Burgos, Alexander N

Subject: FW: second submission of technical changes - Radiation Protection Commission

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From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Thursday, September 24, 2026 11:27 AM
To: Miller, Christopher S <christopher.miller@oah.nc.gov>
Cc: Rules, Oah <oah.rules@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: second submission of technical changes - Radiation Protection Commission

Thanks and have a great weekend.

From: Miller, Christopher S <christopher.miller@oah.nc.gov>
Sent: Thursday, September 24, 2026 11:25 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>
Cc: Rules, Oah <oah.rules@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Miller, Christopher S <christopher.miller@oah.nc.gov>
Subject: RE: second submission of technical changes - Radiation Protection Commission

Thanks, Shanah.

These changes look good to me – I have no further comments. The attached final versions of the rules will be used for RRC review and will be uploaded to the meeting agenda. I anticipate recommending approval for all 27 rules.

Let me know if you have any questions before next week's meeting.

Best,
Chris

Chris Miller
Rules Review Commission Counsel
North Carolina Office of Administrative Hearings | Rules Division
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Raleigh, NC 27609
(984) 236-1935

NOTICE: E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties by authorized State officials.

10A NCAC 15 .0103 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0103 DEFINITIONS

(a) As used in the rules of this ~~Chapter,~~ Chapter and as applied to 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 the 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.~~ "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).

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

~~"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~~ a.m. January 1 to 11:59:59 ~~pm~~ p.m. 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.~~ except where otherwise defined in the rules of this Chapter.

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

(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~~ 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~~ 15 of this Title.

(b) As used in the rules of this ~~Chapter,~~ Chapter and as applied to 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,~~ building or one vehicle at one address 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~~ diagnosis 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~~ or 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.~~

"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 .0209 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.~~

"Registrant" means any person who is registered with the agency, after completing the registration process, in accordance with Rule .0203 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 .0209 of this Chapter.~~

"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.

(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)~~ .0205(e) 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~~.1700, [~~1900,~~] .1900, and .2000 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.*~~*2025;*
Amended Eff. October 1, 2026.

10A NCAC 15 .0104 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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.~~

The "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, hereinafter known as the "Agreement," is [~~hereby~~] incorporated by reference including subsequent amendments and editions. A copy of the Agreement is available free of charge at https://www.nrc.gov/cdn/nmss/pdf/ncagreements.pdf.

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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0201 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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

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

10A NCAC 15 .0201 PURPOSE AND SCOPE

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

(b) A person who acquires, owns, possesses, or receives ~~a radiation machine or~~ an X-Ray [~~machine,~~] machine or a radiation generating ~~device~~ [~~devices,~~] device, or provides other radiologic services 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 that use ~~using~~ ~~radiation machines~~ an X-Ray machine [~~machine,~~] or a radiation generating device for demonstration ~~purposes~~ purposes, or that provide mobile leasing ~~services~~ services, are subject to the additional requirements of Rule .0205 of this Section. Service providers that provide those services by bringing ~~radiation machines~~ an X-ray machine 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~~ X-ray 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~~ Industrial radiographic X-ray machines are subject to the additional requirements of Section .0500 of this Chapter.

(g) ~~Registrants using~~ ~~radiation~~ X-ray machines for ~~human~~ diagnostic imaging and veterinary use are subject to the additional requirements in Section .0600 of this Chapter.

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

(i) ~~Registrants using ionizing radiation~~ Radiation generating devices and X-ray machines for non-human use and non-veterinary use are subject to the additional 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, 2026; October 1, 2025.

10A NCAC 15 .0202 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0202 EXEMPTIONS

(a) Electronic equipment that produces radiation incidental to its operation ~~for other purposes~~ is exempt from the registration and notification requirements of this ~~Section~~ Section, provided that the dose equivalent rate ~~average~~ averaged 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 agency may, upon application, [~~application therefore,~~] grant individual exemptions or exceptions from the requirements of these Rules if it will not result in radiation dose or contamination that exceeds the limits prescribed in these Rules for the protection of public health, safety, or property.

~~(b)~~(c) The following are exempt from the requirements of this Section:

(1) all radioactive materials; and

(2) ~~radiation~~ X-ray machines or radiation generating devices 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0203 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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~~ X-ray ~~machine,~~ machine, or radiation generating device, or an unregistered service ~~provider,~~ 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~~ X-ray 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~~ The owner or the individual responsible for the business operations of a facility with an X-ray machine, radiation generating device, or who ~~is responsible for providing~~ provides radiological services, shall ensure that 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) are 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,~~ radiological 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.~~ https://radiation.ncdhhs.gov/Xray/applic.htm and https://radiation.ncdhhs.gov/Xray/service.htm.

(5) The owner or individual responsible for business operations can designate a responsible person or persons within the organization to sign when amendments are made to forms by notifying the agency in writing.

(c) A Business Application form shall be submitted prior to the operation of a facility or providing services in this ~~State~~ 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~~ X-ray machines or radiation generating [~~device~~] devices at a facility; or

(B) that plans to engage in radiological 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,~~ number, and type of ~~business, days and hours of operation;~~ business;

(C) the name, title, mailing address, phone, and e-mail address of the 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;~~ made available during inspection or upon request by the agency;

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

~~(F) description of facility use;~~

~~(G) description of service provider equipment~~;

~~(H)~~(F) dated and signed by the owner or the individual ~~with administrative control; and~~ responsible for business operations.

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

(d) ~~A Radiation~~ An X-ray 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~~ X-ray 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~~ X-Ray machines or radiation generating devices at a facility; or

(B) that is engaged in leasing or performing demonstrations using an unregistered ~~radiation~~ X-Ray 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 the machine or device when not in use;

(E) installer information; and

(F) ~~shall be~~ dated and signed by the ~~individual with administrative control.~~ owner or individual responsible for business operations. ~~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~~ an X-ray Machine or Radiation Generating Device Form shall be submitted when a facility disposes of ~~a radiation~~ an X-ray 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,~~ relocation, or to update information;

(3) ~~radiation~~ X-ray machine or radiation generating device ~~location;~~ location, manufacturer, ~~model,~~ model and serial number;

(4) identify the ~~reason for~~ method of disposal of the ~~radiation~~ X-ray machine or radiation generating device;

(5) ~~the~~ recipient of the ~~radiation~~ X-ray machine or radiation generating ~~device, to the individual or business name,~~ device, physical and e-mail address, and phone number; and

(6) dated and signed by the owner or the individual ~~with administrative control~~ responsible for business operations of the ~~radiation~~ X-ray 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~~ X-ray machines or radiation generating devices;

(B) providing individual monitoring devices; ~~and~~ or

(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~~ dated and signed by the owner or the individual ~~with administrative control.~~ responsible for business operations.

(g) A Company Employee Services Application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through ~~(H)~~ (G) 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;~~ X-ray machines;

(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~~ X-ray machines or radiation generating devices;

(E) qualified expert consulting services for CT and mammography ~~radiation~~ X-ray machines;

~~(F) radiation protection expert;~~

~~(G)~~(F) shielding designs for ~~diagnostic radiographic and fluoroscopy~~ ~~facilities;~~ X-ray machines; and

~~(H)~~(G) therapeutic ~~facility~~ shielding ~~design, area radiation survey, or calibration.~~ verification and area radiation surveys.

(2) The application requires the following information:

(A) name of the employee to be registered;

(B) start date if the employee is being ~~added~~ 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 owner or the individual ~~with administrative control;~~ responsible for business operations; 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,~~ education requirements of the Class for the services provided, 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 documentation of the requirements in Subparagraph ~~(1)(h)~~ (h)(1) 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~~ involving X-ray 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;~~ responsible for business operations;

(B) submit to the agency, a Disposal of ~~a Radiation~~ an X-ray 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~~ an X-ray 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0204 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0204 FACILITY RESPONSIBILITIES

(a) All forms ~~in~~ required by 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~~ X-ray machines for human, non-human, or veterinary use and prior to structural modification of existing installations, an ~~applicant,~~ applicant shall have the floor plans, shielding specifications, and equipment arrangement reviewed by a registered service provider.

(2) The ~~registrant~~ applicant shall submit ~~the~~ a shielding design and the agency Shielding Design Review Form to the agency for review. Shielding design drawings shall [~~include a scaled drawing.~~] be scaled. The ~~agency form~~ Shielding Design Review Form shall include the following information:

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

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

(C) proposed date of ~~installation.~~ installation or structural modification.

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

(4) ~~A radiation~~ An X-ray 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~~ X-Ray 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 radiation dose that exceeds the limits incorporated 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~~ X-ray absorptiometry (DEXA);

(C) mammography; or

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

(c) Facility ~~registration~~ registration:

(1) Mobile ~~radiation~~ X-ray machines located and used in this ~~State that are fixed in~~ State, and permanently affixed within a vehicle or ~~trailer~~ trailer, shall meet the following requirements prior to use:

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

(B) have ~~a Radiation~~ an X-ray Machine Application ~~or a Radiation Generating Devices Application~~ form submitted in accordance with Rule .0203(d) of this Section. ~~Radiation~~ X-ray machines leased or on loan from a registered service provider shall ~~register the radiation machine~~ be registered with the agency if ~~used~~ maintained for more than 30 days;

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

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

~~(E)~~(D) an individual ~~with administrative control~~ responsible for business operations shall ensure that ~~radiation~~ X-ray machines are operated in accordance with Section .0600 of this Chapter.

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

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

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

(C) an individual responsible for business operations shall ensure that X-ray machines are operated in accordance with Section .0600 of this Chapter.

(3) Mobile radiation generating devices located out-of-state and brought into this State for use shall meet the following requirements prior to use:

(A) have a Radiation Generating Devices Application form submitted in accordance with Rule .0203(d) of this Section. Radiation generating devices leased or on loan from a registered service provider shall be registered with the agency if maintained for use for more than 30 days;

(B) have a copy of the operating and safety procedures describing how to protect operators and the public from radiation submitted to the agency;

(C) submit a written notice, in accordance with Rule .0208 of this Section, and maintain it for agency review during inspection; and

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

~~(3)~~(4) ~~Radiation~~ X-ray machines for ~~human, non-human,~~ diagnostic imaging, non-diagnostic imaging, clinical studies, ~~or~~ veterinary ~~use~~ use, or for use by service providers for demonstration purposes shall meet the following additional requirements:

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

(B) submit ~~a Radiation~~ an X-ray Machine Application form in accordance with Rule ~~.0203 (d)~~ .0203(d) of this Section within 30 days of ~~use.~~ use; and

(C) an individual ~~with administrative control~~ responsible for business operations shall ensure that X-ray machines are operated in accordance with Section .0600 of this Chapter.

~~(4)~~(5) Radiation generating devices covered in Section .0800 of this Chapter shall meet the following additional requirements prior to use:

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

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

~~(5)~~(6) Industrial radiography ~~radiation~~ X-ray machines covered in Section .0500 of this Chapter shall meet the following additional requirements prior to use:

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

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

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

(e) ~~Persons~~ Facilities registered pursuant to ~~Paragraph(c)~~ 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~~ facility 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0205 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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,~~ State 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~~ X-ray machines or radiation generating devices;

(2) Class II - ~~installation, repair,~~ installation or service of the following:

(A) ~~radiation~~ X-ray 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;~~ [~~X-ray machines;~~] X-ray machines except fluoroscopic X-ray machines;

(4) Class IV - shielding designs for ~~diagnostic fluoroscopy facilities;~~ fluoroscopic X-ray machines;

(5) Class V - area radiation surveys and shielding evaluations for ~~diagnostic radiographic and fluoroscopy facilities;~~ [~~X-ray machines;~~] radiographic and fluoroscopic X-ray machines:

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

(7) Class VII - therapeutic ~~facility~~ shielding ~~design, area radiation survey, or verification;~~ verification [~~and area surveys;~~] services;

(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~~ X-ray machines that are ~~fixed in~~ permanently affixed within a vehicle or trailer for demonstration purposes or to ~~that~~ ~~provides~~ provide leasing services shall meet the following requirements prior to use:

(1) mobile ~~radiation~~ X-ray machines located and used in this State shall meet the requirements of Rules .0204(c)(1)(A) through ~~(E)~~ (D) of this Section; and

(2) mobile ~~radiation~~ X-ray machines located out of state and brought into this State for use shall meet the requirements of Rules .0204(c)(2)(A) and ~~(B)~~ (C) of this Section.

(g) Report of installation:

(1) Persons registered pursuant to Paragraph (a) of this Rule who sell, install, transfer, lease, or lend ~~lend, or dispose of radiation~~ an X-ray ~~machines~~ machine or radiation generating ~~[devices]~~ device in this State shall, within ~~15~~ 30 days after each calendar quarter, notify the agency at ~~XrayNORS@dhhs.nc.gov~~ fda2579@dhhs.nc.gov or the address, in accordance with Rule .0111 of this Chapter, of the following:

(A) whether any ~~radiation~~ X-ray machines or radiation generating devices 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~~ X-ray machine or radiation generating devices 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~~ X-ray machine or radiation generating devices 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~~ 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~~ X-ray machines for nonhuman use and radiation generating devices, when a Report of Sale and Installation Form prepared in accordance with Paragraph ~~(i)~~ (h) of this Rule is received by the agency.

(h) Upon the sale or installation of an X-ray machine for non-human use or a radiation generating device, the applicant shall submit a Report of Sale and Installation in accordance with (g)(1). ~~A Report of Sale and Installation of radiation [X ray] machines for nonhuman use or radiation generating devices~~ This form 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~~ X-ray 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 the 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~~ X-ray machines, ~~radiation~~ X-ray machine components, or radiation ~~machine~~ generating devices unless such machines and ~~devices~~ devices, when placed in ~~operation~~ operation, ~~shall~~ meet the requirements of these Rules.

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

(k) ~~Tests~~ Records of tests performed at the time of installation ~~demonstrating~~ that demonstrate the requirements of these Rules are ~~met,~~ met shall be provided to the registrant for agency review during inspection for the following:

(1) ~~fluoroscopy~~ fluoroscopic X-ray machine output measurement; and

(2) radiation generating devices equipment surveys.

(l) Records of any routine maintenance, repair, alterations, or reassembly of ~~radiation~~ X-ray 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0206 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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 shall be met for each service class:

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

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

(A) completion of manufacturer's equipment school for service, maintenance, and installation for the type of ~~radiation~~ X-ray machine or ~~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~~ X-ray machines, radiation generating devices, and machine components. ~~components services are required.~~

(3) Class III - shielding design for ~~diagnostic radiographic facilities:~~ [~~X-ray machine:~~] X-ray machines except fluoroscopic X-ray machines:

(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 shielding design experience ~~in diagnostic radiographic facility and shielding~~ for each type of machine ~~application.~~ modality.

(4) Class IV - shielding design for ~~diagnostic fluoroscopic facilities:~~ fluoroscopic X-ray machines:

(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 shielding design experience ~~in diagnostic fluoroscopic facility and shielding~~ for each type of machine ~~application.~~ type.

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

(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.~~ modality.

(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:~~ verification and area surveys:

(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,~~ 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:~~ devices: The applicant ~~must~~ shall 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~~ consulting. The applicant shall meet ~~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~~ X-ray and radium physics; or

(D) hold a master's or doctorate degree 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~~ X-ray physics.

(b) Any person registered to provide Class IX services prior to ~~the effective date of this Rule~~ October 1, 2025, 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0207 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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,~~ measurements and equipment surveys, Class V area radiation surveys and shielding evaluations for ~~diagnostic~~ radiographic and ~~fluoroscopy facilities,~~ fluoroscopic X-ray machines, or Class VII therapeutic area radiation survey or shielding 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;~~ manufacturer. A frequency other than annually shall be accepted if stated in the manufacturer's manual.

(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~~ surveys, including a list of all guides and references provided to the employed;

(B) a copy of all forms, reports, and documents that will be supplied ~~to registrants;~~ in conjunction with the provided services;

(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 at the time that the service is provided 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,~~ X-ray machines, Class IV shielding designs for ~~diagnostic fluoroscopy facilities,~~ fluoroscopic X-ray machines, and Class VII therapeutic ~~facilities and~~ shielding design verification 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 verification 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0211 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0211 THE INDIVIDUAL ~~REPSONSIBLE~~ 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~~ who can be an ~~actively registered~~ active ~~radiologic technologist,~~ Registered Technologist (RT) by the American Registry of Radiologic Technologists (ARRT), shall be on site or available at all times and be qualified by reason of education, training, and experience. Records of this individual's education, training, and experience shall be available for review during inspections or upon request by the agency. The individual shall meet the following ~~are the minimum qualifications that must be met to carry out the job duties:~~ qualifications:

(1) training in basic radiation protection principles;

(2) completed educational courses relating to ionizing radiation;

(3) ~~know~~ knowledge of potential radiation hazards and emergency precautions; and

(4) training and experience in and ~~knowing~~ knowledge of the proper use of the type of equipment. ~~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~~ occur, to ensure the procedures are current.

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

(A) reviewed;

(B) maintained; and

(C) notifications [~~made~~] reported in accordance with Rule ~~.1601~~ .1001(a)(7) 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~~ 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, 2026; October 1, 2025.

10A NCAC 15 .0212 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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

(a) ~~Radiation~~ X-ray machines or radiation generating devices that do not meet the ~~radiation~~ X-ray machine or radiation generating device 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~~ X-ray machine or radiation generating device and determining if the use of the ~~radiation~~ X-ray machine or radiation generating device 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) The proposed user or manufacturer of the X-ray 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's manual;

(3) description of intended use;

(4) operator training provided to the end user;

(5) an independent equipment survey [~~to include the following:~~] that includes:

(A) all equipment settings available to the operator;

(B) radiation output at the highest setting; and

(C) leakage radiation around the X-ray machine.

(6) an area survey [~~to include the following:~~] that includes:

(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 X-ray [~~machine.~~] machine; and

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

(c) The proposed user or manufacturer of the radiation generating device shall submit the [~~requirements~~] required information in Rule .0808 of this Chapter for agency review.

~~(b)~~(d) After receiving the information in ~~Paragraph (a)~~ Paragraphs (b) and (c) of this Rule, the agency ~~will~~ shall respond to the applicant in writing within 90 calendar days. Upon review, the agency may require additional information to determine if the ~~radiation~~ X-ray machine or radiation generating device 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, 2026; October 1, 2025.

10A NCAC 15 .0214 is repealed as published in 40:19 NCR 1541-1550 as follows:

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

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.~~2015;
Repealed Eff. October 1, 2026.

10A NCAC 15 .0301 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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 ~~BYPRODUCE~~ BYPRODUCT MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 30 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 30:

(1) With the exception of ~~[10 CFR 30.4]~~ 10 CFR 30.4, a reference to "NRC" or "Commission" means the "Agency;"

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

(3) In 10 CFR 30.18(d) and 30.32(g) where a reference is made to "an Agreement State", it means "an Agreement State or the NRC."

~~(a)~~(b) 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~~ For purposes of this Rule, the term "temporary jobsite" shall mean a location where byproduct materials are used and stored other than those ~~location(s)~~ locations 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 applications shall be submitted to the Agency and the requirements of Paragraph ~~(b)~~(c) of this Rule shall be ~~met.~~ 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),~~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)~~(c) 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~~.0111(a) 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)~~ addresses 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0302 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 31 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 31:

(1) 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 31.5(b)(1)(ii), 31.5(c)(3)(ii), 31.5(c)(8)(i), 31.6, 31.7(a), 31.10(a), 31.10(b)(1), and 31.12(c)(4), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC;" and

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

~~(a)~~(b) 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)~~(1) 10 CFR 31.1, "Purpose and scope;"

~~(3)~~(2) 10 CFR 31.2, "Terms and conditions;"

~~(4)~~(3) 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~~ register with the agency. Device registration shall be made in accordance with Paragraph ~~(b)~~(c) of this Rule and shall contain the information required by 10 CFR 31.5(c)(13)(iii);

~~(5)~~(4) 10 CFR 31.6, "General license to install devices generally licensed in 10 CFR 31.5;"

~~(6)~~(5) 10 CFR 31.7, "Luminous safety devices in aircraft;"

~~(7)~~(6) 10 CFR 31.8, "Americium-241 and radium-226 in the form of calibration or reference sources;"

~~(8)~~(7) 10 CFR 31.9, "General license to own byproduct material;"

~~(9)~~(8) 10 CFR 31.10, "General license for strontium 90 in ice detection devices;"

~~(10)~~(9) 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)~~(c) of this Rule;

~~(11)~~(10) 10 CFR 31.12, "General license for certain items and self-luminous products containing radium-226;" and

~~(12)~~(11) 10 CFR 31.21, "Maintenance of ~~records;"~~records."

(c) 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.

~~(b)~~[~~(c)~~](d) 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~~.0111(a) 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~~ signed, and telephone number of the contact person.

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1989; October 1, 1984; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0302 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0304 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 32 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 32:

(1) A reference to "NRC" or "Commission" means the "Agency;"

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

(3) In 10 CFR 32.13, 32.51(a), 32.51(c), 32.56, 32.59, and 32.72(b)(5)(ii), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC."

~~(a)~~(b) 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)~~ 10 CFR 30.14 and 30.18 and incorporated by Rules .0301(b)(11) and ~~.0301(a)(13)~~.0301(b)(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;" and

(3) 10 CFR 32.3, "Maintenance of records."

~~(b)~~(c) All ~~Persons~~ 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)~~(d) All persons manufacturing or initially transferring generally licensed devices containing byproduct material shall comply with Paragraph ~~(g)~~(h) 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)~~(e) All persons manufacturing or initially transferring items or devices containing byproduct material for medical use in humans shall comply with Paragraph ~~(g)~~(h) 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)~~(f) 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)~~(h) of this Rule and the requirements of 10 CFR 32.201.

~~(f)~~(g) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) of this Chapter in lieu of the NRC.

~~(g)~~(h) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses 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~~ indication 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; ~~number shall be provided on the application;~~

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

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20; 10 CFR 30.71;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0304 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0305 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 33 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 33:

(1) A reference to "NRC" or "Commission" means the "Agency;" and

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

~~(a)~~(b) 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)(c) of this Rule shall be met;~~ applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (c) of this Rule;

(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),~~33.17(a) and (b), "Conditions of specific licenses of broad scope."

~~(b)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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)~~(d) 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.~~2024;

Amended Eff. October 1, 2026.

10A NCAC 15 .0306 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 34 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 34:

(1) A reference to "NRC" or "Commission" means the "Agency;" [~~and,~~] and

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

~~(a)~~(b) 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:~~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)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or mailed to the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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~~ https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

~~(c)~~(d) 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)~~(e) 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).~~.0111 of this Chapter in lieu of the NRC. In addition to the information required by 10 CFR 34.101(b), notifications of devices with failed or worn through S-tubes shall contain the serial number and storage location of the device, whether the device has been disposed of or returned to the manufacturer, and whether personnel contamination occurred.

~~(e)~~(f) Requests for exemption from these Rules under 10 CFR 34.111 shall be made to the agency as specified in Paragraph ~~(b)~~(c) 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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0307 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 35 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 35:

(1) A reference to "NRC" or "Commission" means the "Agency;" and

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

~~(a)~~(b) All persons using radioactive materials for medical use in humans shall comply with the ~~general information~~ following 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)[(n)] of this Rule shall be met;~~ applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (n) of this Rule;

(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)~~(c) 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,~~ by no later than May 1, 2027, 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)~~(d) All persons administering radioactive materials to humans not requiring a written directive shall develop, document, maintain, and require the use ~~of,~~ 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~~ Authorized user, and shall ~~include,~~ include the following 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,~~ care and to prevent the occurrence of medical events.

~~(d)~~(e) 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)~~(e)(10) of this ~~Paragraph.~~ Rule. ~~Brachytherapy~~Sealed sources and 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)~~(e)(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)~~(f) 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)~~(g) 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)~~(h) 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 covered by the provisions of 10 CFR Part 35 listed in Subparagraphs ~~(g)(6)~~(h)(6) and ~~(g)(7)~~(h)(7) of this Rule shall be approved by an Authorized Medical Physicist.

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

~~(k)~~(l) 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)~~(m) 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 in accordance with Rule .0111 of this Chapter 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~~.0111(a) 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)~~(n) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*

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Transferred and Recodified from 15A NCAC 11 .0307 Eff. February 1, 2015;
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Readopted Eff. May 1, ~~2024.~~[~~2014.~~]2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0308 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 36 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 36:

(1) A reference to "NRC" or "Commission" means the "Agency;" and

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

~~(a)~~(b) 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~~ remain under NCR jurisdiction and do not apply;

(3) 10 CFR 36.11, "Application for a specific license," except that applications shall be submitted to the Agency and the requirements of Paragraph ~~(b)~~(c) 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~~CFR 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~~.0111(a) of this Chapter unless directed otherwise by the agency, in lieu of the United States Nuclear Regulatory Commission (NRC).

~~(b)~~(c) 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,~~ Licenisng.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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)~~(d) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part036/.

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Readopted Eff. May 1, ~~2024.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0309 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0309 DOMESTIC LICENSING OF SOURCE MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 40 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 40:

(1) With the exception of 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, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~] the same as defined in G.S. [~~104E-5.(16);~~] 104E-5(16); and

(4) In 10 CFR 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".

~~(a)~~(b) 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~~ do 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~~ applications shall be submitted to the agency in accordance with Paragraph ~~(b)~~(c) 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),~~ 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),~~ 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)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication if the application is for a new license, or for the renewal of an existing license, by marking the corresponding check box;

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

(G) ~~applicants shall indicate~~ indication of 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0310 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 70 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 70:

(1) With the exception of 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 70.4, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~] the same as defined in G.S. [~~104E-5.(16).~~]104E-5(16).

(4) 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".

~~(a)~~(b) 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~~ do 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~~ an applications shall be submitted to the agency in accordance with Paragraph ~~(b)~~(c) of this ~~Rule shall be met;~~ Rule;

(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)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0311 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0311 PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 71 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 71:

(1) In 10 CFR 71.0(c), 71.3, [~~71.5~~] 71.5, 71.17(a), (b), 71.22, 71.23(a), (b), [~~10 CFR~~] and 71.101(c)(1), a reference to "NRC" or "Commission" means the "Agency;"

(2) In 10 CFR 71.8(b), (d), and 71.17(b), [~~the Agency is the "quality assurance program approval holder,"~~] references to the NRC with respect to quality assurance program approval mean the Agency; and

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

~~(a)~~(b) 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;~~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;"~~misconduct." In 10 CFR 71.8(a)(3), _____ _____ _____ _____ _____ _____

(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 10 CFR 71.17(a) applies to any licensee of the agency, and the 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)~~ (b)(2) of this ~~Paragraph~~ Rule and to the NRC in accordance with 10 CFR 71.17(c)(3);

(13) 10 CFR 71.21, "General license: Use of foreign approved ~~package;"~~package," except that 10 CFR 71.21(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR [~~71.21b)~~] 71.21(b) shall be issued by the agency or the NRC.

(14) 10 CFR 71.22, "General license: Fissile ~~material;"~~material" except that 10 CFR 71.22(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR 71.22(b) shall be issued by the agency.

(15) 10 CFR 71.23, "General license: Plutonium-beryllium special form ~~material;"~~material," except that 10 CFR 71.23(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR 71.23(b) shall be issued by the agency.

(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;"~~program." Changes to 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;

(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)~~(c) 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)~~(d) 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);*
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Readopted Eff. May 1, ~~2025.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0313 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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:~~apply, and in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~] the same as defined in G.S. [~~104E-5.(16).~~]104E-5(16).

(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;"~~licenses," in addition to the general license authorized by 10 CFR 150.20(a)(1) and subject to the limitations of 10 CFR 150.20(a)(2), any person who holds a specific license issued by an Agreement State or by the NRC is granted a general license to conduct the same activity in North Carolina and the offshore waters within the jurisdiction of the State of North Carolina;

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

(8) 10 CFR 150.32, "Funds for reclamation or maintenance of byproduct ~~material;"~~ 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);*
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10A NCAC 15 .1203 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .1203 LICENSE REQUIRED: LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 61 and to effectuate their joint enforcement, except in 10 CFR 61.2, a reference to "NRC" or "Commission" means the "Agency."

~~(a)~~(b) 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.~~ not granted a low-level waste facility access license by the agency in accordance with G.S. 104E-10.3.

(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~~ .0111(a) of this Chapter in lieu of the NRC.

(4) ~~The requirements found in~~ Applicants and licensees shall comply with the applicable requirements under 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.~~(j).

(5) In addition to the definitions found in 10 CFR 61.2, the definitions in G.S. 104E-5 shall ~~apply. apply~~ to the interpretation and application of this Rule.

(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)~~(c) 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)~~(b) of this Rule.

(1) No person shall transport or transfer waste to a low-level radioactive waste land disposal facility licensed under Paragraph ~~(a)~~(b) of this Rule unless licensed by the agency or ~~otherwise specifically authorized in writing by the agency.~~ authorized in accordance with G.S. 104E-10.3.

(2) The definitions of terms in G.S. 104E-5 shall ~~apply.~~ apply to the interpretation and application of this Rule.

(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,~~ waste as required by G.S. 104E-27(a). ~~including~~ These procedures and practices shall include 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)~~(b) 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)~~(c)(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)~~(d) 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~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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 are available at ~~shall be made available by the agency on the agency's public website~~. https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

~~[(d)](e) 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.~~2023;
Amended Eff. October 1, 2026.

10A NCAC 15 .1301 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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) To reconcile differences between this Rule and the incorporated sections of 10 CFR 39 and to effectuate their joint enforcement, a reference to "NRC" or "Commission" means the "Agency."

~~(a)~~(b) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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, or for exemptions from this Rule, 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 under 10 CFR 39.91 on the application:

(A) legal business name and mailing address;

(B) physical ~~address(es)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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.~~ https://radiation.ncdhhs.gov/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~~ .0111(a) of this Chapter in lieu of the NRC.

(f) Applications for exemptions from this Rule permitted by 10 CFR 39.91 ~~to this Rule~~ shall be submitted to the agency at the address shown in Rule ~~.0111~~.0111(a) 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.~~2022;
Amended Eff. October 1, 2026.

10A NCAC 15 .1601 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 20 and to effectuate their joint enforcement, [~~and to effectuate their joint enforcement,~~] the following words and phrases shall be substituted for the language of 10 CFR 20:

(1) Except in 10 CFR 20.1003, a reference to the "Nuclear Regulatory Commission," "NRC" or "Commission" means the [~~"Agency,"~~] "Agency;" and

(2) In 10 CFR 20.1003, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~]the same as defined in G.S. [~~104E-5.(16).~~]104E-5(16).

~~(a)~~(b) 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 of 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)~~ (b)(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)~~(c) ~~Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.~~ No person shall intentionally expose an individual monitoring device, as defined in 10 CFR 20.1003, to radiation for the purpose of causing the device to indicate a dose not received by the individual to whom the device is assigned.

~~(c)~~(d) Licensees and registrants shall continue to perform all activities required by the rules of this Chapter, and any license or registration conditions imposed by the agency, and shall pay annual fees required by the Rules in Section 10A NCAC 15.1100 ~~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)[(e)] Nothing in the rules of this Chapter shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.~~

(e)[~~(f)~~] 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, 2026; May 1, 2025.

10A NCAC 15 .1701 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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) To reconcile differences between this Rule and the incorporated sections of 10 CFR 37 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 37:

(1) With the exception of 10 CFR 37.5 a reference to “NRC” or “Commission” means the "Agency;" and

(2) A reference to “NRC-licensed” means licensed by the Agency.

~~(a)~~(b) 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)~~(c) 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)~~(d) ~~The Code of Federal Regulations incorporated by this Rule~~ Copies of these regulations 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. October 1, 2026; May 1, 2023.

Burgos, Alexander N

Subject: FW: second submission of technical changes
Attachments: Second Request for Changes - NCRPC - 09 2026 - CSM.docx; 10A NCAC 15 .0201.docx; 10A NCAC 15 .0202.docx; 10A NCAC 15 .0203.docx; 10A NCAC 15 .0204.docx; 10A NCAC 15 .0205.docx; 10A NCAC 15 .0206.docx; 10A NCAC 15 .0207.docx; 10A NCAC 15 .0211.docx; 10A NCAC 15 .0212.docx; 10A NCAC 15 .0214.docx; 10A NCAC 15 .0103.docx; 10A NCAC 15 .0104.docx; 10A NCAC 15 .0301.docx; 10A NCAC 15 .0302.docx; 10A NCAC 15 .0304.docx; 10A NCAC 15 .0305.docx; 10A NCAC 15 .0306.docx; 10A NCAC 15 .0307.docx; 10A NCAC 15 .0308.docx; 10A NCAC 15 .0309.docx; 10A NCAC 15 .0310.docx; 10A NCAC 15 .0311.docx; 10A NCAC 15 .0313.docx; 10A NCAC 15 .1203.docx; 10A NCAC 15 .1301.docx; 10A NCAC 15 .1601.docx; 10A NCAC 15 .1701.docx

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Wednesday, September 23, 2026 1:36 PM
To: Miller, Christopher S <christopher.miller@oah.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: second submission of technical changes

Good afternoon,

I am attaching the technical changes for 10A NCAC 15 .0100, .0200, and .0300 amendments.

Thanks for all of your helpful feedback. The radiation protection has greatly appreciated your advice on these changes.

Shanah Black
Rule-making Coordinator
Division of Health Service Regulation
NC Department of Health and Human Services

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Request for Changes Pursuant to N.C. Gen. Stat. § 150B-21.10

Staff reviewed these Rules to ensure that each Rule is within the agency's statutory authority, reasonably necessary, clear, and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

Questions contained herein suggest that the rule as written is unclear or there is some ambiguity. If this document includes questions and you do not understand the question, please contact the reviewing attorney to discuss. Failure to respond may result in a staff opinion recommending objection.

Staff may suggest the agency "consider" an idea or language in this document. This is in no way a formal request that the agency adopt the idea or language but rather is offered merely for the agency's consideration which the agency may find preferable and clarifying.

To properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

Note the following general instructions:

1. You must submit the revised rule via email to oah.rules@oah.nc.gov and copy RRC Counsel. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
    - Wrong: "~~a~~Association"
    - Right: "~~association~~ Association"
6. Treat punctuation as part of a word. For example:
    - Wrong: "day~~,~~; and"
    - Right: "~~day,~~ day; and"
7. Formatting instructions and examples may be found at: www.ncoah.com/rules/examples.html

If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: ALL RULES

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

> *Use of "X-ray machine": In many places, it seems like you are replacing "radiation machine" with "X-ray machine". Do these two terms have the same meaning? Or is "radiation machine" a broader category of devices? You define "radiation machine" in your rules (and it's also defined by statute). However, "X-ray machine" is left undefined. You should clarify the meaning somewhere in your rules, even if it has the same meaning as a "radiation machine".*

Response: The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two are broken down in Sections .0500, .0600, and .0800.

Understood – thanks for the explanation. So for my understanding, in rule 15 .0201(b), you are replacing "radiation machine" with "an X-Ray machine or a radiation generating device". Both X-Ray machines and radiation generating devices are "radiation machines". Is that correct? So the updated terminology is meant to clarify that the requirements apply to both human use and non-human use equipment? Or is it meant to do something else? Are these two terms just more precise than "radiation machine"?
Response: Yes, the rule is replacing radiation machine with "an X-ray machine or a radiation generating device". Yes, both X-ray machines and radiation generating devices are "radiation machines". Yes, the updated terminology is meant to clarify that the requirements apply to both human use and non-human use equipment. Yes, these two terms are more precise than "radiation machine".

> *Cross-References: Please ensure that all of your cross-references are still accurate. I identified several places where rule cross-references needed to be updated based on the revised versions of the rules in this package.*

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0103

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

General Comment: Definition rules should be ordered alphabetically. Some of your definitions are not in proper order. For example, (a)(3) and (a)(4) should be switched. (b)(12) should come before "Registrant". Please consider fixing this.
Response: Updated in text.

This is not fixed. (b)(10), definition for "Registrant", should be placed in between "Registered" and "Registration".
Updated in text.
(a), lines 4-6: The wording of this paragraph is awkward. I would suggest deleting, "… 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, …". If you want to keep this language, consider revising the start of the paragraph to say, "As used in the rules of this Chapter and as applied to persons …".
Response: Updated in text.

This change is not reflected in the document that you provided.
Response: Updated in text.

(a)(1), line 7: Add "the" before the name of the Act.
Response: Updated in text.

(a)(6): Per the style guide, please use the abbreviations "a.m." and "p.m." to express time.
Response: Updated in text.

(a)(9) and (10): Paragraph (c) does not provide a different meaning for these terms. Rather, it points to different sections of your rules. For clarity, consider revising this to say, "… except where otherwise defined in the rules of this Chapter." Or, specifically identify which rule section would apply to these two terms.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Thank you for the suggestion. This improves the rule. Change made to the rule as requested.

(a)(19): "six month intervals" should include a hyphen.
Response: Updated in text.

(a)(23): "Chapter 10" of what Title? Your rules are in Chapter 15. Am I missing something here?
Response: Updated in text.

(b): Same comment as mentioned above for (a), lines 4-6.
Response: Updated in text.

This change is not reflected in the document that you provided.
Response: Updated in text.
(b)(3), lines 20-21: I don't fully understand what you mean. Should this say, "… within one building or one vehicle at one address and under …"? What is the intent here?
Response: Updated in text.

The change made in the document does not match my suggestion and makes the passage even more confusing. Please revise this further.
Response: Updated in text.

(b)(7), line 32: Change "diagnosing" to "diagnosis".
Response: Updated in text.

(b)(7)(B), line 35: Change "and" to "or".
Response: Updated in text.

(b)(12), line 10: Rule .0207 does not mention any "Notice of Registration". Please correct your cross-reference.
Response: Updated in text.

(b)(15): Rule .0205(d) does not mention any specific services. Please correct your cross-reference.
Response: Updated in text.

This change is not reflected in the document that you provided.
Response: Updated in text.

(c), line 23: Add a period before "1900".
Response: Updated in text.

History Note, Authority: Is 10 CFR 20.1003 still applicable to this rule now that you've moved the CFR definitions to other places throughout your rules?
Response: Thank you very much for your comment. The citation in the History Note referencing 10 CFR 20.1003 is no longer necessary because the regulation in

the 10 CFR is incorporated by reference in 10A NCAC 15 .1601 in the rules currently published on the OAH website. The change to the history note made as suggested.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0104

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

General Question: G.S. 150B-21.6 authorizes incorporation of another agency rule or a code, standard, or regulation adopted by another agency, the federal government, or a generally recognized organization or association. How does this bilateral Agreement fall within one of those categories? And what is the effect of incorporating the Agreement? Are you trying to enforce specific provisions of the Agreement?
Response: The Agreement does not fit precisely within the categories of a code, standard, or regulation identified in G.S. 150B-21.6. However, the Agreement functions as a statement of general applicability that implements federal and State statutory authority and describes the scope of the Agency's regulatory authority. Pursuant to Section 274 of the Atomic Energy Act and North Carolina law, the Agreement authorizes the State to regulate certain activities involving radioactive material while reserving other activities to exclusive federal jurisdiction.

Incorporating the Agreement into Rule .0104 provides notice to the regulated community and guidance to the Agency regarding the scope of activities the State may license and regulate. The Agency is not seeking to enforce individual provisions of the Agreement separately; rather, the Agreement establishes the jurisdictional boundaries within which the Agency exercises its regulatory authority.

Page 2, line 6: Delete "hereby".
Response: Updated in text.

History Note, Authority: Please confirm that all listed statutes are still relevant even with the proposed deletions.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0201

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a): What is the difference between an X-ray machine and a radiation generating device? Are these terms both defined anywhere in your rules? Is there a reason why you use both terms here? Consider adding a definition in .0103
Response: The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two are broken down in Sections .0500, .0600, and .0800.

(b), lines 11-12: Replace the comma after "X-ray machine" with "or" and either delete "a" or change "devices" to "device".
Response: Updated in text.

(b), line 12: Is "radiologic" or "radiological" the proper term? You use the latter in (a). Be consistent in your rule.
Response: Updated in text.

(d), line 16: Do you need the comma here after "X-ray machine"? What is your intent? Consider: "Service providers that use an X-ray machine or radiation generating device for demonstration purposes, or that provide mobile leasing services, are subject …"
Response: Updated in text.

(f): What does "Industrial" mean in this context?
Response: Industry standard uses the term Industrial and Industrial Radiography is a non-destructive testing method that uses ionizing radiation to examine the internal structure of materials, components, and welds without causing damage.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(g), line 24: Change "and" to "or" if these are separate categories.
Response: It is supposed to be "and"

(h), line 27: Change "or by service providers for demonstration purposes" to "or for demonstration purposes conducted by service providers".
Response: Updated in text.

(i): Would this provision apply to veterinary services? And if so, is it possible to comply with both Sections .0600 and .0800 at the same time? Or is this rule not meant to have a cumulative effect with paragraphs (f)-(h)? It is not really clear.
Response: This does not apply for human or veterinary services. When X-ray machines are used in industrial settings this would not be for human or veterinary services. This rule does not have a cumulative effect. Paragraph (g) addresses human diagnostic imaging and veterinary use.

Understood. However, in (j), you simply state, "… machines for non-human use". Veterinary use would fall into "non-human use". So do you now see the issue that I have flagged with the rule text?
Response: Updated in text.

History Note, Authority: How are 104E 9(8) and 104E 19(a) relevant here? Those are fee statutes.
Response: Historically the agency has not changed a history note unless applicable to intent of rule change. The intent of this rule has not changed since written. Does 104E-9(8) and 19(a) establish the legislative authority for the fee related provisions of this Section? Please advise if change is still need.

You can leave as is.

History Note, page 2, line 1: The most recent date should be placed first within the same line. Please correct this.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0202

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 4: What do you mean by "other purposes"? Purposes not covered under rule 10A NCAC 15 .0201? If so, state that in the rule.
Response:

(a), line 5: I believe "average" should be changed to "averaged".
Response: Updated in text.

(b), line 9: Please delete "therefore".
Response: Updated in text.

(b), line 9: Are "exemptions" and "exceptions" different? If they are the same thing, you should just use one term.
Response: Exemption and exception are different. The agency may exempt an entity from a specific requirement or make grant an exception to a requirement under specific circumstances as outlined in Rule .0212.

(b): Are there any other factors that you are considering when exercising this discretion? Or is it solely based on the level of radiation? Also, on line 10, what is "it" referring to? What exactly are you exempting? The rule language is not clear.
Response: The primary factor that is considered when exercising discretion to grant an exemption or exception is the radiation dose. "It" refers to the granted exemption. Exemptions may apply to either a machine requirement or operating requirement.

(b): Are exemptions granted by the Commission or the agency?
Response: Agency and it is stated on line 9.

(c)(2): Same question as for other rules – why are X-ray machines and radiation generating devices now being split out? Do you define both terms?

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: To provide clarity to facilities that RGDs are included in these requirements. The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two is broken down in Sections .0500, .0600, and .0800.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0203

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 6: What is the intent of the change here? You are replacing a defined term, "radiation machine," with an undefined term, "X-ray machine". Are "radiation machines" no longer covered under the revised rule? Or are these meant to mean the same thing? It is not clear to me.
Response: A radiation machine is defined in G.S. 104E-5(13) and the statutory definition includes nuclear particles. During a previous comment period, the commentor noted that using the term radiation machines implied that it could relate to sources regulated by the Radioactive Materials Branch. The terms were split to provide better clarity. Industry standards recognize X-ray machines are for diagnostic imaging and RGDs are not.

(a), line 6: Add "or" before "radiation generating device,".
Response: There is already an "or" on line 6.

(a), sentence 2: What is the effect of this sentence? Once a facility registers one device, the entire facility is then considered registered? I don't understand the rule language.
Response: Submitting a registration application for a single X-ray machine or RGD establishes the initial registration for the entire facility. The facility will then receive an invoice to finalize the registration process.

(b)(4): The new web link provided does not work. Please use an existing, active link.
Response: Updated in text.

(c)(1)(A), line 31: Change "<u>device</u>" to "<u>devices</u>".
Response: Updated in text.

(c)(2)(D): Add "made" before "<u>available during …</u>".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(d)(2)(D): Add "when" before "not in use", if that is your intent.
Response: Not necessary.

If this change is not necessary, then how does this differ from (B), which asks for "machine or device location"? How could you provide location for both the "machine" and "the machine not in use" when you are registering one device?
Response: Updated in text.

(e)(3): Change the semi-colon after "location" to a comma.
Response: Not necessary, there are semi-colon after each line.

"location" appears in the middle of a list in the middle of the sentence; it does not appear at the end of the line. Change the comma to a semi-colon.
Updated in text.
(f)(1)(B): Should the "and" at the end of this line be an "or"?
Response: Updated in text.

(h)(1): Add "requirements of the Class for the services provided" after "meets the education". Also consider adding a cross-reference here to the appropriate requirements for clarity.
Response: Updated in text.

(h)(3): Add "documentation of the " before "requirements in …".
Response: Updated in text.

(h)(3): Do you mean, "Subparagraph (h)(1)"? I think there is a typo here.
Response: Updated in text.

(i)(2)(A): For consistency, should this also be updated to "… or the individual responsible for business operations;"?
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0204

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 4: Change "in this Rule" to "required by this Rule".
Response: Updated in text.

(b)(2): Who is the "registrant" in this instance? The "applicant" or the "registered service provider"? It is not clear.
Response: Will it be confusing if we put applicant. It has always been the registrant. Consider registered service provider since they are the ones that usually submit it.

I suggested "applicant" because that is the terminology you use in (b)(1). So I was trying to promote consistency throughout your rule.
Updated in text.
(b)(2): It would be clearer to state, "Shielding design drawings shall be scaled."
Response: Updated in text.

(b)(2)(C): Couldn't this also apply to a structural modification?
Response: Updated in text.

(b)(5), line 29: "dose" of what? Please specify. Also, rule .1601 doesn't specify any limits. Rather, it points to other standards. So the wording used here does not make sense.
Response: Updated in text.

Add "incorporated" before "in Rule .1601".
Updated the text.
(c), line 37: Add a colon at the end of this.
Response: Updated in text.

(c)(2)(A), line 19: Replace "requirements" with "required documentation".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(c)(4), line 2: Add "for use" before "by service providers …".
Response: Updated in text.

(c)(4)(B): Delete the space between ".0203" and "(d)".
Response: Updated in text

(c)(5): Add "covered" before "in Section .0800 …".
Response: Updated in text.

(c)(6): Add "covered" before "in Section .0500 …".
Response: Updated in text.

(d): "Persons" are not registered under Paragraph (c). Paragraph (c) states facility requirements. Please amend the language here as needed.
Response: Updated in text.

(e): Same comment as above. Also, add a space between "Paragraph" and "(c)" on line 28.
Response: Updated in text.

(f): Same comment as (d) and (e).
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0205

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 5: I would recommend deleting, "… of such services …" The person isn't registering the services, correct? The registration would apply to the person.
Response: Updated in text.

(b), line 7: For clarity, you should specify which section(s) of .0203 specifically apply here since that rule contains various different forms.
Response: Depending on the type of service being provided, multiple application forms may apply

(e)(1): Same question as mentioned for other rules regarding the change of "radiation machine" to "X-ray machine".
Response: To provide clarity to facilities that RGDs are included in these requirements. The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two is broken down in Sections .0500, .0600, and .0800.

(e)(3): If you do shielding designs for fluoroscopic X-ray machines, do you need both a Class III and IV registration? If you only need IV, you should state that Class III does not include fluoroscopic X-ray machines.
Response: Fluoroscopic X-ray machines are a subcategory of X-ray machines that produces a higher output of radiation than standard X-ray machines. This requires different calculations for shielding design.

Understood. So then for Class III, you should state, "… except for fluoroscopic X-ray machines;". Otherwise, they are also captured by the

broader category mentioned in (e)(3) and would have to comply with both Classes. Unless you intend for people to have to apply for both classes if they are providing shielding designs for fluoroscopic X-ray machines – then the current language is fine.
Response: Updated in text.

(f), line 35-36: Change "that provide" to "to provide".
Response: Updated in text.

(f)(1), line 2: Change "(E)" to "(D)", based on your updated rule.
Response: Updated in text.

(f)(2), line 4: Change "(B)" to "(C)", based on your updated rule.
Response: Updated in text.

(g)(1): "Dispose" is not a service mentioned anywhere in the Classes in (e). What Class registration would that fall under?
Response: Disposing of machines that no longer produce radiation does not require registration. Updated in text.

Based on your edits, change "machines" on line 7 to "machine".
Updated in text.
(h): You should specify when a registrant is required to use this form. As written, it's not clear.
Response: The form name provides the description of the requirement when an X-ray machines for nonhuman use or radiation generating device are sold or installed.

Right – but when does the form actually need to be submitted to the agency? Is there a deadline? Can they submit it whenever they want? Your rule does not provide a clear process. Also, based on the way you've worded this sentence, the form is not technically required. You can't create a legal requirement just by the name of a form.
Response: Submission of the form has the deadline requirement as (g)(1). Rule (g)(2)(B) references this form. Updated in text.
(i), line 7: Delete "shall" before "meet".
Response: Updated in text.

(j): Change "Rule .0205 of this Section" to "this Rule".
Response: Updated in text.

(k)(1): For consistency, should this say "fluoroscopic X-ray machines"?
Response: Updated in text.

(l)(1): I suggest deleting "legible". This adjective seems to be unnecessary.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0206

DEADLINE FOR RECEIPT: September 18, 2026

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), lines 5-6: Change this sentence to something more direct, like, "The following qualifications shall be met for each service class:".
Response: Updated in text.

(a)(2), lines 12-13: This does not match the language in rule .0205 for Class II. That rule states: "installation, repair, or service …".
Response: Deleted repair in rule .0205 as it is part of the service. Updated in text.

(a)(2)(A): Should this provision start with something like, "completion of"?
Response: Updated in text.

(a)(2)(C), line 19: Delete "are required". This is redundant.
Response: Updated in text.

(a)(3) and (a)(4): If you do shielding designs for fluoroscopic X-ray machines, do you need both Class III and IV training? If you only need IV, you should state that Class III does not include fluoroscopic X-ray machines.
Response: Fluoroscopic X-ray machines are a subcategory of X-ray machines that produces a higher output of radiation than standard X-ray machines. This requires different calculations for shielding design.

Please see my follow-up comment in Rule .0205. You should clarify the two different classes so they don't overlap.
Response: Updated in text.

(a)(3), line 20: Change "machine" to "machines".
Response: Updated in text.

(a)(3)(C): "one year of experience" doing what? Your rule is not clear.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(a)(4)(C): "one year of experience" doing what? Your rule is not clear.
Response: Updated in text.

(a)(6): This does not match the language of Class VI in rule .0205. That rule states: "radiation survey equipment calibrations".
Response: Updated text in rule .0205.

(a)(8): This does not match the language of Class VIII in rule .0205. That rule states: "providing individual monitoring devices".
Response: Updated text in rule .0206

(a)(8), line 15: Change "must" to "shall".
Response: Updated in text.

(a)(9), lines 18-19: For consistency, this should read as: "… general health or medical physics consulting. The applicant shall meet one of the following:"
Response: Updated in text.

(a)(9)(D): Add "degree" after "doctorate".
Response: Updated in text.

(b), line 29: For clarity, I would now replace "prior to the effective date of this Rule" with the intended fixed date.
Response: Updated in text.

The date here should be the date whenever this rule provision first went into effect. Was (b) drafted during the readoption last year? Or has it always been in the rule? I don't think the date you've included is the intended date.
Response: Yes, (b) was drafted during the readoption last year. Year corrected to October 1, 2025.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0207

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), lines 5-6: The description for Class V services here does not match rule .0205. That rule states that Class V includes "area radiation surveys and shielding evaluations for X-ray machines" and that Class IV includes "shielding designs for fluoroscopic X-ray machines". Please clean up this rule so that the two align.
Response: Updated text in rule .0205.

(a), lines 6-7: Same comment for Class VII services. The two rules do not match. Please correct this.
Response: Updated text in rule .0205.

(a)(2): Do they have to follow the manufacturer's recommended frequency if one is provided? If so, you should also state that in your rule.
Response: The agency requires annual calibrations when the manufacture does not provide a frequency. A frequency other than annually will be accepted if stated in the mfg. manual.

You should clarify this point here in your rule. As written, there is no requirement that you perform calibration at the manual's frequency when provided (unless this is included somewhere else in your rules).
Updated in text.

(a)(3)(A), line 15: I think a word is missing here. Consider adding "provided" before "to the employed;".
Response: Updated in text.

(a)(3)(B): This is vague. What is this meant to capture? I think you need some sort of limiting language here. Consider adding, "… in conjunction with the provided services;".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(a)(3)(C), (D), and (E): Isn't this already covered by (B)?
Response: No, these are not the same.

(b)(1): What does "current" mean in this context? "Current" at the time that the service is provided? It is not clear.
Response: Updated in text.

(c), line 29: Delete "radiographic" for consistency.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0211

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 3: "RESPONSIBLE" is spelled incorrectly.
Response: Updated in text.

(a), lines 6-7: Change "actively registered" to "active". The rule is redundant as written.
Response: Updated in text.

(a), line 8: Shall be "on site" when? At all times?
Response: Changed to available.

Did you mean to delete "on site"? If so, also delete "or" before "available".
Updated in text.

(a), line 10: The last sentence should be more direct. Consider something like, "The individual shall meet the following qualifications:".
Response: Updated in text.

(a)(1)-(4): These requirements are vague/generic. Are there objective minimums or standards for these requirements?
Response: These criteria outline the foundational areas of competency required for radiation safety. Actively holding a registered technologist credential from the ARRT serves as an established standard that satisfies these requirements.

(a)(3): Change this to "knowledge of …".
Response: Updated in text.

(a)(4): Same comment as (a)(3) regarding the use of "knowing".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(a)(4): Delete "used" at the end of the sentence. It is redundant.
Response: Updated in text.

(b)(1)(B): Should this say "and" rather than "or"?
Response: No.

(b)(2), line 21: Insert a period after "personnel", delete "and", and capitalize "records".
Response: Updated in text.

(b)(2)(C): What does this provision mean? The wording/grammar makes it very hard to understand what is being required.
Response: Corrected reference to 1001(a)(7).

This doesn't address my concern. (A) and (B) are both past tense verbs, requiring action to be taken on records of monitoring. (C) then starts with "notifications". Does the individual have to make the notification? Or record it? Or something else? What does the actor have to do?
Updated in text.
History Note, page 2, line 4: The most recent date should come first in the line of dates.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0212

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 3: "EMERGING" is spelled incorrectly.
Response: Updated in text.

(b), line 25: Consider adding "proposed" before "user".
Response: Updated in text.

(b), line 25: Change "the" to "an".
Response: Updated in text.

My apologies – the way this was originally written made more sense. Please revert back to "the".
Updated in text.
(b)(5) and (6): Change "to include the following" to "that includes".
Response: Updated in text.

(b)(5)(B): "output" of what?
Response: Added radiation updated text.

(b)(6)(C): I'd recommend deleting "legible".
Response: Updated in text.

This edit is not reflected in the document you provided.
Updated in text.
(b)(8): Which specific rules are you referring to? This requirement is not clear.
Response: Depending on the emerging technology it would need to the equipment requirements in applicable Sections .0500, .0600, and .0800.

Got it. For (b)(7), please change the period at the end to "; and".
Updated in rule.
(c), line 3: Consider adding "proposed" before "user".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(c), line 3: Change "the" to "a".
Response: Updated in text.

My apologies – the way this was originally written made more sense. Please revert back to "the".
Updated in rule.
(c), line 3: Change "requirements" to "required information".
Response: Updated in text.

One follow up. Submit the information to whom for review? Please clarify in the rule.
Updated in rule.
(d), line 5: Change "will respond" to "shall respond".
Response: Updated in text.

(d): What does "allowed for use" mean? Whether the device can be safely operated? The wording here is vague. What exactly are you determining from the information provided? What is the standard for approval? Be clear and specific.
Response: "Allowed for use" means approved for operation in NC. The information provided is used to verify that radiation dose limits for both the operator and members of the public do not exceed established regulatory standards for similar types of X-ray machines or RGDs. This Standard aligns with CRCP Suggested State Regulations.

History Note, page 2, line 15: The most recent date should come first in the line of dates.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0214 (REPEAL)

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

History Note, line 9: Add "2015;" after the deletion.
Response: Updated in text.

The change is not reflected in the document you provided.
Updated in rule.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0301

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 9: "BYPRODUCT" is spelled incorrectly.
Response: Updated in text.

(a)(1): Add a comma after "10 CFR 30.4".
Response: Updated in text.

(b)(4), second sentence: Consider adding: "For the purposes of this Rule, the term …"
Response: Updated in text.

(b)(4), line 24: Change "location(s)" to "locations".
Response: Updated in text.

(b)(19): What does the exception mean here? That Paragraph (c) governs the form and information requirements for applicants? That Paragraph (c) is an additional requirement? It is not clear given what is specified in 10 CFR 30.32.
Response: Paragraph (c) governs the form, submission, and information requirements for applications submitted to the agency. The exception is intended to clarify that, in lieu of NRC Form 313, "Application for Materials License," applicants shall use the applicable North Carolina forms specified in Paragraph (c): the Application for Radioactive Materials License or the Application for Amendment of Radioactive Materials and Accelerator Licenses. Paragraph (c) also specifies the information required by the agency for those applications. Paragraph (c) is not an additional requirement.

Got it. It would then make more sense if this said something like, "… except that applicants shall comply with the application form, information, and submission requirements in Paragraph (c) of this Rule in lieu of the application form and submission requirements in 10 CFR 30.32(a)." Consider revising.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

The rule has been revised to "except that applications shall be submitted to the Agency and the requirements of Paragraph (b)(c) of this Rule shall be met;"

(b)(20), line 10: In the G.S. cite, remove the period after 9.
Response: Updated in text.

(b)(25): Is there a timing requirement for filing once you've hit the 180 day mark?
Response: Yes. The 180-day period is cumulative and does not have to be consecutive. A licensee operating under reciprocity that anticipates using or storing radioactive material in the State for more than 180 days in a calendar year must apply for the appropriate North Carolina license or reapply for reciprocity before exceeding the 180-day limit.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0302

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 3: "BYPRODUCT" is misspelled.
Response: Updated in text.

(b), line 13: Underline "(b)".
Response: Updated in text.

(b)(1): How does this language align with what you've stated in (b)? Consider moving this requirement to its own paragraph. It doesn't really make sense as written.
Response: Thank you for your suggestion. Moved b(1) to another paragraph.

(b)(4), line 23: Change "shall be registered" to "shall register".
Response: Updated in text.

(b)(4), line 25: Add "10 CFR" before "31.5(c)(13)(iii)".
Response: Updated in text.

(b)(12): This should end with a period rather than a semi-colon.
Response: Updated in text.

(c)(10): Add a comma after "date the form is signed".
Response: Updated in text.

History Note, line 26: This entire line should be in underline.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0304

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b), lines 12-13: Rewrite this to state, "… byproduct material as described in 10 CFR 30.14 and 30.18 and incorporated by Rules .0301(b)(11) and .0301(b)(13) of this Chapter, …"
Response: Updated in text.

(b)(2): Add "and" at the end of this provision.
Response: Updated in text.

(c), line 21: "Persons" should not be capitalized.
Response: Updated in text.

(c)(3): How does this work? You regulate the persons under these provisions of the CFR, but the NRC is responsible for issuing licenses?
Response: Yes, these licensees require a possession license issued by North Carolina. The NRC retains licensing authority for the manufacture and initial transfer for commercial distribution of exempt products containing exempt concentrations or exempt quantities of byproduct material. Paragraph (c) incorporates the applicable requirements of 10 CFR Part 32, while Subparagraph (c)(3) clarifies that applications for these manufacture and initial transfer for commercial distribution licenses are submitted to the NRC rather than the agency. North Carolina retains regulatory authority over other activities involving radioactive material within the scope of the State's Agreement State authority.

(g)(3), line 31: Delete the comma after the email address.
Response: Update in text.

(h), line 34: Delete the comma after the email address.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(h)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(h)(1)(E): The language used here is inconsistent with the rest of the list. Consider stating, "indication if the application is for …".
Response: Updated in text.

(h)(1)(F): Similar comment as (E). Consider deleting "shall be provided on the application". It makes the rule redundant.
Response: Updated in text.

(h)(1)(G): The language used here is inconsistent with the rest of the list. Consider stating, "indication of the type and category …".
Response: Updated in text.

(h)(2)(G): The language used here is inconsistent with the rest of the list. Consider stating, "a description of …". Delete "applicants shall provide".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0305

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

General Comment: In your forms rules, you state, "The instructions for completing the application printed on the application form shall be followed." What exactly do those instructions say? Are you requiring documentation or other actions? If so, you should state them in your rule as requirements rather than making this vague reference back to the form. Otherwise, you could change information requirements while circumventing the rulemaking process.

Response: The application form instructs applicants to complete Items 1 through 5 and to use additional sheets as necessary. These information requirements are stated in the Rule. The form further directs applicants to consult the appropriate licensing guide for information that must accompany the completed application. The requirement to submit supporting documents is already established in Part (c) of this Rule.

An application for a specific license will be approved if it is for a purpose authorized by the Agreement (activities authorized by 10 CFR Parts 30–37, 39, 40, 61, or 70); if the applicant's proposed equipment and facilities adequately protect health and minimize danger to life or property; if the applicant is qualified by training and experience to use the material safely; and if the applicant satisfies all applicable requirements in 10 CFR Parts 30–37, 39, 40, or 70. Licenses for low-level radioactive waste disposal sites must also meet the requirements in 10 CFR Part 61 and N.C.G.S. 104E.

The form refers applicants to the applicable licensing guide for guidance on the supporting documentation used to demonstrate compliance with these requirements. The agency relies on the NUREG-1556 series to help applicants identify documentation that may be used to show compliance with the licensing requirements established by the rules and incorporated federal regulations. The licensing guides do not independently establish substantive regulatory requirements.

The form includes a certification requirement and references other applicable regulatory provisions, including 10A NCAC 15 .1700. The

certification requirement is expressly stated in the Rule, and the reference to Section .1700 simply alerts applicants to additional requirements that may apply elsewhere in this Chapter.

Title, line 3: "DOMESTIC" is misspelled.
Response: Updated in text.

(a)(1): Add "and" at the end of this provision.
Response: Updated in text.

Line 9: I believe a struck through "(a)" is missing at the beginning of this line.
Response: Updated in text.

(b)(3): What does the end of this mean? Is Paragraph (c) an additional requirement or a substitute? Be clear and specific.
Response: Paragraph (c) establishes the State-specific application process for licenses issued by the agency. Applicants remain subject to the applicable requirements of 10 CFR 33.12 and 10 CFR 30.32; however, in lieu of NRC Form 313 and submission to the NRC, applicants shall use the applicable North Carolina application form and submit the application and required supporting information to the agency in accordance with Paragraph (c).

Replaced *(b)(3):* 10 CFR 33.12, "Applications for specific licenses of broad scope," except that applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (c) of this Rule;

(c), line 21: Remove the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses". Also, on lines 28 and 29, do you mean "will be used" rather than "shall be used"?
Response: Updated in text.

(c)(1)(E): The language here does not match the rest of the list. Consider stating, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): The language here does not match the rest of the list. Consider stating, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): The language here does not match the rest of the list. Consider deleting "applicants shall provide ".

Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0306

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(1): Remove the comma after "and".
Response: Updated in text.

(c), line 15: Remove the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B): Do you mean "will be used" rather than "shall be used"? This applies to both lines 21 and 22.
Response: Updated in text.

(c)(1)(E): The language here is inconsistent with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): The language here is inconsistent with the rest of the list. Consider starting this with, "indication of the type and category of …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

(c)(3): Add a period at the end of this. Also, the link here does not work. Please update.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(f): This provision is not clear. What exactly are you requiring? That a form must be submitted per the instructions in (c)? Also, you should specify whether (c)(1) or (c)(2) applies, since they contain different information requirements.

Response: The agency agrees that the provision was unclear. Paragraph (f) has been revised to clarify that a request for exemption from the rules under 10 CFR 34.111 shall be submitted with the applicable application required by Paragraph (c)(1) or (c)(2) of this Rule, as appropriate. Licensees can request exemption from the rules as part of a new application or existing application.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0307

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b): What does it mean to "comply with the general information requirements" of these regulations? This language is not clear. Are you limiting the scope of what is required?
Response: Thank you the phrase "general information requirements" was unclear. Paragraph (b) has been revised to state that persons shall comply with the following requirements of Subpart A to 10 CFR 35.

(b)(8): Is Paragraph (n) a substitute or an additional requirement? Your rule is not clear.
Response: Reworded*(b)(8):* 10 CFR 35.12, "Applications for specific licenses of broad scope," except that applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (n) of this Rule;

(c)(3), line 33: Delete "(3)".
Response: Updated in text.

(c)(3): Replace "within three years of the effective date of this readopted Rule" with the actual intended date.
Response: "(3)" has been deleted and the provision has been revised to state the specific date of May 1, 2027

(d), line 15: What is an "authorized user"? Is this defined somewhere?
Response: "Authorized user" is defined in 10 CFR 35.2, which is incorporated by Subparagraph (b)(2) of this Rule.

Consider capitalizing this since it is a defined term.
Updated in text.
(d), line 15: Delete the comma after "include" and add "the following".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(d)(5): Delete the comma after "patient care".
Response: Updated in text.

(e)(5): Change "of this Paragraph." to "of this Rule."
Response: Updated in text.

(h)(11): Change this to something like, "activities covered by the CFR provisions listed in Subparagraphs (h)(6) and (h)(7) of this Rule shall be …".
Response: Updated in text. Subparagraph (h)(11) has been revised to clarify that activities covered by the CFR provisions listed in Subparagraphs (h)(6) and (h)(7) of this Rule shall be approved by an authorized medical physicist.

(h)(11): What is an "Authorized Medical Physicist"? Authorized by whom?
Response: "Authorized medical physicist" is defined in 10 CFR 35.2, which is incorporated by Subparagraph (b)(2) of this Rule.

(l): Is there a time limit for "maintaining" records?
Response: Yes. The applicable retention periods are specified in the individual recordkeeping provisions of Subpart L to 10 CFR 35 incorporated by this Rule. The retention periods vary depending on the type of record.

(n), line 25: Remove the comma before "or".
Response: Updated in text.

(n)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(n)(1)(B): Do you mean "will be used" rather than "shall be used"? This applies to both lines 31 and 32.
Response: Updated in text.

(n)(1)(E): The language here is inconsistent with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(n)(1)(F): Delete "shall be provided on the application".
Response: Updated in text.

(n)(1)(G): The language here is inconsistent with the rest of the list. Consider starting this with, "indication of the type and category of …".
Response: Updated in text.

(n)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

History Note, page 8, line 2: "2014;" should be "2024;".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0308

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b)(2): You state, "except that references to common defense and security shall not apply". What does this mean? Is something else substituted for these terms? Are these words just to be totally disregarding in the regulations? Your rule is not clear.
Response: The references to common defense and security are not replaced with another term or requirement. The NRC retains regulatory authority, and common defense and security are under exclusive federal jurisdiction. Therefore, those portions of the incorporated definitions do not apply to the agency's regulation under this Rule. Subparagraph (b)(2) has been revised to clarify that the provisions relating to common defense and security do not apply.

There is no revision to subparagraph (b)(2) in the document that you provided.
Common defense and security remains under NRC jurisdiction.

(b)(3): Is Paragraph (c) meant to be a substitute for application requirements? Or additional requirements that must also be met? Your rule is not clear.
Response: Paragraph (c) establishes the State-specific application forms and submission requirements in lieu of the NRC Form 313 and submission requirements in 10 CFR 36.11. Subparagraph (b)(3) has been revised to clarify that applications shall be submitted to the agency in accordance with Paragraph (c) of this Rule.

There is no revision to subparagraph (b)(3) in the document that you provided.
The rule has been revised to "except that applications shall be submitted to the Agency and the requirements of Paragraph (b)(c) of this Rule shall be met;"

(c), line 8: Delete the comma before "or".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B), lines 14 and 15: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".

Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0309

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(3): The mentioned language is not a sentence. I would recommend changing "sentence" to "language".
Response: Updated in text. Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

Special Nuclear Material" has been changed to "special nuclear material" for consistency with the other defined terms in the Rule.

(a)(3), line 11: In the G.S. citation, please delete the period after "5".
Response: Updated in text.

This update is not reflected in the document you provided.
Updated in text.
(a)(4): Add "10 CFR" before you start listing out the regulations.
Response: Updated in text.

(a)(18): Is Paragraph (c) a substitute for the application requirements? Is it an additional requirement that has to also be met? Your rule is not clear.
Response: This comment to refers to Subparagraph (b)(18). Paragraph (c) establishes the State-specific application form and submission requirements in lieu of the NRC-specific application form and submission requirements in 10 CFR 40.31. Subparagraph (b)(18) has been revised to clarify that applications shall be submitted to the agency in accordance with Paragraph (c) of this Rule.

Please delete "shall be met" on line 7. It is now redundant with the other edits made here. Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(a)(18), line 6: In the G.S. citation, please delete the period after "9".
Response: Updated in text.

(a)(19), line 11: Same comment as noted above.
Response: Updated in text.

(c), line 6: Delete the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B), both lines: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0310

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(3): "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is not a sentence. Also, what is it preserved from? Be clear and specific. As written, it's hard to understand what exactly you're trying to do here. Consider something like, "As preserved in G.S. 104E-5(16), the Commission retains primary authority to declare any other materials as special nuclear material."
Response: Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

Special Nuclear Material" has been changed to "special nuclear material" for consistency with the other defined terms in the Rule.

(a)(3), line 11: In the G.S. citation, please delete the period after "5".
Response: Updated in text.

This update is not reflected in the document you provided.
Updated in text.
(a)(14): Is Paragraph (c) a substitute for the application requirements? Is it an additional requirement that has to also be met? Your rule is not clear.
Response: Paragraph (c) establishes the State-specific application form and submission requirements in lieu of the NRC-specific filing requirements addressed by 10 CFR 70.21. Subparagraph (a)(14) has been revised to clarify that applications shall be submitted to the agency in accordance with Paragraph (c) of this Rule.

(c), line 20: Delete the comma before "or".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B), lines 26 and 27: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.
(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0311

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(1): You are missing a comma after "71.5".
Response: Updated in text.

(a)(1): Replace "10 CFR 71.101(c)(1)" with "and 71.101(c)(1)".
Response: Updated in text.

(a)(2): What does this replacement mean? The "Agency" is not used in those regulations. I cannot tell what this provision is meant to do.
Response: Subparagraph (a)(2) was unclear. The provision has been revised to clarify that, in 10 CFR 71.8(b) and (d), references to the NRC with respect to quality assurance program approval mean the Agency.

Line 11: You are missing a struck through "(a)" here.
Response: Updated in text.

(b), line 13: This should end with a colon rather than a semi-colon.
Response: Updated in text.

(b)(7): Same comment as noted for (a)(2).
Response:

(b)(12), line 31: Change "Subparagraph (2) of this Paragraph" to "Subparagraph (b)(2) of this Rule".
Response: Subparagraph (b)(7) was unclear. The provision has been revised to clarify that, in 10 CFR 71.8(a)(3) references to the NRC with respect to quality assurance program approval mean the Agency.

The requested change to (b)(12) is not complete in the document you provided. Change "of this Paragraph" to "of this Rule". Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(b)(12), line 32: Add "10 CFR" before "71.17(c)(3)".
Response: Updated in text.

(b)(13), line 35: You are missing a parenthesis around "(b)".
Response: Updated in text.

Page 3, line 7: This should be updated to "(c)".
Response: Updated in text.

This update is not reflected in the document you provided.
Updated in text.
Page 3, line 17: This should be updated to "(d)".
Response: Updated in text.

This update is not reflected in the document you provided.

Updated in text.
Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0313

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(3), lines 11-13: "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is not a sentence. Also, what is it preserved from? Be clear and specific. As written, it's hard to understand what exactly you're trying to do here. Consider something like, "As preserved in G.S. 104E-5(16), the Commission retains primary authority to declare any other materials as special nuclear material."
Response: Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

(a)(3), line 11: Why is "Special Nuclear Material" all capitalized? You do not capitalize other defined terms in this rule.
Response: Updated in text.

(a)(3), line 13: Delete the period between "5" and "(16)" in the citation.
Response: Updated in text.

This change is not reflected in the document you provided.
Updated in text.
(a)(7), line 23: Replace "material," with "material;".
Response: Updated in text.

(a)(8), line 24: Replace "material;" with "material."
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1203

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b), line 7: Above, you use "Agency" to refer to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section, as defined in 10A NCAC 15 .0103. However, beginning here and continuing intermittently through the Rule, you use "Department", which in G.S. 104E-5 is defined as Department of Health and Human Services. Ensure that your use of the two terms is consistent with your intent. Going back and forth between both can cause confusion.
Response: The use of "Department" and "Agency" is intentional. "Department" refers to the North Carolina Department of Health and Human Services and is used where the applicable statutory provisions assign authority to the Department, including the issuance of licenses for land disposal of low-level radioactive waste. "Agency" refers to the Radiation Protection Section, as defined in Rule .0103 of this Chapter, and is used for regulatory functions administered by the Section. The Rule has been reviewed to ensure that each term is used consistently with this distinction.

(b)(2): For clarity, consider writing this to end with, "… unless a written authorization has been issued by the agency to the recipient."
Response: Updated in text. Subparagraph (b)(2) has been revised for clarity

(b)(3), line 14: Delete "which".
Response: Updated in text.

(b)(3), line 19: Replace ".0111" with ".0111(a)" for consistency and clarity.
Response: Updated in text.

(b)(4): "Shall be met" by who and under what circumstances? Be clear and specific.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: The provision was unclear. Subparagraph (b)(4) has been revised to clarify that applicants and licensees shall comply with the applicable requirements under the cited statutory provisions.

Delete "shall be met" on line 23. It is now redundant given the changes made. Updated in text.

(b)(5): "Shall apply" to who or what? To licensees?

Response: Subparagraph (b)(5) has been revised to clarify that the definitions in G.S. 104E-5 apply to the interpretation and application of this Rule.

(c)(1): Same comment as above for (b)(2).

Response: Subparagraphs (c)(1) has been revised for clarity.

The revisions to the sentence do not make sense as written. Please reconsider this and revise as needed.

Rule has been revised for clarity.

"not granted a low-level waste facility access license by the agency" was initially added to address the requested revision; however, because this language was never published and only appeared in materials submitted for review, we are removing it.

(c)(2): Same comment as above for (b)(5).

Response: Subparagraph (c)(2) has been revised to clarify that the definitions in G.S. 104E-5 apply to the interpretation and application of this Rule.

(c)(3), line 33, and (c)(4), page 2, line 6: "Prevent" means to stop while "minimize" and "reduce" both mean to decrease. They are two different things that can't simultaneously be expected. Do you expect them to completely prevent or only decrease? Revise the language here to most clearly convey the expectation.

Response: Generators, waste brokers and waste processors shall develop procedures and implement practices to prevent, minimize, and reduce the generation of low-level waste as required by G.S. 104E-27(a). These procedures shall include segregating waste by half-life and holding low-level radioactive waste for decay in storage.

The rule remains unchanged. In the language of the general statue includes prevention, minimization and reduction.

(d)(1)(B): Replace "address(es)" with "addresses".

Response: Updated in text.

(d)(1)(B), lines 22 and 23: Should "shall be used" be changed to "will be used"?

Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(d)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(d)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(d)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(d)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

(d)(3): Include the web address to locate the form, if possible.
Response: Updated in text.

(e): Is this necessary? What is the purpose of this paragraph?
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1301

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(c)(1), line 32: Rather than adding " under 10 CFR 39.91" on line 32, consider revising the first sentence to state: "Persons applying for new radioactive materials licenses, ~~or~~ for the renewal of existing radioactive materials licenses, or for exemptions from this Rule, shall submit …". I think this would be much clearer given the revisions you've made in paragraph (f).
Change made to the rule as requested.

(c)(1)(B): Replace "address(es)" with "addresses".
Response: Updated in text.

(c)(1)(B), lines 34 and 35: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

(c)(3): The web link is no longer effective. Please update.
Response: updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(e), page 3, line 2: Change ".0111" to ".0111(a)" for consistency.
Response: Updated in text.

(f): Do you have any requirements for exemption applications? Or is this an informal process? Your rule does not provide any sort of standard or process. Is there something you could cross-reference here?

Response: The provision was unclear. The standards for granting an exemption are provided in 10 CFR 39.91. Paragraph (f) has been revised to cross-reference 10 CFR 39.91 and specify that exemption applications shall be submitted to the agency in accordance with Rule .0111(a) of this Chapter.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1601

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 7: Remove the repetition of "and to effectuate their joint enforcement,".
Response: Updated in text.

(a)(1), line 9: Add "10 CFR" before "20.1003".
Response: Updated in text.

(a)(1), line 10: Change "Agency," to "Agency;".
Response: Updated in text.

(a)(2): "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is not a sentence. Also, what is it preserved from? Be clear and specific. As written, it's hard to understand what exactly you're trying to do here. Consider something like, "As preserved in G.S. 104E-5(16), the Commission retains primary authority to declare any other materials as special nuclear material."
Response: Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

Special Nuclear Material" has been changed to "special nuclear material" for consistency with the other defined terms in the Rule.

On line 14, please remove the period after "5" in the G.S. citation.
Updated in text.
(b)(61), page 3, line 21: Add "of" between "individuals" and "exceeding." The CFR title is "Reports to individuals of exceeding dose limits".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(b)(63), page 3, line 26: You refer to Subparagraph (a)(6) of this rule, but this rule does not have an (a)(6). Do you mean (b)(6)?
Response: Updated in text.

(c): What is a "personnel monitoring device"? Is it defined in another rule or statute that can be referenced? Exposure to what, by whom, and what is the deception? This Paragraph needs context and clarity.

Response: The provision was unclear. Paragraph (c) has been revised to use the term "individual monitoring device" as defined in 10 CFR 20.1003 and to clarify that no person may intentionally expose such a device to radiation for the purpose of causing it to indicate a dose not received by the individual to whom the device is assigned.

(d), first sentence, lines 12-13: Something is missing in this sentence. Consider, "… all activities required by the rules of this Chapter, and any license or registration conditions imposed by the agency, and shall pay …".
Response: The first sentence of Paragraph (d) has been revised to clarify that licensees and registrants shall continue to perform activities required by the rules of this Chapter and applicable license or registration conditions until termination.

Consider adding back in "until the license or registration is terminated." Your revisions took this out of the rule text and did not add it back in.
Thank you for your comment. Since the original text was struck out as part of the revision, and this language was never published we are removing the strikeout and highlighting.

(d), line 13: Consider referencing your fee rule(s) here for clarity.
Response: Paragraph (d) has been revised to cross-reference the annual fee requirements in Section .1100 of this Chapter

(e): Why is this paragraph needed? What is it doing?
Response: Paragraph has been removed.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1701

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(1): Add "and" to the end of this.
Response: Updated in text.

(d): For consistency, change "The Code of Federal Regulations incorporated by this Rule" to "Copies of these regulations".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

10A NCAC 15 .0103 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0103 DEFINITIONS

(a) As used in the rules of this [~~Chapter,~~] Chapter and as applied to 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 the 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.~~] "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).

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

[~~"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~~] a.m. January 1 to 11:59:59 [~~pm~~]p.m. 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.~~] except where otherwise defined in the rules of this Chapter.

(10) "Department" has the meaning as defined in G.S. 104E-5(6) [~~except as stated in Paragraph (c) of this Rule.~~] except where otherwise defined in the rules of this Chapter.

(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~~] 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~~] 15 of this Title.

(b) As used in the rules of this [~~Chapter,~~] Chapter and as applied to 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,~~] building or one vehicle at one address 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~~] diagnosis 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~~] or 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)~~](10)"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 .0209 of this Chapter.

~~["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.]~~

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

(12) "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.

[~~"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 .0209 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)~~] .0205(e) 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~~.1700, [~~1900,~~] .1900, and .2000 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.*~~*2025;*
Amended Eff. October 1, 2026.

10A NCAC 15 .0104 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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.~~

The "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, hereinafter known as the "Agreement," is [~~hereby~~] incorporated by reference including subsequent amendments and editions. A copy of the Agreement is available free of charge at https://www.nrc.gov/cdn/nmss/pdf/ncagreements.pdf.

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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0201 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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

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

10A NCAC 15 .0201 PURPOSE AND SCOPE

(a) This Section provides for the registration of ~~radiation~~ X-ray machines, radiation generating devices, facilities, and persons providing other [~~radiological~~] radiologic services.

(b) A person who acquires, owns, possesses, or receives ~~a radiation machine or~~ an X-Ray [~~machine,~~] machine or a radiation generating ~~device~~ [~~devices,~~] device, or provides other radiologic services 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 that use [~~using~~] ~~radiation machines~~ an X-Ray machine [~~machine,~~] or a radiation generating device for demonstration [~~purposes~~] purposes, or that provide mobile leasing ~~services~~ services, are subject to the additional requirements of Rule .0205 of this Section. Service providers that provide those services by bringing ~~radiation machines~~ an X-ray machine 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~~ X-ray 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~~ Industrial radiographic X-ray machines are subject to the additional requirements of Section .0500 of this Chapter.

(g) ~~Registrants using~~ ~~radiation~~ X-ray machines for ~~human~~ diagnostic imaging and veterinary use are subject to the additional requirements in Section .0600 of this Chapter.

(h) ~~Registrants using radiation~~ X-ray machines for ~~non-human use~~ non-diagnostic imaging at educational facilities, ~~for forensic medicine,~~ for clinical studies, or [~~by service providers for demonstration purposes~~] for demonstration purposes conducted by service providers, are subject to the additional requirements of Section .0600 of this Chapter.

(i) ~~Registrants using ionizing radiation~~ Radiation generating devices and X-ray machines for non-human use and non-veterinary use are subject to the additional 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, 2026; October 1, 2025.

10A NCAC 15 .0202 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0202 EXEMPTIONS

(a) Electronic equipment that produces radiation incidental to its operation [~~for other purposes~~] is exempt from the registration and notification requirements of this ~~Section~~ Section, provided that the dose equivalent rate [~~average~~] averaged 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 agency may, upon application, [~~application therefore,~~] grant individual exemptions or exceptions from the requirements of these Rules if it will not result in radiation dose or contamination that exceeds the limits prescribed in these Rules for the protection of public health, safety, or property.

~~(b)~~(c) The following are exempt from the requirements of this Section:

(1) all radioactive materials; and

(2) ~~radiation~~ X-ray machines or radiation generating devices 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0203 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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~~ X-ray machine, radiation generating device, or an unregistered service ~~provider,~~ 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~~ X-ray 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~~ The owner or the individual responsible for the business operations of a facility with an X-ray machine, radiation generating device, or who ~~is responsible for providing~~ provides radiological services, shall ensure that 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) are 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,~~ radiological 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.~~ https://radiation.ncdhhs.gov/Xray/applic.htm and https://radiation.ncdhhs.gov/Xray/service.htm.

(5) The owner or individual responsible for business operations can designate a responsible person or persons within the organization to sign when amendments are made to forms by notifying the agency in writing.

(c) A Business Application form shall be submitted prior to the operation of a facility or providing services in this ~~State~~ 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~~ X-ray machines or radiation generating [~~device~~] devices at a facility; or

(B) that plans to engage in radiological 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,~~ number, and type of ~~business, days and hours of operation;~~ business;

(C) the name, title, mailing address, phone, and e-mail address of the 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;~~ made available during inspection or upon request by the agency;

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

~~(F) description of facility use;~~

~~(G) description of service provider equipment~~;

~~(H)~~(F) dated and signed by the owner or the individual ~~with administrative control; and~~ responsible for business operations.

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

(d) ~~A Radiation~~ An X-ray 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~~ X-ray 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~~ X-Ray machines or radiation generating devices at a facility; or

(B) that is engaged in leasing or performing demonstrations using an unregistered ~~radiation~~ X-Ray 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 the machine or device when not in use;

(E) installer information; and

(F) ~~shall be~~ dated and signed by the ~~individual with administrative control.~~ owner or individual responsible for business operations. ~~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~~ an X-ray Machine or Radiation Generating Device Form shall be submitted when a facility disposes of ~~a radiation~~ an X-ray 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,~~ relocation, or to update information;

(3) ~~radiation~~ X-ray machine or radiation generating device [~~location;~~] location, manufacturer, ~~model,~~ model and serial number;

(4) identify the ~~reason for~~ method of disposal of the ~~radiation~~ X-ray machine or radiation generating device;

(5) ~~the~~ recipient of the ~~radiation~~ X-ray machine or radiation generating ~~device, to the individual or business name,~~ device, physical and e-mail address, and phone number; and

(6) dated and signed by the owner or the individual ~~with administrative control~~ responsible for business operations of the ~~radiation~~ X-ray 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~~ X-ray machines or radiation generating devices;

(B) providing individual monitoring devices; [~~and~~] or

(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~~ dated and signed by the owner or the individual ~~with administrative control.~~ responsible for business operations.

(g) A Company Employee Services Application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through ~~(H)~~ (G) 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;~~ X-ray machines;

(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~~ X-ray machines or radiation generating devices;

(E) qualified expert consulting services for CT and mammography ~~radiation~~ X-ray machines;

~~(F) radiation protection expert;~~

~~(G)~~(F) shielding designs for ~~diagnostic radiographic and fluoroscopy~~ ~~facilities;~~ X-ray machines; and

~~(H)~~(G) therapeutic ~~facility~~ shielding ~~design, area radiation survey, or calibration.~~ verification and area radiation surveys.

(2) The application requires the following information:

(A) name of the employee to be registered;

(B) start date if the employee is being ~~added~~ 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 owner or the individual ~~with administrative control;~~ responsible for business operations; 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,~~] education requirements of the Class for the services provided, 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 documentation of the requirements in Subparagraph [~~(1)(h)~~] (h)(1) 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~~ involving X-ray 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;~~] responsible for business operations;

(B) submit to the agency, a Disposal of ~~a Radiation~~ an X-ray 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~~ an X-ray 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0204 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0204 FACILITY RESPONSIBILITIES

(a) All forms [~~in~~] required by 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~~ X-ray machines for human, non-human, or veterinary use and prior to structural modification of existing installations, an ~~applicant,~~ applicant shall have the floor plans, shielding specifications, and equipment arrangement reviewed by a registered service provider.

(2) The [~~registrant~~] applicant shall submit ~~the~~ a shielding design and the agency Shielding Design Review Form to the agency for review. Shielding design drawings shall [~~include a scaled drawing.~~] be scaled. The ~~agency form~~ Shielding Design Review Form shall include the following information:

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

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

(C) proposed date of [~~installation.~~] installation or structural modification.

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

(4) ~~A radiation~~ An X-ray 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~~ X-Ray 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 radiation dose that exceeds the limits incorporated 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~~ X-ray absorptiometry (DEXA);

(C) mammography; or

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

(c) Facility [~~registration~~] registration:

(1) Mobile ~~radiation~~ X-ray machines located and used in this ~~State that are fixed in~~ State, and permanently affixed within a vehicle or ~~trailer~~ trailer, shall meet the following requirements prior to use:

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

(B) have ~~a Radiation~~ an X-ray Machine Application ~~or a Radiation Generating Devices Application~~ form submitted in accordance with Rule .0203(d) of this Section. ~~Radiation~~ X-ray machines leased or on loan from a registered service provider shall ~~register the radiation machine~~ be registered with the agency if ~~used~~ maintained for more than 30 days;

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

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

~~(E)~~(D) an individual ~~with administrative control~~ responsible for business operations shall ensure that ~~radiation~~ X-ray machines are operated in accordance with Section .0600 of this Chapter.

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

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

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

(C) an individual responsible for business operations shall ensure that X-ray machines are operated in accordance with Section .0600 of this Chapter.

(3) Mobile radiation generating devices located out-of-state and brought into this State for use shall meet the following requirements prior to use:

(A) have a Radiation Generating Devices Application form submitted in accordance with Rule .0203(d) of this Section. Radiation generating devices leased or on loan from a registered service provider shall be registered with the agency if maintained for use for more than 30 days;

(B) have a copy of the operating and safety procedures describing how to protect operators and the public from radiation submitted to the agency;

(C) submit a written notice, in accordance with Rule .0208 of this Section, and maintain it for agency review during inspection; and

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

~~(3)~~(4) ~~Radiation~~ X-ray machines for ~~human, non-human,~~ diagnostic imaging, non-diagnostic imaging, clinical studies, ~~or~~ veterinary ~~use~~ use, or for use by service providers for demonstration purposes shall meet the following additional requirements:

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

(B) submit ~~a Radiation~~ an X-ray Machine Application form in accordance with Rule [~~.0203 (d)~~] .0203(d) of this Section within 30 days of ~~use.~~ use; and

(C) an individual ~~with administrative control~~ responsible for business operations shall ensure that X-ray machines are operated in accordance with Section .0600 of this Chapter.

~~(4)~~(5) Radiation generating devices covered in Section .0800 of this Chapter shall meet the following additional requirements prior to use:

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

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

~~(5)~~(6) Industrial radiography ~~radiation~~ X-ray machines covered in Section .0500 of this Chapter shall meet the following additional requirements prior to use:

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

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

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

(e) [~~Persons~~] Facilities registered pursuant to [~~Paragraph(c)~~] 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~~] facility 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0205 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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,~~ State 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~~ X-ray machines or radiation generating devices;

(2) Class II – [~~installation, repair,~~] installation or service of the following:

(A) ~~radiation~~ X-ray 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;~~ [~~X-ray machine:~~] X-ray machines except fluoroscopic X-ray machines:

(4) Class IV - shielding designs for ~~diagnostic fluoroscopy facilities;~~ fluoroscopic X-ray machines;

(5) Class V - area radiation surveys and shielding evaluations for ~~diagnostic radiographic and fluoroscopy facilities;~~ [~~X-ray machines;~~] radiographic and fluoroscopic X-ray machines:

(6) Class VI - radiation [~~survey equipment~~] instrument calibrations;

(7) Class VII - therapeutic ~~facility~~ shielding ~~design, area radiation survey, or verification;~~ verification [~~and area surveys;~~] services;

(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~~ X-ray machines that are ~~fixed in~~ permanently affixed within a vehicle or trailer for demonstration purposes or to [~~that~~] ~~provides~~ provide leasing services shall meet the following requirements prior to use:

(1) mobile ~~radiation~~ X-ray machines located and used in this State shall meet the requirements of Rules .0204(c)(1)(A) through [~~(E)~~] (D) of this Section; and

(2) mobile ~~radiation~~ X-ray machines located out of state and brought into this State for use shall meet the requirements of Rules .0204(c)(2)(A) and [~~(B)~~] (C) of this Section.

(g) Report of installation:

(1) Persons registered pursuant to Paragraph (a) of this Rule who sell, install, transfer, lease, or lend [~~lend, or dispose of~~] ~~radiation~~ an X-ray [~~machines~~] machine or radiation generating [~~devices~~] device in this State shall, within ~~15~~ 30 days after each calendar quarter, notify the agency at ~~XrayNORS@dhhs.nc.gov~~ fda2579@dhhs.nc.gov or the address, in accordance with Rule .0111 of this Chapter, of the following:

(A) whether any ~~radiation~~ X-ray machines or radiation generating devices 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~~ X-ray machine or radiation generating devices 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~~ X-ray machine or radiation generating devices 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~~ 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~~ X-ray machines for nonhuman use and radiation generating devices, when a Report of Sale and Installation Form prepared in accordance with Paragraph ~~(i)~~ (h) of this Rule is received by the agency.

(h) Upon the sale or installation of an X-ray machine for nonhuman use or a radiation generating device, the applicant shall submit A Report of Sale and Installation in accordance with (g)(1). ~~of~~ ~~radiation~~ [~~X-ray~~] ~~machines for nonhuman use or radiation generating devices~~ This form 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~~ X-ray 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 the 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~~ X-ray machines, ~~radiation~~ X-ray machine components, or radiation ~~machine~~ generating devices unless such machines and ~~devices~~ devices, when placed in ~~operation~~ operation, [~~shall~~] meet the requirements of these Rules.

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

(k) ~~Tests~~ Records of tests performed at the time of installation ~~demonstrating~~ that demonstrate the requirements of these Rules are ~~met,~~ met shall be provided to the registrant for agency review during inspection for the following:

(1) ~~fluoroscopy~~ fluoroscopic X-ray machine output measurement; and

(2) radiation generating devices equipment surveys.

(l) Records of any routine maintenance, repair, alterations, or reassembly of ~~radiation~~ X-ray 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0206 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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 shall be met for each service class:

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

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

(A) completion of manufacturer's equipment school for service, maintenance, and installation for the type of ~~radiation~~ X-ray machine or ~~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~~ X-ray machines, radiation generating devices, and machine components. [~~components~~] ~~services [are required.~~]

(3) Class III - shielding design for ~~diagnostic radiographic facilities:~~ [~~X-ray machine:~~] X-ray machines except fluoroscopic X-ray machines:

(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 shielding design experience ~~in diagnostic radiographic facility and shielding~~ for each type of machine ~~application.~~ modality.

(4) Class IV - shielding design for ~~diagnostic fluoroscopic facilities:~~ fluoroscopic X-ray machines:

(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 shielding design experience ~~in diagnostic fluoroscopic facility and shielding~~ for each type of machine ~~application.~~ type.

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

(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.~~ modality.

(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:~~ verification and area surveys:

(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,~~ 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:~~] devices: The applicant [~~must~~] shall 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~~] consulting. The applicant shall meet ~~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~~ X-ray and radium physics; or

(D) hold a master's or doctorate degree 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~~ X-ray physics.

(b) Any person registered to provide Class IX services prior to [~~the effective date of this Rule~~] October 1, 2025, 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0207 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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,~~ measurements and equipment surveys, Class V area radiation surveys and shielding evaluations for ~~diagnostic~~ radiographic and ~~fluoroscopy facilities,~~ fluoroscopic X-ray machines, or Class VII therapeutic area radiation survey or shielding 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;~~] manufacturer. A frequency other than annually will be accepted if stated in the manufacturer manual.

(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~~ surveys, including a list of all guides and references provided to the employed;

(B) a copy of all forms, reports, and documents that will be supplied [~~to registrants;~~] in conjunction with the provided services;

(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 at the time that the service is provided 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,~~ X-ray machines, Class IV shielding designs for ~~diagnostic fluoroscopy facilities,~~ fluoroscopic X-ray machines, and Class VII therapeutic ~~facilities and~~ shielding design verification 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 verification 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0211 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0211 THE INDIVIDUAL [~~REPSONSIBLE~~] 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~~ who can be an [~~actively registered~~] active ~~radiologic technologist,~~ Registered Technologist (RT) by the American Registry of Radiologic Technologists (ARRT), shall be on site or available at all times and be qualified by reason of education, training, and experience. Records of this individual's education, training, and experience shall be available for review during inspections or upon request by the agency. The individual shall meet the following [~~are the minimum qualifications that must be met to carry out the job duties:~~] qualifications:

(1) training in basic radiation protection principles;

(2) completed educational courses relating to ionizing radiation;

(3) [~~know~~] knowledge of potential radiation hazards and emergency precautions; and

(4) training and experience in and [~~knowing~~] knowledge of the proper use of the type of equipment. [~~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~~ occur, to ensure the procedures are current.

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

(A) reviewed;

(B) maintained; and

(C) notifications [~~made~~] reported in accordance with Rule [~~.1601~~] .1001(a)(7) 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~~ 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, 2026; October 1, 2025.

10A NCAC 15 .0212 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0212 [~~EMERGEING~~] EMERGING TECHNOLOGIES NOT MEETING EXISTING EQUIPMENT REQUIREMENTS

(a) ~~Radiation~~ X-ray machines or radiation generating devices that do not meet the ~~radiation~~ X-ray machine or radiation generating device 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~~ X-ray machine or radiation generating device and determining if the use of the ~~radiation~~ X-ray machine or radiation generating device 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) The proposed user or manufacturer of the X-ray 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's manual;

(3) description of intended use;

(4) operator training provided to the end user;

(5) an independent equipment survey [~~to include the following:~~] that includes:

(A) all equipment settings available to the operator;

(B) radiation output at the highest setting; and

(C) leakage radiation around the X-ray machine.

(6) an area survey [~~to include the following:~~] that includes:

(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 X-ray [~~machine.~~] machine; and

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

(c) The proposed user or manufacturer of the radiation generating device shall submit the [~~requirements~~] required information in Rule .0808 of this Chapter for agency review.

~~(b)~~(d) After receiving the information in ~~Paragraph (a)~~ Paragraphs (b) and (c) of this Rule, the agency [~~will~~] shall respond to the applicant in writing within 90 calendar days. Upon review, the agency may require additional information to determine if the ~~radiation~~ X-ray machine or radiation generating device 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, 2026; October 1, 2025.

10A NCAC 15 .0214 is repealed as published in 40:19 NCR 1541-1550 as follows:

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

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~~ 2015;
Repealed Eff. October 1, 2026.

10A NCAC 15 .0301 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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 ~~BYPRODUCE~~ BYPRODUCT MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 30 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 30:

(1) With the exception of ~~[10 CFR 30.4]~~ 10 CFR 30.4, a reference to "NRC" or "Commission" means the "Agency;"

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

(3) In 10 CFR 30.18(d) and 30.32(g) where a reference is made to "an Agreement State", it means "an Agreement State or the NRC."

~~(a)~~(b) 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~~] For purposes of this Rule, the term "temporary jobsite" shall mean a location where byproduct materials are used and stored other than those [~~location(s)~~] locations 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 applications shall be submitted to the Agency and the requirements of Paragraph ~~(b)~~(c) of this Rule shall be [~~met.~~] 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),~~]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)~~(c) 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~~.0111(a) 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)~~] addresses 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0302 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 31 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 31:

(1) 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 31.5(b)(1)(ii), 31.5(c)(3)(ii), 31.5(c)(8)(i), 31.6, 31.7(a), 31.10(a), 31.10(b)(1), and 31.12(c)(4), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC;" and

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

~~(a)~~(b) 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)]~~(1) 10 CFR 31.1, "Purpose and scope;"

~~[(3)]~~(2) 10 CFR 31.2, "Terms and conditions;"

~~[(4)]~~(3) 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~~] register with the agency. Device registration shall be made in accordance with Paragraph ~~(b)~~(c) of this Rule and shall contain the information required by 10 CFR 31.5(c)(13)(iii);

~~[(5)]~~(4) 10 CFR 31.6, "General license to install devices generally licensed in 10 CFR 31.5;"

~~[(6)]~~(5) 10 CFR 31.7, "Luminous safety devices in aircraft;"

~~[(7)]~~(6) 10 CFR 31.8, "Americium-241 and radium-226 in the form of calibration or reference sources;"

~~[(8)]~~(7) 10 CFR 31.9, "General license to own byproduct material;"

~~[(9)]~~(8) 10 CFR 31.10, "General license for strontium 90 in ice detection devices;"

~~[(10)]~~(9) 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)~~(c) of this Rule;

~~[(11)]~~(10) 10 CFR 31.12, "General license for certain items and self-luminous products containing radium-226;" and

~~[(12)]~~(11) 10 CFR 31.21, "Maintenance of [~~records;"~~]records."

(c) 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;

~~(b)~~[~~(c)~~](d) 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~~.0111(a) 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~~] signed, and telephone number of the contact person.

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1989; October 1, 1984; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0302 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0304 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 32 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 32:

(1) A reference to "NRC" or "Commission" means the "Agency;"

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

(3) In 10 CFR 32.13, 32.51(a), 32.51(c), 32.56, 32.59, and 32.72(b)(5)(ii), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC."

~~(a)~~(b) 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)~~ 10 CFR 30.14 and 30.18 and incorporated by Rules .0301(b)(11) and ~~.0301(a)(13)~~.0301(b)(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;" and

(3) 10 CFR 32.3, "Maintenance of records."

~~(b)~~(c) All [~~Persons~~] 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)~~(d) All persons manufacturing or initially transferring generally licensed devices containing byproduct material shall comply with Paragraph ~~(g)~~(h) 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)~~(e) All persons manufacturing or initially transferring items or devices containing byproduct material for medical use in humans shall comply with Paragraph ~~(g)~~(h) 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)~~(f) 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)~~(h) of this Rule and the requirements of 10 CFR 32.201.

~~(f)~~(g) 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,~~] Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) of this Chapter in lieu of the NRC.

~~(g)~~(h) 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,~~] Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~] addresses 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~~] indication 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: [~~number shall be provided on the application;~~]

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

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20; 10 CFR 30.71;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0304 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0305 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 33 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 33:

(1) A reference to "NRC" or "Commission" means the "Agency;" and

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

~~[(a)]~~(b) 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 [~~the requirements of Paragraph (b)(c) of this Rule shall be met;~~] applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (c) of this Rule;

(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),~~33.17(a) and (b), "Conditions of specific licenses of broad scope."

~~(b)~~(c) 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,~~] Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~] addresses where radioactive material [~~shall~~] will be used or possessed. The application shall indicate if radioactive materials [~~shall~~] will 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~~] indication 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; [~~number shall be provided on the application;~~]

(G) [~~applicants shall indicate~~] indication of 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)~~(d) 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.~~2024;

Amended Eff. October 1, 2026.

10A NCAC 15 .0306 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 34 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 34:

(1) A reference to "NRC" or "Commission" means the "Agency;" [~~and,~~]

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

~~(a)~~(b) 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:~~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)~~(c) 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,~~] Licensing.RAM@dhhs.nc.gov or mailed to the address shown in Rule ~~.0111~~.0111(a) 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)~~] addresses where radioactive material [~~shall~~] will be used or possessed. The application shall indicate if radioactive materials [~~shall~~] will 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~~] indication 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; [~~number shall be provided on the application;~~]

(G) [~~applicants shall indicate~~] indication of 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~~]
https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm

~~(c)~~(d) 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)~~(e) 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).~~.0111 of this Chapter in lieu of the NRC. In addition to the information required by 10 CFR 34.101(b), notifications of devices with failed or worn through S-tubes shall contain the serial number and storage location of the device, whether the device has been disposed of or returned to the manufacturer, and whether personnel contamination occurred.

~~(e)~~(f) Requests for exemption from these Rules under 10 CFR 34.111 shall be made to the agency as specified in Paragraph ~~(b)~~(c) 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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0307 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 35 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 35:

(1) A reference to "NRC" or "Commission" means the "Agency;" and

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

~~(a)~~(b) All persons using radioactive materials for medical use in humans shall comply with the [~~general information~~] following 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)[(n)] of this Rule shall be met;~~] applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (n) of this Rule;

(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)~~(c) 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,~~] by no later than May 1, 2027, 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)~~(d) All persons administering radioactive materials to humans not requiring a written directive shall develop, document, maintain, and require the use ~~of,~~ 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~~] Authorized user, and shall [~~include,~~] include the following 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,~~] care and to prevent the occurrence of medical events.

~~(d)~~(e) 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)~~(e)(10) of this [~~Paragraph.~~] Rule. ~~Brachytherapy~~Sealed sources and 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)~~(e)(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)~~(f) 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)~~(g) 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)~~(h) 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 covered by the provisions of 10 CFR Part 35 listed in Subparagraphs ~~(g)(6)~~(h)(6) and ~~(g)(7)~~(h)(7) of this Rule shall be approved by an Authorized Medical Physicist.

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

~~(k)~~(l) 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)~~(m) 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 in accordance with Rule .0111 of this Chapter 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~~.0111(a) 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)~~(n) 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,~~] Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~] addresses where radioactive material [~~shall~~] will be used or possessed. The application shall indicate if radioactive materials [~~shall~~] will 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~~] indication 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; [~~number shall be provided on the application;~~]

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*

Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0307 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~[~~2014.~~]2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0308 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 36 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 36:

(1) A reference to "NRC" or "Commission" means the "Agency;" and

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

~~(a)~~(b) 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~~] remain under NCR jurisdiction and do not apply;

(3) 10 CFR 36.11, "Application for a specific license," except that applications shall be submitted to the Agency and that the requirements of Paragraph ~~(b)~~(c) 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~~CFR 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~~.0111(a) of this Chapter unless directed otherwise by the agency, in lieu of the United States Nuclear Regulatory Commission (NRC).

~~(b)~~(c) 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.~~] Licenisng.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~] addresses where radioactive material [~~shall~~] will be used or possessed. The application shall indicate if radioactive materials [~~shall~~] will 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~~] indication 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; [~~number shall be provided on the application;~~]

(G) [~~applicants shall indicate~~] indication of 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0309 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0309 DOMESTIC LICENSING OF SOURCE MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 40 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 40:

(1) With the exception of 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, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~] the same as defined in G.S. [~~104E-5.(16);~~] 104E-5(16); and

(4) In 10 CFR 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".

~~(a)~~(b) 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~~] do 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~~] applications shall be submitted to the agency in accordance with Paragraph ~~(b)~~(c) 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),~~] 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),~~]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)~~(c) 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,~~] Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~] addresses where radioactive material [~~shall~~] will be used or possessed. The application shall indicate if radioactive materials [~~shall~~] will 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~~] indication if the application is for a new license, or for the renewal of an existing license, by marking the corresponding check box;

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

(G) [~~applicants shall indicate~~] indication of 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0310 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 70 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 70:

(1) With the exception of 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 70.4, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~] the same as defined in G.S. [~~104E-5.(16).~~]104E-5(16).

(4) 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".

~~(a)~~(b) 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~~] do 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~~] an applications shall be submitted to the agency in accordance with Paragraph ~~(b)~~(c) of this [~~Rule shall be met;~~] Rule;

(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)~~(c) 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.~~] Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~] addresses where radioactive material [~~shall~~] will be used or possessed. The application shall indicate if radioactive materials [~~shall~~] will 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~~] indication 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; [~~number shall be provided on the application;~~]

(G) [~~applicants shall indicate~~] indication of 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0311 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0311 PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 71 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 71:

(1) In 10 CFR 71.0(c), 71.3, [~~71.5~~] 71.5, 71.17(a), (b), 71.22, 71.23(a), (b), [~~10 CFR~~] and 71.101(c)(1), a reference to "NRC" or "Commission" means the "Agency;"

(2) In 10 CFR 71.8(b), (d), and 71.17(b), [~~the Agency is the "quality assurance program approval holder,"~~] references to the NRC with respect to quality assurance program approval mean the Agency; and

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

~~(a)~~(b) 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;~~]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;"~~misconduct." In 10 CFR 71.8(a)(3), [redacted]

(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 10 CFR 71.17(a) applies to any licensee of the agency, and the 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)~~] (b)(2) of this [~~Paragraph~~] Rule and to the NRC in accordance with 10 CFR 71.17(c)(3);

(13) 10 CFR 71.21, "General license: Use of foreign approved ~~package;"~~package," except that 10 CFR 71.21(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR [~~71.21b)~~] 71.21(b) shall be issued by the agency or the NRC.

(14) 10 CFR 71.22, "General license: Fissile ~~material;"~~material" except that 10 CFR 71.22(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR 71.22(b) shall be issued by the agency.

(15) 10 CFR 71.23, "General license: Plutonium-beryllium special form ~~material;"~~material," except that 10 CFR 71.23(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR 71.23(b) shall be issued by the agency.

(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;"~~program." Changes to 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;

(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)]~~(c) 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)]~~(d) 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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0313 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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:~~apply, and in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~] the same as defined in G.S. [~~104E-5.(16).~~]104E-5(16).

(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;"~~licenses," in addition to the general license authorized by 10 CFR 150.20(a)(1) and subject to the limitations of 10 CFR 150.20(a)(2), any person who holds a specific license issued by an Agreement State or by the NRC is granted a general license to conduct the same activity in North Carolina and the offshore waters within the jurisdiction of the State of North Carolina;

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

(8) 10 CFR 150.32, "Funds for reclamation or maintenance of byproduct [~~material;"~~] 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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .1203 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .1203 LICENSE REQUIRED: LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 61 and to effectuate their joint enforcement, except in 10 CFR 61.2, a reference to "NRC" or "Commission" means the "Agency."

~~(a)~~(b) 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.~~] not granted a low-level waste facility access license by the agency in accordance with G.S. 104E-10.3.

(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~~] .0111(a) of this Chapter in lieu of the NRC.

(4) [~~The requirements found in~~] Applicants and licensees shall comply with the applicable requirements under 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.~~](j).

(5) In addition to the definitions found in 10 CFR 61.2, the definitions in G.S. 104E-5 shall [~~apply.~~] apply to the interpretation and application of this Rule.

(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)~~(c) 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)~~(b) of this Rule.

(1) No person shall transport or transfer waste to a low-level radioactive waste land disposal facility licensed under Paragraph ~~(a)~~(b) of this Rule unless licensed by the agency or [~~otherwise specifically authorized in writing by the agency. not granted a low-level waste facility access license by the agency~~] in accordance with G.S. 104E-10.3.

(2) The definitions of terms in G.S. 104E-5 shall [~~apply.~~] apply to the interpretation and application of this Rule.

(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,~~] waste as required by G.S. 104E-27(a). [~~including~~] ~~-~~These procedures and practices shall include 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)~~(b) 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)~~(c)(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)~~(d) 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~~.0111(a) 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)~~] addresses where radioactive material [~~shall~~] will be used or possessed. The application shall indicate if radioactive materials [~~shall~~] will 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~~] indication 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; [~~number shall be provided on the application;~~]

(G) [~~applicants shall indicate~~] indication of 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 are available at [~~shall be made available by the agency on the agency's public website.~~] https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

~~[(d)(e) 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.~~2023;
Amended Eff. October 1, 2026.

10A NCAC 15 .1301 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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) To reconcile differences between this Rule and the incorporated sections of 10 CFR 39 and to effectuate their joint enforcement, a reference to "NRC" or "Commission" means the "Agency."

~~(a)~~(b) 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,~~] Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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, or for exemptions from this Rule, 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 under 10 CFR 39.91 on the application:

(A) legal business name and mailing address;

(B) physical [~~address(es)~~] addresses where radioactive material [~~shall~~] will be used or possessed. The application shall indicate if radioactive materials [~~shall~~] will 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~~] indication 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; [~~number shall be provided on the application;~~]

(G) [~~applicants shall indicate~~] indication of 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.~~] https://radiation.ncdhhs.gov/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~~] .0111(a) of this Chapter in lieu of the NRC.

(f) Applications for exemptions from this Rule permitted by 10 CFR 39.91 [~~to this Rule~~] shall be submitted to the agency at the address shown in Rule ~~.0111~~.0111(a) 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.~~2022;
Amended Eff. October 1, 2026.

10A NCAC 15 .1601 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 20 and to effectuate their joint enforcement, [~~and to effectuate their joint enforcement,~~] the following words and phrases shall be substituted for the language of 10 CFR 20:

(1) Except in 10 CFR 20.1003, a reference to the "Nuclear Regulatory Commission," "NRC" or "Commission" means the [~~"Agency,"~~] "Agency;" and

(2) In 10 CFR 20.1003, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~]the same as defined in G.S. [~~104E-5.(16).~~]104E-5(16).

~~(a)~~(b) 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 of 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)~~] (b)(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)~~(c) [~~Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.~~] No person shall intentionally expose an individual monitoring device, as defined in 10 CFR 20.1003, to radiation for the purpose of causing the device to indicate a dose not received by the individual to whom the device is assigned.

~~(c)~~(d) Licensees and registrants shall continue to perform all activities required by the rules of this Chapter, and any license or registration conditions imposed by the agency, and shall pay annual fees required by the Rules in Section 10A NCAC 15.1100 [~~15.1100. 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)(e) Nothing in the rules of this Chapter shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.]~~

(e)[~~(f)~~] 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, 2026; May 1, 2025.

10A NCAC 15 .1701 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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) To reconcile differences between this Rule and the incorporated sections of 10 CFR 37 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 37:

(1) With the exception of 10 CFR 37.5 a reference to “NRC” or “Commission” means the "Agency;" and

(2) A reference to “NRC-licensed” means licensed by the Agency.

~~(a)~~(b) 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)~~(c) 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)~~(d) [~~The Code of Federal Regulations incorporated by this Rule~~] Copies of these regulations 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. October 1, 2026; May 1, 2023.

Burgos, Alexander N

Subject: FW: Tech changes for 10A NCAC 15 amendments

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Tuesday, September 22, 2026 10:20 AM
To: Miller, Christopher S <christopher.miller@oah.nc.gov>
Cc: Rules, Oah <oah.rules@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Tech changes for 10A NCAC 15 amendments

Thank you. I will send to the radiation protection section and get these back to you as soon as possible.

Thanks

From: Miller, Christopher S <christopher.miller@oah.nc.gov>
Sent: Tuesday, September 22, 2026 10:16 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>
Cc: Rules, Oah <oah.rules@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Miller, Christopher S <christopher.miller@oah.nc.gov>
Subject: RE: Tech changes for 10A NCAC 15 amendments

Thank you for your technical changes. I have some follow-up questions and comments for your consideration. Please see the **red text** in the attached RFC document. Please provide me with your responses and rule edits **by EOD on Thursday the 24th.** The remaining fixes and responses should be quick. But let me know if you need additional time, and we can consider an extension request.

Also, please use the attached versions of the rules when making further changes. I made some formatting updates to the rules (highlighting/underlining/bracketing/strikethrough) where changes were made but the formatting was off.

Let me know if you have any questions.

Regards,
Chris

Chris Miller
Rules Review Commission Counsel
North Carolina Office of Administrative Hearings | Rules Division
1711 New Hope Church Road
Raleigh, NC 27609
(984) 236-1935

NOTICE: E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties by authorized State officials.

Request for Changes Pursuant to N.C. Gen. Stat. § 150B-21.10

Staff reviewed these Rules to ensure that each Rule is within the agency's statutory authority, reasonably necessary, clear, and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

Questions contained herein suggest that the rule as written is unclear or there is some ambiguity. If this document includes questions and you do not understand the question, please contact the reviewing attorney to discuss. Failure to respond may result in a staff opinion recommending objection.

Staff may suggest the agency "consider" an idea or language in this document. This is in no way a formal request that the agency adopt the idea or language but rather is offered merely for the agency's consideration which the agency may find preferable and clarifying.

To properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

Note the following general instructions:

1. You must submit the revised rule via email to oah.rules@oah.nc.gov and copy RRC Counsel. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
    - Wrong: "~~a~~Association"
    - Right: "~~association~~ Association"
6. Treat punctuation as part of a word. For example:
    - Wrong: "day~~,~~; and"
    - Right: "~~day,~~ day; and"
7. Formatting instructions and examples may be found at: www.ncoah.com/rules/examples.html

If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: ALL RULES

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

> *Use of "X-ray machine": In many places, it seems like you are replacing "radiation machine" with "X-ray machine". Do these two terms have the same meaning? Or is "radiation machine" a broader category of devices? You define "radiation machine" in your rules (and it's also defined by statute). However, "X-ray machine" is left undefined. You should clarify the meaning somewhere in your rules, even if it has the same meaning as a "radiation machine".*

Response: The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two are broken down in Sections .0500, .0600, and .0800.

Understood – thanks for the explanation. So for my understanding, in rule 15 .0201(b), you are replacing "radiation machine" with "an X-Ray machine or a radiation generating device". Both X-Ray machines and radiation generating devices are "radiation machines". Is that correct? So the updated terminology is meant to clarify that the requirements apply to both human use and non-human use equipment? Or is it meant to do something else? Are these two terms just more precise than "radiation machine"?

> *Cross-References: Please ensure that all of your cross-references are still accurate. I identified several places where rule cross-references needed to be updated based on the revised versions of the rules in this package.*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0103

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

General Comment: Definition rules should be ordered alphabetically. Some of your definitions are not in proper order. For example, (a)(3) and (a)(4) should be switched. (b)(12) should come before "Registrant". Please consider fixing this.
Response: Updated in text.

This is not fixed. (b)(10), definition for "Registrant", should be placed in between "Registered" and "Registration".

(a), lines 4-6: The wording of this paragraph is awkward. I would suggest deleting, "… 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, …". If you want to keep this language, consider revising the start of the paragraph to say, "As used in the rules of this Chapter and as applied to persons …".
Response: Updated in text.

This change is not reflected in the document that you provided.

(a)(1), line 7: Add "the" before the name of the Act.
Response: Updated in text.

(a)(6): Per the style guide, please use the abbreviations "a.m." and "p.m." to express time.
Response: Updated in text.

(a)(9) and (10): Paragraph (c) does not provide a different meaning for these terms. Rather, it points to different sections of your rules. For clarity, consider revising this to say, "… except where otherwise defined in the rules of this Chapter." Or, specifically identify which rule section would apply to these two terms.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Thank you for the suggestion. This improves the rule. Change made to the rule as requested.

(a)(19): "six month intervals" should include a hyphen.
Response: Updated in text.

(a)(23): "Chapter 10" of what Title? Your rules are in Chapter 15. Am I missing something here?
Response: Updated in text.

(b): Same comment as mentioned above for (a), lines 4-6.
Response: Updated in text.

This change is not reflected in the document that you provided.

(b)(3), lines 20-21: I don't fully understand what you mean. Should this say, "… within one building or one vehicle at one address and under …"? What is the intent here?
Response: Updated in text.

The change made in the document does not match my suggestion and makes the passage even more confusing. Please revise this further.

(b)(7), line 32: Change "diagnosing" to "diagnosis".
Response: Updated in text.

(b)(7)(B), line 35: Change "and" to "or".
Response: Updated in text.

(b)(12), line 10: Rule .0207 does not mention any "Notice of Registration". Please correct your cross-reference.
Response: Updated in text.

(b)(15): Rule .0205(d) does not mention any specific services. Please correct your cross-reference.
Response: Updated in text.

This change is not reflected in the document that you provided.

(c), line 23: Add a period before "1900".
Response: Updated in text.

History Note, Authority: Is 10 CFR 20.1003 still applicable to this rule now that you've moved the CFR definitions to other places throughout your rules?
Response: Thank you very much for your comment. The citation in the History Note referencing 10 CFR 20.1003 is no longer necessary because the regulation in the 10 CFR is incorporated by reference in 10A NCAC 15 .1601 in the rules

currently published on the OAH website. The change to the history note made as suggested.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0104

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

General Question: G.S. 150B-21.6 authorizes incorporation of another agency rule or a code, standard, or regulation adopted by another agency, the federal government, or a generally recognized organization or association. How does this bilateral Agreement fall within one of those categories? And what is the effect of incorporating the Agreement? Are you trying to enforce specific provisions of the Agreement?
Response: The Agreement does not fit precisely within the categories of a code, standard, or regulation identified in G.S. 150B-21.6. However, the Agreement functions as a statement of general applicability that implements federal and State statutory authority and describes the scope of the Agency's regulatory authority. Pursuant to Section 274 of the Atomic Energy Act and North Carolina law, the Agreement authorizes the State to regulate certain activities involving radioactive material while reserving other activities to exclusive federal jurisdiction.

Incorporating the Agreement into Rule .0104 provides notice to the regulated community and guidance to the Agency regarding the scope of activities the State may license and regulate. The Agency is not seeking to enforce individual provisions of the Agreement separately; rather, the Agreement establishes the jurisdictional boundaries within which the Agency exercises its regulatory authority.

Page 2, line 6: Delete "hereby".
Response: Updated in text.

History Note, Authority: Please confirm that all listed statutes are still relevant even with the proposed deletions.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0201

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a): What is the difference between an X-ray machine and a radiation generating device? Are these terms both defined anywhere in your rules? Is there a reason why you use both terms here? Consider adding a definition in .0103
Response: The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two are broken down in Sections .0500, .0600, and .0800.

(b), lines 11-12: Replace the comma after "X-ray machine" with "or" and either delete "a" or change "devices" to "device".
Response: Updated in text.

(b), line 12: Is "radiologic" or "radiological" the proper term? You use the latter in (a). Be consistent in your rule.
Response: Updated in text.

(d), line 16: Do you need the comma here after "X-ray machine"? What is your intent? Consider: "Service providers that use an X-ray machine or radiation generating device for demonstration purposes, or that provide mobile leasing services, are subject …"
Response: Updated in text.

(f): What does "Industrial" mean in this context?
Response: Industry standard uses the term Industrial and Industrial Radiography is a non-destructive testing method that uses ionizing radiation to examine the internal structure of materials, components, and welds without causing damage.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(g), line 24: Change "and" to "or" if these are separate categories.
Response: It is supposed to be "and"

(h), line 27: Change "or by service providers for demonstration purposes" to "or for demonstration purposes conducted by service providers".
Response: Updated in text.

(i): Would this provision apply to veterinary services? And if so, is it possible to comply with both Sections .0600 and .0800 at the same time? Or is this rule not meant to have a cumulative effect with paragraphs (f)-(h)? It is not really clear.
Response: This does not apply for human or veterinary services. When X-ray machines are used in industrial settings this would not be for human or veterinary services. This rule does not have a cumulative effect. Paragraph (g) addresses human diagnostic imaging and veterinary use.

Understood. However, in (j), you simply state, "… machines for non-human use". Veterinary use would fall into "non-human use". So do you now see the issue that I have flagged with the rule text?

History Note, Authority: How are 104E 9(8) and 104E 19(a) relevant here? Those are fee statutes.
Response: Historically the agency has not changed a history note unless applicable to intent of rule change. The intent of this rule has not changed since written. Does 104E-9(8) and 19(a) establish the legislative authority for the fee related provisions of this Section? Please advise if change is still need.

You can leave as is.

History Note, page 2, line 1: The most recent date should be placed first within the same line. Please correct this.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0202

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 4: What do you mean by "other purposes"? Purposes not covered under rule 10A NCAC 15 .0201? If so, state that in the rule.
Response:

(a), line 5: I believe "average" should be changed to "averaged".
Response: Updated in text.

(b), line 9: Please delete "therefore".
Response: Updated in text.

(b), line 9: Are "exemptions" and "exceptions" different? If they are the same thing, you should just use one term.
Response: Exemption and exception are different. The agency may exempt an entity from a specific requirement or make grant an exception to a requirement under specific circumstances as outlined in Rule .0212.

(b): Are there any other factors that you are considering when exercising this discretion? Or is it solely based on the level of radiation? Also, on line 10, what is "it" referring to? What exactly are you exempting? The rule language is not clear.
Response: The primary factor that is considered when exercising discretion to grant an exemption or exception is the radiation dose. "It" refers to the granted exemption. Exemptions may apply to either a machine requirement or operating requirement.

(b): Are exemptions granted by the Commission or the agency?
Response: Agency and it is stated on line 9.

(c)(2): Same question as for other rules – why are X-ray machines and radiation generating devices now being split out? Do you define both terms?

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: To provide clarity to facilities that RGDs are included in these requirements. The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two is broken down in Sections .0500, .0600, and .0800.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0203

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 6: What is the intent of the change here? You are replacing a defined term, "radiation machine," with an undefined term, "X-ray machine". Are "radiation machines" no longer covered under the revised rule? Or are these meant to mean the same thing? It is not clear to me.
Response: A radiation machine is defined in G.S. 104E-5(13) and the statutory definition includes nuclear particles. During a previous comment period, the commentor noted that using the term radiation machines implied that it could relate to sources regulated by the Radioactive Materials Branch. The terms were split to provide better clarity. Industry standards recognize X-ray machines are for diagnostic imaging and RGDs are not.

(a), line 6: Add "or" before "radiation generating device,".
Response: There is already an "or" on line 6.

(a), sentence 2: What is the effect of this sentence? Once a facility registers one device, the entire facility is then considered registered? I don't understand the rule language.
Response: Submitting a registration application for a single X-ray machine or RGD establishes the initial registration for the entire facility. The facility will then receive an invoice to finalize the registration process.

(b)(4): The new web link provided does not work. Please use an existing, active link.
Response: Updated in text.

(c)(1)(A), line 31: Change "<u>device</u>" to "<u>devices</u>".
Response: Updated in text.

(c)(2)(D): Add "made" before "<u>available during …</u>".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(d)(2)(D): Add "when" before "not in use", if that is your intent.
Response: Not necessary.

If this change is not necessary, then how does this differ from (B), which asks for "machine or device location"? How could you provide location for both the "machine" and "the machine not in use" when you are registering one device?

(e)(3): Change the semi-colon after "location" to a comma.
Response: Not necessary, there are semi-colon after each line.

"location" appears in the middle of a list in the middle of the sentence; it does not appear at the end of the line. Change the comma to a semi-colon.

(f)(1)(B): Should the "and" at the end of this line be an "or"?
Response: Updated in text.

(h)(1): Add "requirements of the Class for the services provided" after "meets the education". Also consider adding a cross-reference here to the appropriate requirements for clarity.
Response: Updated in text.

(h)(3): Add "documentation of the " before "requirements in …".
Response: Updated in text.

(h)(3): Do you mean, "Subparagraph (h)(1)"? I think there is a typo here.
Response: Updated in text.

(i)(2)(A): For consistency, should this also be updated to "… or the individual responsible for business operations;"?
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0204

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 4: Change "in this Rule" to "required by this Rule".
Response: Updated in text.

(b)(2): Who is the "registrant" in this instance? The "applicant" or the "registered service provider"? It is not clear.
Response: Will it be confusing if we put applicant. It has always been the registrant. Consider registered service provider since they are the ones that usually submit it.

I suggested "applicant" because that is the terminology you use in (b)(1). So I was trying to promote consistency throughout your rule.

(b)(2): It would be clearer to state, "Shielding design drawings shall be scaled."
Response: Updated in text.

(b)(2)(C): Couldn't this also apply to a structural modification?
Response: Updated in text.

(b)(5), line 29: "dose" of what? Please specify. Also, rule .1601 doesn't specify any limits. Rather, it points to other standards. So the wording used here does not make sense.
Response: Updated in text.

Add "incorporated" before "in Rule .1601".

(c), line 37: Add a colon at the end of this.
Response: Updated in text.

(c)(2)(A), line 19: Replace "requirements" with "required documentation".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(c)(4), line 2: Add "for use" before "by service providers …".
Response: Updated in text.

(c)(4)(B): Delete the space between ".0203" and "(d)".
Response: Updated in text

(c)(5): Add "covered" before "in Section .0800 …".
Response: Updated in text.

(c)(6): Add "covered" before "in Section .0500 …".
Response: Updated in text.

(d): "Persons" are not registered under Paragraph (c). Paragraph (c) states facility requirements. Please amend the language here as needed.
Response: Updated in text.

(e): Same comment as above. Also, add a space between "Paragraph" and "(c)" on line 28.
Response: Updated in text.

(f): Same comment as (d) and (e).
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0205

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 5: I would recommend deleting, "… of such services …" The person isn't registering the services, correct? The registration would apply to the person.
Response: Updated in text.

(b), line 7: For clarity, you should specify which section(s) of .0203 specifically apply here since that rule contains various different forms.
Response: Depending on the type of service being provided, multiple application forms may apply

(e)(1): Same question as mentioned for other rules regarding the change of "radiation machine" to "X-ray machine".
Response: To provide clarity to facilities that RGDs are included in these requirements. The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two is broken down in Sections .0500, .0600, and .0800.

(e)(3): If you do shielding designs for fluoroscopic X-ray machines, do you need both a Class III and IV registration? If you only need IV, you should state that Class III does not include fluoroscopic X-ray machines.
Response: Fluoroscopic X-ray machines are a subcategory of X-ray machines that produces a higher output of radiation than standard X-ray machines. This requires different calculations for shielding design.

Understood. So then for Class III, you should state, "… except for fluoroscopic X-ray machines;". Otherwise, they are also captured by the

broader category mentioned in (e)(3) and would have to comply with both Classes. Unless you intend for people to have to apply for both classes if they are providing shielding designs for fluoroscopic X-ray machines – then the current language is fine.

(f), line 35-36: Change "that provide" to "to provide".
Response: Updated in text.

(f)(1), line 2: Change "(E)" to "(D)", based on your updated rule.
Response: Updated in text.

(f)(2), line 4: Change "(B)" to "(C)", based on your updated rule.
Response: Updated in text.

(g)(1): "Dispose" is not a service mentioned anywhere in the Classes in (e). What Class registration would that fall under?
Response: Disposing of machines that no longer produce radiation does not require registration. Updated in text.

Based on your edits, change "machines" on line 7 to "machine".

(h): You should specify when a registrant is required to use this form. As written, it's not clear.
Response: The form name provides the description of the requirement when an X-ray machines for nonhuman use or radiation generating device are sold or installed.

Right – but when does the form actually need to be submitted to the agency? Is there a deadline? Can they submit it whenever they want? Your rule does not provide a clear process. Also, based on the way you've worded this sentence, the form is not technically required. You can't create a legal requirement just by the name of a form.

(i), line 7: Delete "shall" before "meet".
Response: Updated in text.

(j): Change "Rule .0205 of this Section" to "this Rule".
Response: Updated in text.

(k)(1): For consistency, should this say "fluoroscopic X-ray machines"?
Response: Updated in text.

(l)(1): I suggest deleting "legible". This adjective seems to be unnecessary.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0206

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), lines 5-6: Change this sentence to something more direct, like, "The following qualifications shall be met for each service class:".
Response: Updated in text.

(a)(2), lines 12-13: This does not match the language in rule .0205 for Class II. That rule states: "installation, repair, or service …".
Response: Deleted repair in rule .0205 as it is part of the service. Updated in text.

(a)(2)(A): Should this provision start with something like, "completion of"?
Response: Updated in text.

(a)(2)(C), line 19: Delete "are required". This is redundant.
Response: Updated in text.

(a)(3) and (a)(4): If you do shielding designs for fluoroscopic X-ray machines, do you need both Class III and IV training? If you only need IV, you should state that Class III does not include fluoroscopic X-ray machines.
Response: Fluoroscopic X-ray machines are a subcategory of X-ray machines that produces a higher output of radiation than standard X-ray machines. This requires different calculations for shielding design.

Please see my follow-up comment in Rule .0205. You should clarify the two different classes so they don't overlap.

(a)(3), line 20: Change "machine" to "machines".
Response: Updated in text.

(a)(3)(C): "one year of experience" doing what? Your rule is not clear.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(a)(4)(C): "one year of experience" doing what? Your rule is not clear.
Response: Updated in text.

(a)(6): This does not match the language of Class VI in rule .0205. That rule states: "radiation survey equipment calibrations".
Response: Updated text in rule .0205.

(a)(8): This does not match the language of Class VIII in rule .0205. That rule states: "providing individual monitoring devices".
Response: Updated text in rule .0206

(a)(8), line 15: Change "must" to "shall".
Response: Updated in text.

(a)(9), lines 18-19: For consistency, this should read as: "… general health or medical physics consulting. The applicant shall meet one of the following:"
Response: Updated in text.

(a)(9)(D): Add "degree" after "doctorate".
Response: Updated in text.

(b), line 29: For clarity, I would now replace "prior to the effective date of this Rule" with the intended fixed date.
Response: Updated in text.

The date here should be the date whenever this rule provision first went into effect. Was (b) drafted during the readoption last year? Or has it always been in the rule? I don't think the date you've included is the intended date.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0207

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), lines 5-6: The description for Class V services here does not match rule .0205. That rule states that Class V includes "area radiation surveys and shielding evaluations for X-ray machines" and that Class IV includes "shielding designs for fluoroscopic X-ray machines". Please clean up this rule so that the two align.
Response: Updated text in rule .0205.

(a), lines 6-7: Same comment for Class VII services. The two rules do not match. Please correct this.
Response: Updated text in rule .0205.

(a)(2): Do they have to follow the manufacturer's recommended frequency if one is provided? If so, you should also state that in your rule.
Response: The agency requires annual calibrations when the manufacture does not provide a frequency. A frequency other than annually will be accepted if stated in the mfg. manual.

You should clarify this point here in your rule. As written, there is no requirement that you perform calibration at the manual's frequency when provided (unless this is included somewhere else in your rules).

(a)(3)(A), line 15: I think a word is missing here. Consider adding "provided" before "to the employed;".
Response: Updated in text.

(a)(3)(B): This is vague. What is this meant to capture? I think you need some sort of limiting language here. Consider adding, "… in conjunction with the provided services;".
Response: Updated in text.

(a)(3)(C), (D), and (E): Isn't this already covered by (B)?

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: No, these are not the same.

(b)(1): What does "current" mean in this context? "Current" at the time that the service is provided? It is not clear.
Response: Updated in text.

(c), line 29: Delete "radiographic" for consistency.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0211

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 3: "RESPONSIBLE" is spelled incorrectly.
Response: Updated in text.

(a), lines 6-7: Change "actively registered" to "active". The rule is redundant as written.
Response: Updated in text.

(a), line 8: Shall be "on site" when? At all times?
Response: Changed to available.

Did you mean to delete "on site"? If so, also delete "or" before "available".

(a), line 10: The last sentence should be more direct. Consider something like, "The individual shall meet the following qualifications:".
Response: Updated in text.

(a)(1)-(4): These requirements are vague/generic. Are there objective minimums or standards for these requirements?
Response: These criteria outline the foundational areas of competency required for radiation safety. Actively holding a registered technologist credential from the ARRT serves as an established standard that satisfies these requirements.

(a)(3): Change this to "knowledge of …".
Response: Updated in text.

(a)(4): Same comment as (a)(3) regarding the use of "knowing".
Response: Updated in text.

(a)(4): Delete "used" at the end of the sentence. It is redundant.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(b)(1)(B): Should this say "and" rather than "or"?
Response: No.

(b)(2), line 21: Insert a period after "personnel", delete "and", and capitalize "records".
Response: Updated in text.

(b)(2)(C): What does this provision mean? The wording/grammar makes it very hard to understand what is being required.
Response: Corrected reference to 1001(a)(7).

This doesn't address my concern. (A) and (B) are both past tense verbs, requiring action to be taken on records of monitoring. (C) then starts with "notifications". Does the individual have to make the notification? Or record it? Or something else? What does the actor have to do?

History Note, page 2, line 4: The most recent date should come first in the line of dates.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0212

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 3: "EMERGING" is spelled incorrectly.
Response: Updated in text.

(b), line 25: Consider adding "proposed" before "user".
Response: Updated in text.

(b), line 25: Change "the" to "an".
Response: Updated in text.

My apologies – the way this was originally written made more sense. Please revert back to "the".

(b)(5) and (6): Change "to include the following" to "that includes".
Response: Updated in text.

(b)(5)(B): "output" of what?
Response: Added radiation updated text.

(b)(6)(C): I'd recommend deleting "legible".
Response: Updated in text.

This edit is not reflected in the document you provided.

(b)(8): Which specific rules are you referring to? This requirement is not clear.
Response: Depending on the emerging technology it would need to the equipment requirements in applicable Sections .0500, .0600, and .0800.

Got it. For (b)(7), please change the period at the end to "; and".

(c), line 3: Consider adding "proposed" before "user".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(c), line 3: Change "the" to "a".
Response: Updated in text.

My apologies – the way this was originally written made more sense. Please revert back to "the".

(c), line 3: Change "requirements" to "required information".
Response: Updated in text.

One follow up. Submit the information to whom for review? Please clarify in the rule.

(d), line 5: Change "will respond" to "shall respond".
Response: Updated in text.

(d): What does "allowed for use" mean? Whether the device can be safely operated? The wording here is vague. What exactly are you determining from the information provided? What is the standard for approval? Be clear and specific.
Response: "Allowed for use" means approved for operation in NC. The information provided is used to verify that radiation dose limits for both the operator and members of the public do not exceed established regulatory standards for similar types of X-ray machines or RGDs. This Standard aligns with CRCP Suggested State Regulations.

History Note, page 2, line 15: The most recent date should come first in the line of dates.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0214 (REPEAL)

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

History Note, line 9: Add "2015;" after the deletion.
Response: Updated in text.

The change is not reflected in the document you provided.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0301

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 9: "BYPRODUCT" is spelled incorrectly.
Response: Updated in text.

(a)(1): Add a comma after "10 CFR 30.4".
Response: Updated in text.

(b)(4), second sentence: Consider adding: "For the purposes of this Rule, the term …"
Response: Updated in text.

(b)(4), line 24: Change "location(s)" to "locations".
Response: Updated in text.

(b)(19): What does the exception mean here? That Paragraph (c) governs the form and information requirements for applicants? That Paragraph (c) is an additional requirement? It is not clear given what is specified in 10 CFR 30.32.
Response: Paragraph (c) governs the form, submission, and information requirements for applications submitted to the agency. The exception is intended to clarify that, in lieu of NRC Form 313, "Application for Materials License," applicants shall use the applicable North Carolina forms specified in Paragraph (c): the Application for Radioactive Materials License or the Application for Amendment of Radioactive Materials and Accelerator Licenses. Paragraph (c) also specifies the information required by the agency for those applications. Paragraph (c) is not an additional requirement.

Got it. It would then make more sense if this said something like, "… except that applicants shall comply with the application form, information, and submission requirements in Paragraph (c) of this Rule in lieu of the application form and submission requirements in 10 CFR 30.32(a)." Consider revising.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(b)(20), line 10: In the G.S. cite, remove the period after 9.
Response: Updated in text.

(b)(25): Is there a timing requirement for filing once you've hit the 180 day mark?
Response: Yes. The 180-day period is cumulative and does not have to be consecutive. A licensee operating under reciprocity that anticipates using or storing radioactive material in the State for more than 180 days in a calendar year must apply for the appropriate North Carolina license or reapply for reciprocity before exceeding the 180-day limit.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0302

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 3: "BYPRODUCT" is misspelled.
Response: Updated in text.

(b), line 13: Underline "(b)".
Response: Updated in text.

(b)(1): How does this language align with what you've stated in (b)? Consider moving this requirement to its own paragraph. It doesn't really make sense as written.
Response: Thank you for your suggestion. Moved b(1) to another paragraph.

(b)(4), line 23: Change "shall be registered" to "shall register".
Response: Updated in text.

(b)(4), line 25: Add "10 CFR" before "31.5(c)(13)(iii)".
Response: Updated in text.

(b)(12): This should end with a period rather than a semi-colon.
Response: Updated in text.

(c)(10): Add a comma after "date the form is signed".
Response: Updated in text.

History Note, line 26: This entire line should be in underline.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0304

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b), lines 12-13: Rewrite this to state, "… byproduct material as described in 10 CFR 30.14 and 30.18 and incorporated by Rules .0301(b)(11) and .0301(b)(13) of this Chapter, …"
Response: Updated in text.

(b)(2): Add "and" at the end of this provision.
Response: Updated in text.

(c), line 21: "Persons" should not be capitalized.
Response: Updated in text.

(c)(3): How does this work? You regulate the persons under these provisions of the CFR, but the NRC is responsible for issuing licenses?
Response: Yes, these licensees require a possession license issued by North Carolina. The NRC retains licensing authority for the manufacture and initial transfer for commercial distribution of exempt products containing exempt concentrations or exempt quantities of byproduct material. Paragraph (c) incorporates the applicable requirements of 10 CFR Part 32, while Subparagraph (c)(3) clarifies that applications for these manufacture and initial transfer for commercial distribution licenses are submitted to the NRC rather than the agency. North Carolina retains regulatory authority over other activities involving radioactive material within the scope of the State's Agreement State authority.

(g)(3), line 31: Delete the comma after the email address.
Response: Update in text.

(h), line 34: Delete the comma after the email address.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(h)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(h)(1)(E): The language used here is inconsistent with the rest of the list. Consider stating, "indication if the application is for …".
Response: Updated in text.

(h)(1)(F): Similar comment as (E). Consider deleting "shall be provided on the application". It makes the rule redundant.
Response: Updated in text.

(h)(1)(G): The language used here is inconsistent with the rest of the list. Consider stating, "indication of the type and category …".
Response: Updated in text.

(h)(2)(G): The language used here is inconsistent with the rest of the list. Consider stating, "a description of …". Delete "applicants shall provide".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0305

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

General Comment: In your forms rules, you state, "The instructions for completing the application printed on the application form shall be followed." What exactly do those instructions say? Are you requiring documentation or other actions? If so, you should state them in your rule as requirements rather than making this vague reference back to the form. Otherwise, you could change information requirements while circumventing the rulemaking process.

Response: The application form instructs applicants to complete Items 1 through 5 and to use additional sheets as necessary. These information requirements are stated in the Rule. The form further directs applicants to consult the appropriate licensing guide for information that must accompany the completed application. The requirement to submit supporting documents is already established in Part (c) of this Rule.

An application for a specific license will be approved if it is for a purpose authorized by the Agreement (activities authorized by 10 CFR Parts 30–37, 39, 40, 61, or 70); if the applicant's proposed equipment and facilities adequately protect health and minimize danger to life or property; if the applicant is qualified by training and experience to use the material safely; and if the applicant satisfies all applicable requirements in 10 CFR Parts 30–37, 39, 40, or 70. Licenses for low-level radioactive waste disposal sites must also meet the requirements in 10 CFR Part 61 and N.C.G.S. 104E.

The form refers applicants to the applicable licensing guide for guidance on the supporting documentation used to demonstrate compliance with these requirements. The agency relies on the NUREG-1556 series to help applicants identify documentation that may be used to show compliance with the licensing requirements established by the rules and incorporated federal regulations. The licensing guides do not independently establish substantive regulatory requirements.

The form includes a certification requirement and references other applicable regulatory provisions, including 10A NCAC 15 .1700. The

certification requirement is expressly stated in the Rule, and the reference to Section .1700 simply alerts applicants to additional requirements that may apply elsewhere in this Chapter.

Title, line 3: "DOMESTIC" is misspelled.
Response: Updated in text.

(a)(1): Add "and" at the end of this provision.
Response: Updated in text.

Line 9: I believe a struck through "(a)" is missing at the beginning of this line.
Response: Updated in text.

(b)(3): What does the end of this mean? Is Paragraph (c) an additional requirement or a substitute? Be clear and specific.
Response: Paragraph (c) establishes the State-specific application process for licenses issued by the agency. Applicants remain subject to the applicable requirements of 10 CFR 33.12 and 10 CFR 30.32; however, in lieu of NRC Form 313 and submission to the NRC, applicants shall use the applicable North Carolina application form and submit the application and required supporting information to the agency in accordance with Paragraph (c).

Replaced *(b)(3):* 10 CFR 33.12, "Applications for specific licenses of broad scope," except that applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (c) of this Rule;

(c), line 21: Remove the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses". Also, on lines 28 and 29, do you mean "will be used" rather than "shall be used"?
Response: Updated in text.

(c)(1)(E): The language here does not match the rest of the list. Consider stating, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): The language here does not match the rest of the list. Consider stating, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): The language here does not match the rest of the list. Consider deleting "applicants shall provide ".

Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0306

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(1): Remove the comma after "and".
Response: Updated in text.

(c), line 15: Remove the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B): Do you mean "will be used" rather than "shall be used"? This applies to both lines 21 and 22.
Response: Updated in text.

(c)(1)(E): The language here is inconsistent with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): The language here is inconsistent with the rest of the list. Consider starting this with, "indication of the type and category of …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

(c)(3): Add a period at the end of this. Also, the link here does not work. Please update.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(f): This provision is not clear. What exactly are you requiring? That a form must be submitted per the instructions in (c)? Also, you should specify whether (c)(1) or (c)(2) applies, since they contain different information requirements.

Response: The agency agrees that the provision was unclear. Paragraph (f) has been revised to clarify that a request for exemption from the rules under 10 CFR 34.111 shall be submitted with the applicable application required by Paragraph (c)(1) or (c)(2) of this Rule, as appropriate. Licensees can request exemption from the rules as part of a new application or existing application.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0307

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b): What does it mean to "comply with the general information requirements" of these regulations? This language is not clear. Are you limiting the scope of what is required?
Response: Thank you the phrase "general information requirements" was unclear. Paragraph (b) has been revised to state that persons shall comply with the following requirements of Subpart A to 10 CFR 35.

(b)(8): Is Paragraph (n) a substitute or an additional requirement? Your rule is not clear.
Response: Reworded*(b)(8):* 10 CFR 35.12, "Applications for specific licenses of broad scope," except that applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (n) of this Rule;

(c)(3), line 33: Delete "(3)".
Response: Updated in text.

(c)(3): Replace "within three years of the effective date of this readopted Rule" with the actual intended date.
Response: "(3)" has been deleted and the provision has been revised to state the specific date of May 1, 2027

(d), line 15: What is an "authorized user"? Is this defined somewhere?
Response: "Authorized user" is defined in 10 CFR 35.2, which is incorporated by Subparagraph (b)(2) of this Rule.

Consider capitalizing this since it is a defined term.

(d), line 15: Delete the comma after "include" and add "the following".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(d)(5): Delete the comma after "patient care".
Response: Updated in text.

(e)(5): Change "of this Paragraph." to "of this Rule."
Response: Updated in text.

(h)(11): Change this to something like, "activities covered by the CFR provisions listed in Subparagraphs (h)(6) and (h)(7) of this Rule shall be …".
Response: Updated in text. Subparagraph (h)(11) has been revised to clarify that activities covered by the CFR provisions listed in Subparagraphs (h)(6) and (h)(7) of this Rule shall be approved by an authorized medical physicist.

(h)(11): What is an "Authorized Medical Physicist"? Authorized by whom?
Response: "Authorized medical physicist" is defined in 10 CFR 35.2, which is incorporated by Subparagraph (b)(2) of this Rule.

(l): Is there a time limit for "maintaining" records?
Response: Yes. The applicable retention periods are specified in the individual recordkeeping provisions of Subpart L to 10 CFR 35 incorporated by this Rule. The retention periods vary depending on the type of record.

(n), line 25: Remove the comma before "or".
Response: Updated in text.

(n)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(n)(1)(B): Do you mean "will be used" rather than "shall be used"? This applies to both lines 31 and 32.
Response: Updated in text.

(n)(1)(E): The language here is inconsistent with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(n)(1)(F): Delete "shall be provided on the application".
Response: Updated in text.

(n)(1)(G): The language here is inconsistent with the rest of the list. Consider starting this with, "indication of the type and category of …".
Response: Updated in text.

(n)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

History Note, page 8, line 2: "2014;" should be "2024;".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0308

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b)(2): You state, "except that references to common defense and security shall not apply". What does this mean? Is something else substituted for these terms? Are these words just to be totally disregarding in the regulations? Your rule is not clear.
Response: The references to common defense and security are not replaced with another term or requirement. The NRC retains regulatory authority, and common defense and security are under exclusive federal jurisdiction. Therefore, those portions of the incorporated definitions do not apply to the agency's regulation under this Rule. Subparagraph (b)(2) has been revised to clarify that the provisions relating to common defense and security do not apply.

There is no revision to subparagraph (b)(2) in the document that you provided.

(b)(3): Is Paragraph (c) meant to be a substitute for application requirements? Or additional requirements that must also be met? Your rule is not clear.
Response: Paragraph (c) establishes the State-specific application forms and submission requirements in lieu of the NRC Form 313 and submission requirements in 10 CFR 36.11. Subparagraph (b)(3) has been revised to clarify that applications shall be submitted to the agency in accordance with Paragraph (c) of this Rule.

There is no revision to subparagraph (b)(3) in the document that you provided.

(c), line 8: Delete the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(c)(1)(B), lines 14 and 15: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".

Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0309

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(3): The mentioned language is not a sentence. I would recommend changing "sentence" to "language".
Response: Updated in text. Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

Special Nuclear Material" has been changed to "special nuclear material" for consistency with the other defined terms in the Rule.

(a)(3), line 11: In the G.S. citation, please delete the period after "5".
Response: Updated in text.

This update is not reflected in the document you provided.

(a)(4): Add "10 CFR" before you start listing out the regulations.
Response: Updated in text.

(a)(18): Is Paragraph (c) a substitute for the application requirements? Is it an additional requirement that has to also be met? Your rule is not clear.
Response: This comment to refers to Subparagraph (b)(18). Paragraph (c) establishes the State-specific application form and submission requirements in lieu of the NRC-specific application form and submission requirements in 10 CFR 40.31. Subparagraph (b)(18) has been revised to clarify that applications shall be submitted to the agency in accordance with Paragraph (c) of this Rule.

Please delete "shall be met" on line 7. It is now redundant with the other edits made here.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(a)(18), line 6: In the G.S. citation, please delete the period after "9".
Response: Updated in text.

(a)(19), line 11: Same comment as noted above.
Response: Updated in text.

(c), line 6: Delete the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B), both lines: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0310

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(3): "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is not a sentence. Also, what is it preserved from? Be clear and specific. As written, it's hard to understand what exactly you're trying to do here. Consider something like, "As preserved in G.S. 104E-5(16), the Commission retains primary authority to declare any other materials as special nuclear material."
Response: Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

Special Nuclear Material" has been changed to "special nuclear material" for consistency with the other defined terms in the Rule.

(a)(3), line 11: In the G.S. citation, please delete the period after "5".
Response: Updated in text.

This update is not reflected in the document you provided.

(a)(14): Is Paragraph (c) a substitute for the application requirements? Is it an additional requirement that has to also be met? Your rule is not clear.
Response: Paragraph (c) establishes the State-specific application form and submission requirements in lieu of the NRC-specific filing requirements addressed by 10 CFR 70.21. Subparagraph (a)(14) has been revised to clarify that applications shall be submitted to the agency in accordance with Paragraph (c) of this Rule.

(c), line 20: Delete the comma before "or".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B), lines 26 and 27: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.
(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0311

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(1): You are missing a comma after "71.5".
Response: Updated in text.

(a)(1): Replace "10 CFR 71.101(c)(1)" with "and 71.101(c)(1)".
Response: Updated in text.

(a)(2): What does this replacement mean? The "Agency" is not used in those regulations. I cannot tell what this provision is meant to do.
Response: Subparagraph (a)(2) was unclear. The provision has been revised to clarify that, in 10 CFR 71.8(b) and (d), references to the NRC with respect to quality assurance program approval mean the Agency.

Line 11: You are missing a struck through "(a)" here.
Response: Updated in text.

(b), line 13: This should end with a colon rather than a semi-colon.
Response: Updated in text.

(b)(7): Same comment as noted for (a)(2).
Response:

(b)(12), line 31: Change "Subparagraph (2) of this Paragraph" to "Subparagraph (b)(2) of this Rule".
Response: Subparagraph (b)(7) was unclear. The provision has been revised to clarify that, in 10 CFR 71.8(a)(3) references to the NRC with respect to quality assurance program approval mean the Agency.

The requested change to (b)(12) is not complete in the document you provided. Change "of this Paragraph" to "of this Rule".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(b)(12), line 32: Add "10 CFR" before "71.17(c)(3)".
Response: Updated in text.

(b)(13), line 35: You are missing a parenthesis around "(b)".
Response: Updated in text.

Page 3, line 7: This should be updated to "(c)".
Response: Updated in text.

This update is not reflected in the document you provided.

Page 3, line 17: This should be updated to "(d)".
Response: Updated in text.

This update is not reflected in the document you provided.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0313

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(3), lines 11-13: "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is not a sentence. Also, what is it preserved from? Be clear and specific. As written, it's hard to understand what exactly you're trying to do here. Consider something like, "As preserved in G.S. 104E-5(16), the Commission retains primary authority to declare any other materials as special nuclear material."
Response: Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

(a)(3), line 11: Why is "Special Nuclear Material" all capitalized? You do not capitalize other defined terms in this rule.
Response: Updated in text.

(a)(3), line 13: Delete the period between "5" and "(16)" in the citation.
Response: Updated in text.

This change is not reflected in the document you provided.

(a)(7), line 23: Replace "material," with "material;".
Response: Updated in text.

(a)(8), line 24: Replace "material;" with "material."
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1203

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b), line 7: Above, you use "Agency" to refer to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section, as defined in 10A NCAC 15 .0103. However, beginning here and continuing intermittently through the Rule, you use "Department", which in G.S. 104E-5 is defined as Department of Health and Human Services. Ensure that your use of the two terms is consistent with your intent. Going back and forth between both can cause confusion.
Response: The use of "Department" and "Agency" is intentional. "Department" refers to the North Carolina Department of Health and Human Services and is used where the applicable statutory provisions assign authority to the Department, including the issuance of licenses for land disposal of low-level radioactive waste. "Agency" refers to the Radiation Protection Section, as defined in Rule .0103 of this Chapter, and is used for regulatory functions administered by the Section. The Rule has been reviewed to ensure that each term is used consistently with this distinction.

(b)(2): For clarity, consider writing this to end with, "… unless a written authorization has been issued by the agency to the recipient."
Response: Updated in text. Subparagraph (b)(2) has been revised for clarity

(b)(3), line 14: Delete "which".
Response: Updated in text.

(b)(3), line 19: Replace ".0111" with ".0111(a)" for consistency and clarity.
Response: Updated in text.

(b)(4): "Shall be met" by who and under what circumstances? Be clear and specific.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: The provision was unclear. Subparagraph (b)(4) has been revised to clarify that applicants and licensees shall comply with the applicable requirements under the cited statutory provisions.

Delete "shall be met" on line 23. It is now redundant given the changes made.

(b)(5): "Shall apply" to who or what? To licensees?
Response: Subparagraph (b)(5) has been revised to clarify that the definitions in G.S. 104E-5 apply to the interpretation and application of this Rule.

(c)(1): Same comment as above for (b)(2).
Response: Subparagraphs (c)(1) has been revised for clarity.

The revisions to the sentence do not make sense as written. Please reconsider this and revise as needed.

(c)(2): Same comment as above for (b)(5).
Response: Subparagraph (c)(2) has been revised to clarify that the definitions in G.S. 104E-5 apply to the interpretation and application of this Rule.

(c)(3), line 33, and (c)(4), page 2, line 6: "Prevent" means to stop while "minimize" and "reduce" both mean to decrease. They are two different things that can't simultaneously be expected. Do you expect them to completely prevent or only decrease? Revise the language here to most clearly convey the expectation.

Response: Generators, waste brokers and waste processors shall develop procedures and implement practices to prevent, minimize, and reduce the generation of low-level waste as required by G.S. 104E-27(a). These procedures shall include segregating waste by half-life and holding low-level radioactive waste for decay in storage.
The rule remains unchanged. In the language of the general statue includes prevention, minimization and reduction.

(d)(1)(B): Replace "address(es)" with "addresses".
Response: Updated in text.

(d)(1)(B), lines 22 and 23: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(d)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(d)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(d)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(d)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

(d)(3): Include the web address to locate the form, if possible.
Response: Updated in text.

(e): Is this necessary? What is the purpose of this paragraph?
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1301

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(c)(1), line 32: Rather than adding " under 10 CFR 39.91" on line 32, consider revising the first sentence to state: "Persons applying for new radioactive materials licenses, ~~or~~ for the renewal of existing radioactive materials licenses, or for exemptions from this Rule, shall submit …". I think this would be much clearer given the revisions you've made in paragraph (f).

(c)(1)(B): Replace "address(es)" with "addresses".
Response: Updated in text.

(c)(1)(B), lines 34 and 35: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

(c)(3): The web link is no longer effective. Please update.
Response: updated in text.

(e), page 3, line 2: Change ".0111" to ".0111(a)" for consistency.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(f): Do you have any requirements for exemption applications? Or is this an informal process? Your rule does not provide any sort of standard or process. Is there something you could cross-reference here?

Response: The provision was unclear. The standards for granting an exemption are provided in 10 CFR 39.91. Paragraph (f) has been revised to cross-reference 10 CFR 39.91 and specify that exemption applications shall be submitted to the agency in accordance with Rule .0111(a) of this Chapter.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1601

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 7: Remove the repetition of "and to effectuate their joint enforcement,".
Response: Updated in text.

(a)(1), line 9: Add "10 CFR" before "20.1003".
Response: Updated in text.

(a)(1), line 10: Change "Agency," to "Agency;".
Response: Updated in text.

(a)(2): "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is not a sentence. Also, what is it preserved from? Be clear and specific. As written, it's hard to understand what exactly you're trying to do here. Consider something like, "As preserved in G.S. 104E-5(16), the Commission retains primary authority to declare any other materials as special nuclear material."
Response: Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

Special Nuclear Material" has been changed to "special nuclear material" for consistency with the other defined terms in the Rule.

On line 14, please remove the period after "5" in the G.S. citation.

(b)(61), page 3, line 21: Add "of" between "individuals" and "exceeding." The CFR title is "Reports to individuals of exceeding dose limits".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(b)(63), page 3, line 26: You refer to Subparagraph (a)(6) of this rule, but this rule does not have an (a)(6). Do you mean (b)(6)?
Response: Updated in text.

(c): What is a "personnel monitoring device"? Is it defined in another rule or statute that can be referenced? Exposure to what, by whom, and what is the deception? This Paragraph needs context and clarity.

Response: The provision was unclear. Paragraph (c) has been revised to use the term "individual monitoring device" as defined in 10 CFR 20.1003 and to clarify that no person may intentionally expose such a device to radiation for the purpose of causing it to indicate a dose not received by the individual to whom the device is assigned.

(d), first sentence, lines 12-13: Something is missing in this sentence. Consider, "… all activities required by the rules of this Chapter, and any license or registration conditions imposed by the agency, and shall pay …".
Response: The first sentence of Paragraph (d) has been revised to clarify that licensees and registrants shall continue to perform activities required by the rules of this Chapter and applicable license or registration conditions until termination.

Consider adding back in "until the license or registration is terminated." Your revisions took this out of the rule text and did not add it back in.

(d), line 13: Consider referencing your fee rule(s) here for clarity.
Response: Paragraph (d) has been revised to cross-reference the annual fee requirements in Section .1100 of this Chapter

(e): Why is this paragraph needed? What is it doing?
Response: Paragraph has been removed.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1701

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(1): Add "and" to the end of this.
Response: Updated in text.

(d): For consistency, change "The Code of Federal Regulations incorporated by this Rule" to "Copies of these regulations".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

10A NCAC 15 .0103 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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 the 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.~~ "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).

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

~~"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~~ a.m. January 1 to 11:59:59 ~~pm~~ p.m. 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.~~ except where otherwise defined in the rules of this Chapter.

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

(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~~ 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~~ 15 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 building, ~~at one address or vehicle~~, building or vehicle at one address 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~~ diagnosis 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~~ or 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) "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 .0209 of this Chapter.

~~"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) "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.

~~"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 .0209 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~~.1700, [~~1900,~~] .1900, and .2000 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.*~~*2025;*
Amended Eff. October 1, 2026.

10A NCAC 15 .0201 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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

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

10A NCAC 15 .0201 PURPOSE AND SCOPE

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

(b) A person who acquires, owns, possesses, or receives ~~a radiation machine or~~ an X-Ray [~~machine,~~] machine or a radiation generating ~~device~~ ~~devices,~~ device, or provides other radiologic services 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 that use ~~using~~ ~~radiation machines~~ an X-Ray machine [~~machine,~~] or a radiation generating device for demonstration ~~purposes~~ purposes, or that provide mobile leasing ~~services~~ services, are subject to the additional requirements of Rule .0205 of this Section. Service providers that provide those services by bringing ~~radiation machines~~ an X-ray machine 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~~ X-ray 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~~ Industrial radiographic X-ray machines are subject to the additional requirements of Section .0500 of this Chapter.

(g) ~~Registrants using~~ ~~radiation~~ X-ray machines for ~~human~~ diagnostic imaging and veterinary use are subject to the additional requirements in Section .0600 of this Chapter.

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

(i) ~~Registrants using ionizing radiation~~ Radiation generating devices and X-ray machines for non-human use are subject to the additional 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, 2026; October 1, 2025.

10A NCAC 15 .0203 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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~~ X-ray ~~machine,~~ machine, or radiation generating device, or an unregistered service ~~provider,~~ 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~~ X-ray 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~~ The owner or the individual responsible for the business operations of a facility with an X-ray machine, radiation generating device, or who ~~is responsible for providing~~ provides radiological services, shall ensure that 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) are 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,~~ radiological 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.~~ https://radiation.ncdhhs.gov/Xray/applic.htm and https://radiation.ncdhhs.gov/Xray/service.htm.

(5) The owner or individual responsible for business operations can designate a responsible person or persons within the organization to sign when amendments are made to forms by notifying the agency in writing.

(c) A Business Application form shall be submitted prior to the operation of a facility or providing services in this ~~State~~ 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~~ X-ray machines or radiation generating [~~device~~] devices at a facility; or

(B) that plans to engage in radiological 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,~~ number, and type of ~~business, days and hours of operation;~~ business;

(C) the name, title, mailing address, phone, and e-mail address of the 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;~~ made available during inspection or upon request by the agency;

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

~~(F) description of facility use;~~

~~(G) description of service provider equipment~~;

~~(H)~~(F) dated and signed by the owner or the individual ~~with administrative control; and~~ responsible for business operations.

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

(d) ~~A Radiation~~ An X-ray 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~~ X-ray 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~~ X-Ray machines or radiation generating devices at a facility; or

(B) that is engaged in leasing or performing demonstrations using an unregistered ~~radiation~~ X-Ray 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 the machine or device not in use;

(E) installer information; and

(F) ~~shall be~~ dated and signed by the ~~individual with administrative control.~~ owner or individual responsible for business operations. ~~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~~ an X-ray Machine or Radiation Generating Device Form shall be submitted when a facility disposes of ~~a radiation~~ an X-ray 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,~~ relocation, or to update information;

(3) ~~radiation~~ X-ray machine or radiation generating device location; manufacturer, ~~model,~~ model and serial number;

(4) identify the ~~reason for~~ method of disposal of the ~~radiation~~ X-ray machine or radiation generating device;

(5) ~~the~~ recipient of the ~~radiation~~ X-ray machine or radiation generating ~~device, to the individual or business name,~~ device, physical and e-mail address, and phone number; and

(6) dated and signed by the owner or the individual ~~with administrative control~~ responsible for business operations of the ~~radiation~~ X-ray 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~~ X-ray machines or radiation generating devices;

(B) providing individual monitoring devices; ~~and~~ or

(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~~ dated and signed by the owner or the individual ~~with administrative control.~~ responsible for business operations.

(g) A Company Employee Services Application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through ~~(H)~~ (G) 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;~~ X-ray machines;

(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~~ X-ray machines or radiation generating devices;

(E) qualified expert consulting services for CT and mammography ~~radiation~~ X-ray machines;

~~(F) radiation protection expert;~~

~~(G)~~(F) shielding designs for ~~diagnostic radiographic and fluoroscopy~~ ~~facilities;~~ X-ray machines; and

~~(H)~~(G) therapeutic ~~facility~~ shielding ~~design, area radiation survey, or calibration.~~ verification and area radiation surveys.

(2) The application requires the following information:

(A) name of the employee to be registered;

(B) start date if the employee is being ~~added~~ 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 owner or the individual ~~with administrative control;~~ responsible for business operations; 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,~~ education requirements of the Class for the services provided, 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 documentation of the requirements in Subparagraph ~~(1)(h)~~ (h)(1) 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~~ involving X-ray 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;~~ responsible for business operations;

(B) submit to the agency, a Disposal of ~~a Radiation~~ an X-ray 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~~ an X-ray 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0204 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0204 FACILITY RESPONSIBILITIES

(a) All forms ~~in~~ required by 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~~ X-ray machines for human, non-human, or veterinary use and prior to structural modification of existing installations, an ~~applicant,~~ applicant shall have the floor plans, shielding specifications, and equipment arrangement reviewed by a registered service provider.

(2) The ~~registrant~~ applicant shall submit ~~the~~ a shielding design and the agency Shielding Design Review Form to the agency for review. Shielding design drawings shall [~~include a scaled drawing.~~] be scaled. The ~~agency form~~ Shielding Design Review Form shall include the following information:

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

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

(C) proposed date of ~~installation.~~ installation or structural modification.

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

(4) ~~A radiation~~ An X-ray 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~~ X-Ray 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 radiation 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~~ X-ray absorptiometry (DEXA);

(C) mammography; or

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

(c) Facility ~~registration~~ registration:

(1) Mobile ~~radiation~~ X-ray machines located and used in this ~~State that are fixed in~~ State, and permanently affixed within a vehicle or ~~trailer~~ trailer, shall meet the following requirements prior to use:

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

(B) have ~~a Radiation~~ an X-ray Machine Application ~~or a Radiation Generating Devices Application~~ form submitted in accordance with Rule .0203(d) of this Section. ~~Radiation~~ X-ray machines leased or on loan from a registered service provider shall ~~register the radiation machine~~ be registered with the agency if ~~used~~ maintained for more than 30 days;

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

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

~~(E)~~(D) an individual ~~with administrative control~~ responsible for business operations shall ensure that ~~radiation~~ X-ray machines are operated in accordance with Section .0600 of this Chapter.

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

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

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

(C) an individual responsible for business operations shall ensure that X-ray machines are operated in accordance with Section .0600 of this Chapter.

(3) Mobile radiation generating devices located out-of-state and brought into this State for use shall meet the following requirements prior to use:

(A) have a Radiation Generating Devices Application form submitted in accordance with Rule .0203(d) of this Section. Radiation generating devices leased or on loan from a registered service provider shall be registered with the agency if maintained for use for more than 30 days;

(B) have a copy of the operating and safety procedures describing how to protect operators and the public from radiation submitted to the agency;

(C) submit a written notice, in accordance with Rule .0208 of this Section, and maintain it for agency review during inspection; and

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

~~(3)~~(4) ~~Radiation~~ X-ray machines for ~~human, non-human,~~ diagnostic imaging, non-diagnostic imaging, clinical studies, ~~or~~ veterinary ~~use~~ use, or for use by service providers for demonstration purposes shall meet the following additional requirements:

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

(B) submit ~~a Radiation~~ an X-ray Machine Application form in accordance with Rule ~~.0203 (d)~~ .0203(d) of this Section within 30 days of ~~use.~~ use; and

(C) an individual ~~with administrative control~~ responsible for business operations shall ensure that X-ray machines are operated in accordance with Section .0600 of this Chapter.

~~(4)~~(5) Radiation generating devices covered in Section .0800 of this Chapter shall meet the following additional requirements prior to use:

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

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

~~(5)~~(6) Industrial radiography ~~radiation~~ X-ray machines covered in Section .0500 of this Chapter shall meet the following additional requirements prior to use:

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

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

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

(e) ~~Persons~~ Facilities registered pursuant to ~~Paragraph(c)~~ 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~~ facility 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0205 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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,~~ State 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~~ X-ray machines or radiation generating devices;

(2) Class II - ~~installation, repair,~~ installation or service of the following:

(A) ~~radiation~~ X-ray 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;~~ X-ray machines;

(4) Class IV - shielding designs for ~~diagnostic fluoroscopy facilities;~~ fluoroscopic X-ray machines;

(5) Class V - area radiation surveys and shielding evaluations for ~~diagnostic radiographic and fluoroscopy facilities;~~ ~~[X-ray machines;]~~ radiographic and fluoroscopic X-ray machines:

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

(7) Class VII - therapeutic ~~facility~~ shielding ~~design, area radiation survey, or verification;~~ verification ~~[and area surveys;]~~ services;

(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~~ X-ray machines that are ~~fixed in~~ permanently affixed within a vehicle or trailer for demonstration purposes or to ~~that~~ ~~provides~~ provide leasing services shall meet the following requirements prior to use:

(1) mobile ~~radiation~~ X-ray machines located and used in this State shall meet the requirements of Rules .0204(c)(1)(A) through ~~(E)~~ (D) of this Section; and

(2) mobile ~~radiation~~ X-ray machines located out of state and brought into this State for use shall meet the requirements of Rules .0204(c)(2)(A) and ~~(B)~~ (C) of this Section.

(g) Report of installation:

(1) Persons registered pursuant to Paragraph (a) of this Rule who sell, install, transfer, lease, or lend ~~lend, or dispose of~~ ~~radiation~~ an X-ray machines or radiation generating ~~[devices]~~ device in this State shall, within ~~15~~ 30 days after each calendar quarter, notify the agency at ~~XrayNORS@dhhs.nc.gov~~ fda2579@dhhs.nc.gov or the address, in accordance with Rule .0111 of this Chapter, of the following:

(A) whether any ~~radiation~~ X-ray machines or radiation generating devices 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~~ X-ray machine or radiation generating devices 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~~ X-ray machine or radiation generating devices 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~~ 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~~ X-ray machines for nonhuman use and radiation generating devices, when a Report of Sale and Installation Form prepared in accordance with Paragraph ~~(i)~~ (h) of this Rule is received by the agency.

(h) A Report of Sale and Installation of ~~radiation~~ X-ray 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~~ X-ray 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 the 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~~ X-ray machines, ~~radiation~~ X-ray machine components, or radiation ~~machine~~ generating devices unless such machines and ~~devices~~ devices, when placed in ~~operation~~ operation, ~~shall~~ meet the requirements of these Rules.

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

(k) ~~Tests~~ Records of tests performed at the time of installation ~~demonstrating~~ that demonstrate the requirements of these Rules are ~~met,~~ met shall be provided to the registrant for agency review during inspection for the following:

(1) ~~fluoroscopy~~ fluoroscopic X-ray machine output measurement; and

(2) radiation generating devices equipment surveys.

(l) Records of any routine maintenance, repair, alterations, or reassembly of ~~radiation~~ X-ray 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0206 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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 shall be met for each service class:

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

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

(A) completion of manufacturer's equipment school for service, maintenance, and installation for the type of ~~radiation~~ X-ray machine or ~~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~~ X-ray machines, radiation generating devices, and machine components. ~~components services are required.~~

(3) Class III - shielding design for ~~diagnostic radiographic facilities:~~ [~~X-ray machine:~~] X-ray machines:

(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 shielding design experience ~~in diagnostic radiographic facility and shielding~~ for each type of machine ~~application.~~ modality.

(4) Class IV - shielding design for ~~diagnostic fluoroscopic facilities:~~ fluoroscopic X-ray machines:

(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 shielding design experience ~~in diagnostic fluoroscopic facility and shielding~~ for each type of machine ~~application.~~ type.

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

(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.~~ modality.

(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:~~ verification and area surveys:

(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,~~ 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:~~ devices: The applicant ~~must~~ shall 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~~ consulting. The applicant shall meet ~~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~~ X-ray and radium physics; or

(D) hold a master's or doctorate degree 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~~ X-ray physics.

(b) Any person registered to provide Class IX services prior to ~~the effective date of this Rule~~ October 1, 2026, 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0207 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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,~~ measurements and equipment surveys, Class V area radiation surveys and shielding evaluations for ~~diagnostic~~ radiographic and ~~fluoroscopy facilities,~~ fluoroscopic X-ray machines, or Class VII therapeutic area radiation survey or shielding 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~~ surveys, including a list of all guides and references provided to the employed;

(B) a copy of all forms, reports, and documents that will be supplied ~~to registrants:~~ in conjunction with the provided services;

(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 at the time that the service is provided 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,~~ X-ray machines, Class IV shielding designs for ~~diagnostic fluoroscopy facilities,~~ fluoroscopic X-ray machines, and Class VII therapeutic ~~facilities and~~ shielding design verification 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 verification 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0211 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0211 THE INDIVIDUAL ~~REPSONSIBLE~~ 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~~ who can be an ~~actively registered~~ active ~~radiologic technologist,~~ Registered Technologist (RT) by the American Registry of Radiologic Technologists (ARRT), shall be ~~on site~~ or available at all times and be qualified by reason of education, training, and experience. Records of this individual's education, training, and experience shall be available for review during inspections or upon request by the agency. The individual shall meet the following ~~are the minimum qualifications that must be met to carry out the job duties:~~ qualifications:

(1) training in basic radiation protection principles;

(2) completed educational courses relating to ionizing radiation;

(3) ~~know~~ knowledge of potential radiation hazards and emergency precautions; and

(4) training and experience in and ~~knowing~~ knowledge of the proper use of the type of equipment. ~~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~~ occur, to ensure the procedures are current.

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

(A) reviewed;

(B) maintained; and

(C) notifications made in accordance with Rule ~~.1601~~ .1001(a)(7) 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~~ 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, 2026; October 1, 2025.

10A NCAC 15 .0212 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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

(a) ~~Radiation~~ X-ray machines or radiation generating devices that do not meet the ~~radiation~~ X-ray machine or radiation generating device 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~~ X-ray machine or radiation generating device and determining if the use of the ~~radiation~~ X-ray machine or radiation generating device 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) The proposed user or manufacturer of ~~[the]~~ an X-ray 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's manual;

(3) description of intended use;

(4) operator training provided to the end user;

(5) an independent equipment survey ~~[to include the following:]~~ that includes:

(A) all equipment settings available to the operator;

(B) radiation output at the highest setting; and

(C) leakage radiation around the X-ray machine.

(6) an area survey ~~[to include the following:]~~ that includes:

(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 X-ray machine.

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

(c) The proposed user or manufacturer of [~~the~~] a radiation generating device shall submit the [~~requirements~~] required information in Rule .0808 of this Chapter for review.

~~(b)~~(d) After receiving the information in ~~Paragraph (a)~~ Paragraphs (b) and (c) of this Rule, the agency ~~will~~ shall respond to the applicant in writing within 90 calendar days. Upon review, the agency may require additional information to determine if the ~~radiation~~ X-ray machine or radiation generating device 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, 2026; October 1, 2025.

10A NCAC 15 .0214 is repealed as published in 40:19 NCR 1541-1550 as follows:

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

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.~~
Repealed Eff. October 1, 2026.

10A NCAC 15 .0301 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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 ~~BYPRODUCE~~ BYPRODUCT MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 30 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 30:

(1) With the exception of ~~[10 CFR 30.4]~~ 10 CFR 30.4, a reference to "NRC" or "Commission" means the "Agency;"

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

(3) In 10 CFR 30.18(d) and 30.32(g) where a reference is made to "an Agreement State", it means "an Agreement State or the NRC."

~~(a)~~(b) 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~~ For purposes of this Rule, the term "temporary jobsite" shall mean a location where byproduct materials are used and stored other than those ~~location(s)~~ locations 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)~~(c) 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),~~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)~~(c) 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~~.0111(a) 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)~~ addresses 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0307 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 35 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 35:

(1) A reference to "NRC" or "Commission" means the "Agency;" and

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

~~(a)~~(b) All persons using radioactive materials for medical use in humans shall comply with the ~~general information~~ following 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)[(n)] of this Rule shall be met;~~ applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (n) of this Rule;

(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)~~(c) 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,~~ by no later than May 1, 2027, 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)~~(d) All persons administering radioactive materials to humans not requiring a written directive shall develop, document, maintain, and require the use ~~of,~~ 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,~~ include the following 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,~~ care and to prevent the occurrence of medical events.

~~(d)~~(e) 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)~~(e)(10) of this ~~Paragraph.~~ Rule. ~~Brachytherapy~~Sealed sources and 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)~~(e)(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)~~(f) 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)~~(g) 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)~~(h) 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 covered by the provisions of 10 CFR Part 35 listed in Subparagraphs ~~(g)(6)~~(h)(6) and ~~(g)(7)~~(h)(7) of this Rule shall be approved by an Authorized Medical Physicist.

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

~~(k)~~(l) 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)~~(m) 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 in accordance with Rule .0111 of this Chapter 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~~.0111(a) 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)~~(n) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*

Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0307 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~[~~2014.~~]2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0308 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 36 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 36:

(1) A reference to “NRC” or “Commission” means the "Agency;” and

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

~~(a)~~(b) 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)~~(c) 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~~CFR 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~~.0111(a) of this Chapter unless directed otherwise by the agency, in lieu of the United States Nuclear Regulatory Commission (NRC).

~~(b)~~(c) 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,~~ Licenisng.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0309 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0309 DOMESTIC LICENSING OF SOURCE MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 40 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 40:

(1) With the exception of 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, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~] the same as defined in G.S. 104E-5.(16); and

(4) In 10 CFR 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".

~~(a)~~(b) 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~~ do 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~~ applications shall be submitted to the agency in accordance with Paragraph ~~(b)~~(c) 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),~~ 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),~~ 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)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication if the application is for a new license, or for the renewal of an existing license, by marking the corresponding check box;

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

(G) ~~applicants shall indicate~~ indication of 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0310 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 70 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 70:

(1) With the exception of 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 70.4, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~] the same as defined in G.S. 104E-5.(16).

(4) 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".

~~(a)~~(b) 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~~ do 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~~ an applications shall be submitted to the agency in accordance with Paragraph ~~(b)~~(c) of this ~~Rule shall be met;~~ Rule;

(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)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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)~~(d) 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);*
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Amended Eff. October 1, 2026.

10A NCAC 15 .0311 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0311 PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 71 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 71:

(1) In 10 CFR 71.0(c), 71.3, [~~71.5~~] 71.5, 71.17(a), (b), 71.22, 71.23(a), (b), [~~10 CFR~~] and 71.101(c)(1), a reference to "NRC" or "Commission" means the "Agency;"

(2) In 10 CFR 71.8(b), (d), and 71.17(b), [~~the Agency is the "quality assurance program approval holder,"~~] references to the NRC with respect to quality assurance program approval mean the Agency; and

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

~~(a)~~(b) 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;~~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;"~~misconduct." In 10 CFR 71.8(a)(3), _____ _____ _____ _____ _____ _____

(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 10 CFR 71.17(a) applies to any licensee of the agency, and the 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 ~~—~~ _____ 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;"~~package," except that 10 CFR 71.21(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR [~~71.21b)~~] 71.21(b) shall be issued by the agency or the NRC.

(14) 10 CFR 71.22, "General license: Fissile ~~material;"~~material" except that 10 CFR 71.22(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR 71.22(b) shall be issued by the agency.

(15) 10 CFR 71.23, "General license: Plutonium-beryllium special form ~~material;"~~material," except that 10 CFR 71.23(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR 71.23(b) shall be issued by the agency.

(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;"~~program." Changes to 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;

(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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0313 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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:~~apply, and in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~] the same as defined in G.S. 104E-5.(16).

(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;"~~licenses," in addition to the general license authorized by 10 CFR 150.20(a)(1) and subject to the limitations of 10 CFR 150.20(a)(2), any person who holds a specific license issued by an Agreement State or by the NRC is granted a general license to conduct the same activity in North Carolina and the offshore waters within the jurisdiction of the State of North Carolina;

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

(8) 10 CFR 150.32, "Funds for reclamation or maintenance of byproduct ~~material;"~~ 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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .1203 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .1203 LICENSE REQUIRED: LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 61 and to effectuate their joint enforcement, except in 10 CFR 61.2, a reference to "NRC" or "Commission" means the "Agency."

~~(a)~~(b) 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.~~ not granted a low-level waste facility access license by the agency in accordance with G.S. 104E-10.3.

(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~~ .0111(a) of this Chapter in lieu of the NRC.

(4) ~~The requirements found in~~ Applicants and licensees shall comply with the applicable requirements under 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.~~ apply to the interpretation and application of this Rule.

(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)~~(c) 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)~~(b) of this Rule.

(1) No person shall transport or transfer waste to a low-level radioactive waste land disposal facility licensed under Paragraph ~~(a)~~(b) of this Rule unless licensed by the agency or ~~otherwise specifically authorized in writing by the agency.~~ not granted a low-level waste facility access license by the agency in accordance with G.S. 104E-10.3.

(2) The definitions of terms in G.S. 104E-5 shall ~~apply.~~ apply to the interpretation and application of this Rule.

(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,~~ waste as required by G.S. 104E-27(a). ~~including~~ These procedures and practices shall include 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)~~(b) 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)~~(c)(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)~~(d) 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~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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 are available at ~~shall be made available by the agency on the agency's public website~~. https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

~~[(d)](e) 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.~~2023;
Amended Eff. October 1, 2026.

10A NCAC 15 .1301 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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) To reconcile differences between this Rule and the incorporated sections of 10 CFR 39 and to effectuate their joint enforcement, a reference to "NRC" or "Commission" means the "Agency."

~~(a)~~(b) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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 under 10 CFR 39.91 on the application:

(A) legal business name and mailing address;

(B) physical ~~address(es)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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.~~ https://radiation.ncdhhs.gov/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~~ .0111(a) of this Chapter in lieu of the NRC.

(f) Applications for exemptions from this Rule permitted by 10 CFR 39.91 ~~to this Rule~~ shall be submitted to the agency at the address shown in Rule ~~.0111~~.0111(a) 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.~~2022;
Amended Eff. October 1, 2026.

10A NCAC 15 .1601 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 20 and to effectuate their joint enforcement, [~~and to effectuate their joint enforcement,~~] the following words and phrases shall be substituted for the language of 10 CFR 20:

(1) Except in 10 CFR 20.1003, a reference to the "Nuclear Regulatory Commission," "NRC" or "Commission" means the [~~"Agency,"~~] "Agency;" and

(2) In 10 CFR 20.1003, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", [~~the sentence~~] the phrase "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~~]the same as defined in G.S. 104E-5.(16).

~~(a)~~(b) 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 of 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)~~ (b)(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)~~(c) ~~Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.~~ No person shall intentionally expose an individual monitoring device, as defined in 10 CFR 20.1003, to radiation for the purpose of causing the device to indicate a dose not received by the individual to whom the device is assigned.

~~(c)~~(d) Licensees and registrants shall continue to perform all activities required by the rules of this Chapter, and any license or registration conditions imposed by the agency, and shall pay annual fees required by the Rules in Section 10A NCAC 15.1100. ~~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)[(e)] Nothing in the rules of this Chapter shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.~~

(e)[~~(f)~~] 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, 2026; May 1, 2025.

Burgos, Alexander N

From: Black, Shanah
Sent: Friday, September 18, 2026 10:51 AM
To: Miller, Christopher S; Rules, Oah; Burgos, Alexander N
Subject: Tech changes for 10A NCAC 15 amendments
Attachments: 10A NCAC 15 .0201.docx; 10A NCAC 15 .0202.docx; 10A NCAC 15 .0203.docx; 10A NCAC 15 .0204.docx; 10A NCAC 15 .0205.docx; 10A NCAC 15 .0206.docx; 10A NCAC 15 .0207.docx; 10A NCAC 15 .0211.docx; 10A NCAC 15 .0212.docx; 10A NCAC 15 .0214.docx; Request for Changes - NCRPC - 09 2026.docx; 10A NCAC 15 .0103.docx; 10A NCAC 15 .0104.docx; 10A NCAC 15 .0301.docx; 10A NCAC 15 .0302.docx; 10A NCAC 15 .0304.docx; 10A NCAC 15 .0305.docx; 10A NCAC 15 .0306.docx; 10A NCAC 15 .0307.docx; 10A NCAC 15 .0308.docx; 10A NCAC 15 .0309.docx; 10A NCAC 15 .0310.docx; 10A NCAC 15 .0311.docx; 10A NCAC 15 .0313.docx; 10A NCAC 15 .1203.docx; 10A NCAC 15 .1301.docx; 10A NCAC 15 .1601.docx; 10A NCAC 15 .1701.docx

Good morning,

We are submitting these technical changes you requested.

Have a good weekend.

Thanks,

Shanah Black
Rule-making Coordinator
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REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: ALL RULES

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Use of "X-ray machine": In many places, it seems like you are replacing "radiation machine" with "X-ray machine". Do these two terms have the same meaning? Or is "radiation machine" a broader category of devices? You define "radiation machine" in your rules (and it's also defined by statute). However, "X-ray machine" is left undefined. You should clarify the meaning somewhere in your rules, even if it has the same meaning as a "radiation machine".

Response: The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two are broken down in Sections .0500, .0600, and .0800.

Cross-References: Please ensure that all of your cross-references are still accurate. I identified several places where rule cross-references needed to be updated based on the revised versions of the rules in this package.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0103

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

General Comment: Definition rules should be ordered alphabetically. Some of your definitions are not in proper order. For example, (a)(3) and (a)(4) should be switched. (b)(12) should come before "Registrant". Please consider fixing this.
Response: Updated in text.

(a), lines 4-6: The wording of this paragraph is awkward. I would suggest deleting, "… 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, …". If you want to keep this language, consider revising the start of the paragraph to say, "As used in the rules of this Chapter and as applied to persons …".
Response: Updated in text.

(a)(1), line 7: Add "the" before the name of the Act.
Response: Updated in text.

(a)(6): Per the style guide, please use the abbreviations "a.m." and "p.m." to express time.
Response: Updated in text.

(a)(9) and (10): Paragraph (c) does not provide a different meaning for these terms. Rather, it points to different sections of your rules. For clarity, consider revising this to say, "… except where otherwise defined in the rules of this Chapter." Or, specifically identify which rule section would apply to these two terms.
Response: Thank you for the suggestion. This improves the rule. Change made to the rule as requested.

(a)(19): "six month intervals" should include a hyphen.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(a)(23): "Chapter 10" of what Title? Your rules are in Chapter 15. Am I missing something here?
Response: Updated in text.
(b): Same comment as mentioned above for (a), lines 4-6.
Response: Updated in text.

(b)(3), lines 20-21: I don't fully understand what you mean. Should this say, "… within one building or one vehicle at one address and under …"? What is the intent here?
Response: Updated in text.

(b)(7), line 32: Change "diagnosing" to "diagnosis".
Response: Updated in text.

(b)(7)(B), line 35: Change "and" to "or".
Response: Updated in text.

(b)(12), line 10: Rule .0207 does not mention any "Notice of Registration". Please correct your cross-reference.
Response: Updated in text.

(b)(15): Rule .0205(d) does not mention any specific services. Please correct your cross-reference.
Response: Updated in text.

(c), line 23: Add a period before "1900".
Response: Updated in text.

History Note, Authority: Is 10 CFR 20.1003 still applicable to this rule now that you've moved the CFR definitions to other places throughout your rules?
Response: Thank you very much for your comment. The citation in the History Note referencing 10 CFR 20.1003 is no longer necessary because the regulation in the 10 CFR is incorporated by reference in 10A NCAC 15 .1601 in the rules currently published on the OAH website. The change to the history note made as suggested.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0104

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

General Question: G.S. 150B-21.6 authorizes incorporation of another agency rule or a code, standard, or regulation adopted by another agency, the federal government, or a generally recognized organization or association. How does this bilateral Agreement fall within one of those categories? And what is the effect of incorporating the Agreement? Are you trying to enforce specific provisions of the Agreement?
Response: The Agreement does not fit precisely within the categories of a code, standard, or regulation identified in G.S. 150B-21.6. However, the Agreement functions as a statement of general applicability that implements federal and State statutory authority and describes the scope of the Agency's regulatory authority. Pursuant to Section 274 of the Atomic Energy Act and North Carolina law, the Agreement authorizes the State to regulate certain activities involving radioactive material while reserving other activities to exclusive federal jurisdiction.

Incorporating the Agreement into Rule .0104 provides notice to the regulated community and guidance to the Agency regarding the scope of activities the State may license and regulate. The Agency is not seeking to enforce individual provisions of the Agreement separately; rather, the Agreement establishes the jurisdictional boundaries within which the Agency exercises its regulatory authority.

Page 2, line 6: Delete "hereby".
Response: Updated in text.

History Note, Authority: Please confirm that all listed statutes are still relevant even with the proposed deletions.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0201

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a): What is the difference between an X-ray machine and a radiation generating device? Are these terms both defined anywhere in your rules? Is there a reason why you use both terms here? Consider adding a definition in .0103
Response: The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two are broken down in Sections .0500, .0600, and .0800.

(b), lines 11-12: Replace the comma after "X-ray machine" with "or" and either delete "a" or change "devices" to "device".
Response: Updated in text.

(b), line 12: Is "radiologic" or "radiological" the proper term? You use the latter in (a). Be consistent in your rule.
Response: Updated in text.

(d), line 16: Do you need the comma here after "X-ray machine"? What is your intent? Consider: "Service providers that use an X-ray machine or radiation generating device for demonstration purposes, or that provide mobile leasing services, are subject …"
Response: Updated in text.

(f): What does "Industrial" mean in this context?
Response: Industry standard uses the term Industrial and Industrial Radiography is a non-destructive testing method that uses ionizing radiation to examine the internal structure of materials, components, and welds without causing damage.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(g), line 24: Change "and" to "or" if these are separate categories.
Response: It is supposed to be "and"

(h), line 27: Change "or by service providers for demonstration purposes" to "or for demonstration purposes conducted by service providers".
Response: Updated in text.

(i): Would this provision apply to veterinary services? And if so, is it possible to comply with both Sections .0600 and .0800 at the same time? Or is this rule not meant to have a cumulative effect with paragraphs (f)-(h)? It is not really clear.
Response: This does not apply for human or veterinary services. When X-ray machines are used in industrial settings this would not be for human or veterinary services. This rule does not have a cumulative effect. Paragraph (g) addresses human diagnostic imaging and veterinary use.

History Note, Authority: How are 104E 9(8) and 104E 19(a) relevant here? Those are fee statutes.
Response: Historically the agency has not changed a history note unless applicable to intent of rule change. The intent of this rule has not changed since written. Does 104E-9(8) and 19(a) establish the legislative authority for the fee related provisions of this Section? Please advise if change is still need.

History Note, page 2, line 1: The most recent date should be placed first within the same line. Please correct this.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0202

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 4: What do you mean by "other purposes"? Purposes not covered under rule 10A NCAC 15 .0201? If so, state that in the rule.
Response:

(a), line 5: I believe "average" should be changed to "averaged".
Response: Updated in text.

(b), line 9: Please delete "therefore".
Response: Updated in text.

(b), line 9: Are "exemptions" and "exceptions" different? If they are the same thing, you should just use one term.
Response: Exemption and exception are different. The agency may exempt an entity from a specific requirement or make grant an exception to a requirement under specific circumstances as outlined in Rule .0212.

(b): Are there any other factors that you are considering when exercising this discretion? Or is it solely based on the level of radiation? Also, on line 10, what is "it" referring to? What exactly are you exempting? The rule language is not clear.
Response: The primary factor that is considered when exercising discretion to grant an exemption or exception is the radiation dose. "It" refers to the granted exemption. Exemptions may apply to either a machine requirement or operating requirement.

(b): Are exemptions granted by the Commission or the agency?
Response: Agency and it is stated on line 9.

(c)(2): Same question as for other rules – why are X-ray machines and radiation generating devices now being split out? Do you define both terms?

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: To provide clarity to facilities that RGDs are included in these requirements. The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two is broken down in Sections .0500, .0600, and .0800.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0203

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 6: What is the intent of the change here? You are replacing a defined term, "radiation machine," with an undefined term, "X-ray machine". Are "radiation machines" no longer covered under the revised rule? Or are these meant to mean the same thing? It is not clear to me.
Response: A radiation machine is defined in G.S. 104E-5(13) and the statutory definition includes nuclear particles. During a previous comment period, the commentor noted that using the term radiation machines implied that it could relate to sources regulated by the Radioactive Materials Branch. The terms were split to provide better clarity. Industry standards recognize X-ray machines are for diagnostic imaging and RGDs are not.

(a), line 6: Add "or" before "radiation generating device,".
Response: There is already an "or" on line 6.

(a), sentence 2: What is the effect of this sentence? Once a facility registers one device, the entire facility is then considered registered? I don't understand the rule language.
Response: Submitting a registration application for a single X-ray machine or RGD establishes the initial registration for the entire facility. The facility will then receive an invoice to finalize the registration process.

(b)(4): The new web link provided does not work. Please use an existing, active link.
Response: Updated in text.

(c)(1)(A), line 31: Change "<u>device</u>" to "<u>devices</u>".
Response: Updated in text.

(c)(2)(D): Add "made" before "<u>available during …</u>".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(d)(2)(D): Add "when" before "not in use", if that is your intent.
Response: Not necessary.

(e)(3): Change the semi-colon after "location" to a comma.
Response: Not necessary, there are semi-colon after each line.

(f)(1)(B): Should the "and" at the end of this line be an "or"?
Response: Updated in text.

(h)(1): Add "requirements of the Class for the services provided" after "meets the education". Also consider adding a cross-reference here to the appropriate requirements for clarity.
Response: Updated in text.

(h)(3): Add "documentation of the " before "requirements in …".
Response: Updated in text.

(h)(3): Do you mean, "Subparagraph (h)(1)"? I think there is a typo here.
Response: Updated in text.

(i)(2)(A): For consistency, should this also be updated to "… or the individual responsible for business operations;"?
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0204

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 4: Change "in this Rule" to "required by this Rule".
Response: Updated in text.

(b)(2): Who is the "registrant" in this instance? The "applicant" or the "registered service provider"? It is not clear.
Response: Will it be confusing if we put applicant. It has always been the registrant. Consider registered service provider since they are the ones that usually submit it.

(b)(2): It would be clearer to state, "Shielding design drawings shall be scaled."
Response: Updated in text.

(b)(2)(C): Couldn't this also apply to a structural modification?
Response: Updated in text.

(b)(5), line 29: "dose" of what? Please specify. Also, rule .1601 doesn't specify any limits. Rather, it points to other standards. So the wording used here does not make sense.
Response: Updated in text.

(c), line 37: Add a colon at the end of this.
Response: Updated in text.

(c)(2)(A), line 19: Replace "requirements" with "required documentation".
Response: Updated in text.

(c)(4), line 2: Add "for use" before "by service providers …".
Response: Updated in text.

(c)(4)(B): Delete the space between ".0203" and "(d)".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text

(c)(5): Add "covered" before "in Section .0800 …".
Response: Updated in text.

(c)(6): Add "covered" before "in Section .0500 …".
Response: Updated in text.

(d): "Persons" are not registered under Paragraph (c). Paragraph (c) states facility requirements. Please amend the language here as needed.
Response: Updated in text.

(e): Same comment as above. Also, add a space between "Paragraph" and "(c)" on line 28.
Response: Updated in text.

(f): Same comment as (d) and (e).
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0205

DEADLINE FOR RECEIPT: September 18, 2026

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 5: I would recommend deleting, "… of such services …" The person isn't registering the services, correct? The registration would apply to the person.
Response: Updated in text.

(b), line 7: For clarity, you should specify which section(s) of .0203 specifically apply here since that rule contains various different forms.
Response: Depending on the type of service being provided, multiple application forms may apply

(e)(1): Same question as mentioned for other rules regarding the change of "radiation machine" to "X-ray machine".
Response: To provide clarity to facilities that RGDs are included in these requirements. The regulatory distinction is categorical. X-ray machines are typically used on humans and RGDs are not used on humans, with the exception of Security Screening Systems in Section .0807. Industry standard uses the term RGD. Compliance requirements apply to the broader category, with additional or more specific controls depending on how the X-ray machine is used in practice. Use of the two is broken down in Sections .0500, .0600, and .0800.

(e)(3): If you do shielding designs for fluoroscopic X-ray machines, do you need both a Class III and IV registration? If you only need IV, you should state that Class III does not include fluoroscopic X-ray machines.
Response: Fluoroscopic X-ray machines are a subcategory of X-ray machines that produces a higher output of radiation than standard X-ray machines. This requires different calculations for shielding design.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(f), line 35-36: Change "that provide" to "to provide".
Response: Updated in text.

(f)(1), line 2: Change "(E)" to "(D)", based on your updated rule.
Response: Updated in text.

(f)(2), line 4: Change "(B)" to "(C)", based on your updated rule.
Response: Updated in text.

(g)(1): "Dispose" is not a service mentioned anywhere in the Classes in (e). What Class registration would that fall under?
Response: Disposing of machines that no longer produce radiation does not require registration. Updated in text.
(h): You should specify when a registrant is required to use this form. As written, it's not clear.
Response: The form name provides the description of the requirement when an X-ray machines for nonhuman use or radiation generating device are sold or installed.

(i), line 7: Delete "shall" before "meet".
Response: Updated in text.

(j): Change "Rule .0205 of this Section" to "this Rule".
Response: Updated in text.

(k)(1): For consistency, should this say "fluoroscopic X-ray machines"?
Response: Updated in text.

(l)(1): I suggest deleting "legible". This adjective seems to be unnecessary.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0206

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), lines 5-6: Change this sentence to something more direct, like, "The following qualifications shall be met for each service class:".
Response: Updated in text.

(a)(2), lines 12-13: This does not match the language in rule .0205 for Class II. That rule states: "installation, repair, or service …".
Response: Deleted repair in rule .0205 as it is part of the service. Updated in text.

(a)(2)(A): Should this provision start with something like, "completion of"?
Response: Updated in text.

(a)(2)(C), line 19: Delete "are required". This is redundant.
Response: Updated in text.

(a)(3) and (a)(4): If you do shielding designs for fluoroscopic X-ray machines, do you need both Class III and IV training? If you only need IV, you should state that Class III does not include fluoroscopic X-ray machines.
Response: Fluoroscopic X-ray machines are a subcategory of X-ray machines that produces a higher output of radiation than standard X-ray machines. This requires different calculations for shielding design.

(a)(3), line 20: Change "machine" to "machines".
Response: Updated in text.

(a)(3)(C): "one year of experience" doing what? Your rule is not clear.
Response: Updated in text.

(a)(4)(C): "one year of experience" doing what? Your rule is not clear.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(a)(6): This does not match the language of Class VI in rule .0205. That rule states: "radiation survey equipment calibrations".
Response: Updated text in rule .0205.

(a)(8): This does not match the language of Class VIII in rule .0205. That rule states: "providing individual monitoring devices".
Response: Updated text in rule .0206

(a)(8), line 15: Change "must" to "shall".
Response: Updated in text.

(a)(9), lines 18-19: For consistency, this should read as: "… general health or medical physics consulting. The applicant shall meet one of the following:"
Response: Updated in text.

(a)(9)(D): Add "degree" after "doctorate".
Response: Updated in text.

(b), line 29: For clarity, I would now replace "prior to the effective date of this Rule" with the intended fixed date.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0207

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), lines 5-6: The description for Class V services here does not match rule .0205. That rule states that Class V includes "area radiation surveys and shielding evaluations for X-ray machines" and that Class IV includes "shielding designs for fluoroscopic X-ray machines". Please clean up this rule so that the two align.
Response: Updated text in rule .0205.
(a), lines 6-7: Same comment for Class VII services. The two rules do not match. Please correct this.
Response: Updated text in rule .0205.

(a)(2): Do they have to follow the manufacturer's recommended frequency if one is provided? If so, you should also state that in your rule.
Response: The agency requires annual calibrations when the manufacture does not provide a frequency. A frequency other than annually will be accepted if stated in the mfg. manual.

(a)(3)(A), line 15: I think a word is missing here. Consider adding "provided" before "to the employed;".
Response: Updated in text.

(a)(3)(B): This is vague. What is this meant to capture? I think you need some sort of limiting language here. Consider adding, "… in conjunction with the provided services;".
Response: Updated in text.

(a)(3)(C), (D), and (E): Isn't this already covered by (B)?
Response: No, these are not the same.

(b)(1): What does "current" mean in this context? "Current" at the time that the service is provided? It is not clear.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(c), line 29: Delete "radiographic" for consistency.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0211

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 3: "RESPONSIBLE" is spelled incorrectly.
Response: Updated in text.

(a), lines 6-7: Change "actively registered" to "active". The rule is redundant as written.
Response: Updated in text.

(a), line 8: Shall be "on site" when? At all times?
Response: Changed to available.

(a), line 10: The last sentence should be more direct. Consider something like, "The individual shall meet the following qualifications:".
Response: Updated in text.

(a)(1)-(4): These requirements are vague/generic. Are there objective minimums or standards for these requirements?
Response: These criteria outline the foundational areas of competency required for radiation safety. Actively holding a registered technologist credential from the ARRT serves as an established standard that satisfies these requirements.

(a)(3): Change this to "knowledge of …".
Response: Updated in text.

(a)(4): Same comment as (a)(3) regarding the use of "knowing".
Response: Updated in text.

(a)(4): Delete "used" at the end of the sentence. It is redundant.
Response: Updated in text.

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(b)(1)(B): Should this say "and" rather than "or"?
Response: No.

(b)(2), line 21: Insert a period after "personnel", delete "and", and capitalize "records".
Response: Updated in text.

(b)(2)(C): What does this provision mean? The wording/grammar makes it very hard to understand what is being required.
Response: Corrected reference to 1001(a)(7).

History Note, page 2, line 4: The most recent date should come first in the line of dates.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0212

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 3: "EMERGING" is spelled incorrectly.
Response: Updated in text.

(b), line 25: Consider adding "proposed" before "user".
Response: Updated in text.

(b), line 25: Change "the" to "an".
Response: Updated in text.

(b)(5) and (6): Change "to include the following" to "that includes".
Response: Updated in text.

(b)(5)(B): "output" of what?
Response: Added radiation updated text.
(b)(6)(C): I'd recommend deleting "legible".
Response: Updated in text.

(b)(8): Which specific rules are you referring to? This requirement is not clear.
Response: Depending on the emerging technology it would need to the equipment requirements in applicable Sections .0500, .0600, and .0800.

(c), line 3: Consider adding "proposed" before "user".
Response: Updated in text.

(c), line 3: Change "the" to "a".
Response: Updated in text.

(c), line 3: Change "requirements" to "required information".
Response: Updated in text.

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Date submitted to agency: September 8, 2026

(d), line 5: Change "will respond" to "shall respond".
Response: Updated in text.

(d): What does "allowed for use" mean? Whether the device can be safely operated? The wording here is vague. What exactly are you determining from the information provided? What is the standard for approval? Be clear and specific.
Response: "Allowed for use" means approved for operation in NC. The information provided is used to verify that radiation dose limits for both the operator and members of the public do not exceed established regulatory standards for similar types of X-ray machines or RGDs. This Standard aligns with CRCP Suggested State Regulations.

History Note, page 2, line 15: The most recent date should come first in the line of dates.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0214 (REPEAL)

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

History Note, line 9: Add "2015;" after the deletion.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0301

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 9: "BYPRODUCT" is spelled incorrectly.
Response: Updated in text.

(a)(1): Add a comma after "10 CFR 30.4".
Response: Updated in text.

(b)(4), second sentence: Consider adding: "For the purposes of this Rule, the term …"
Response: Updated in text.

(b)(4), line 24: Change "location(s)" to "locations".
Response: Updated in text.

(b)(19): What does the exception mean here? That Paragraph (c) governs the form and information requirements for applicants? That Paragraph (c) is an additional requirement? It is not clear given what is specified in 10 CFR 30.32.
Response: Paragraph (c) governs the form, submission, and information requirements for applications submitted to the agency. The exception is intended to clarify that, in lieu of NRC Form 313, "Application for Materials License," applicants shall use the applicable North Carolina forms specified in Paragraph (c): the Application for Radioactive Materials License or the Application for Amendment of Radioactive Materials and Accelerator Licenses. Paragraph (c) also specifies the information required by the agency for those applications. Paragraph (c) is not an additional requirement.

(b)(20), line 10: In the G.S. cite, remove the period after 9.
Response: Updated in text.

(b)(25): Is there a timing requirement for filing once you've hit the 180 day mark?

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Date submitted to agency: September 8, 2026

Response: Yes. The 180-day period is cumulative and does not have to be consecutive. A licensee operating under reciprocity that anticipates using or storing radioactive material in the State for more than 180 days in a calendar year must apply for the appropriate North Carolina license or reapply for reciprocity before exceeding the 180-day limit.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0302

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Title, line 3: "BYPRODUCT" is misspelled.
Response: Updated in text.

(b), line 13: Underline "(b)".
Response: Updated in text.

(b)(1): How does this language align with what you've stated in (b)? Consider moving this requirement to its own paragraph. It doesn't really make sense as written.
Response: Thank you for your suggestion. Moved b(1) to another paragraph.

(b)(4), line 23: Change "shall be registered" to "shall register".
Response: Updated in text.

(b)(4), line 25: Add "10 CFR" before "31.5(c)(13)(iii)".
Response: Updated in text.

(b)(12): This should end with a period rather than a semi-colon.
Response: Updated in text.

(c)(10): Add a comma after "date the form is signed".
Response: Updated in text.

History Note, line 26: This entire line should be in underline.
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0304

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b), lines 12-13: Rewrite this to state, "… byproduct material as described in 10 CFR 30.14 and 30.18 and incorporated by Rules .0301(b)(11) and .0301(b)(13) of this Chapter, …"
Response: Updated in text.

(b)(2): Add "and" at the end of this provision.
Response: Updated in text.

(c), line 21: "Persons" should not be capitalized.
Response: Updated in text.

(c)(3): How does this work? You regulate the persons under these provisions of the CFR, but the NRC is responsible for issuing licenses?
Response: Yes, these licensees require a possession license issued by North Carolina. The NRC retains licensing authority for the manufacture and initial transfer for commercial distribution of exempt products containing exempt concentrations or exempt quantities of byproduct material. Paragraph (c) incorporates the applicable requirements of 10 CFR Part 32, while Subparagraph (c)(3) clarifies that applications for these manufacture and initial transfer for commercial distribution licenses are submitted to the NRC rather than the agency. North Carolina retains regulatory authority over other activities involving radioactive material within the scope of the State's Agreement State authority.

(g)(3), line 31: Delete the comma after the email address.
Response: Update in text.

(h), line 34: Delete the comma after the email address.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(h)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(h)(1)(E): The language used here is inconsistent with the rest of the list. Consider stating, "indication if the application is for …".
Response: Updated in text.

(h)(1)(F): Similar comment as (E). Consider deleting "shall be provided on the application". It makes the rule redundant.
Response: Updated in text.

(h)(1)(G): The language used here is inconsistent with the rest of the list. Consider stating, "indication of the type and category …".
Response: Updated in text.

(h)(2)(G): The language used here is inconsistent with the rest of the list. Consider stating, "a description of …". Delete "applicants shall provide".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0305

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

General Comment: In your forms rules, you state, "The instructions for completing the application printed on the application form shall be followed." What exactly do those instructions say? Are you requiring documentation or other actions? If so, you should state them in your rule as requirements rather than making this vague reference back to the form. Otherwise, you could change information requirements while circumventing the rulemaking process.

Response: The application form instructs applicants to complete Items 1 through 5 and to use additional sheets as necessary. These information requirements are stated in the Rule. The form further directs applicants to consult the appropriate licensing guide for information that must accompany the completed application. The requirement to submit supporting documents is already established in Part (c) of this Rule.

An application for a specific license will be approved if it is for a purpose authorized by the Agreement (activities authorized by 10 CFR Parts 30–37, 39, 40, 61, or 70); if the applicant's proposed equipment and facilities adequately protect health and minimize danger to life or property; if the applicant is qualified by training and experience to use the material safely; and if the applicant satisfies all applicable requirements in 10 CFR Parts 30–37, 39, 40, or 70. Licenses for low-level radioactive waste disposal sites must also meet the requirements in 10 CFR Part 61 and N.C.G.S. 104E.

The form refers applicants to the applicable licensing guide for guidance on the supporting documentation used to demonstrate compliance with these requirements. The agency relies on the NUREG-1556 series to help applicants identify documentation that may be used to show compliance with the licensing requirements established by the rules and incorporated federal regulations. The licensing guides do not independently establish substantive regulatory requirements.

The form includes a certification requirement and references other applicable regulatory provisions, including 10A NCAC 15 .1700. The

certification requirement is expressly stated in the Rule, and the reference to Section .1700 simply alerts applicants to additional requirements that may apply elsewhere in this Chapter.

Title, line 3: "DOMESTIC" is misspelled.
Response: Updated in text.

(a)(1): Add "and" at the end of this provision.
Response: Updated in text.

Line 9: I believe a struck through "(a)" is missing at the beginning of this line.
Response: Updated in text.

(b)(3): What does the end of this mean? Is Paragraph (c) an additional requirement or a substitute? Be clear and specific.
Response: Paragraph (c) establishes the State-specific application process for licenses issued by the agency. Applicants remain subject to the applicable requirements of 10 CFR 33.12 and 10 CFR 30.32; however, in lieu of NRC Form 313 and submission to the NRC, applicants shall use the applicable North Carolina application form and submit the application and required supporting information to the agency in accordance with Paragraph (c).

Replaced *(b)(3):* 10 CFR 33.12, "Applications for specific licenses of broad scope," except that applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (c) of this Rule;

(c), line 21: Remove the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses". Also, on lines 28 and 29, do you mean "will be used" rather than "shall be used"?
Response: Updated in text.

(c)(1)(E): The language here does not match the rest of the list. Consider stating, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): The language here does not match the rest of the list. Consider stating, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): The language here does not match the rest of the list. Consider deleting "applicants shall provide ".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0306

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(1): Remove the comma after "and".
Response: Updated in text.

(c), line 15: Remove the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B): Do you mean "will be used" rather than "shall be used"? This applies to both lines 21 and 22.
Response: Updated in text.

(c)(1)(E): The language here is inconsistent with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): The language here is inconsistent with the rest of the list. Consider starting this with, "indication of the type and category of …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

(c)(3): Add a period at the end of this. Also, the link here does not work. Please update.
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(f): This provision is not clear. What exactly are you requiring? That a form must be submitted per the instructions in (c)? Also, you should specify whether (c)(1) or (c)(2) applies, since they contain different information requirements.

Response: The agency agrees that the provision was unclear. Paragraph (f) has been revised to clarify that a request for exemption from the rules under 10 CFR 34.111 shall be submitted with the applicable application required by Paragraph (c)(1) or (c)(2) of this Rule, as appropriate. Licensees can request exemption from the rules as part of a new application or existing application.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0307

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b): What does it mean to "comply with the general information requirements" of these regulations? This language is not clear. Are you limiting the scope of what is required?
Response: Thank you the phrase "general information requirements" was unclear. Paragraph (b) has been revised to state that persons shall comply with the following requirements of Subpart A to 10 CFR 35.

(b)(8): Is Paragraph (n) a substitute or an additional requirement? Your rule is not clear.
Response: Reworded*(b)(8):* 10 CFR 35.12, "Applications for specific licenses of broad scope," except that applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (n) of this Rule;

(c)(3), line 33: Delete "(3)".
Response: Updated in text.

(c)(3): Replace "within three years of the effective date of this readopted Rule" with the actual intended date.
Response: "(3)" has been deleted and the provision has been revised to state the specific date of May 1, 2027

(d), line 15: What is an "authorized user"? Is this defined somewhere?
Response: "Authorized user" is defined in 10 CFR 35.2, which is incorporated by Subparagraph (b)(2) of this Rule.

(d), line 15: Delete the comma after "include" and add "the following".
Response: Updated in text.

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(d)(5): Delete the comma after "patient care".
Response: Updated in text.

(e)(5): Change "of this Paragraph." to "of this Rule."
Response: Updated in text.

(h)(11): Change this to something like, "activities covered by the CFR provisions listed in Subparagraphs (h)(6) and (h)(7) of this Rule shall be …".
Response: Updated in text. Subparagraph (h)(11) has been revised to clarify that activities covered by the CFR provisions listed in Subparagraphs (h)(6) and (h)(7) of this Rule shall be approved by an authorized medical physicist.
(h)(11): What is an "Authorized Medical Physicist"? Authorized by whom?
Response: "Authorized medical physicist" is defined in 10 CFR 35.2, which is incorporated by Subparagraph (b)(2) of this Rule.

(l): Is there a time limit for "maintaining" records?
Response: Yes. The applicable retention periods are specified in the individual recordkeeping provisions of Subpart L to 10 CFR 35 incorporated by this Rule. The retention periods vary depending on the type of record.

(n), line 25: Remove the comma before "or".
Response: Updated in text.

(n)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(n)(1)(B): Do you mean "will be used" rather than "shall be used"? This applies to both lines 31 and 32.
Response: Updated in text.

(n)(1)(E): The language here is inconsistent with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(n)(1)(F): Delete "shall be provided on the application".
Response: Updated in text.

(n)(1)(G): The language here is inconsistent with the rest of the list. Consider starting this with, "indication of the type and category of …".
Response: Updated in text.

(n)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

History Note, page 8, line 2: "2014;" should be "2024;".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0308

DEADLINE FOR RECEIPT: September 18, 2026

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b)(2): You state, "except that references to common defense and security shall not apply". What does this mean? Is something else substituted for these terms? Are these words just to be totally disregarding in the regulations? Your rule is not clear.
Response: The references to common defense and security are not replaced with another term or requirement. The NRC retains regulatory authority, and common defense and security are under exclusive federal jurisdiction. Therefore, those portions of the incorporated definitions do not apply to the agency's regulation under this Rule. Subparagraph (b)(2) has been revised to clarify that the provisions relating to common defense and security do not apply.

(b)(3): Is Paragraph (c) meant to be a substitute for application requirements? Or additional requirements that must also be met? Your rule is not clear.
Response: Paragraph (c) establishes the State-specific application forms and submission requirements in lieu of the NRC Form 313 and submission requirements in 10 CFR 36.11. Subparagraph (b)(3) has been revised to clarify that applications shall be submitted to the agency in accordance with Paragraph (c) of this Rule.

(c), line 8: Delete the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B), lines 14 and 15: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".

Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0309

DEADLINE FOR RECEIPT: September 18, 2026

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(3): The mentioned language is not a sentence. I would recommend changing "sentence" to "language".
Response: Updated in text. Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

Special Nuclear Material" has been changed to "special nuclear material" for consistency with the other defined terms in the Rule.

(a)(3), line 11: In the G.S. citation, please delete the period after "5".
Response: Updated in text.

(a)(4): Add "10 CFR" before you start listing out the regulations.
Response: Updated in text.

(a)(18): Is Paragraph (c) a substitute for the application requirements? Is it an additional requirement that has to also be met? Your rule is not clear.
Response: This comment to refers to Subparagraph (b)(18). Paragraph (c) establishes the State-specific application form and submission requirements in lieu of the NRC-specific application form and submission requirements in 10 CFR 40.31. Subparagraph (b)(18) has been revised to clarify that applications shall be submitted to the agency in accordance with Paragraph (c) of this Rule.

(a)(18), line 6: In the G.S. citation, please delete the period after "9".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(a)(19), line 11: Same comment as noted above.
Response: Updated in text.

(c), line 6: Delete the comma before "or".
Response: Updated in text.

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B), both lines: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0310

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(3): "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is not a sentence. Also, what is it preserved from? Be clear and specific. As written, it's hard to understand what exactly you're trying to do here. Consider something like, "As preserved in G.S. 104E-5(16), the Commission retains primary authority to declare any other materials as special nuclear material."
Response: Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

Special Nuclear Material" has been changed to "special nuclear material" for consistency with the other defined terms in the Rule.

(a)(3), line 11: In the G.S. citation, please delete the period after "5".
Response: Updated in text.

(a)(14): Is Paragraph (c) a substitute for the application requirements? Is it an additional requirement that has to also be met? Your rule is not clear.
Response: Paragraph (c) establishes the State-specific application form and submission requirements in lieu of the NRC-specific filing requirements addressed by 10 CFR 70.21. Subparagraph (a)(14) has been revised to clarify that applications shall be submitted to the agency in accordance with Paragraph (c) of this Rule.

(c), line 20: Delete the comma before "or".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(c)(1)(B): Change "address(es)" to "addresses".
Response: Updated in text.

(c)(1)(B), lines 26 and 27: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.
(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0311

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(1): You are missing a comma after "71.5".
Response: Updated in text.

(a)(1): Replace "10 CFR 71.101(c)(1)" with "and 71.101(c)(1)".
Response: Updated in text.

(a)(2): What does this replacement mean? The "Agency" is not used in those regulations. I cannot tell what this provision is meant to do.
Response: Subparagraph (a)(2) was unclear. The provision has been revised to clarify that, in 10 CFR 71.8(b) and (d), references to the NRC with respect to quality assurance program approval mean the Agency.

Line 11: You are missing a struck through "(a)" here.
Response: Updated in text.

(b), line 13: This should end with a colon rather than a semi-colon.
Response: Updated in text.

(b)(7): Same comment as noted for (a)(2).
Response:

(b)(12), line 31: Change "Subparagraph (2) of this Paragraph" to "Subparagraph (b)(2) of this Rule".
Response: Subparagraph (b)(7) was unclear. The provision has been revised to clarify that, in 10 CFR 71.8(a)(3) references to the NRC with respect to quality assurance program approval mean the Agency.

(b)(12), line 32: Add "10 CFR" before "71.17(c)(3)".

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(b)(13), line 35: You are missing a parenthesis around "(b)".
Response: Updated in text.

Page 3, line 7: This should be updated to "(c)".
Response: Updated in text.

Page 3, line 17: This should be updated to "(d)".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0313

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(3), lines 11-13: "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is not a sentence. Also, what is it preserved from? Be clear and specific. As written, it's hard to understand what exactly you're trying to do here. Consider something like, "As preserved in G.S. 104E-5(16), the Commission retains primary authority to declare any other materials as special nuclear material."
Response: Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

(a)(3), line 11: Why is "Special Nuclear Material" all capitalized? You do not capitalize other defined terms in this rule.
Response: Updated in text.

(a)(3), line 13: Delete the period between "5" and "(16)" in the citation.
Response: Updated in text.

(a)(7), line 23: Replace "material," with "material;".
Response: Updated in text.

(a)(8), line 24: Replace "material;" with "material."
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1203

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(b), line 7: Above, you use "Agency" to refer to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section, as defined in 10A NCAC 15 .0103. However, beginning here and continuing intermittently through the Rule, you use "Department", which in G.S. 104E-5 is defined as Department of Health and Human Services. Ensure that your use of the two terms is consistent with your intent. Going back and forth between both can cause confusion.
Response: The use of "Department" and "Agency" is intentional. "Department" refers to the North Carolina Department of Health and Human Services and is used where the applicable statutory provisions assign authority to the Department, including the issuance of licenses for land disposal of low-level radioactive waste. "Agency" refers to the Radiation Protection Section, as defined in Rule .0103 of this Chapter, and is used for regulatory functions administered by the Section. The Rule has been reviewed to ensure that each term is used consistently with this distinction.

(b)(2): For clarity, consider writing this to end with, "… unless a written authorization has been issued by the agency to the recipient."
Response: Updated in text. Subparagraph (b)(2) has been revised for clarity

(b)(3), line 14: Delete "which".
Response: Updated in text.

(b)(3), line 19: Replace ".0111" with ".0111(a)" for consistency and clarity.
Response: Updated in text.

(b)(4): "Shall be met" by who and under what circumstances? Be clear and specific.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: The provision was unclear. Subparagraph (b)(4) has been revised to clarify that applicants and licensees shall comply with the applicable requirements under the cited statutory provisions.

(b)(5): "Shall apply" to who or what? To licensees?
Response: Subparagraph (b)(5) has been revised to clarify that the definitions in G.S. 104E-5 apply to the interpretation and application of this Rule.

(c)(1): Same comment as above for (b)(2).
Response: Subparagraphs (c)(1) has been revised for clarity.

(c)(2): Same comment as above for (b)(5).
Response: Subparagraph (c)(2) has been revised to clarify that the definitions in G.S. 104E-5 apply to the interpretation and application of this Rule.

(c)(3), line 33, and (c)(4), page 2, line 6: "Prevent" means to stop while "minimize" and "reduce" both mean to decrease. They are two different things that can't simultaneously be expected. Do you expect them to completely prevent or only decrease? Revise the language here to most clearly convey the expectation.

Response: Generators, waste brokers and waste processors shall develop procedures and implement practices to prevent, minimize, and reduce the generation of low-level waste as required by G.S. 104E-27(a). These procedures shall include segregating waste by half-life and holding low-level radioactive waste for decay in storage.
The rule remains unchanged. In the language of the general statue includes prevention, minimization and reduction.

(d)(1)(B): Replace "address(es)" with "addresses".
Response: Updated in text.

(d)(1)(B), lines 22 and 23: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(d)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(d)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(d)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

(d)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

(d)(3): Include the web address to locate the form, if possible.
Response: Updated in text.

(e): Is this necessary? What is the purpose of this paragraph?
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1301

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(c)(1)(B): Replace "address(es)" with "addresses".
Response: Updated in text.

(c)(1)(B), lines 34 and 35: Should "shall be used" be changed to "will be used"?
Response: Updated in text.

(c)(1)(E): This language does not match with the rest of the list. Consider starting this with, "indication if the application is for …".
Response: Updated in text.

(c)(1)(F): Delete " shall be provided on the application".
Response: Updated in text.

(c)(1)(G): This language does not match with the rest of the list. Consider starting this with, "indication of the type and category …".
Response: Updated in text.

(c)(2)(G): Delete "applicants shall provide ".
Response: Updated in text.

(c)(3): The web link is no longer effective. Please update.
Response: updated in text.

(e), page 3, line 2: Change ".0111" to ".0111(a)" for consistency.
Response: Updated in text.

(f): Do you have any requirements for exemption applications? Or is this an informal process? Your rule does not provide any sort of standard or process. Is there something you could cross-reference here?

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: The provision was unclear. The standards for granting an exemption are provided in 10 CFR 39.91. Paragraph (f) has been revised to cross-reference 10 CFR 39.91 and specify that exemption applications shall be submitted to the agency in accordance with Rule .0111(a) of this Chapter.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1601

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a), line 7: Remove the repetition of "and to effectuate their joint enforcement,".
Response: Updated in text.

(a)(1), line 9: Add "10 CFR" before "20.1003".
Response: Updated in text.

(a)(1), line 10: Change "Agency," to "Agency;".
Response: Updated in text.

(a)(2): "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material" is not a sentence. Also, what is it preserved from? Be clear and specific. As written, it's hard to understand what exactly you're trying to do here. Consider something like, "As preserved in G.S. 104E-5(16), the Commission retains primary authority to declare any other materials as special nuclear material."
Response: Thank you, the provision was unclear. Subparagraph (a)(3) has been revised to remove "the sentence" and added 'the phrase.' The words "preserved as implemented by" have been revised to read the "same as defined" has been inserted.

Special Nuclear Material" has been changed to "special nuclear material" for consistency with the other defined terms in the Rule.

(b)(61), page 3, line 21: Add "of" between "individuals" and "exceeding." The CFR title is "Reports to individuals of exceeding dose limits".
Response: Updated in text.

(b)(63), page 3, line 26: You refer to Subparagraph (a)(6) of this rule, but this rule does not have an (a)(6). Do you mean (b)(6)?

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

Response: Updated in text.

(c): What is a "personnel monitoring device"? Is it defined in another rule or statute that can be referenced? Exposure to what, by whom, and what is the deception? This Paragraph needs context and clarity.

Response: The provision was unclear. Paragraph (c) has been revised to use the term "individual monitoring device" as defined in 10 CFR 20.1003 and to clarify that no person may intentionally expose such a device to radiation for the purpose of causing it to indicate a dose not received by the individual to whom the device is assigned.

(d), first sentence, lines 12-13: Something is missing in this sentence. Consider, "… all activities required by the rules of this Chapter, and any license or registration conditions imposed by the agency, and shall pay …".

Response: The first sentence of Paragraph (d) has been revised to clarify that licensees and registrants shall continue to perform activities required by the rules of this Chapter and applicable license or registration conditions until termination.

(d), line 13: Consider referencing your fee rule(s) here for clarity.

Response: Paragraph (d) has been revised to cross-reference the annual fee requirements in Section .1100 of this Chapter

(e): Why is this paragraph needed? What is it doing?

Response: Paragraph has been removed.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1701

DEADLINE FOR RECEIPT: September 18, 2026

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

(a)(1): Add "and" to the end of this.
Response: Updated in text.

(d): For consistency, change "The Code of Federal Regulations incorporated by this Rule" to "Copies of these regulations".
Response: Updated in text.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Christopher S. Miller
Commission Counsel
Date submitted to agency: September 8, 2026

10A NCAC 15 .0103 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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 the 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.~~ "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).

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

~~"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~~ a.m. January 1 to 11:59:59 ~~pm~~ p.m. 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.~~ except where otherwise defined in the rules of this Chapter.

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

(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~~ 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~~ 15 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 building, ~~at one address or vehicle~~, building or vehicle at one address 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~~ diagnosis 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~~ or 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) "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~~].[0209] of this Chapter.

~~"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) "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.

~~"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 .0209 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~~.1700, ~~1900,~~ .1900, and .2000 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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0104 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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.~~

The "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, hereinafter known as the "Agreement," is ~~hereby~~ incorporated by reference including subsequent amendments and editions. A copy of the Agreement is available free of charge at https://www.nrc.gov/cdn/nmss/pdf/ncagreements.pdf.

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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0201 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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

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

10A NCAC 15 .0201 PURPOSE AND SCOPE

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

(b) A person who acquires, owns, possesses, or receives ~~a radiation machine or~~ an X-Ray ~~machine,~~ machine or a radiation generating ~~device~~ ~~devices,~~ device, or provides other radiologic services 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 that use ~~using~~ ~~radiation machines~~ an X-Ray machine ~~machine,~~ or a radiation generating device for demonstration ~~purposes~~ purposes, or that provide mobile leasing ~~services~~ services, are subject to the additional requirements of Rule .0205 of this Section. Service providers that provide those services by bringing ~~radiation machines~~ an X-ray machine 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~~ X-ray 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~~ Industrial radiographic X-ray machines are subject to the additional requirements of Section .0500 of this Chapter.

(g) ~~Registrants using~~ ~~radiation~~ X-ray machines for ~~human~~ diagnostic imaging and veterinary use are subject to the additional requirements in Section .0600 of this Chapter.

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

(i) ~~Registrants using ionizing radiation~~ Radiation generating devices and X-ray machines for non-human use are subject to the additional 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, 2026; October 1, 2025.

10A NCAC 15 .0202 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0202 EXEMPTIONS

(a) Electronic equipment that produces radiation incidental to its operation ~~for other purposes~~ is exempt from the registration and notification requirements of this ~~Section~~ Section, provided that the dose equivalent rate ~~average~~ averaged 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 agency may, upon application, ~~application therefore,~~ grant individual exemptions or exceptions from the requirements of these Rules if it will not result in radiation dose or contamination that exceeds the limits prescribed in these Rules for the protection of public health, safety, or property.

~~(b)~~(c) The following are exempt from the requirements of this Section:

(1) all radioactive materials; and

(2) ~~radiation~~ X-ray machines or radiation generating devices 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0203 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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~~ X-ray ~~machine,~~ machine or radiation generating device, or an unregistered service ~~provider,~~ 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~~ X-ray 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~~ The owner or the individual responsible for the business operations of a facility with an X-ray machine, radiation generating device, or who ~~is responsible for providing~~ provides radiological services, shall ensure that 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) are 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,~~ radiological 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.~~ https://radiation.ncdhhs.gov/Xray/applic.htm and https://radiation.ncdhhs.gov/Xray/service.htm.

(5) The owner or individual responsible for business operations can designate a responsible person or persons within the organization to sign when amendments are made to forms by notifying the agency in writing.

(c) A Business Application form shall be submitted prior to the operation of a facility or providing services in this ~~State~~ 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~~ X-ray machines or radiation generating ~~device~~ devices at a facility; or

(B) that plans to engage in radiological 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,~~ number, and type of ~~business, days and hours of operation;~~ business;

(C) the name, title, mailing address, phone, and e-mail address of the 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;~~ made available during inspection or upon request by the agency;

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

~~(F) description of facility use;~~

~~(G) description of service provider equipment~~;

~~(H)~~(F) dated and signed by the owner or the individual ~~with administrative control; and~~ responsible for business operations.

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

(d) ~~A Radiation~~ An X-ray 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~~ X-ray 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~~ X-Ray machines or radiation generating devices at a facility; or

(B) that is engaged in leasing or performing demonstrations using an unregistered ~~radiation~~ X-Ray 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 the machine or device not in use;

(E) installer information; and

(F) ~~shall be~~ dated and signed by the ~~individual with administrative control.~~ owner or individual responsible for business operations. ~~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~~ an X-ray Machine or Radiation Generating Device Form shall be submitted when a facility disposes of ~~a radiation~~ an X-ray 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,~~ relocation, or to update information;

(3) ~~radiation~~ X-ray machine or radiation generating device location; manufacturer, ~~model,~~ model and serial number;

(4) identify the ~~reason for~~ method of disposal of the ~~radiation~~ X-ray machine or radiation generating device;

(5) ~~the~~ recipient of the ~~radiation~~ X-ray machine or radiation generating ~~device, to the individual or business name,~~ device, physical and e-mail address, and phone number; and

(6) dated and signed by the owner or the individual ~~with administrative control~~ responsible for business operations of the ~~radiation~~ X-ray 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~~ X-ray machines or radiation generating devices;

(B) providing individual monitoring devices; ~~and~~ or

(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~~ dated and signed by the owner or the individual ~~with administrative control.~~ responsible for business operations.

(g) A Company Employee Services Application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through ~~(H)~~ (G) 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;~~ X-ray machines;

(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~~ X-ray machines or radiation generating devices;

(E) qualified expert consulting services for CT and mammography ~~radiation~~ X-ray machines;

~~(F) radiation protection expert;~~

~~(G)~~(F) shielding designs for ~~diagnostic radiographic and fluoroscopy~~ ~~facilities;~~ X-ray machines; and

~~(H)~~(G) therapeutic ~~facility~~ shielding ~~design, area radiation survey, or calibration.~~ verification and area radiation surveys.

(2) The application requires the following information:

(A) name of the employee to be registered;

(B) start date if the employee is being ~~added~~ 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 owner or the individual ~~with administrative control;~~ responsible for business operations; 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,~~ education requirements of the Class for the services provided, 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 documentation of the requirements in Subparagraph ~~(1)(h)~~ (h)(1) 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~~ involving X-ray 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;~~responsible for business operations;

(B) submit to the agency, a Disposal of ~~a Radiation~~ an X-ray 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~~ an X-ray 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0204 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0204 FACILITY RESPONSIBILITIES

(a) All forms ~~in~~ required by 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~~ X-ray machines for human, non-human, or veterinary use and prior to structural modification of existing installations, an ~~applicant,~~ applicant shall have the floor plans, shielding specifications, and equipment arrangement reviewed by a registered service provider.

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

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

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

(C) proposed date of ~~installation.~~ installation or structural modification.

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

(4) ~~A radiation~~ An X-ray 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~~ X-Ray 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 radiation 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~~ X-ray absorptiometry (DEXA);

(C) mammography; or

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

(c) Facility ~~registration~~ registration:

(1) Mobile ~~radiation~~ X-ray machines located and used in this ~~State that are fixed in~~ State, and permanently affixed within a vehicle or ~~trailer~~ trailer, shall meet the following requirements prior to use:

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

(B) have ~~a Radiation~~ an X-ray Machine Application ~~or a Radiation Generating Devices Application~~ form submitted in accordance with Rule .0203(d) of this Section. ~~Radiation~~ X-ray machines leased or on loan from a registered service provider shall ~~register the radiation machine~~ be registered with the agency if ~~used~~ maintained for more than 30 days;

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

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

~~(E)~~(D) an individual ~~with administrative control~~ responsible for business operations shall ensure that ~~radiation~~ X-ray machines are operated in accordance with Section .0600 of this Chapter.

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

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

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

(C) an individual responsible for business operations shall ensure that X-ray machines are operated in accordance with Section .0600 of this Chapter.

(3) Mobile radiation generating devices located out-of-state and brought into this State for use shall meet the following requirements prior to use:

(A) have a Radiation Generating Devices Application form submitted in accordance with Rule .0203(d) of this Section. Radiation generating devices leased or on loan from a registered service provider shall be registered with the agency if maintained for use for more than 30 days;

(B) have a copy of the operating and safety procedures describing how to protect operators and the public from radiation submitted to the agency;

(C) submit a written notice, in accordance with Rule .0208 of this Section, and maintain it for agency review during inspection; and

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

~~(3)~~(4) ~~Radiation~~ X-ray machines for ~~human, non-human,~~ diagnostic imaging, non-diagnostic imaging, clinical studies, ~~or~~ veterinary ~~use~~ use, or for use by service providers for demonstration purposes shall meet the following additional requirements:

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

(B) submit ~~a Radiation~~ an X-ray Machine Application form in accordance with Rule ~~.0203 (d)~~ .0203(d) of this Section within 30 days of ~~use.~~ use; and

(C) an individual ~~with administrative control~~ responsible for business operations shall ensure that X-ray machines are operated in accordance with Section .0600 of this Chapter.

~~(4)~~(5) Radiation generating devices covered in Section .0800 of this Chapter shall meet the following additional requirements prior to use:

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

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

~~(5)~~(6) Industrial radiography ~~radiation~~ X-ray machines covered in Section .0500 of this Chapter shall meet the following additional requirements prior to use:

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

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

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

(e) ~~Persons~~ Facilities registered pursuant to ~~Paragraph(c)~~ 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~~ facility 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0205 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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,~~ State 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~~ X-ray machines or radiation generating devices;

(2) Class II - ~~installation, repair,~~ installation or service of the following:

(A) ~~radiation~~ X-ray 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;~~ X-ray machines;

(4) Class IV - shielding designs for ~~diagnostic fluoroscopy facilities;~~ fluoroscopic X-ray machines;

(5) Class V - area radiation surveys and shielding evaluations for ~~diagnostic radiographic and fluoroscopy facilities; X-ray machines;~~ radiographic and fluoroscopic X-ray machines:

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

(7) Class VII - therapeutic ~~facility~~ shielding ~~design, area radiation survey, or verification;~~ verification ~~and area surveys;~~ services;

(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~~ X-ray machines that are ~~fixed in~~ permanently affixed within a vehicle or trailer for demonstration purposes or to ~~that~~ ~~provides~~ provide leasing services shall meet the following requirements prior to use:

(1) mobile ~~radiation~~ X-ray machines located and used in this State shall meet the requirements of Rules .0204(c)(1)(A) through ~~(E)~~ (D) of this Section; and

(2) mobile ~~radiation~~ X-ray machines located out of state and brought into this State for use shall meet the requirements of Rules .0204(c)(2)(A) and ~~(B)~~ (C) of this Section.

(g) Report of installation

(1) Persons registered pursuant to Paragraph (a) of this Rule who sell, install, transfer, lease, or lends ~~lend, or dispose of radiation~~ an X-ray machines or radiation generating ~~devices~~ device in this State shall, within ~~15~~ 30 days after each calendar quarter, notify the agency at ~~XrayNORS@dhhs.nc.gov~~ fda2579@dhhs.nc.gov or the address, in accordance with Rule .0111 of this Chapter, of the following:

(A) whether any ~~radiation~~ X-ray machines or radiation generating devices 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~~ X-ray machine or radiation generating devices 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~~ X-ray machine or radiation generating devices 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~~ 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~~ X-ray machines for nonhuman use and radiation generating devices, when a Report of Sale and Installation Form prepared in accordance with Paragraph ~~(i)~~ (h) of this Rule is received by the agency.

(h) A Report of Sale and Installation of ~~radiation~~ X-ray 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~~ X-ray 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 the 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~~ X-ray machines, ~~radiation~~ X-ray machine components, or radiation ~~machine~~ generating devices unless such machines and ~~devices~~ devices, when placed in ~~operation~~ operation, ~~shall~~ meet the requirements of these Rules.

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

(k) ~~Tests~~ Records of tests performed at the time of installation ~~demonstrating~~ that demonstrate the requirements of these Rules are ~~met,~~ met shall be provided to the registrant for agency review during inspection for the following:

(1) ~~fluoroscopy~~ fluoroscopic X-ray machine output measurement; and

(2) radiation generating devices equipment surveys.

(l) Records of any routine maintenance, repair, alterations, or reassembly of ~~radiation~~ X-ray 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0206 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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 shall be met for each service class:

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

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

(A) completion of manufacturer's equipment school for service, maintenance, and installation for the type of ~~radiation~~ X-ray machine or ~~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~~ X-ray machines, radiation generating devices, and machine components. ~~components services are required.~~

(3) Class III - shielding design for ~~diagnostic radiographic facilities:~~ ~~X-ray machine:~~X-ray machines:

(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 shielding design experience ~~in diagnostic radiographic facility and shielding~~ for each type of machine ~~application.~~ modality.

(4) Class IV - shielding design for ~~diagnostic fluoroscopic facilities:~~ fluoroscopic X-ray machines:

(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 shielding design experience ~~in diagnostic fluoroscopic facility and shielding~~ for each type of machine ~~application.~~ type.

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

(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.~~ modality.

(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:~~ verification and area surveys:

(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,~~ 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:~~ devices: The applicant ~~must~~ shall 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~~ consulting. The applicant shall meet ~~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~~ X-ray and radium physics; or

(D) hold a master's or doctorate degree 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~~ X-ray physics.

(b) Any person registered to provide Class IX services prior to ~~the effective date of this Rule~~ October 1, 2026, 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0207 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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,~~ measurements and equipment surveys, Class V area radiation surveys and shielding evaluations for ~~diagnostic~~ radiographic and ~~fluoroscopy facilities,~~ fluoroscopic X-ray machines, or Class VII therapeutic area radiation survey or shielding 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~~ surveys, including a list of all guides and references provided to the employed;

(B) a copy of all forms, reports, and documents that will be supplied ~~to registrants:~~ in conjunction with the provided services;

(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 at the time that the service is provided 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,~~ X-ray machines, Class IV shielding designs for ~~diagnostic fluoroscopy facilities,~~ fluoroscopic X-ray machines, and Class VII therapeutic ~~facilities and~~ shielding design verification 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 verification 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.~~ 2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0211 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

10A NCAC 15 .0211 THE INDIVIDUAL ~~REPSONSIBLE~~ 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~~ who can be an ~~actively registered~~ active ~~radiologic technologist,~~ Registered Technologist (RT) by the American Registry of Radiologic Technologists (ARRT), shall be ~~on site~~ or available at all times and be qualified by reason of education, training, and experience. Records of this individual's education, training, and experience shall be available for review during inspections or upon request by the agency. The individual shall meet the following ~~are the minimum qualifications that must be met to carry out the job duties:~~qualifications:

(1) training in basic radiation protection principles;

(2) completed educational courses relating to ionizing radiation;

(3) ~~know~~ knowledge of potential radiation hazards and emergency precautions; and

(4) training and experience in and ~~knowing~~ knowledge of the proper use of the type of equipment. ~~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~~ occur, to ensure the procedures are current.

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

(A) reviewed;

(B) maintained; and

(C) notifications made in accordance with Rule ~~.1601~~ .1001(a)(7) 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~~ 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, 2026; October 1, 2025.

10A NCAC 15 .0212 is amended with changes as published in 40:19 NCR 1541-1550 as follows:

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

(a) ~~Radiation~~ X-ray machines or radiation generating devices that do not meet the ~~radiation~~ X-ray machine or radiation generating device 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~~ X-ray machine or radiation generating device and determining if the use of the ~~radiation~~ X-ray machine or radiation generating device 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) The proposed user or manufacturer of ~~the~~ an X-ray 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's manual;

(3) description of intended use;

(4) operator training provided to the end user;

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

(A) all equipment settings available to the operator;

(B) radiation output at the highest setting; and

(C) leakage radiation around the X-ray machine.

(6) an area survey ~~to include the following:~~ that includes:

(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 X-ray machine.

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

(c) The proposed user or manufacturer of ~~the~~ a radiation generating device shall submit the ~~requirements~~ required information in Rule .0808 of this Chapter for review.

~~(b)~~(d) After receiving the information in ~~Paragraph (a)~~ Paragraphs (b) and (c) of this Rule, the agency ~~will~~ shall respond to the applicant in writing within 90 calendar days. Upon review, the agency may require additional information to determine if the ~~radiation~~ X-ray machine or radiation generating device 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, 2026; October 1, 2025.

10A NCAC 15 .0214 is repealed as published in 40:19 NCR 1541-1550 as follows:

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

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.~~
Repealed Eff. October 1, 2026.

10A NCAC 15 .0301 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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 ~~BYPRODUCE~~ BYPRODUCT MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 30 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 30:

(1) With the exception of ~~10 CFR 30.4~~10 CFR 30.4, a reference to "NRC" or "Commission" means the "Agency;"

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

(3) In 10 CFR 30.18(d) and 30.32(g) where a reference is made to "an Agreement State", it means "an Agreement State or the NRC."

~~(a)~~(b) 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~~ For purposes of this rule, the term "temporary jobsite" shall mean a location where byproduct materials are used and stored other than those ~~location(s)~~ locations 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)~~(c) 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)~~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)~~(c) 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~~.0111(a) 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)~~ addresses 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0302 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 31 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 31:

(1) 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 31.5(b)(1)(ii), 31.5(c)(3)(ii), 31.5(c)(8)(i), 31.6, 31.7(a), 31.10(a), 31.10(b)(1), and 31.12(c)(4), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC;" and

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

~~(a)~~(b) 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)~~(1) 10 CFR 31.1, "Purpose and scope;"

~~(3)~~(2) 10 CFR 31.2, "Terms and conditions;"

~~(4)~~(3) 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~~ register with the agency. Device registration shall be made in accordance with Paragraph ~~(b)~~(c) of this Rule and shall contain the information required by 10 CFR 31.5(c)(13)(iii);

~~(5)~~(4) 10 CFR 31.6, "General license to install devices generally licensed in 10 CFR 31.5;"

~~(6)~~(5) 10 CFR 31.7, "Luminous safety devices in aircraft;"

~~(7)~~(6) 10 CFR 31.8, "Americium-241 and radium-226 in the form of calibration or reference sources;"

~~(8)~~(7) 10 CFR 31.9, "General license to own byproduct material;"

~~(9)~~(8) 10 CFR 31.10, "General license for strontium 90 in ice detection devices;"

~~(10)~~(9) 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)~~(c) of this Rule;

~~(11)~~(10) 10 CFR 31.12, "General license for certain items and self-luminous products containing radium-226;" and

~~(12)~~(11) 10 CFR 31.21, "Maintenance of ~~records;"~~records."

(c) 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;

~~(b)~~~~(c)~~(d) 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~~.0111(a) 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~~ signed, and telephone number of the contact person.

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1989; October 1, 1984; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0302 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0304 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 32 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 32:

(1) A reference to "NRC" or "Commission" means the "Agency;"

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

(3) In 10 CFR 32.13, 32.51(a), 32.51(c), 32.56, 32.59, and 32.72(b)(5)(ii), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC."

~~(a)~~(b) 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)~~ 10 CFR 30.14 and 30.18 and incorporated by Rules .0301(b)(11) and ~~.0301(a)(13)~~.0301(b)(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;" and

(3) 10 CFR 32.3, "Maintenance of records."

~~(b)~~(c) All ~~Persons~~ 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)~~(d) All persons manufacturing or initially transferring generally licensed devices containing byproduct material shall comply with Paragraph ~~(g)~~(h) 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)~~(e) All persons manufacturing or initially transferring items or devices containing byproduct material for medical use in humans shall comply with Paragraph ~~(g)~~(h) 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)~~(f) 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)~~(h) of this Rule and the requirements of 10 CFR 32.201.

~~(f)~~(g) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) of this Chapter in lieu of the NRC.

~~(g)~~(h) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses 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~~ indication 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; ~~number shall be provided on the application;~~

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

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20; 10 CFR 30.71;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0304 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0305 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 33 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 33:

(1) A reference to "NRC" or "Commission" means the "Agency;" and

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

~~(a)~~(b) 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 ~~the requirements of Paragraph (b)(c) of this Rule shall be met;~~ applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph (c) of this Rule;

(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),~~33.17(a) and (b), "Conditions of specific licenses of broad scope."

~~(b)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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)~~(d) 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.~~2024;

Amended Eff. October 1, 2026.

10A NCAC 15 .0306 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 34 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 34:

(1) A reference to "NRC" or "Commission" means the "Agency;" ~~and,~~ and

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

~~(a)~~(b) 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:~~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)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or mailed to the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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~~ https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm

~~(c)~~(d) 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)~~(e) 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).~~.0111 of this Chapter in lieu of the NRC. In addition to the information required by 10 CFR 34.101(b), notifications of devices with failed or worn through S-tubes shall contain the serial number and storage location of the device, whether the device has been disposed of or returned to the manufacturer, and whether personnel contamination occurred.

~~(e)~~(f) Requests for exemption from these Rules under 10 CFR 34.111 shall be made to the agency as specified in Paragraph ~~(b)~~(c) 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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0307 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 35 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 35:

(1) A reference to "NRC" or "Commission" means the "Agency;" and

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

~~(a)~~(b) All persons using radioactive materials for medical use in humans shall comply with the ~~general information~~ following 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)(n) of this Rule shall be met;~~ applications shall be submitted to the agency on forms provided by the agency in accordance with Paragraph ~~(m)~~(n) of this Rule;

(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)~~(c) 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~~ no later than May 1, 2027, 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)~~(d) All persons administering radioactive materials to humans not requiring a written directive shall develop, document, maintain, and require the use ~~of,~~ 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,~~ include the following 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,~~ patient care and to prevent the occurrence of medical events.

~~(d)~~(e) 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)~~(e)(10) of this ~~Paragraph.~~ Rule. ~~Brachytherapy~~Sealed sources and 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)~~(e)(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)~~(f) 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)~~(g) 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)~~(h) 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 covered by the provisions of 10 CFR Part 35 listed in Subparagraphs ~~(g)(6)~~(h)(6) and ~~(g)(7)~~(h)(7) of this Rule shall be approved by an Authorized Medical Physicist.

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

~~(k)~~(l) 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)~~(m) 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 in accordance with Rule .0111 of this Chapter 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~~.0111(a) 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)~~(n) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*

Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0307 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~~~2014;~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0308 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 36 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 36:

(1) A reference to “NRC” or “Commission” means the "Agency;” and

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

~~(a)~~(b) 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)~~(c) 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~~CFR 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~~.0111(a) of this Chapter unless directed otherwise by the agency, in lieu of the United States Nuclear Regulatory Commission (NRC).

~~(b)~~(c) 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,~~ Licenisng.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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)~~(d) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part036/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
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Transferred and Recodified from 15A NCAC 11 .0308 Eff. February 1, 2015;
Amended Eff. March 1, 2017;
Readopted Eff. May 1, ~~2024.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0309 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0309 DOMESTIC LICENSING OF SOURCE MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 40 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 40:

(1) With the exception of 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, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", ~~the sentence~~ the phrase "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~~ the same as defined in G.S. 104E-5.(16). and

(4) In 10 CFR 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".

~~(a)~~(b) 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~~ do 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 ~~he requirements of~~ applications shall be submitted to the agency in accordance with Paragraph ~~(b)~~(c) 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),~~ 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),~~ 113(A)-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)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication if the application is for a new license, or for the renewal of an existing license, by marking the corresponding check box;

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

(G) ~~applicants shall indicate~~ indication of 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)~~(d) 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);*
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Amended Eff. October 1, 2026.

10A NCAC 15 .0310 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 70 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 70:

(1) With the exception of 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 70.4, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", ~~the sentence~~ the phrase "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~~ the same as defined in G.S. 104E-5.(16).

(4) 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".

~~(a)~~(b) 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~~ do 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~~ an applications shall be submitted to the agency in accordance with Paragraph ~~(b)~~(c) of this ~~Rule shall be met;~~ Rule;

(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)~~(c) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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)~~(d) 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.~~2024;
Amended Eff. October 1, 2026.

10A NCAC 15 .0311 is amended as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .0311 PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 71 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 71:

(1) In 10 CFR 71.0(c), 71.3, ~~71.5~~ 71.5, 71.17(a), (b), 71.22, 71.23(a), (b), ~~10 CFR~~ 71.101(c)(1), a reference to "NRC" or "Commission" means the "Agency;"

(2) In 10 CFR 71.8(b), (d), and 71.17(b), ~~the Agency is the "quality assurance program approval holder,"~~ references to the NRC with respect to quality assurance program approval mean the Agency. and

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

~~(a)~~(b) 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;~~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;"~~misconduct." In 10 CFR 71.8(a)(3), ~~the agency is the "quality assurance program approval holder;"~~ references to the NRC with respect to quality

(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 10 CFR 71.17(a) applies to any licensee of the agency, and the 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 — 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;"~~package," except that 10 CFR 71.21(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR ~~71.21b)~~ 71.21(b) shall be issued by the agency or the NRC.

(14) 10 CFR 71.22, "General license: Fissile ~~material;"~~material" except that 10 CFR 71.22(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR 71.22(b) shall be issued by the agency.

(15) 10 CFR 71.23, "General license: Plutonium-beryllium special form ~~material;"~~material," except that 10 CFR 71.23(a) applies to any licensee of the agency, and the quality assurance program approval required by 10 CFR 71.23(b) shall be issued by the agency.

(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;"~~program." Changes to 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;

(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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .0313 is amended as published in 40:19 NCR 1516-1541 as follows:

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:~~apply, and in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", ~~the sentence~~ the phrase "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~~ the same as defined in G.S. 104E-5.(16).

(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;"~~licenses," in addition to the general license authorized by 10 CFR 150.20(a)(1) and subject to the limitations of 10 CFR 150.20(a)(2), any person who holds a specific license issued by an Agreement State or by the NRC is granted a general license to conduct the same activity in North Carolina and the offshore waters within the jurisdiction of the State of North Carolina;

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

(8) 10 CFR 150.32, "Funds for reclamation or maintenance of byproduct ~~material;"~~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.~~2025;
Amended Eff. October 1, 2026.

10A NCAC 15 .1203 is amended as published in 40:19 NCR 1516-1541 as follows:

10A NCAC 15 .1203 LICENSE REQUIRED: LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 61 and to effectuate their joint enforcement, except in 10 CFR 61.2, a reference to "NRC" or "Commission" means the "Agency."

~~(a)~~(b) 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.~~ not granted a low-level waste facility access license by the agency in accordance with G.S. 104E-10.3.

(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~~ .0111(a) of this Chapter in lieu of the NRC.

(4) ~~The requirements found in~~ Applicants and licensees shall comply with the applicable requirements under 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.~~ apply to the interpretation and application of this Rule.

(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)~~(c) 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)~~(b) of this Rule.

(1) No person shall transport or transfer waste to a low-level radioactive waste land disposal facility licensed under Paragraph ~~(a)~~(b) of this Rule unless licensed by the agency or ~~otherwise specifically authorized in writing by the agency.~~ not granted a low-level waste facility access license by the agency in accordance with G.S. 104E-10.3.

(2) The definitions of terms in G.S. 104E-5 shall ~~apply.~~ apply to the interpretation and application of this Rule.

(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,~~ waste as required by G.S. 104E-27(a). ~~including~~ These procedures and practices shall include 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)~~(b) 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)~~(c)(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)~~(d) 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~~.0111(a) 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)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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 are available at ~~shall be made available by the agency on the agency's public website~~. https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

~~[(d)](e) 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.~~2023;
Amended Eff. October 1, 2026.

10A NCAC 15 .1301 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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) To reconcile differences between this Rule and the incorporated sections of 10 CFR 39 and to effectuate their joint enforcement, a reference to "NRC" or "Commission" means the "Agency."

~~(a)~~(b) 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,~~ Licensing.RAM@dhhs.nc.gov or at the address shown in Rule ~~.0111~~.0111(a) 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 under 10 CFR 39.91 on the application:

(A) legal business name and mailing address;

(B) physical ~~address(es)~~ addresses where radioactive material ~~shall~~ will be used or possessed. The application shall indicate if radioactive materials ~~shall~~ will 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~~ indication 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; ~~number shall be provided on the application;~~

(G) ~~applicants shall indicate~~ indication of 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.~~ https://radiation.ncdhhs.gov/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~~ .0111(a) of this Chapter in lieu of the NRC.

(f) Applications for exemptions from this Rule permitted by 10 CFR 39.91 ~~to this Rule~~ shall be submitted to the agency at the address shown in Rule ~~.0111~~.0111(a) 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.~~2022;
Amended Eff. October 1, 2026.

10A NCAC 15 .1601 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION

(a) To reconcile differences between this Rule and the incorporated sections of 10 CFR 20 and to effectuate their joint enforcement, ~~and to effectuate their joint enforcement,~~ the following words and phrases shall be substituted for the language of 10 CFR 20:

(1) Except in 10 CFR 20.1003, a reference to the "Nuclear Regulatory Commission," "NRC" or "Commission" means the ~~"Agency;"~~ "Agency;" and

(2) In 10 CFR 20.1003, in the definition of [~~"Special Nuclear Material"~~] "special nuclear material", ~~the sentence~~ the phrase "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~~ the same as defined in G.S. 104E-5.(16).

~~(a)~~(b) 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 of 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)~~ (b)(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)~~(c) ~~Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.~~ No person shall intentionally expose an individual monitoring device, as defined in 10 CFR 20.1003, to radiation for the purpose of causing the device to indicate a dose not received by the individual to whom the device is assigned.

~~(c)~~(d) Licensees and registrants shall continue to perform all activities required by the rules of this Chapter, and any license or registration conditions imposed by the agency, and shall pay annual fees required by the Rules in Section 10A NCAC 15.1100.~~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)[(e)] Nothing in the rules of this Chapter shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.~~

(e)[~~(f)~~] 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, 2026; May 1, 2025.

10A NCAC 15 .1701 is amended with changes as published in 40:19 NCR 1516-1541 as follows:

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) To reconcile differences between this Rule and the incorporated sections of 10 CFR 37 and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of 10 CFR 37:

(1) With the exception of 10 CFR 37.5 a reference to “NRC” or “Commission” means the "Agency;" and

(2) A reference to “NRC-licensed” means licensed by the Agency.

~~(a)~~(b) 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)~~(c) 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)~~(d) ~~The Code of Federal Regulations incorporated by this Rule~~ Copies of these regulations 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. October 1, 2026; May 1, 2023.

Burgos, Alexander N

From: Black, Shanah
Sent: Wednesday, September 9, 2026 7:40 AM
To: Miller, Christopher S; Albright, James; Kissinger, Regina
Cc: Burgos, Alexander N
Subject: RE: N.C. Radiation Protection Commission - Rules for September 2026

Good morning,

Thank you for the feedback. Regina Kissinger is working on the amendments for the .0200 radiation protection rules. James Albright is amending the rest of the rules.

Thanks

From: Miller, Christopher S <christopher.miller@oah.nc.gov>
Sent: Tuesday, September 8, 2026 2:41 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Albright, James <james.albright@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Miller, Christopher S <christopher.miller@oah.nc.gov>
Subject: N.C. Radiation Protection Commission - Rules for September 2026

Good afternoon!

I'm the staff attorney who reviewed the rules submitted by the N.C. Radiation Protection Commission for the September 2026 RRC meeting. The RRC will formally review these rules at its meeting on Tuesday, September 29, 2026, at 10:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get close to the meeting. If there are any other representatives from your agency who want to attend virtually, please let me know prior to the meeting, and we will get evites out to them as well.

Attached is my Request for Changes pursuant to G.S. 150B-21.10. Please submit the responses and revised rules to me via email, no later than **5 p.m. on September 18, 2026.**

Let me know if you have any questions.

Thanks!

Chris Miller
Rules Review Commission Counsel
North Carolina Office of Administrative Hearings | Rules Division
1711 New Hope Church Road
Raleigh, NC 27609
(984) 236-1935

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