of device malfunction, emergency, or incident involving radiation exposure; and

(3) instructions on reporting to the individual responsible for radiation protection of actual or suspected accidental exposure or other radiation safety concerns, such as any unusual occurrence or malfunction that may involve exposure to radiation.

(e) Open beam and portable handheld RGDs

(1) Registrants shall have operating procedures developed to ensure radiation protective measures are:

(A) provided to meet the requirements of Rule .1601(a)(15) of this Chapter;

(B) taken to avoid exposure to any individual from the transmitted primary x-ray beam in cases where the primary x-ray beam is not intercepted by a detector device during operation; and

(C) available to all individuals operating the RGD.

(2) Operators shall not do the following while operating an RGD:

(A) point the primary beam at any individual including him or herself;

(B) allow their hand to approach the primary beam; or

(C) hold a sample. If a sample is small and it is necessary to hold the sample while operating the RGD, the sample shall be placed in a shielded sample enclosure.

(f) Operating and emergency procedures shall be available for review by the individual responsible for radiation protection during inspection.

(g) Alignment procedures shall be performed as recommended by the RGD manufacturer.

(h) Special alignment procedures shall only be used when approved by the individual responsible for radiation protection and manufacturer of the RGD.

(i) Safety Devices

(1) Testing

(A) Safety devices including interlocks, shutters, and warning lights shall be tested once annually for proper operation on all RGDs in use. If any safety device fails, the RGD shall be taken out of service until corrective action is performed or temporary administrative controls are established and approved in writing by the individual responsible for radiation protection.

(B) Testing records shall include the date test was performed, the list of safety devices tested, the survey instrument used, the calibration date, the results of the test, the name of the individual that performed the test, and any corrective actions for a failed test.

(C) Records of the testing shall be retained by the registrant for agency review during inspection.

(2) Bypassing

(A) No individual shall bypass a safety device unless the person has obtained approval from the individual responsible for radiation protection. Procedures for bypassing a safety device shall be incorporated into the radiation protection program by the individual responsible for radiation protection, as set forth in Rule .1601 of this Chapter, and the operating procedures as set forth in Paragraph (c) of this Rule.

(B) The written approval, as granted by the individual responsible for radiation protection, shall include the start and end date of approval.

(C) 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 x-ray source housing and the control panel during the bypassing period.

(j) An individual shall determine the tube is off, and will remain off until safe conditions have been restored, prior to an individual modifying the following;

(1) x-ray tube system, resulting in the removal of tube housings, covers, or shielding materials;

(2) shutters;

(3) collimators; or

(4) beam stops.

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;
Amended Eff. November 1, 2024.

10A NCAC 15 .0805 AREA REQUIREMENTS

(a) Each radiation area, as defined in Rule .1601(a)(3) of this Chapter, containing RGDs shall be:

(1) conspicuously posted with caution signs, in accordance with the requirements of Rule .1601(a)(34) of this Chapter, bearing the words "CAUTION – RADIATION AREA", or words having a similar meaning; and

(2) supervised continuously during operation of the RDG or shall utilize one or more of the following:

(A) door interlocks;

(B) entry monitors; or

(C) engineering controls.

(b) Access to each restricted area where an individual may receive a dose equivalent exceeding 100 mrem in any year, but does not exceed levels of a radiation area, shall be designated as a controlled area. The area shall be controlled by:

(1) visibly separating adjacent uncontrolled areas so doses do not exceed the limits of Rule .1601(a)(15) of this Chapter; and

(2) posting a sign bearing the words "Warning: X-rays in Use", or words having a similar meaning.

(c) 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 result in a dose to an individual in excess of the dose limits in Rule .1601(a)(15) of this Chapter.

(d) Surveys shall be performed for each RGD, as set forth in Rule .1601(a)(23) of this Chapter, to show compliance with Paragraph (c) of this Rule.

(1) Radiation survey instruments shall be:

(A) capable of measuring the radiation energies of the RGD surveyed; and

(B) calibrated annually when a frequency is not recommended by the manufacturer.

(2) Equipment surveys shall confirm radiation levels do not exceed the requirements of Rule .0806(c)(7); .0806(d)(3); and .0806(h)(2) of this Section. Surveys shall be performed:

(A) prior to initial use and include testing of warning and safety devices;

(B) prior to use following any change in the initial arrangement, including the number or type of local components in the system or x-ray tube source housing;

(C) prior to use following any maintenance requiring the disassembly or removal of a local component in the system or x-ray tube source housing that could affect the radiation exposure to personnel; and

(D) during the performance of calibration, maintenance, or any alignment procedure if the presence of a primary x-ray beam is required while any local component in the system is disassembled or removed.

(3) A registrant may apply to the agency for approval of procedures differing from those in Subparagraph (d) of this Rule, provided that the registrant demonstrates satisfactory compliance with Paragraph (c) of this Rule.

(4) Records shall be available for agency review during inspection.

(e) RGDs in Rule .0806(i) and .0807(2) of this Section, installed after the effective date of this Rule, shall ensure the following provisions are met:

(1) A floor plan with equipment arrangement shall be submitted to the agency for review and acknowledgement prior to installation of the system. The floor plan shall include:

(A) the proposed location of the system;

(B) direction of the useful beam;

(C) adjacent areas; and

(D) location of the operator.

(2) An area radiation survey shall be performed prior to initial use to show compliance with dose limits of the rules in Section .1600 of this Chapter. The survey shall include:

(A) a drawing of the room indicating the location of the x-ray tube and orientation of the useful beam;

(B) radiation levels at the operator location and adjacent areas;

(C) survey instrument used; and

(D) name of the service provider that is registered, in accordance with Rule .0205 of this Chapter, and date the survey was performed.

(3) Modifications to the room, RGD, or adjacent areas that may increase the radiation dose to any individual shall require a new survey.

(4) Records of the floor plan with equipment arrangement and survey shall be available for review by an authorized representative of the Radiation Protection Section during inspection.

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;
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Amended Eff. November 1, 2024.

10A NCAC 15 .0806 EQUIPMENT REQUIREMENTS

(a) Certified and certifiable cabinet x-ray systems shall comply with the following provisions of 21 C.F.R. 1020.40, which are hereby incorporated by reference including subsequent amendments and editions.

(1) 21 C.F.R. 1020.40(a) Applicability;

(2) 21 C.F.R. 1020.40(b) Definitions;

(3) 21 C.F.R. 1020.40(c) Requirements; and

(4) 21 C.F.R. 1020.40(d) Modifications of a certified system.

(b) The regulations cited in Paragraph (a) of this Rule are available free of charge at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.40.

(c) All RGD's shall meet the following requirements, except certified and certifiable cabinet x-ray systems in Paragraph (a) of this Rule:

(1) Warning devices shall be labeled so the purpose is easily identified.

(2) Warning lights of a fail-safe design labeled with the words "X-RAY ON", or words having a similar meaning, shall be located:

(A) within sight of any switch that energizes an x-ray tube;

(B) in a conspicuous location near the x-ray tube source housing and x-ray beam, and

(C) visible from all instrument access areas.

(3) Warning lights shall activate when the x-ray tube is energized.

(4) Each shutter shall be equipped with a "shutter open" warning light or device of a fail-safe design.

(5) A readily visible and legible label bearing the radiation symbol and the words "CAUTION – RADIATION: THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar meaning, shall be located near any switch that energizes an x-ray tube.

(6) Systems containing an x-ray tube shall be equipped with a fail-safe interlock that will shut off high voltage to the tube if the x-ray tube source housing is disassembled or if the tube is removed.

(7) High voltage generator enclosures or any accessible area 5 centimeters from the RGD shall not exceed a dose rate of .25 mrem/hr (.0025 mSv/hr).

(d) All open beam RGDs shall meet the following additional requirements:

(1) Each beam port of the x-ray tube source housing shall be equipped with a beam shutter interlocked with the x-ray accessory coupling, or collimator, so that the port will not open unless a collimator or a component coupling is in place.

(2) Shutters at unused ports shall be secured in the closed position to prevent unintended opening.

(3) The x-ray tube source housing shall be constructed so that when all shutters are closed, the leakage radiation measured at a distance of five centimeters from the housing surface does not exceed 2.5 mrem (25 microSv) in one hour.

(4) A safety device or interlock shall prevent the entry of any portion of an individual's body into the primary x-ray beam or which causes the primary beam to shut off upon entry into its path.

(5) A registrant may apply to the agency, as defined in Rule .0106 of this Chapter, for an exemption from the requirement of a safety device in Subparagraph (d)(3) of this Rule. The request shall include:

(A) justification for the use of an open beam system instead of an enclosed beam system;

(B) a description of other safety devices that have been evaluated and reason why a safety devices cannot be used; and

(C) 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.

(e) All enclosed beam RGDs shall meet the following additional requirements:

(1) The radiation source, sample or object, detector, and analyzing crystal (if used) shall be enclosed to prevent entry of any portion of the body during normal operation.

(2) All doors and panels shall be equipped with an interlock. The interlock shall be of a fail-safe design.

(f) Bimodal beam RGDs with the ability to override interlocks between enclosed and open beam shall be designed to be engaged with a device or tool and meet the following requirements:

(1) The tool or key shall only be used by designated individuals as outlined in operating procedures.

(2) When the tool or key is in use, it shall be captive in the equipment and removal of the tool or key returns the RGD to enclosed beam mode.

(3) System use requirements must follow the current use mode.

(g) Portable x-ray fluorescence analyzers manufactured to be used in a hand-held configuration without safety devices are exempt from the requirements of Subparagraph (d)(4) of this Rule. The following additional requirements shall be provided on the analyzer:

(1) A power switch with the power logo: I/O.

(2) A label with the words "CAUTION: THIS EQUIPMENT PRODUCES X-RAYS WHEN OPERATED", or words with similar meaning.

(3) Indicators visible to operators when x-rays are on. The indicator shall be in the form of a light and a warning symbol or text with the words "X-RAY ON", or words with similar meaning.

(4) Warning labels near each beam port that bear a radiation symbol and the words "WARNING HIGH INTENSITY X-RAYS – DO NOT EXPOSE ANY PART OF BODY TO BEAM", or words having a similar meaning.

(h) All gauging devices shall meet the following additional requirements:

(1) The RGD shall be designed to restrict access to the x-ray beam by personnel who are not trained in accordance with Rule .0803 of this Section.

(2) A useful beam control system shall be provided whenever the useful beam is accessible, and the radiation levels exceed one hundred mrem per hour (100 mrem/hr)(1 mSv/hr) at five centimeters from any accessible surface or five mrem per hour (5 mrem/h)(.05 mSv/h) at thirty centimeters (30 cm). The useful beam controls may include a moving shutter, a moving source, or a high voltage power supply.

(3) On-Off indicators shall be marked with symbols or wording clarifying the status of the device.

(4) Each indicating system for automatic beam controls shall consist of at least one "ON" indicating signal, and one "OFF" indicating signal. If lights are used, green indicates the "OFF" and red indicates any other condition of the useful beam control.

(5) Indicators for RGDs high voltage control shall be a yellow or amber warning light with the words "HIGH VOLTAGE ON" and shall be located on the control panel and near the x-ray tube source housing. The warning light shall illuminate only when power is applied to the RGD.

(6) Interlocks shall be used to prevent accidental exposure to high voltage and ionizing radiation.

(7) The RGD shall be conspicuously marked with a label permanently affixed to the device with the following information:

(A) ANSI device classification;

(B) name of manufacturer;

(C) model; and

(D) serial number.

(8) Radiation safety labels shall provide instructions and precautions for safe operation. If space is limited on the RGD, operating or service manuals may be referenced for the information.

(i) Radiographic and radioscopic non-healing arts x-ray equipment operating below energies of 1 MeV designed for non-medical x-ray shall comply with the following additional requirements:

(1) Written instructions shall be supplied by the manufacturer or supplier at the time of sale or transfer to the first user. When the manufacturer or supplier does not provide services to the RGD, installation instructions shall describe:

(A) radiation safety pertaining to each unit or accessory;
(B) instruction for assembly operations when assembly not performed by manufacturer;
(C) interconnections instructions of interlocks, warning lights and audible alarms systems;
(D) test instructions to determine if the RGD and accessory components are properly operating; and
(E) if the x-ray tube assembly is shielded or non-shielded.

(2) Operating instructions shall be supplied by the manufacturer or supplier, at the time of sale or transfer to the first user, in accordance with operating requirements of Rule .0804 of this Section.

(3) The controls shall be:
(A) clearly marked with for the "on-off" position of the component disconnecting the power; and
(B) equipped with a means to prevent production of x-rays when in the "off" position, such as a key or password. When a key is used, the RGD shall be manufactured so it may only be removed when the key is in the "off" position.

(4) The "X-ray On" indicator control shall be:
(A) yellow or amber in color;
(B) be of a fail-safe design; and
(C) have two indicators viewable from the control panel indicating when x-rays are being produced in a period of greater than 0.5 seconds.

(5) The "X-ray Off" indicators shall be:
(A) red in color; and
(B) permanently marked.

(6) Shutters devices that control emission of the primary beam shall activate two visual indicators of contrasting colors from the operator's station. One shall activate when shutters are fully closed and the other shall activate when the shutters are not fully closed.

(7) Selection indicators shall indicate which tube assembly or focal spot has been selected if more than one x-ray tube assembly or focal spot can be operated from the control panel.

(8) Warning Device: A red warning lamp or audible device shall be provided on or near the tube assembly in an open beam, for non-permanent installations.

(j) All RGDs shall be secured to prevent access and operation of the device by any individual not meeting the requirements of Rule .0803 of this Section.

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;
Amended Eff. November 1, 2024.

10A NCAC 15 .0807 SECURITY SCREENING EQUIPMENT REQUIREMENTS FOR GOVERNMENT USE ONLY

(a) All security screening devices shall meet the following additional requirements:

(1) Security screening RGDs shall only be utilized by accredited bomb squads, certified bomb technicians, law enforcement agencies, or forensic investigators.

(2) The operator must be present and maintain access control during operation of the RGD. If the RGD is not operated in a restricted area and the RGD is capable of producing a radiation area, the operator shall:
(A) establish a visible barrier;
(B) perform a visual check of the controlled area to ensure all unauthorized individuals are removed prior to activating or initiating the RGD; and
(C) if the operator is unable to maintain visual control of the area during operation of the RGD, the operator is required to implement additional means to control the area so no one can access the radiation area.

(3) Utilization logs shall be maintained each time the RGD is used and accurately include the following:

(A) date and time of use;
(B) location of use; and
(C) operator of the RGD.

(4) Records of utilization logs shall be available for agency review during inspection.

(b) All security screening systems shall meet the following additional requirements:

(1) Security screening systems shall only be utilized in a correctional institution, detention center, jail, or prison for public safety and security screening purposes.

(2) No individual shall be exposed to the useful beam unless authorized by a law enforcement agency representative.

(3) No individual shall be exposed to the useful beam for demonstration or training purposes.

(4) Screening of staff for training purposes is prohibited.

(5) Policies and procedures shall be established for screening of minors and pregnant individuals.

(6) An inspection zone shall be:

(A) established around the system where bystanders are prohibited during operation;
(B) visibly marked; and
(C) the ambient dose equivalent outside the inspection zone shall not exceed 2 mrem (20 microSv) in any 1 hour.

(7) The system shall be stationary, and the exposure switch shall be located in a manner requiring the operator to remain behind a protected barrier during the entire exposure while able to view the following:

(A) the individual being scanned;
(B) the inspection zone; and
(C) any access areas.

(8) Equipment surveys shall be conducted to verify compliance with reference effective dose limits, the inspection zone, and manufacturer specified parameters. Surveys shall be performed:

(A) upon installation;
(B) every 12 months; and
(C) after maintenance that may affect the system's shielding or x-ray beam.

(9) Reference effective dose limits shall be met as follows:

(A) General-use systems reference effective dose shall not exceed 25 microrem (.25 microSv) per screening.
(B) Limited-use systems reference effective dose shall not exceed 1 mrem (10 microSv) per screening.
(C) The reference effective dose received by an individual shall not exceed 25 mrem (250 microSv) in a 12-month period for both general use and limited-use systems.

(10) Compliance to reference effective dose limits shall be demonstrated by the registrant maintaining records of each individual screened. Records shall show one of the following:

(A) the number of screenings each individual received, for General-use systems, does not exceed 1,000 in a 12-month period; or
(B) the reference effective dose multiplied by the number of screenings, for both General-use and Limited-use systems, does not exceed 25 mrem (250 microSv) in a 12-month period.

(11) Records of each individual scanned at the same facility shall be available for review by an authorized representative of the Radiation Protection Section during inspection.

(12) Each individual being screened shall be informed the system emits radiation and be provided with the following prior to scanning:

(A) the estimated effective dose from one screening;
(B) an example to compare the dose to a commonly known source of radiation; and
(C) confirmation the screening complies with the reference effective dose limits in Subparagraph (b)(9) of this Rule.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2015;
Amended Eff. November 1, 2024.

10A NCAC 15 .0808 OTHER EQUIPMENT REQUIREMENTS

(a) RGD's not listed in Rule .0801 of this Section, or that are not able to meet the equipment requirements of either Rule .0806 or .0807 of this Section, shall not be sold, installed, or used prior to the agency completing review of information regarding the RGD and determining if use of the RGD is allowed. The user or manufacturer of the RGD shall submit the following information to the agency for review:

(1) equipment form for application;
(2) manufacturer manual;
(3) description of use;
(4) operator training;
(5) a survey in accordance with Rule.0805(d) of this Section;
(6) an area survey in accordance with Rule.0805(e)(2) of this Section;
(7) the hazard level associated with use of the RGD; and
(8) means to achieve radiation protection equivalent to the rules of this Section.

(b) After receiving the information in Paragraph (a) of this Rule, the agency will respond to the applicant in writing within 30 days. Upon review, the agency may require additional information if use of the RGD is allowed.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2015;
Amended Eff. November 1, 2024.

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, and:

(1) Licensees engaged in the production of radioactive material or possessing radioactive material incidental to operating an accelerator are subject to the requirements of Section .0300 of this Chapter;
(2) Licensees engaged in the treatment of humans are subject to the requirements of Section .1900 of this Chapter, and
(3) Licensees engaged in the veterinary treatment of animals are subject to the requirements of Section .2000 of this Chapter.

(c) Persons engaged in industrial radiographic operations utilizing electronic radiation machines for non-human use are subject to the requirements of Rule .0501 of this Chapter in lieu of the Rules in this Section.

(d) 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;
Readopted Eff. October 1, 2025.

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 Rule .0903 of this Section.

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;
Readopted Eff. October 1, 2025.

10A NCAC 15 .0903 REQUIREMENTS FOR ISSUANCE OF A LICENSE FOR ACCELERATORS

(a) Application for use of a particle accelerator will be approved only if the agency determines that:

(1) The applicant and the applicant's particle accelerator 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, and

(3) The applicant's management has appointed a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The applicant, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and the requirements of this Section.

(4) The applicant for therapeutic use of a particle accelerator on humans shall:

(A) have a board-certified physician licensed as outlined in Rule .1903(c)(1) of Section .1900 of this Chapter and licensed to practice medicine in the State of North Carolina; and,

(B) have a board-certified physicist outlined in Rule .1903(d) of Section .1900 of this Chapter.

(b) Applications required by Paragraph (a) of this Rule shall be made on forms provided by the Agency. Applications and supporting material shall be submitted to the agency via email to Licensing.ram@dhhs.nc.gov unless directed otherwise by the Agency:

(1) Persons applying for new accelerator licenses, or for the renewal of existing accelerator licenses, shall submit an Application for Accelerator 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 accelerators shall be used or possessed. The application shall indicate if accelerators 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 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 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0903 Eff. February 1, 2015;
Readopted Eff. October 1, 2025.

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 their assignment.

(b) 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;
Readopted Eff. October 1, 2025.

10A NCAC 15 .0905 SHIELDING AND SAFETY DESIGN

(a) For medical use, a qualified expert registered to provide Class VII services by the Agency pursuant to Rule .0205 of this Chapter, or an Authorized Medical Physicist named on the licensee's license, shall be consulted in the design of a particle accelerator installation and 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.

(b) For Veterinary use, a qualified expert registered to provide Class VII services pursuant to Rule .0205 of this Chapter by the Agency or an Authorized Medical Physicist named on the licensee's license, shall be consulted in the design of a particle accelerator installation and 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.

(c) For non-medical use, a qualified expert registered to provide Class VII or Class IX services by the Agency pursuant to Rule .0205 of this Chapter, an individual with a Master's Degree in physics or higher, or the licensee's Radiation Safety Officer shall be consulted in the design of a particle accelerator and 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. The Radiation Safety Officer may delegate performing the radiation survey to another individual provided the Radiation Safety Officer reviews the final survey results.

(d) Persons registered with the Agency to provide Class VII services providing shielding and design, or post-installation survey services to demonstrate compliance with Rule .1601 of this Chapter prior to the effective date of this Rule shall be authorized to conduct activities authorized by Paragraphs (a) – (c) of this Rule.

(e) A copy of the survey performed to document compliance with Rule .1601 of the Chapter shall be submitted to the agency by the licensee prior to use of the particle accelerator for its licensed purpose.

(f) Plans for construction of accelerator installations shall be submitted to the Agency.

(g) Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with Rule .1601 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;
Readopted Eff. October 1, 2025.

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 .1601 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 the interlock that has been tripped.

(d) Each safety interlock shall operate independently of all other safety interlocks.

(e) All safety interlocks shall be fail-safe, meaning that safety interlocks are 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;
Readopted Eff. October 1, 2025.

10A NCAC 15 .0907 WARNING DEVICES

(a) Except in facilities designed for human exposure, all locations designated as high radiation areas and entrances to such locations shall be equipped with easily observable warning lights that operate only when radiation is being produced. Facilities designed for human exposure shall be equipped with easily observable warning lights outside the entrances to high radiation areas that operate 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 operating equipment capable of creating a high radiation area. This warning device shall be clearly discernible in all high radiation areas and all radiation areas.

(c) All barriers and pathways leading to high radiation areas shall be identified in accordance with Rule .1601 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;
Readopted Eff. October 1, 2025.

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 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) 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.

(e) 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;
Readopted Eff. October 1, 2025.

10A NCAC 15 .0909 RADIATION MONITORING REQUIREMENTS

(a) Except for persons licensed for activities authorized by Section .1900 of this Chapter possessing non-portable therapeutic radiation machines, 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 for the provision of Class VII, Class IX services or an Authorized Medical Physicist named on the licensee's license when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas. The licensee shall submit the report or a copy of the report to the Agency by email to licensing.ram@dhhs.nc.gov or at one of the addresses found in Rule .0111(a) 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) Surveys shall be performed to determine the amount of airborne particulate radioactivity present in areas of airborne hazards at least annually.

(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 written procedures approved by the Radiation Safety Officer of the 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;
Readopted October 1, 2025.

10A NCAC 15 .0910 VENTILATION SYSTEMS

(a) Adequate ventilation shall be provided in areas where airborne radioactivity may be produced to comply with Rule .1601 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 .1601 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;
Readopted Eff. October 1, 2025.

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 .0103(b) of this Chapter;

(B) "licensed" means "registered" as defined in Rule .0103(b) of this Chapter;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) licensee or registrant name;

(B) license or registration number;

(C) name of the individual requesting the exemption;

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

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

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

(b) Notwithstanding Subparagraph (a)(5) of this Rule, registrants temporarily working in North Carolina and licensees working in North Carolina under reciprocity may post the Notice to Employees, NRC Form 3, or an equivalent form issued under the authority of the regulatory agency issuing the registration or license.
(c) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part019/.

History Note: *Authority G.S. 104E-7; 104E-12;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1001 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. October 1, 2025; 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
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10A NCAC 15 .1317 SECURITY
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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

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 .0103(b) of this Chapter;
    (B) "licensed" shall have the same meaning as "registered" as defined in Rule .0103(b) of this Chapter;
    (C) "licensed material" shall have the same meaning as "radiation machine" as defined in Rule .0103(b) of this Chapter, and
    (D) "licensee" shall have the same meaning as "registrant" as defined in Rule .0103(b) of this Chapter;
(4) 20.1004, "Units of radiation dose;"
(5) 20.1005, "Units of radioactivity;"
(6) 20.1007, "Communications," except that licensees and registrants shall address communications regarding these rules, notifications, and reports to the Agency as instructed by Rule .0111 of this Chapter in lieu of the NRC;

(7) 20.1101, "Radiation protection programs;"
(8) 20.1201, "Occupational dose limits for adults;"
(9) 20.1202, "Compliance with requirements for summation of external and internal doses;"
(10) 20.1203, "Determination of external dose from airborne radioactive material;"
(11) 20.1204, "Determination of internal exposure;"
(12) 20.1206, "Planned special exposures;"
(13) 20.1207, "Occupational dose limits for minors;"
(14) 20.1208, "Dose equivalent to an embryo/fetus;"
(15) 20.1301, "Dose limits for individual members of the public;"
(16) 20.1302, "Compliance with dose limits for individual members of the public;"
(17) 20.1401, "General provisions and scope;"
(18) 20.1402, "Radiological criteria for unrestricted use;"
(19) 20.1403, "Criteria for license termination under restricted conditions;"
(20) 20.1404, "Alternate criteria for license termination;"
(21) 20.1405, "Public notification and public participation," except the Agency shall not publish a notice in the Federal Register;
(22) 20.1406, "Minimization of contamination," except that 20.1406(b) shall not apply;
(23) 20.1501, "General;"
(24) 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose;"
(25) 20.1601, "Control of access to high radiation areas;"
(26) 20.1602, "Control of access to very high radiation areas;"
(27) 20.1701, "Use of process or other engineering controls;"
(28) 20.1702, "Use of other controls;"
(29) 20.1703, "Use of individual respiratory protection equipment;"
(30) 20.1704, "Further restrictions on the use of respiratory equipment;"
(31) 20.1705, "Application for use of higher assigned protection factors;"
(32) 20.1801, "Security of stored material;"
(33) 20.1802, "Control of material not in storage;"
(34) 20.1901, "Caution signs;"
(35) 20.1902, "Posting requirements;"
(36) 20.1903, "Exceptions to posting requirements;"
(37) 20.1904, "Labeling containers;"
(38) 20.1905, "Exemptions to labeling requirements," except that 20.1905(g) shall not apply;
(39) 20.1906, "Procedures for receiving and opening packages;"
(40) 20.2001, "General requirements;"
(41) 20.2002, "Method for obtaining approval of proposed disposal procedures;"
(42) 20.2003, "Disposal by release to sanitary sewerage;"
(43) 20.2004, "Treatment or disposal by incineration;"
(44) 20.2005, "Disposal of specific wastes;"
(45) 20.2006, "Transfer for disposal and manifests;"
(46) 20.2007, "Compliance with environmental and health protection regulations;"
(47) 20.2008, "Disposal of certain byproduct material;"
(48) 20.2101, "General provisions;"
(49) 20.2102, "Records of radiation protection programs;"
(50) 20.2103, "Records of surveys;"
(51) 20.2104, "Determination of prior occupational dose;"
(52) 20.2105, "Records of planned special exposures;"
(53) 20.2106, "Records of individual monitoring results;"
(54) 20.2107, "Records of dose to individual members of the public;"
(55) 20.2108, "Records of waste disposal;"
(56) 20.2110, "Form of records;"
(57) 20.2201, "Reports of theft or loss of material." Persons registered with the Agency pursuant to the rules in Section .0200 of this Chapter shall make telephone reports of the theft or loss of radiation machines in accordance with 20.2201(a)(1)(i);
(58) 20.2202, "Notifications of incidents;"

(59) 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits," except that 20.2203(c) shall not apply;
(60) 20.2204, "Reports of planned special exposures;"
(61) 20.2205, "Reports to individuals exceeding dose limits;"
(62) 20.2206, "Reports of individual monitoring," except that 20.2206(a)(1), and 20.2206(a)(3) through (a)(5) shall not apply. The report required by 20.2206(b) shall be submitted upon request by the agency in lieu of the requirements of 20.2206(c);
(63) 20.2207, "Reports of transactions involving nationally tracked sources." Notwithstanding Subparagraph (a)(6) of this Rule, reports required by this Subparagraph shall be made in accordance with 20.2207(f) and (g);
(64) 20.2301, "Application for exemptions," except that the request for exemption shall be made on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the Agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the Agency. To request an exemption, the following information shall be submitted to the Agency:
    (A) licensee or registrant name;
    (B) license or registration number;
    (C) name and contact information for the individual requesting the exemption;
    (D) a description of the exemption being requested, and
    (E) an explanation describing why the exemption is necessary;
(65) 20.2302, "Additional requirements;"
(66) Appendix A to Part 20, "Assigned Protection Factors for Respirators;"
(67) Appendix B to Part 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage;"
(68) Appendix C to Part 20, "Quantities of Radioactive Material Requiring Labeling;"
(69) Appendix E to Part 20, "Nationally Tracked Source Thresholds," and
(70) Appendix G to Part 20, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests."

(b) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(c) Licensees and registrants shall continue to perform all activities required by the rules of this Chapter, license or registration condition, and shall pay annual fees as instructed on an invoice issued by the Agency until the license or registration is terminated. Registrants shall maintain registration of all radiation machines under their control until those units are disposed.

(d) Nothing in the rules of this Chapter shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.

(e) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/.

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994;
Amended Eff. August 1, 1998;
Transferred and Recodified from 15A NCAC 11 .1601 Eff. February 1, 2015;
Readopted Eff. October 1, 2023;
Amended Eff. October 1, 2025.

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;
Eff. March 24, 2025.

SECTION .1900 – THERAPEUTIC RADIATION MACHINES

10A NCAC 15 .1901 PURPOSE AND SCOPE

(a) This Section establishes requirements for use of therapeutic radiation machines to treat disease in humans. The requirements of this Section are in addition to the requirements of Sections .0100, .0200, .0900, .1000, and .1600 of this Chapter.
(b) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training and experience criteria established by Rule .1903(c) of this Section.
(c) In addition to the requirements of this Section, all therapeutic radiation machine licensees are subject to the annual fee provisions contained in Section .1100 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .1902 DEFINITIONS

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

(1) "Acceptance testing" means an evaluation of equipment and systems to confirm they meet the specifications stated by the manufacturer.
(2) "Annually" means at intervals not to exceed 12 consecutive months, plus or minus 30 days.
(3) "Authorized Medical Physicist" means an individual authorized in accordance with Rule .1903(d) of this Section.
(4) "Authorized user" means a physician who meets the training requirements of Rule .1903(c) of this Section and is authorized by license condition to use a therapeutic radiation machine covered by this Section.
(5) "Barrier" see "Protective barrier".
(6) "Biennially" means at intervals not to exceed 24 consecutive months, plus or minus 30 days.
(7) "Commissioning" means an intricate and methodical process designed to:
    (A) acquire needed machine-specific beam data;
    (B) validate the safe, accurate, and effective operation of a therapeutic radiation machine, treatment planning systems, ancillary systems, and associated procedural protocols; and,
    (C) set baseline for future measurements for performance constancy.
(8) "Dosimetry systems" means radiation detecting equipment that may be used to characterize the radiation beam and quantify the energy it may deposit within a medium.
(9) "Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.
(10) "Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.
(11) "Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.
(12) "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
(13) "Human research subject" means an individual defined pursuant to 10A NCAC 15 .0307(a)(4) and shall include radiation therapy treatments covered by this Section.
(14) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.
(15) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
(16) "Irradiation" means the exposure of a living being or matter to ionizing radiation.
(17) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.
(18) "Kilovolt," "kV," "kilo electron volt," and "keV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. Current convention is to use kV for photons and keV for electrons.
(19) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.
(20) "Licensee" means any person who is licensed by the agency pursuant to the rules of this Section .0900 of this Chapter.

(21) "Light field" means the area illuminated by light, simulating the radiation field.

(22) "Megavolt," "MV," "mega electron volt," and "MeV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.

(23) "Method of Delivery" means mode of radiation to be used during treatment, which may include photons, electrons, or protons.

(24) "Patient" means an individual, for whom a written directive is intended, subjected to machine produced radiation for the purposes of medical therapy.

(25) "Periodic quality assurance check" means a procedure which is performed to ensure that a previous parameter or condition continues to be valid.

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

(27) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive.

(28) "Primary protective barrier" (see "Protective barrier").

(29) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(A) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

(B) "Secondary protective barrier" means the material which attenuates stray radiation.

(30) "Qualified Expert" means a person registered by the agency pursuant to Rule .0205 of this Chapter for the provision of Class VII services and who meets the training and experience requirements listed in Rule .0214(a)(7)(A) or (B) of this Chapter.

(31) "Quarterly" means at intervals not to exceed 13 consecutive weeks, plus or minus 7 consecutive days.

(32) "Radiation oncology safety team" means, minimally, a group of individuals consisting of an authorized user, authorized medical physicist, medical dosimetrist, radiation therapist and oncology nurse whose purpose is to work together to deliver radiation safely and reproducibly.

(33) "Referring physician" means the physician whom referred the patient or human research subject to the licensee for specialized care.

(34) "Semiannually" means at intervals not to exceed 6 consecutive months, plus or minus 15 consecutive days.

(35) "Sievert" and "Sv" mean the SI unit of dose equivalent measured as joule per kilogram.

(36) "Supervision" shall be defined as follows:

(A) "General supervision" means the activity is performed under the overall direction and control of a supervising individual. The supervising individual's physical presence shall not be required during the performance of the procedure but must be available by phone to provide assistance and direction if needed.

(B) "Direct supervision" means an individual exercise General Supervision and be present within the facility and immediately available to furnish assistance and direction throughout the performance of the activity. Direct Supervision does not require that the supervising individual must be present in the room when the procedure is being performed.

(C) "Personal supervision" means an individual exercises General Supervision and be present in the room during the performance of the procedure.

(37) "Therapeutic radiation machine" means equipment that is designed and used for external beam radiation therapy in the healing arts. For these regulations, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

(38) "Therapeutic radiation machine medical event" means an event that meets the criteria in Rule .1905(a)(4).

(39) "Treatment room shielding" means a location which contains fixed protective barriers to limit radiation exposures to members of the public and occupationally exposed workers to within regulatory limits.

(40) "Weekly" means at least once per calendar week.

(41) "Written directive" means an order in writing for the administration of radiation to a specific patient or human research subject, as specified in .1905(a)(1).

(b) Definitions of certain other words and phrases used in the Rules in this Section are set forth in Rules .0103, .1001 and .1601 of this Chapter.

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Eff. October 1, 2025.

10A NCAC 15 .1903 GENERAL ADMINISTRATIVE REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

(a) The licensee shall be responsible for directing the operation of the therapeutic radiation machines that have been licensed with the Agency. The licensee or the licensee's agent shall ensure that the requirements of this Section are met in the operation of the therapeutic radiation machines.

(b) A therapeutic radiation machine that does not meet the provisions of these rules shall not be used for irradiation of patients or human research subjects.

(c) Training for Therapeutic Radiation Machine Authorized Users: The licensee for any therapeutic radiation machine subject to Rules within this Paragraph shall require the authorized user to be a physician who:

(1) Holds Certification in General Radiology issued by the American Board of Radiology of a physician who confines their professional practice to radiation oncology or certification in Radiation Oncology or Therapeutic Radiology issued by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec; or

(2) Has satisfactory completion of a radiation oncology residency program approved by the American Council of Graduate Medicine Education, the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, or the American Osteopathic Association. Radiation oncologists who are eligible for certification by one of the certifying organizations listed in Subparagraph (c)(1) of this Rule but not yet certified by the date of initial employment shall be certified by one of the certifying organizations listed in Subparagraph (c)(1) of this Rule within 6 years of initial certification eligibility; and,

(3) Be an individual listed on an Agency or an Agreement State medical accelerator license as an authorized user on or before the effective date of this Rule. Individuals listed on an Agency or Agreement State medical accelerator license as Authorized Users need not comply with Subparagraphs (c)(1) through (c)(2) of this Rule, except they must meet the training requirements defined in this Rule for any uses for which they were not authorized on or before the effective date of this Rule, and shall document 75 hours of continuing education every three years that is acceptable to the certifying organizations identified in Subparagraphs (c)(1) through (c)(2) of this Rule.

(d) Training for Authorized Medical Physicist: The licensee for any therapeutic radiation machine subject to Rules within this Section shall require the Authorized Medical Physicist to:

(1) Be certified and maintain certification by the American Board of Radiology in:
  (A) Therapeutic Radiological Physics; or
  (B) Therapeutic Medical Physics; or

(2) Be certified and maintain certification by the American Board of Medical Physics in Radiation Oncology Physics; or

(3) Be certified and maintain certification by the Canadian College of Medical Physics in Radiation Oncology Physics; or,

(4) Be an individual listed on an Agency or an Agreement State medical accelerator license as an authorized medical physicist on or before the effective date of this Rule. Individuals listed on an Agency or Agreement State medical accelerator license need not comply with Subparagraphs (d)(1) through (d)(3) of this Rule, except they must meet the training requirements defined in other Paragraphs of this Rule for any uses for which they were not authorized on or before the effective date of this Rule, and shall document 75 hours of accredited continuing education every three years that is acceptable to the certifying organizations identified in Subparagraphs (d)(1) through (d)(3) of this Rule.

(e) Training for Therapeutic Radiation Machine Radiation Safety Officer: The licensee for any therapeutic radiation machine subject to Rules within this Paragraph shall require the Radiation Safety Officer:

(1) Be listed as an Authorized User or Authorized Medical Physicist on the license; or,

(2) Be certified by the American Board of Health Physics in Health Physics; or,

(3) Be certified by the American Board of Science in Nuclear Medicine in Radiation Protection; or,
(4) Be certified by the American Board of Radiology in:
(A) Diagnostic Radiologic Physics;
(B) Diagnostic Medical Physics;
(C) Medical Nuclear Physics;
(D) Nuclear Medical Physics; or,
(5) Be certified by the American Board of Medical Physics in Medical Health Physics; or,
(6) Be an individual listed on an Agency or an Agreement State medical accelerator license as a Therapeutic Radiation Machine Radiation Safety Officer on or before the effective date of this Rule. Individuals listed on an Agency or Agreement State medical accelerator on or before the effective date of this Rule need not comply with Subparagraphs (e)(1) through (e)(5) of this Rule, except they must meet the training requirements in radiation safety, regulatory issues, and emergency procedures for the types of use for which they were not authorized on or before the effective date of this Rule, and shall document 60 hours of accredited continuing education every three years that is acceptable to the certifying organizations identified in Subparagraphs (e)(2) through (e)(5) of this Rule.

(f) Qualifications of Operators:
(1) Direct Human Use – Operators: Individuals who will be operating a therapeutic radiation machine on humans or irradiation of products to be used by humans, shall:
(A) Be a registered Radiation Therapy Technologists by the American Registry of Radiologic Technologists; or,
(B) Be American Registry of Radiologic Technologists registry-eligible as Radiation Therapy Technologists provided the individual is under the personal supervision of an individual that meets the requirements of Subparagraph (A) of this Paragraph; and,
(C) Successfully complete a licensee-developed initial and ongoing competency program in the use of the therapeutic radiation machine as well as other ancillary systems used by the operator in medical use applications. This competency program shall be documented, and records shall include the list of topics evaluated, and each individual's completion of the competency program shall be approved, signed, and dated. Records required by this Subparagraph shall be maintained for a minimum of three years.
(2) Non-direct Human Use – Operators: Individuals who will be operating a therapeutic radiation machine for the purposes of quality assurance and/or non-human research, shall:
(A) Comply with Paragraph (d) of this Rule; or,
(B) Comply with Subparagraph (1)(A) of this Paragraph; or,
(C) Comply with the requirements of Section .0900 of this Chapter; and,
(D) Successfully complete a licensee-developed initial and ongoing competency program in the use of the therapeutic radiation machine as well as other ancillary systems used by the operator for quality assurance or non-human research. The competency program shall be documented, and records shall include the list of topics evaluated, and each individual's completion of the competency program shall be approved, signed, and dated. Records required by this subparagraph shall be maintained for a minimum of three years.

(g) Documented safety procedures shall be developed by an Authorized Medical Physicist and shall be readily accessible in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.
(h) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a therapeutic radiation machine authorized user. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing-arts purposes.
(i) Visiting Authorized User: A licensee may permit any physician to act as a visiting authorized user under the term of the licensee's license for a total of 60 days per calendar year under the following conditions:
(1) The visiting authorized user has the prior approval of the licensee's facility management; and
(2) The visiting authorized user meets the requirements established for authorized user(s) in Subparagraph (c) of this Rule; and
(3) The licensee shall maintain copies of the documentation of the approval and that the visiting authorized user met the requirements of Subparagraph (i)(2) of this Rule for three years from the date of the last visit.

(j) Visiting Authorized Medical Physicist: A licensee may permit any medical physicist to act as a visiting authorized medical physicist under the term of the licensee's license for a total of 60 days per calendar year under the following conditions:

(1) The visiting qualified medical physicist has the prior approval of the licensee's facility management; and

(2) The visiting authorized medical physicist meets the requirements established for authorized medical physicists in Subparagraphs (d) of this Rule; and

(3) The licensee shall maintain copies of the documentation of the approval and proof that the visiting authorized medical physicist met the requirements of Subparagraph (j)(2) of this Rule for three years from the date of the last visit.

(k) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the licensee's quality management program. In addition to the requirements of this Section, these individuals are also subject to the requirements of Rules .1601(a)(8), (a)(24) and (a)(51) of this Chapter.

(l) Unless otherwise specified by license condition, whenever patients or human research subjects are being treated by a therapeutic radiation machine, a physician shall be accessible. This physician does not need to be an authorized user.

(m) A licensee that permits supervised activities within this Section is responsible for the acts and omissions of the supervised individual.

(n) Information and Maintenance Record and Associated Information: The licensee shall maintain the following information in a separate file or package for each therapeutic radiation machine for inspection by the Agency:

(1) Report of acceptance testing and commissioning;

(2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this Section, as well as the names of persons who performed such activities;

(3) Records of maintenance and/or modifications performed on the therapeutic radiation machine after the effective date of this Rule as well as the names of persons who performed such services;

(4) Assessments performed by an Authorized Medical Physicist, prior to the return of a therapeutic radiation machine to clinical use, after significant service, repair, or upgrade that may result in variances of machine functions more than the thresholds established within the quality management program.

(o) Records Retention: All records required by this Section shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in this Section.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .1904 GENERAL TECHNICAL REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

(a) Protection Surveys:

(1) The licensee shall ensure that radiation shielding surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with Rule .1908 of this Chapter. The radiation protection survey shall be performed by, or under the direction of, an Authorized Medical Physicist or a qualified expert and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition:

(A) Radiation levels in restricted areas are not likely to cause personnel exposures more than the limits specified in Rule .1601(a)(8) of this Chapter; and

(B) Radiation levels in unrestricted areas do not exceed the limits specified in Rule .1601(a)(15) of this Chapter.

(2) In addition to the requirements of Subparagraph (a)(1) of this Rule, a radiation protection survey shall also be performed:

(A) After making any change in the treatment room shielding;

(B) After making any change in the location of the therapeutic radiation machine within the treatment room;

(C) After relocating the therapeutic radiation machine;

(D) After changes in occupancy of surrounding areas; or

(E) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

(4) If the results of the surveys required by this Paragraph indicate any radiation levels in excess of the limits specified in Parts (A) or (B) of Subparagraph(a)(1) of this Rule, the licensee shall disable the machine from use, label clearly, and not use the unit:

(A) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(B) Until the licensee has received a specific exemption from the Agency.

(b) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by Subparagraph (a) of this Rule indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by Rule .1601(a)(15) of this Chapter, before beginning the treatment program the licensee shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with Paragraph Rule .1601(a)(15) of this Chapter;

(2) Perform the survey required by Subparagraph (a)(1) of this Rule again; and

(3) Include in the report required by Subparagraph (d) of this Rule the results of the initial survey, a description of the modification made to comply with Subparagraph (b)(1) of this Paragraph, and the results of the second survey; or

(4) Request and receive a license amendment authorizing radiation levels in unrestricted areas greater than those permitted by Paragraph Rule .1601(a)(15) of this Chapter.

(c) Radiation Measuring Equipment. The licensee shall have, when required, appropriate and operable radiation measuring equipment available for use and calibrated in accordance with Rule .1908 of this Section. Radiation measuring equipment includes, but is not limited to, dosimetry systems, survey instruments, and other radiation measuring devices used in planning, guiding, and administering radiation.

(d) Reports of External Beam Radiation Therapy Surveys and Measurements. The licensee for any therapeutic radiation machine subject to Rules within this Part shall furnish a copy of the records required in Subparagraphs (a) and (b) of this Rule to the Agency within 30 days following completion of the action that initiated the record requirement.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .1905 QUALITY MANAGEMENT PROGRAM

(a) Each licensee or applicant subject to Rules within this Section shall develop, implement, and maintain a quality management program to ensure that radiation will be administered as directed by the authorized user. The quality management program shall address the following specific objectives:

(1) Written Directives:

(A) A written directive must be approved by an authorized user prior to the administration of radiation. If a delay in the order to provide a written revision to an existing written directive would jeopardize the patient or human research subject's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient or human research subject's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(B) The written directive must contain the patient or human research subject's name, treatment site, method of delivery, dose per fraction, total number of fractions, and total dose.

(C) A written revision to an existing written directive may be made provided that the revision is dated and approved by an authorized user prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

(D) The licensee shall retain a copy of the written directive for three years.

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

(A) Prior to the administration of each course of radiation treatment, the patient or human research subject's identity is verified by more than one method as the individual named in the written directive;

(B) Each administration is in accordance with the written directive;

(C) Develop a table-shift policy describing action to be taken by staff in the event shifts are used for patient or human research subject setup and a table shift exceeds limitations established within the treatment plan.

(D) Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by checking both manual and computer-generated dose calculations to verify they are correct and in accordance with the written directive; and verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(E) Any unintended deviation from the written directive is identified, evaluated and action is taken; and

(F) The licensee retains a copy of the procedures for administrations for the duration of the license.

(3) New Procedures on Established Equipment: Licensees possessing established and commissioned therapeutic radiation machines shall reevaluate equipment parameters, pursuant to this Section, when new procedures are to be performed if the parameters, including dose rate, field size, imaging accuracy, maximum dose, fall outside of the original commissioned parameters.

(4) Documentation, Reports, and Notifications of Medical Events:

(A) Any unintended treatment deviation from the written directive or approved treatment plan shall be identified, evaluated, and documented. Licensees shall document the corrective action taken by the licensee as a result of any unintended deviation from the written directive or approved treatment plan.

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

(C) Except as required by Part (B) of this Subparagraph, licensees shall report any treatment deviation as a medical event, except for a treatment deviation that results from intervention by a patient or human research subject, when the treatment deviation is caused by any of the conditions listed in Parts (D), (E), or (F) of this Subparagraph.

(D) Treatment deviations in which the administration of radiation from therapy equipment involves the administration of radiation to an individual using a treatment plan intended for another patient or human research subject;

(E) Treatment deviations in which the administration of radiation to a patient or human research subject does not conform to the written directive and the approved treatment plan, and the administered dose over the entire treatment course differs from the prescribed dose as stated in the written directive by twenty percent or more; or,

(F) Treatment deviations in which the administered dose delivered differs from the prescribed dose, for a single fraction, by an overdose of 50 percent or more.

(G) The licensee shall notify the Agency by telephone no later than the next calendar day after the licensee determines that a medical event occurred.

(5) The licensee shall submit a written report to the Agency within fifteen days after the initial report of the medical event. The written report must include:

(A) The licensee name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the individual who received the medical event;
(F) Actions, if any, that have been taken, or are planned, to prevent recurrence;
(G) Certification that the licensee notified the patient, or the patient's responsible relative or guardian, and if not, why not, and
(H) The report shall not contain the patient's name or any other information that could lead to the identification of the patient;

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

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

(8) The licensee shall retain a record of each unintended deviation in accordance with Part (4)(A) of this Paragraph. If the unintended deviation is a medical event, a copy of the record shall be provided to the referring physician if other than the licensee within 15 days after its discovery.

(9) The licensee shall retain a record of each unintended deviation for three years. The record must contain the following:
(A) The licensee name and the names of the individuals involved;
(B) A unique identification number, if one has been assigned, of the individual who is the subject of the unintended deviation;
(C) A brief description of the event; why it occurred; the effect, if any, on the individual;
(D) The actions, if any, taken or planned to prevent recurrence; and
(E) Whether the licensee notified the individual, or the individual's responsible relative or guardian; and, if not, whether such failure to notify was based on guidance from the referring physician.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .1906 THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 KV

(a) The licensee shall provide documentation that equipment authorized by this Section conforms to the relevant International Electrotechnical Commission standard, documentation of US Food and Drug Administration clearance, or documentation of participation in a research study approved by the licensee's Institutional Review Board.

(b) Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of Rule .1909 of this Section, the treatment room shall meet the following design requirements:

(1) Aural Communication. Provision shall be made for continuous two-way aural communication between the patient or human research subject and the operator at the control panel;

(2) Viewing Systems. Provision shall be made to permit continuous observation of the patient or human research subject during irradiation and the viewing system shall be so located that the operator can observe the patient or human research subject from the control panel. The therapeutic radiation machine shall not be used for patient or human research subject irradiation unless at least one viewing system is operational.

(c) Additional Requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

(1) All protective barriers shall be fixed except for entrance doors or beam interceptors;
(2) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
(4) When any door referred to in Subparagraph (3) of this Paragraph is opened while the x-ray tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one mGy (100 mrad) per hour.

(d) Acceptance Testing, Commissioning, and Calibration Measurements. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to the Rules of this Chapter shall be performed by, or under the direct supervision of, an Authorized Medical Physicist:

(1) Acceptance testing and commissioning shall be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies, that includes the American Association of Physicists in Medicine, the American College of Radiology, and the American Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed. Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.
(2) A licensee authorized to use a therapeutic radiation machine for medical use shall perform calibration measurements on each therapeutic radiation machine:
    (A) Before the first medical use of the unit; and
    (B) Before medical use whenever spot-check measurements indicate that the output, for each specific mode and energy, differs by more than five percent from the output obtained at the last calibration, following reinstallation of the therapeutic radiation machine in a new location, following any repair of the therapeutic radiation machine that would likely impact the radiation output beyond the normal range of expected fluctuation, and
    (C) At intervals not to exceed annually.
(3) To satisfy the requirement of Paragraph (a) of this Rule, an authorized medical physicist shall design and implement a calibration procedure for each radiation therapy machine which is consistent with the specifications recommended by the manufacturer of the equipment and consistent with nationally recognizable standards. The calibration procedure shall be designed to ensure accurate patient or human research subject treatments, in accordance with the written directive and treatment plan. The calibration procedure shall include, but not be limited to, the following:
    (A) Accuracy of output measurements to within ± five percent of radiations used medically; and
    (B) Evaluation and accuracy of auxiliary systems, such as motion tracking or gating and image guidance, used during patient or human research subject treatments.
(4) A licensee shall use the dosimetry system described in Rule .1908 of this Section to measure the output for one set of exposure conditions. The remaining radiation measurements required in Part (3)(A) of this Paragraph may be made using a dosimetry system that indicates relative dose rates.
(5) The evaluations and measurements for:
    (A) Acceptance, commissioning, and calibration measurements in Part (3)(A) of this Paragraph shall be performed under the direct supervision of an authorized medical physicist;
    (B) full calibration measurements in Part (3)(B) of this Paragraph shall be performed by an authorized medical physicist or under the general supervision of an authorized medical physicist.
(6) A licensee shall maintain a record of each therapeutic radiation machine calibration for three years. The record must include:
    (A) The date of the calibration;
    (B) The manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to calibrate the unit(s);

(C) The results and an assessment of the calibrations; and
(D) The name of the authorized medical physicist who approves the calibration.

(7) A licensee shall maintain a record of each therapeutic radiation machine acceptance testing and commissioning for the lifetime of the machine. The record must include:
(A) The date of the acceptance testing or commissioning;
(B) The manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to evaluate the unit(s);
(C) The results and an assessment of acceptance testing and/or commissioning; and
(D) The name of the authorized medical physicist who approves the acceptance testing and/or commissioning.

(e) Independent Verification of Therapeutic Radiation Machine Output:

(1) In addition to the full calibration required by Paragraph (a) of this Rule, the licensee shall have the outputs, for all clinically used radiations, independently verified:
(A) Within 90 days of first clinical use of a new installation;
(B) Within 90 days of first clinical use following a reinstallation in a new location; and
(C) Biennially, thereafter.

(2) Verification may be obtained by:
(A) irradiating dosimeters from an AAPM Accredited Dosimetry Calibration Laboratory; or
(B) evaluation by a registered qualified expert using an independent dosimetry system meeting Rule .1908 of this Section.

(3) A licensee shall maintain a record of each independent verification of therapeutic radiation machine output for three years. The record must include:
(A) If obtained by Part (2)(A) of this Paragraph: The date of the irradiation, the date of the analysis by the dosimetry center, the name, address and contact information for the AAPM Accredited Dosimetry Calibration Laboratory, and the results of the independent verification.
(B) If obtained by Part (2)(B) of this Paragraph: The date of the calibration, the manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to calibrate the unit(s), the results and an assessment of the independent verification, and the name of the registered qualified expert who provided the independent verification.

(f) Quality Assurance Checks:

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to this Rule, which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of Subparagraph (1) of this Paragraph, quality assurance checks shall meet the following requirements:
(A) The licensee shall perform quality assurance checks, to include ensuring the proper function of requirements outlined in Paragraphs (d) and (e) of this Rule, in accordance with written procedures established by the Authorized Medical Physicist; and
(B) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in Paragraph (d) of this Rule. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in Paragraph (d) of this Rule, shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the Authorized Medical Physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Authorized Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in Subparagraph (d)(2) of this Rule;

(5) The licensee shall use the dosimetry system described in Rule .1908 of this Chapter to make the quality assurance check required in Subparagraph (2) of this Paragraph;

(6) The licensee shall maintain a record of each quality assurance check required by this Paragraph for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's

name; model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

(g) Operating Procedures:

(1) The therapeutic radiation machine shall not be used for irradiation of patients or human research subjects unless the requirements of Paragraphs (d) and (e) of this Rule have been met;

(2) Therapeutic radiation machines shall not be left unattended unless secured pursuant to Rules .1601(a)(32) and (33) of this Chapter;

(3) When a patient or human research subject must be held in position for radiation therapy, mechanical supports or immobilization devices shall be used;

(4) The tube housing or any other part of the imaging assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(6) No individual other than the patient or human research subject shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient or human research subject, in the treatment room shall be protected by a barrier sufficient to meet the requirements of Rule .1601(a)(8) of this Chapter.

(h) Electronic brachytherapy devices are subject to the requirements of Rule .1911 of this Section and are exempt from the requirements of this Rule.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .1907 THERAPEUTIC RADIATION MACHINES OF 500 KEV AND ABOVE

(a) The licensee shall provide documentation that equipment within this section conforms to the relevant International Electrotechnical Commission standard, documentation of US Food and Drug Administration clearance, or documentation of participation in a research study approved by the licensee's Institutional Review Board.

(b) Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of Rule .1909 of this Section, the following design requirements are made:

(1) Protective Barriers. All protective barriers shall be fixed and permanent with respect to the radiation source and designed to comply with Rules .1601(a)(8) and .1601(a)(15) of this Chapter external to the dedicated space, except for access doors to the treatment space or movable beam interceptors;

(2) Control Panel. In addition to other requirements specified within this Section, the control panel shall also:

(A) Be located outside the treatment space and complies with Rules .1601(a)(8) and .1601(a)(15) of this Chapter as required; and

(B) Provide an indication of whether radiation is being produced;

(3) Include access controls that will prevent unauthorized use of the therapeutic radiation machine;

(4) Viewing Systems. Viewing system shall be provided to permit continuous observation of the patient or human research subject following positioning and during irradiation and shall be so located that the operator may observe the patient or human research subject from the treatment control panel. The therapeutic radiation machine shall not be used for patient or human research subject irradiation unless at least one viewing system is operational;

(5) Communication Device or Technique. Provision shall be made for continuous two-way communication between the patient or human research subject and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients or human research subjects unless continuous two-way communication device or technique is possible;

(6) Entrances. Treatment space entrances shall be provided with warning lights in a viewable location outside of all entrances, which will indicate when the useful beam is "ON" and when it is "OFF";

(7) Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control,

it shall not be possible to restore the machine to operation without activating the access control and reinitiating irradiation by manual action at the control panel;

(8) Movable Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a movable beam interceptor to ensure compliance with Rule .1601(a)(15) of this Chapter, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers;

(9) Emergency Cutoff Switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch; and

(10) Safety Interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(c) Authorized Medical Physicist Support.

(1) The services of an Authorized Medical Physicist shall be required in facilities having therapeutic radiation machines. The Authorized Medical Physicist shall be responsible for:

(A) Calibrations required by Paragraph (d) of this Rule and radiation safety surveys required by Rule .1904(a) of this Section;

(B) Beam data acquisition and configuration for treatment planning, and supervision of its use;

(C) Quality assurance, including quality assurance check review required by Paragraph (f) of this Rule.

(D) Consultation with the authorized user in treatment planning, as needed; and

(E) Perform calculations/assessments regarding medical events.

(2) The operating procedures required by Paragraph (d) of this Rule shall also specifically address how the Authorized Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Authorized Medical Physicist can be contacted.

(d) Operating Procedures.

(1) No individual, other than the patient or human research subject, shall be in the treatment space during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of Rule .1904(a) of this Section, and Paragraphs (e), (f) and (g) of this Rule have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use pursuant to Rules .1601(a)(32) and (33) of this Chapter;

(4) When a patient or human research subject must be held in position for radiation therapy, mechanical supports or immobilization devices shall be used;

(5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

(e) Acceptance Testing, Commissioning and Calibration Measurements. Acceptance testing, commissioning, and calibration of a therapeutic radiation machine subject to this Rule shall be performed by, or under the direct supervision of, an Authorized Medical Physicist:

(1) Acceptance testing and commissioning shall be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies, that includes the American Association of Physicists in Medicine (AAMP), the American College of Radiology and the American Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.

(2) A licensee authorized to use a therapeutic radiation machine for medical use shall perform calibration measurements on each therapeutic radiation machine:

(A) Before the first medical use of the unit; and

(B) Before medical use under the following conditions: Whenever spot-check measurements indicate that the output, for each specific mode and energy, differs by more than five percent from the output obtained at the last calibration, following reinstallation of the therapeutic radiation machine in a new location, following any repair of the therapeutic

radiation machine that would likely impact the radiation output beyond the normal range of expected fluctuation; and

(C) At intervals not to exceed annually.

(3) To satisfy the requirement of Paragraph (d) of this Rule, an authorized medical physicist shall design and implement a calibration procedure for each radiation therapy machine which is consistent with the specifications recommended by the manufacturer of the equipment and consistent with nationally recognizable standards. The calibration procedure shall be designed to ensure accurate patient or human research subject treatments, in accordance with the written directive and treatment plan. The calibration procedure shall include, but not be limited to, the following:

(A) Accuracy of output measurements to within ± five percent of radiations used medically; and,

(B) Evaluation and accuracy of auxiliary systems, such as motion tracking or gating and image guidance, used during patient or human research subject treatments.

(f) Independent Verification of Therapeutic Radiation Machine Output

(1) In addition to the calibration required by Paragraph (e) of this Rule, the licensee shall have the outputs, for all clinically used radiations, independently verified:

(A) Within 90 days of first clinical use of a new installation;

(B) Within 90 days of first clinical use following a reinstallation in a new location; and

(C) Biennially, thereafter.

(2) Verification may be obtained by:

(A) the authorized medical physicist irradiating dosimeters from an AAPM Accredited Dosimetry Calibration Laboratory; or

(B) evaluation by an independent registered qualified expert using an independent dosimetry system meeting Rule .1908 of this Section.

(3) A licensee shall maintain a record of each independent verification of therapeutic radiation machine output for three years. The record must include:

(A) If obtained by Part (e)(2)(A) of this Rule: The date of the irradiation, the date of the analysis by the dosimetry center, the name, address and contact information for the AAPM Accredited Dosimetry Calibration Laboratory, and the results of the independent verification.

(B) If obtained by Part (e)(2)(B) of this Rule: The date of the calibration, The manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to calibrate the units, the results and an assessment of the independent verification, and the name of the independent registered qualified expert who provided the independent verification.

(g) Quality Assurance Checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to this Rule, which are capable of operation at greater than or equal to 500 kV.

(2) To satisfy the requirement of Subparagraph (f)(1) of this Rule, quality assurance checks shall meet the following requirements:

(A) The licensee shall perform quality assurance checks, to include ensuring the proper function of requirements outlined in Paragraphs (d) and (e) of this Rule, in accordance with written procedures established by the Authorized Medical Physicist; and

(B) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in Paragraph (d) of this Rule. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in Paragraph (d) of this Rule, shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the Authorized Medical Physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Authorized Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required by Paragraph (d) of this Rule;

(5) The licensee shall use the dosimetry system described in Rule .1908 of this Section to make the quality assurance check required by Paragraph (f) of this Rule;

(6) The licensee shall maintain a record of each quality assurance check required by (f) of this Paragraph for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .1908 CALIBRATION OF SURVEY INSTRUMENTS AND DOSIMETRY SYSTEMS

(a) Administrative: Survey Instruments, when employed by the licensee to perform surveys required by this Section:

(1) The licensee shall ensure that the survey instruments used to show compliance with this Section have been calibrated before first use, at intervals not to exceed 12 months and following repair.

(2) To satisfy the requirements of Subparagraph (a)(1) of this Rule, the licensee shall:

(A) Calibrate all scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology;

(B) Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale; and

(3) To satisfy the requirements of Subparagraph (a)(2) of this Rule, the licensee shall consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent.

(4) The licensee shall retain a record of each calibration required in Paragraph (a) of this Rule for three years. The record shall include:

(A) A description of the calibration procedure; and

(B) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(5) The licensee may obtain the services of individuals licensed by the Agency, the US Nuclear Regulatory Commission or an Agreement State to perform calibrations of survey instruments. Records of calibrations that contain information required by Paragraph (c) of this Rule shall be maintained by the licensee.

(6) The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(b) Dosimetry system:

(1) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(A) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(B) The system must have been intercompared with another dosimetry system that was calibrated within the previous two years by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than two percent.

(2) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done for three years after the record is made. For each calibration, intercomparison, or comparison, the record must include:

(A) The date;

(B) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by Parts (1)(A) or (1)(B) of this Paragraph;

(C) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(c) The names of the individuals who performed the calibration, intercomparison, or comparison.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .1909 SHIELDING AND SAFETY DESIGN REQUIREMENTS

(a) Each therapeutic radiation machine subject to Rules within this Section shall be provided with such primary and secondary barriers as are necessary to ensure compliance with Rules .1601(a)(8) and .1601(a)(15) of this Chapter and must consider the types of radiation generated in the use of the equipment.

(b) Facility shielding and safety designs shall be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies, such as the American Association of Physicists in Medicine and the National Council on Radiation Protection and Measurements. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.

(c) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of different model, higher energy or workload into a room not previously approved for that energy, isocenter or planned workload shall be submitted for Agency approval prior to actual installation of the therapeutic radiation machine.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .1910 OTHER USE OF ELECTRONICALLY-PRODUCED RADIATION TO DELIVER THERAPEUTIC RADIATION DOSAGE

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not regulated under any existing category of therapeutic radiation machine, until:

(1) The applicant or licensee has, at a minimum, provided the Agency with:

(2) Documentation that equipment to be licensed conforms to the relevant International Electrotechnical Commission standard, documentation of US Food and Drug Administration clearance, or documentation of participation in a research study approved by the licensee's Institutional Review Board;

(3) A detailed description of the device and its intended application(s);

(4) Facility design requirements, including shielding and access control;

(5) Documentation of appropriate training for authorized user physician(s), authorized medical physicist(s), and other personnel who will be involved in performing quality assurance tasks and/or setting up patients or human research subjects for treatment or delivering treatment;

(6) Methodology for measurement of dosages to be administered to patients or human research subjects;

(7) Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for quality assurance and radiation safety

(8) Radiation safety precautions and instructions; and

(9) Other information requested by the Agency in its review of the application; and

(10) The applicant or licensee has received written approval from the Agency to utilize the device in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the device.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .1911 EMERGING TECHNOLOGIES

(a) Each registrant shall develop, implement, and maintain a dedicated quality management program to control the processes used to administer therapeutic radiation with US Food and Drug Administration cleared emerging technologies or previously unused features of a future or existing technology system.
(b) Implementation and on-going clinical use of the technology dated before the technology arrives at the facility or the new features are used:

(1) Must include an explicit strategy to ensure quality of processes and patient or human research subject safety.
(2) Must include approval from facility management and the radiation oncology safety team before the technology arrives or new features are used.

(c) The quality management program shall be developed by the radiation oncology safety team.
(d) The quality management program shall address, at a minimum:

(1) Education and training about the new technology or features;
(2) A system and timeline for on-going competency assessment;
(3) A system for real-time recording of on-going issues related to the technology and clinical use of the new technology or features;
(4) A strategy for timely investigation and adjudication of accidents and process deviations that may be captured in the system developed in Subparagraph (b)(1) of this Rule;
(5) A strategy for routine review at intervals not to exceed 13 months of the clinical use of the new technology or features which includes an assessment of the current use compared to Paragraph (b) of this Rule and plan to either update the clinical use plan or steps to bring the clinical use back into alignment with Paragraph (b) of this Rule;
(6) A strategy to ensure quality of equipment functions;
(7) A strategy for ensuring quality after hardware and software updates and after equipment repair.

(e) The quality management program shall be developed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies, that includes the American Association of Physicists in Medicine, the American College of Radiology and the American Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocol shall be followed.
(f) New technology issues should be reported through the vendor or manufacturer, applicable regulatory agency alerts, or customer service bulletins and be reviewed and addressed via a documented reporting system.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

SECTION .2000 - VETERINARY USES OF THERAPEUTIC RADIATION MACHINES

10A NCAC 15 .2001 PURPOSE AND SCOPE

(a) This Section establishes requirements for licensing and use of veterinary therapeutic radiation machines to treat disease in animals other than humans. In addition to the requirements of this Section, all licensees are subject to the rules in Sections .0100, .0200, .0900, .1000, and .1600 of this Chapter.
(b) The use of veterinary therapeutic radiation machines shall be authorized by a licensed practitioner of veterinary medicine who meets the training and experience criteria established by Rule .2003(b) of this Section.
(c) In addition to the requirements of this Section, all veterinary therapeutic radiation machine licensees are subject to the annual fee provisions contained in Section .1100 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2002 DEFINITIONS

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

(1) "Acceptance testing" means an evaluation of equipment and systems to confirm they meet the specifications stated by the manufacturer.
(2) "Animal" means any mammal other than human, and includes birds, fish, and reptiles, wild or domestic, living or dead.
(3) "Annually" means at intervals not to exceed 12 consecutive months, plus or minus 30 days.

(4) "Authorized Medical Physicist" means an individual authorized in accordance with Rule .2003(c) of this Section.

(5) "Authorized user" means a veterinarian who meets the training requirements of Rule .2003(b) of this Section and is authorized by license condition to use a therapeutic radiation machine covered by this Section.

(6) "Barrier" see "Protective barrier".

(7) "Biennially" means at intervals not to exceed 24 consecutive months, plus or minus 30 days.

(8) "Commissioning" means an intricate and methodical process designed to:

(A) acquire needed machine-specific beam data;

(B) validate the safe, accurate, and effective operation of a therapeutic radiation machine, treatment planning systems, ancillary systems, and associated procedural protocols; and,

(C) set baseline for future measurements for performance constancy.

(9) "Dosimetry systems" means radiation detecting equipment that may be used to characterize the radiation beam and quantify the energy it may deposit within a medium.

(10) "Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

(11) "Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

(12) "Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

(13) "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(14) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(15) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(16) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

(17) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

(18) "Kilovolt," "kV," "kilo electron volt," and "keV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. Current convention is to use kV for photons and keV for electrons

(19) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.

(20) "Licensee" means any person who is licensed by the agency pursuant to the Rules of Section .0900 of this Chapter.

(21) "Light field" means the area illuminated by light, simulating the radiation field.

(22) "Megavolt," "MV," "mega electron volt," and "MeV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.

(23) "Method of Delivery" means mode of radiation to be used during treatment, which may include photons, electrons, or protons.

(24) "Patient" means an animal, for whom a written directive is intended, subjected to machine produced radiation for the purposes of medical therapy.

(25) "Periodic quality assurance check" means a procedure which is performed to ensure that a previous parameter or condition continues to be valid.

(26) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive.

(27) "Primary protective barrier" see "Protective barrier".

(28) "Protective barrier" means a barrier of radiation absorbing materials used to reduce radiation exposure. The types of protective barriers are as follows:

(A) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

(B) "Secondary protective barrier" means the material which attenuates stray radiation.

(29) "Qualified Expert" means a person registered by the agency pursuant to Rule .0205 of this Chapter for the provision of either Class VII or IX services.
(30) "Quarterly" means at intervals not to exceed 13 consecutive weeks, plus or minus seven days.
(31) "Radiation oncology safety team" means, minimally, a group of individuals consisting of an authorized user, authorized medical physicist, and veterinary therapeutic radiation machine operator whose purpose is to work together to deliver radiation safely and reproducibly.
(32) "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.
(33) "Semiannually" means at intervals not to exceed six consecutive months, plus or minus 15 days.
(34) "Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram.
(35) "Supervision" shall be defined as follows:
    (A) "General supervision" means the activity is performed under the overall direction and control of a supervising individual. The supervising individual's physical presence shall not be required during the performance of the procedure but must be available by phone to provide assistance and direction if needed.
    (B) "Direct supervision" means an individual exercise General Supervision and be present within the facility and immediately available to furnish assistance and direction throughout the performance of the activity. Direct Supervision does not require that the supervising individual must be present in the room when the procedure is being performed.
    (C) "Personal supervision" means an individual exercises General Supervision and be present in the room during the performance of the procedure.
(36) "Treatment room shielding" means a location which contains fixed protective barriers to limit radiation exposures to members of the public and occupationally exposed workers to within regulatory limits.
(37) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.
(38) "Veterinarian" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 11.
(39) "Veterinary therapeutic radiation machine," also known as a "Therapeutic radiation machine," means equipment that is designed and used for external beam radiation therapy in the healing arts. For these regulations, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.
(40) "Weekly" means at least once per calendar week.
(41) "Written directive" means an order in writing for the administration of radiation to a specific patient, as specified in Rule .2005(b)(1) of this Section.

(b) Definitions of certain other words and phrases used in the rules in this Section are set forth in Rules .0103, .1001 and .1601 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2003 GENERAL ADMINISTRATIVE REQUIREMENTS FOR VETERINARY FACILITIES USING THERAPEUTIC RADIATION MACHINES

(a) Administrative Controls: Licensees shall be responsible for directing the operation of the therapeutic radiation machines that have been licensed with the Agency. The licensee or the licensee's agent shall ensure that the requirements of this Section are met in the operation of the therapeutic radiation machines. A therapeutic radiation machine that does not meet the provisions of these regulations shall not be used for irradiation of patients.

(b) Training for Veterinary Therapeutic Radiation Machine Authorized Users: The licensee for any therapeutic radiation machine subject to Rules within this subpart shall require the authorized user to be a veterinarian who:

(1) Certification in Radiation Oncology by the American College of Veterinary Radiology; or
(2) Satisfactory completion of a radiation oncology residency program approved by the American College of Veterinary Radiology. For radiation oncologists who are eligible for certification by the

American College of Veterinary Radiology in accordance with Subparagraph (c)(1) of this Rule but not yet certified by the date of application, certification shall be required within six years of initial certification eligibility; and

(3) Recentness of Training: The training and experience specified within Paragraph (c) of this Rule must have been obtained within the seven years preceding the date of hire or the individual must have had related continuing education and experience since the required training and experience was completed.

(c) Training for Veterinary Authorized Medical Physicist or Authorized Medical Physicist: The licensee for any therapeutic radiation machine subject to rules within this Section shall require the Authorized Medical Physicist to:

(1) Be certified and maintaining certification by the American Board of Radiology in:
   (A) Therapeutic radiological physics; or
   (B) Therapeutic medical physics; or

(2) Be certified and maintaining certification by the American Board of Medical Physics in Radiation Oncology Physics; or

(3) Be certified and maintaining certification by the Canadian College of Medical Physics in Radiation Oncology Physics; or

(4) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and
   (A) Completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide external beam therapy with photons and electrons with energies greater than or equal to 1 million electron volts and brachytherapy services and must include: Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable to the veterinary practice, and conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable to the veterinary practice; and
   (B) Completed training for the types of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the types of use for which the individual is seeking authorization; or, be a qualified expert registered by the agency to provide Class VII or Class IX services in accordance with Rule .0205(c) of this Chapter.

(5) An individual identified on an Agency or an Agreement State medical accelerator license as an authorized medical physicist on or before the effective date of this Rule need not comply with Subparagraphs (1) through (4) of this Paragraph, except they must meet the training requirements defined in other sections of this rule for any uses for which they were not authorized on or before this date.

(d) Training for Veterinary Therapeutic Radiation Machine Radiation Safety Officer: The licensee for any therapeutic radiation machine subject to Rules within this subpart shall require the Radiation Safety Officer:

(1) Be listed as an Authorized User or Authorized Medical Physicist on the license; or

(2) Be certified by the American Board of Health Physics in Health Physics; or,

(3) Be certified by the American Board of Science in Nuclear Medicine in Radiation Protection; or

(4) Be certified by the American Board of Radiology in:
   (A) Diagnostic Radiologic Physics;
   (B) Diagnostic Medical Physics;
   (C) Medical Nuclear Physics;
   (D) Nuclear Medical Physics; or

(5) Be certified by the American Board of Medical Physics in Medical Health Physics; or

(6) Has completed a structured educational program consisting of both:
   (A) 200 hours of classroom and laboratory training in the following areas: Radiation physics and instrumentation, radiation protection, radiation biology, and radiation dosimetry, and

(B) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agreement State license or permit that authorizes similar type(s) of use(s) of radiation sources;

(7) An individual identified on an Agency or an Agreement State medical accelerator license as an Therapeutic Radiation Machine Radiation Safety Officer on or before the effective date of this Rule need not comply with Subparagraphs (1) through (6) of this Paragraph, except they must meet the training requirements in radiation safety, regulatory issues, and emergency procedures for the types of use which they were not authorized on or before this date; and

(8) Receive training in the requirements of the rules in Sections .1000 and .1600 of this Chapter and the Rules of this Section.

(e) Qualifications of Operators: Individuals who will be operating therapeutic radiation machines on patients or irradiation of products to be used by patients, shall:

(1) Comply with the requirements of Section .0900 of this Chapter; and

(2) Successfully complete a licensee-developed initial and ongoing competency program in the use of the therapeutic radiation machine as well as other ancillary systems used by the operator in veterinary medical use applications. The competency program shall be documented, and documentation of training shall include the list of topics evaluated, and shall be approved by the licensee, signed, and dated. Records required by this subparagraph shall be maintained for three years from the completion date of the approved competency program.

(f) Documented safety procedures shall be developed by an Authorized Medical Physicist and shall be readily accessible in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these Rules.

(g) Patients shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a therapeutic radiation machine authorized user. This provision specifically prohibits deliberate exposure of a patient for training, demonstration, or other non-healing-arts purposes.

(h) Visiting Veterinary Authorized User: A licensee may permit any veterinarian to act as a visiting authorized user under the term of the licensee's license for a total of 60 days per calendar year under the following conditions:

(1) The visiting authorized user has the prior approval of the licensee's management; and

(2) The visiting authorized user meets the requirements established for authorized users in Paragraph (b) of this Rule; and

(3) The licensee shall maintain copies of the documentation of the approval and that the visiting authorized user met the requirements of this Rule for three years from the date of the last visit.

(i) Visiting Veterinary Authorized Medical Physicist: A licensee may permit any medical physicist to act as a visiting authorized medical physicist under the term of the licensee's license for a total of 60 days per calendar year under the following conditions:

(1) The visiting authorized medical physicist has the prior approval of the licensee's management; and

(2) The visiting authorized medical physicist meets the requirements established for authorized user(s) in Subparagraphs (c)(1) through (c)(5) of this Rule; and

(3) The licensee shall maintain copies of the documentation of the approval and that the visiting authorized medical physicist met the requirements of this Rule for three years from the date of the last visit.

(j) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the licensee's quality management program. In addition to the requirements of this Section, these individuals are also subject to the requirements of Rules .1601(a)(8), (a)(24) and (a)(51) of this Chapter.

(k) Unless otherwise specified by license condition, whenever patients are being treated by a therapeutic radiation machine, a veterinarian shall be accessible. This veterinarian does not need to be an authorized user.

(l) A licensee that permits supervised activities within this subpart is responsible for the acts and omissions of the supervised individual.

(m) Information and Maintenance Record and Associated Information: The licensee shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Agency:

(1) Report of acceptance testing and commissioning;

(2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this Section, as well as the name(s) of person(s) who performed such activities;

(3) Records of maintenance or modifications performed on the therapeutic radiation machine after the effective date of this Rule, as well as the name(s) of person(s) who performed such services;

(4) Assessments performed by an Authorized Medical Physicist, prior to the return of a therapeutic radiation machine to clinical use, after significant service, repair, or upgrade that may result in variances of machine function(s) more than the threshold(s) established within the quality management program.

(n) Records Retention: All records required by this Section shall be retained until these records have been inspected by the Agency, unless another retention period is specifically authorized in this Section.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2004 GENERAL TECHNICAL REQUIREMENTS FOR FACILITIES USING VETERINARY THERAPEUTIC RADIATION MACHINES

(a) Protection Surveys:

(1) The licensee shall ensure that radiation shielding surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with Rule .2008 of this Section. The radiation protection survey shall be performed by, or under the direction of, an Authorized Medical Physicist or a qualified expert, and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition:

(A) Radiation levels in restricted areas are not likely to cause personnel exposures more than the limits specified in Rule .1601(a)(8) of this Chapter; and

(B) Radiation levels in unrestricted areas do not exceed the limits specified in Rule .1601(a)(15) of this Chapter.

(2) In addition to the requirements of Subparagraph (a)(1) of this Rule, a radiation protection survey shall also be performed:

(A) After making any change in the treatment room shielding;

(B) After making any change in the location of the therapeutic radiation machine within the treatment room;

(C) After relocating the therapeutic radiation machine;

(D) After changes in occupancy of surrounding areas; or

(E) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instruments used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

(4) If the results of the surveys required by this Paragraph indicate any radiation levels in excess of the limits specified in Parts (1)(A) or (B) of this Paragraph, the licensee shall disable the machine from use, label clearly, and not use the unit:

(A) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(B) Until the licensee has received a specific exemption from the Agency.

(b) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by Paragraph (a) of this rule indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by Rule .1601 of this Chapter, before beginning the treatment program the licensee shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with Rule .1601 of this Chapter;

(2) Perform the survey required by Paragraph (a) of this Rule again; and

(3) Include in the report required by Paragraph (d) of this Rule the results of the initial survey, a description of the modification made to comply with Subparagraph (b)(1) of this Rule, and the results of the second survey; or

(4) Receive an amended license issued by the agency that authorizes radiation levels in unrestricted areas greater than those permitted by Rule .1601 of this Chapter.

(c) Radiation Measuring Equipment. The licensee shall have, when required, appropriate and operable radiation measuring equipment available for use and calibrated in accordance with Rule .2008 of this Section. Radiation measuring equipment includes, but is not limited to, dosimetry systems, survey instruments, and other radiation measuring devices used in planning, guiding, and administering radiation.

(d) Reports of External Beam Radiation Therapy Surveys and Measurements. The licensee for any therapeutic radiation machine subject to Rules within this subpart shall furnish a copy of the records required in Paragraphs (a) and (b) of this Rule to the Agency within 30 days following completion of the action that initiated the record requirement.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2005 QUALITY MANAGEMENT PROGRAM

(a) Each licensee or applicant subject to Rules within this subpart shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the authorized user.

(b) Scope and Applicability. The quality management program shall address, as a minimum, the following specific objectives:

(1) Written Directives:

(A) A written directive must be approved by an authorized user prior to the administration of radiation. If because of the patient's condition, a delay in the 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 will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(B) The written directive must contain the patient's name, treatment site, method of delivery, dose per fraction, total number of fractions, and total dose.

(C) A written revision to an existing written directive may be made provided that the revision is dated and approved by an authorized user prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

(D) The licensee shall retain a copy of the written directive for three years.

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

(A) Prior to the administration of each course of radiation treatments, the patient's identity is verified.

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

(C) Develop a table-shift policy describing action to be taken by staff in the event shifts are used for patient setup and a table shift exceeds limitations established within the treatment plan.

(D) Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by: Checking both manual and computer-generated dose calculations to verify they are correct and in accordance with the written directive, and verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(E) Any unintended deviation from the written directive is identified, evaluated, corrective action taken, the unintended deviation documented; and

(F) The licensee retains a copy of the procedures for administrations for the duration of the license.

(c) New Procedures on Established Equipment. Established and commissioned therapeutic radiation machines shall reevaluate equipment parameters, pursuant to this Section, when new procedures are to be performed if the parameters, including dose rate, field size, imaging accuracy, maximum dose, falls outside of the original commissioned parameters.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2006 VETERINARY THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 KV

(a) The licensee shall provide documentation that equipment within this section conforms to the relevant International Electrotechnical Commission standard, documentation of US Food and Drug Administration clearance, or documentation of participation in a clinical research study approved by the licensee's Institutional Animal Care and Use Committee.

(b) Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV shall meet the requirements of Rule .2009 of this Section and shall permit continuous observation of the patient subject during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(c) Additional Requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

(1) All protective barriers shall be fixed except for entrance doors or beam interceptors;

(2) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(4) When any interlocked door is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 1 mGy or 100 mrad per hour.

(d) Acceptance Testing, Commissioning, and Calibration Measurements. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to this Rule shall be performed by, or under the direct supervision of, an Authorized Medical Physicist:

(1) Acceptance testing and commissioning shall be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies, such as the American Association of Physicists in Medicine, the American College of Radiology and the American Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed. Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

(2) A licensee authorized to use a therapeutic radiation machine for medical use shall perform calibration measurements on each therapeutic radiation machine:

(A) Before the first medical use of the unit;

(B) Whenever spot-check measurements indicate that the output, for each specific mode and energy, differs by more than five percent from the output obtained at the last calibration;

(C) Following reinstallation of the therapeutic radiation machine in a new location;

(D) Following any repair of the therapeutic radiation machine that would likely impact the radiation output beyond the normal range of expected fluctuation; and

(E) at intervals not exceeding annually.

(3) To satisfy the requirement of Paragraph (a) of this Rule, an authorized medical physicist shall design and implement a calibration procedure for each radiation therapy machine which is consistent with the specifications recommended by the manufacturer of the equipment and consistent with nationally recognizable standards. The calibration procedure shall be designed to ensure accurate patient treatments, in accordance with the written directive and treatment plan. The calibration procedure shall include, but not be limited to, the following:

(A) Accuracy of output measurements to within ± five percent of radiations used medically; and,

(B) Evaluation and accuracy of auxiliary systems, such as motion tracking or gating and image guidance, used during patient treatments.

(4) A licensee shall use the dosimetry system described in Rule .2008 of this Section to measure the output for one set of exposure conditions. The remaining radiation measurements required in Part (3)(A) of this Paragraph may be made using a dosimetry system that indicates relative dose rates.

(5) The evaluations and measurements for:

(A) Acceptance, commissioning, and calibration measurements required by Part (3)(A) of this Paragraph shall be performed under the direct supervision of an authorized medical physicist;

(B) Full calibration measurements required by Part (3)(B) of this Paragraph shall be performed by an authorized medical physicist or under the general supervision of an authorized medical physicist.

(6) A licensee shall maintain a record of each therapeutic radiation machine calibration for three years. The record must include:

(A) The date of the calibration;

(B) The manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to calibrate the units;

(C) The results and an assessment of the calibrations; and

(D) The name of the authorized medical physicist who approves the calibration.

(7) A licensee shall maintain a record of each therapeutic radiation machine acceptance testing and commissioning for the lifetime of the machine. The record must include:

(A) The date of the acceptance testing or commissioning;

(B) The manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to evaluate the units;

(C) The results and an assessment of acceptance testing or commissioning; and

(D) The name of the authorized medical physicist who approves the acceptance testing or commissioning.

(e) Independent Verification of Therapeutic Radiation Machine Output

(1) In addition to the full calibration required by Paragraph (a) of this Rule, the licensee shall have the outputs, for all clinically used radiations, independently verified:

(A) Within 90 days of first clinical use of a new installation;

(B) Within 90 days of first clinical use following a reinstallation in a new location; and

(C) Biennially, thereafter.

(2) Verification may be obtained by:

(A) irradiating dosimeters from an American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory; or

(B) evaluation by a registered qualified expert using an independent dosimetry system meeting the requirements of Rule .0947 of this Chapter.

(3) A licensee shall maintain a record of each independent verification of therapeutic radiation machine output for three years. The record must include:

(A) If obtained by Part (2)(A) of this Paragraph: The date of the irradiation, the date of the analysis by the dosimetry center, name, address and contact information for the American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory, and the results of the independent verification.

(B) If obtained by Part (2)(B) of this Paragraph: the date of the calibration, the manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to calibrate the units, The results and an assessment of the independent verification, and the name of the registered qualified expert who provided the independent verification.

(f) Quality Assurance Checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to this Rule, which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of Subparagraph (1) of this Paragraph, quality assurance checks shall meet the following requirements:

(A) The licensee shall perform quality assurance checks, to include ensuring the proper function of requirements outlined in Paragraphs (d) and (e) of this Rule, in accordance with written procedures established by the Authorized Medical Physicist; and

(B) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in Paragraph (d) of this Rule. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in Paragraph (d) of this Rule shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the Authorized Medical Physicist shall be investigated and corrected before the system is used for patient irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Authorized Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in Subparagraph (d)(2) of this Rule;

(5) The licensee shall use the dosimetry system described in Rule .2008 of this Section to make the quality assurance check required in Subparagraph (2) of this Paragraph;

(6) The licensee shall maintain a record of each quality assurance check required by this Paragraph for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

(g) Operating Procedures.

(1) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of Paragraphs (d) and (e) of this Rule have been met;

(2) Therapeutic radiation machines shall not be left unattended unless secured pursuant to Rules .1601(a)(32) and (33) of this Chapter;

(3) When a patient must be held in position for radiation therapy, mechanical supports or immobilization devices shall be used;

(4) The tube housing or any other part of the imaging assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(6) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of Rule .1601(a)(8) of this Chapter.

(h) Electronic brachytherapy devices are subject to the requirements of Rule .2011 of this Chapter and are exempt from the requirements of this Rule.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2007 VETERINARY THERAPEUTIC RADIATION MACHINES OF 500 KEV AND ABOVE

(a) The licensee shall provide documentation that equipment within this section conforms to the relevant International Electrotechnical Commission standard, documentation of US Food and Drug Administration clearance, or documentation of participation in a clinical research study approved by the licensee's Institutional Animal Care and Use Committee.

(b) Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of Rule .2009 of this Section, the following design requirements are made:

(1) Protective Barriers. All protective barriers shall be fixed and permanent with respect to the radiation source and designed to comply with the dose limits required by Rules .1601(a)(8) and .1601(a)(15) of this Chapter and shall be external to the dedicated space, except for access doors to the treatment space or movable beam interceptors;

(2) Control Panel. In addition to other requirements specified within this Section, the control panel shall also:

(A) Be located outside the treatment space and shall comply with the dose limits required by Rules .1601(a)(8) and .1601(a)(15) of this Chapter; and

(B) Provide a visual indication of when radiation is being produced;

(3) Include access controls that will prevent unauthorized use of the therapeutic radiation machine;

(4) Viewing Systems. Viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

(5) Entrances. Treatment space entrances shall be provided with warning lights in a viewable location outside of all entrances, which will indicate when the useful beam is "ON" and when it is "OFF";

(6) Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without activating the access control and reinitiating irradiation by manual action at the control panel;

(7) Movable Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a movable beam interceptor to ensure compliance with Rule .1601(a)(15) of this Chapter, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers;

(8) Emergency Cutoff Switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch; and

(9) Safety Interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(c) Authorized Medical Physicist Support.

(1) The services of an Authorized Medical Physicist shall be required in facilities having therapeutic radiation machines. The Authorized Medical Physicist shall be responsible for:

(A) Calibrations required by Paragraph (d) of this Rule and the protection surveys required by Rule .2004(a) of this Section;

(B) Beam data acquisition and configuration for treatment planning, and supervision of its use;

(C) Quality assurance, including quality assurance check review required by Paragraph (f) of this Rule.

(D) Consultation with the authorized user in treatment planning, as needed; and

(E) Perform calculations and assessments regarding medical events.

(2) The operating procedures required by Paragraph (c) of this Rule shall also address how the Authorized Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Authorized Medical Physicist can be contacted.

(d) Operating Procedures.

(1) No person shall be in the treatment space during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of Rule .2004(a) of this Chapter, and Paragraphs (d), (e) and (f) of this Rule have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use pursuant to Rules .1601(a)(32) and (33) of this Chapter;

(4) When a patient must be held in position for radiation therapy, mechanical supports or immobilization devices shall be used;

(5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

(e) Acceptance Testing, Commissioning and Calibration Measurements. Acceptance testing, commissioning, and calibration of a therapeutic radiation machine subject to this Rule shall be performed by, or under the direct supervision of, an Authorized Medical Physicist:

(1) Acceptance testing and commissioning shall be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of

therapeutic radiation technologies, that includes the American Association of Physicists in Medicine, the American College of Radiology and the American Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.

(2) A licensee authorized to use a therapeutic radiation machine for medical use shall perform calibration measurements on each therapeutic radiation machine:

(A) Before the first medical use of the unit; and

(B) Before medical use under the following conditions: Whenever spot-check measurements indicate that the output, for each specific mode and energy, differs by more than five percent from the output obtained at the last calibration, following reinstallation of the therapeutic radiation machine in a new location, or following any repair of the therapeutic radiation machine that would likely impact the radiation output beyond the normal range of expected fluctuation, and at intervals not exceeding annually.

(3) To satisfy the requirement of Paragraph (d) of this Rule, an authorized medical physicist shall design and implement a calibration procedure for each radiation therapy machine which is consistent with the specifications recommended by the manufacturer of the equipment and consistent with nationally recognizable standards. The calibration procedure shall be designed to ensure accurate patient treatments, in accordance with the written directive and treatment plan. The calibration procedure shall include, but not be limited to, the following:

(A) Accuracy of output measurements to within ± five percent of radiations used medically; and,

(B) Evaluation and accuracy of auxiliary systems, such as motion tracking or gating and image guidance, used during patient treatments.

(f) Independent Verification of Therapeutic Radiation Machine Output

(1) In addition to the calibration required by Paragraph (d) of this Rule, the licensee shall have the outputs, for all clinically used radiations, independently verified:

(A) Within 90 days of first clinical use of a new installation;

(B) Within 90 days of first clinical use following a reinstallation in a new location; and

(C) Biennially, thereafter.

(2) Verification may be obtained by:

(A) the authorized medical physicist irradiating dosimeters from an American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory; or

(B) evaluation by an independent registered qualified expert using an independent dosimetry system meeting the requirements of Rule .2008 of this Chapter.

(3) A licensee shall maintain a record of each independent verification of therapeutic radiation machine output for three years. The record must include:

(A) If obtained by Part (e)(2)(A) of this Rule: The date of the irradiation, the date of the analysis by the dosimetry center, name, address and contact information for the American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory, and the results of the independent verification.

(B) If obtained by Part (e)(2)(B) of this Rule: The date of the calibration, the manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to calibrate the unit(s), the results and an assessment of the independent verification, and the name of the independent registered qualified expert who provided the independent verification.

(g) Quality Assurance Checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to this Rule, which are capable of operation at greater than or equal to 500 kV.

(2) To satisfy the requirement of Subparagraph (f)(1) of this Rule, quality assurance checks shall meet the following requirements:

(A) The licensee shall perform quality assurance checks, to include ensuring the proper function of requirements outlined in Paragraphs (d) and (e) of this Rule, in accordance with written procedures established by the Authorized Medical Physicist; and

(B) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in

Paragraph (d) of this Rule. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in Paragraph (d) of this Rule, shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the Authorized Medical Physicist shall be investigated and corrected before the system is used for patient irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Authorized Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in Paragraph (d) of this rule;

(5) The licensee shall use the dosimetry system described in Rule .2008 of this Section to make the quality assurance check required in Paragraph (f) of this rule;

(6) The licensee shall maintain a record of each quality assurance check required by Paragraph (f) of this Rule for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2008 CALIBRATION OF SURVEY INSTRUMENTS AND DOSIMETRY SYSTEMS

(a) Survey Instruments, when employed by the licensee to perform surveys required by this section:

(1) The licensee shall ensure that the survey instruments used to show compliance with the provisions of this Rule have been calibrated before first use, at intervals not to exceed 12 months and following repair.

(2) To satisfy the requirements of Subparagraph (1) of this Paragraph, the licensee shall:

(A) Calibrate all required scale readings up to 10 mSv or 1000 mrem per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology;

(B) Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale; and

(3) To satisfy the requirements of Subparagraph (a)(2) of this Rule, the licensee shall consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent.

(4) The licensee shall retain a record of each calibration required in Paragraph (a) of this rule for three years. The record shall include:

(A) A description of the calibration procedure; and

(B) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(5) The licensee may obtain the services of individuals licensed by the Agency, the US Nuclear Regulatory Commission or an Agreement State to perform calibrations of survey instruments. Records of calibrations that contain information required by Paragraph (d) of this Rule shall be maintained for three years by the licensee.

(6) The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(b) Dosimetry system:

(1) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(A) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(B) The system must have been intercompared with another dosimetry system that was calibrated within the previous two years by National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than two percent.

(2) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done for three years after the record is made. For each calibration, intercomparison, or comparison, the record must include:

(A) The date;

(B) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by Paragraphs (b)(1) and (b)(2) of this Rule;

(C) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(D) The names of the individuals who performed the calibration, intercomparison, or comparison.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2009 SHIELDING AND SAFETY DESIGN REQUIREMENTS

(a) Each therapeutic radiation machine subject to Rules within this subpart shall be provided with such primary or secondary barriers as are necessary to ensure compliance with Rules .1601(a)(8) and .1601(a)(15) of this Chapter and must consider the types of radiations generated in the use of the equipment.

(b) Facility shielding and safety designs shall be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies, such as the American Association of Physicists in Medicine and the National Council on Radiation Protection and Measurements. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.

(c) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of different model, higher energy or workload into a room not previously approved for that energy, isocenter or planned workload shall be submitted for Agency approval prior to actual installation of the therapeutic radiation machine.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2010 OTHER USE OF ELECTRONICALLY-PRODUCED RADIATION TO DELIVER THERAPEUTIC RADIATION DOSAGE

(a) A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not regulated under any existing category of therapeutic radiation machine, until the applicant or licensee has, at a minimum, provided the Agency with:

(1) Documentation that equipment to be licensed conforms to the relevant International Electrotechnical Commission standard, documentation of US Food and Drug Administration clearance, or documentation of participation in a clinical research study approved by the licensee's Institutional Animal Care and Use Committee.

(2) A detailed description of the device and its intended applications;

(3) Facility design requirements, including shielding and access control;

(4) Documentation of appropriate training for authorized users, authorized medical physicists, and other personnel who will be involved in performing quality assurance tasks and setting up patients for treatment or delivering treatment;

(5) Methodology for measurement of dosages to be administered to patients;

(6) Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for quality assurance and radiation safety

(7) Radiation safety precautions and instructions; and

(8) Other information requested by the Agency in its review of the application; and

(b) The applicant or licensee has received written approval from the Agency to utilize the device in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the device.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.

10A NCAC 15 .2011 EMERGING TECHNOLOGIES

(a) Each registrant shall develop, implement, and maintain a dedicated quality management program to control the processes used to administer therapeutic radiation with US Food and Drug Administration cleared emerging technologies or previously unused features of a future or existing technology system.

(b) Implementation and on-going clinical use of the technology dated before the technology arrives at the facility or the new features are used:

(1) Must include an explicit strategy to ensure quality of processes and patient safety.

(2) Must include approval from facility management and the radiation oncology safety team before the technology arrives or new features are used.

(c) The quality management program shall be developed by the radiation oncology safety team.

(d) The quality management program shall address, at a minimum:

(1) Education and training about new technologies and features;

(2) A system and timeline for on-going competency assessment;

(3) A system for real-time recording of on-going issues related to the technology and clinical use of the new technology or features;

(4) A strategy for timely investigation and adjudication of accidents and process deviations that may be captured in the system developed in Subparagraph (b)(1) of this Rule;

(5) A strategy for routine review at intervals not to exceed 13 months of the clinical use of the new technology or features which includes an assessment of the current use compared to Paragraph (b) of this Rule and a plan to either update the clinical use plan or steps to bring the clinical use back into compliance with Paragraph (b) of this Rule;

(6) A strategy to ensure quality of equipment functions;

(7) An strategy for ensuring quality after hardware and software updates and after equipment repair.

(e) The quality management program shall be developed and maintained in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies, such as the American Association of Physicists in Medicine, the American College of Radiology, and the American Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocol shall be followed.

(f) New technology issues should be reported through the vendor or manufacturer, applicable regulatory agency alerts, and customer service bulletins and be reviewed and addressed via a documented reporting system.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.