

1 10A NCAC 15 .0103 is amended as published in 40:19 NCR 1516-1541 as follows:

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3 **10A NCAC 15 .0103 DEFINITIONS**

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

- 7 (1) "Act" means North Carolina Radiation Protection Act as defined in G.S. 104E-1.
8 (2) "Agency" means the North Carolina Department of Health and Human Services, Division of Health
9 Service Regulation, Radiation Protection Section.
10 (3) "Authorized representative of the agency" means an employee of the agency.
11 (4) "Annually" means either:
12 (A) at intervals not to exceed 12 consecutive months; or
13 (B) once per year at the same time each year (completed during the same month each year over
14 a period of multiple years).
15 (5) "Calendar month" means January, February, March, April, May, June, July, August, September,
16 October, November, or December.
17 (6) "Calendar year" means the period of time between 12:00:00 am January 1 to 11:59:59 pm December
18 31.
19 (7) "Calibration" means the determination of the reading or response of an instrument to known
20 radiation values over the range of the instrument, or the strength of a source of radiation relative to
21 a standard.
22 (8) "CFR" means Code of Federal Regulations.
23 (9) "Commission" has the meaning as defined in G.S. 104E-5(5), except as stated in Paragraph (c) of
24 this Rule.
25 (10) "Department" has the meaning as defined in G.S. 104E-5(6) except as stated in Paragraph (c) of this
26 Rule.
27 (11) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.
28 (12) "Human use" means the internal or external administration of radiation or radioactive materials to
29 human beings.
30 (13) "Inspection" means an examination or observation by an authorized representative of the agency to
31 determine compliance with rules, orders, requirements, and conditions of the agency or the
32 Commission.
33 (14) "Monthly" means once every calendar month.
34 (15) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
35 (16) "Person" has the same meaning as defined in G.S. 104E-5(11).
36 (17) "Quarterly" means four times per calendar year, and:
37 (A) at intervals not to exceed 13 weeks; or

- (B) once per month during the months of January, April, July, and October; or
- (C) once per month during the months of February, May, August, and November; or
- (D) once per month during the months of March, June, September, and December.
- (18) "Radiation" except as otherwise defined in Section .1400 of this Chapter, has the meaning as defined in G.S. 104E-5(12).
- (19) "Semiannually" means twice per calendar year at six month intervals.
- (20) "SI unit" means a unit of measure from the International System of Units as established by the General Conference of Weights and Measures.
- (21) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.
- (22) "State" means the State of North Carolina.
- (23) "These Rules" means Chapter 10 of this Title.
- (b) As used in the rules of this Chapter, persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following definitions shall apply:
- (1) "Clinical study" means human use of a radiation machine for research and development. The terms "clinical investigation", "clinical research", "research", and "study" also mean "clinical study".
- (2) "Consulting" means providing professional technical advice on radiological matters by an expert registered with the agency in accordance with Rule .0205 of this Chapter.
- (3) "Facility" means the location at which one or more radiation machines or sources of radiation are installed or located within one building, at one address or vehicle, and are under the same administrative control.
- (4) "Healing arts" means the art or science of diagnostic examination using a source of radiation in the diagnosis or treatment of human or animal diseases.
- (5) "Individual responsible for radiation protection" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules, for persons registered with the agency in accordance with Section .0200 of this Chapter, commensurate with the scope of the activities authorized by the registrant.
- (6) "Install or installation" means the assembly, placement, initial calibration, operational testing, or other actions that allow a radiation machine to be used in a new location or after being moved from one location to another.
- (7) "Licensed practitioner" means a person authorized to order diagnostic exams that use radiation machines for diagnosing or treatment of human or animal diseases. The person shall be:
- (A) a physician in accordance with Subparagraph (8) of this Paragraph; or
- (B) licensed by the appropriate licensing board in North Carolina pursuant to G.S. Chapter 90 to provide professional services in chiropractic, dentistry, podiatry, and veterinary medicine.

- (8) "Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 1.
- (9) "Radiation machine" has the same meaning as defined in G.S. 104E-5(13).
- (10) "Registrant" means any person who is registered with the agency, after completing the registration process, in accordance with Rule .0203 of this Chapter.
- (11) "Registration" means the process of registration, with the agency, by completing and submitting agency forms in accordance with Rules .0203 and .0205 of this Chapter.
- (12) "Registered" means a facility or service provider that has completed the registration process in accordance with Rules .0203 and .0205 of this Chapter and has been issued a Notice of Registration in accordance with Rule .0207 of this Chapter.
- (13) "Research and development" means:
- (A) theoretical analysis, exploration, or experimentation; or
 - (B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.
- (14) "Service" means calibration, conversion, repair, routine maintenance, or other testing performed on a radiation machine, x-ray system or subsystem, or source of radiation, other than those actions taken during installation.
- (15) "Service Provider" means any person engaged in equipment services included in Rule .0205(d) of this Chapter.

(c) Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600, .0800, .1000, .1200, .1300, .1400, .1600, ~~and .1700~~, 1700, 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(e)(4), 32.13, 32.51(a), 32.51(e), 32.56, 32.59, 32.72(b)(5)(ii), 40.13(e)(10), 40.22(e), 40.25(b), 40.25(d)(3), 40.54, 40.55(e), (e)(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".~~

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

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

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

10 (A) ~~total dose;~~

11 (B) ~~dose per fraction;~~

12 (C) ~~treatment site, and~~

13 (D) ~~number of fractions.~~

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

16 *Eff. February 1, 1980;*

17 *Transferred and Recodified from 10 NCAC 3G .2203 Eff. January 4, 1990;*

18 *Transferred and Recodified from 15A NCAC 11 .0103 Eff. February 1, 2015;*

19 *Readopted Eff. May 1, ~~2025-2025~~;*

20 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0104 is amended as published in 40:19 NCR 1516-1541 as follows:

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3 **10A NCAC 15 .0104 INCORPORATION BY REFERENCE**

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

6 (1) ~~The following parts of 21 CFR Subchapter J:~~

7 (A) ~~Part 1000, "General;"~~

8 (B) ~~Subpart A 1000.1, "General Provisions General;"~~

9 (C) ~~Subpart A 1000.3(a) through (j),(k),(l), and (n) through (t), "Definitions;"~~

10 (D) ~~Subpart A 1000.15, "Examples of electronic products subject to the Radiation Control for~~
11 ~~Health and Safety Act of 1968;"~~

12 (E) ~~Part 1002, "Records and Reports;"~~

13 (F) ~~Subpart A 1002.1(a) and (e)(4), "Applicability;"~~

14 (G) ~~Subpart D 1002.31, "Preservation and inspection of records;"~~

15 (H) ~~Part 1003, "Notification of Defects of Failures to Comply;"~~

16 (I) ~~Subpart A 1003.1, "Applicability;"~~

17 (J) ~~Subpart A 1003.2, "Defect in an electronic product;"~~

18 (K) ~~Subpart C 1003.21, "Notification by the manufacturer to affected persons;"~~

19 (L) ~~Part 1010, "Performance Standards for Electronic Products General;"~~

20 (M) ~~Subpart A 1010.1, "Scope;"~~

21 (N) ~~Subpart A 1010.2(a),(b), and (d), "Certification;"~~

22 (O) ~~Subpart A 1010.3, "Identification;"~~

23 (P) ~~Subpart A 1010.4(a) and (d), "Variances;"~~

24 (Q) ~~Part 1020, "Performance Standards for Ionizing Radiation Emitting Products;"~~

25 (R) ~~Section 1020.20, "Cold cathode gas discharge tubes;"~~

26 (S) ~~Section 1020.30, "Diagnostic x ray systems and their main components;"~~

27 (T) ~~Section 1020.31, "Radiographic equipment;"~~

28 (U) ~~Section 1020.32, "Fluoroscopic equipment;" and~~

29 (V) ~~Section 1020.33, "Computed tomography (CT) equipment."~~

30 (2) ~~"Agreement Between the United States Atomic Energy Commission and the State of North Carolina~~
31 ~~for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the~~
32 ~~State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended," signed July 21,~~
33 ~~1964.~~

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

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

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

3 The "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for
4 Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section
5 274 of the Atomic Energy Act of 1954, as Amended," signed July 21, 1964, hereinafter known as the "Agreement."
6 is hereby incorporated by reference including subsequent amendments and editions. A copy of the Agreement is
7 available free of charge at <https://www.nrc.gov/cdn/nmss/pdf/ncagreements.pdf>.

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9 *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;*
10 *Eff. February 1, 1980;*
11 *Amended Eff. November 1, 1989; June 1, 1989; October 1, 1984;*
12 *Transferred and Recodified from 10 NCAC 03G .2204 Eff. January 4, 1990;*
13 *Amended Eff. January 1, 1994; May 1, 1992;*
14 *Temporary Amendment Eff. August 20, 1994, for a Period of 180 Days or until the permanent rule*
15 *becomes effective, whichever is sooner;*
16 *Amended Eff. October 1, 2013; November 1, 2007; May 1, 2006; January 1, 2005; August 1, 2002;*
17 *April 1, 1999; August 1, 1998; May 1, 1995;*
18 *Transferred and Recodified from 15A NCAC 11 .0104 Eff. February 1, 2015;*
19 *Readopted Eff. May 1, ~~2025-2025~~;*
20 *Amended Eff. October 1, 2026.*

10A NCAC 15 .0201 is amended 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 services.

(b) A person who acquires, owns, possesses, or receives ~~a radiation machine or~~ an X-Ray machine, a radiation generating ~~device~~ devices, 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 using ~~radiation machines~~ an X-Ray machine, or a radiation generating device for demonstration 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 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;

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

1 10A NCAC 15 .0202 is amended as published in 40:19 NCR 1541-1550 as follows:

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3 **10A NCAC 15 .0202 EXEMPTIONS**

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

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

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

- 13 (1) all radioactive materials; and
14 (2) ~~radiation~~ X-ray machines or radiation generating devices while in transit.

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16 *History Note: Authority G.S. 104E-7;*
17 *Eff. February 1, 1980;*
18 *Transferred and Recodified from 15A NCAC 11 .0202 Eff. February 1, 2015;*
19 *Readopted Eff. October 1, ~~2025~~ 2025;*
20 *Amended Eff. October 1, 2026.*

10A NCAC 15 .0203 is amended 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 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;~~ 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
 - (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:

- 1 (A) area radiation surveys for ~~diagnostic radiographic and fluoroscopy facilities;~~ X-ray
- 2 machines;
- 3 (B) equipment surveys and shielding designs for radiation generating devices;
- 4 (C) general health physics consulting services to perform dose estimates, radiation output
- 5 measurements, radiation safety program development, and radiation safety program
- 6 training;
- 7 (D) installation or service repair of ~~radiation~~ X-ray machines or radiation generating devices;
- 8 (E) qualified expert consulting services for CT and mammography ~~radiation~~ X-ray machines;
- 9 ~~(F) radiation protection expert;~~
- 10 ~~(G)(F)~~ shielding designs for ~~diagnostic radiographic and fluoroscopy facilities;~~ X-ray machines;
- 11 and
- 12 ~~(H)(G)~~ therapeutic facility shielding design, area radiation survey, or calibration. verification and
- 13 area radiation surveys.
- 14 (2) The application requires the following information:
- 15 (A) name of the employee to be registered;
- 16 (B) start date if the employee is being ~~added~~ added, and the stop date if the employee is being
- 17 removed from the registration;
- 18 (C) business registration number, name, physical address, and contact e-mail;
- 19 (D) class identification and modality of services to be provided;
- 20 (E) training and experience to submit for each class of services to be provided;
- 21 (F) date and signature of the employee applying for registration;
- 22 (G) date and signature of the owner or the individual ~~with administrative control;~~ responsible
- 23 for business operations; and
- 24 (H) additional information the agency determines is necessary for evaluating the application
- 25 for registration.
- 26 (h) Owners of radiation imaging systems and in-house personnel employed by a facility or corporation shall be exempt
- 27 from the registration requirements in this Rule to provide services in this State, provided such personnel:
- 28 (1) meets the education, or is supervised by an individual who meets the training and experience
- 29 requirements of the Class for the services provided;
- 30 (2) provides services at one facility or corporation; and
- 31 (3) provides requirements in Subparagraph (1)(h) of this Rule for agency review during inspection.
- 32 (i) The following general requirements apply to all facilities and services provided in North Carolina.
- 33 (1) The registrant shall notify the agency when any change will render the information in an application
- 34 for registration or notice of registration no longer accurate.
- 35 (2) A registrant that terminates all activities of ~~radiation~~ involving X-ray machines, radiation generating
- 36 devices, or providing services shall meet the following requirements within 30 days:

- 1 (A) request termination of the notice of registration in writing by the owner or the individual
- 2 with administrative control;
- 3 (B) submit to the agency, a Disposal of a ~~Radiation~~ Radiation an X-ray Machine or Radiation Generating
- 4 Device Form in accordance with Paragraph (e) of this Rule; and
- 5 (C) pay any outstanding fees pursuant to Section .1100 of this Chapter.
- 6 (3) A registrant shall not transfer the registration as part of a change of ownership.
- 7 (4) A person who takes possession of a ~~radiation~~ an X-ray machine or radiation generating device
- 8 because of bankruptcy, foreclosure, or state auction may possess the machine or device when the
- 9 following additional requirements are met:
- 10 (A) The machine or device shall be posted with a visible sign stating that the new owner is
- 11 responsible for registering with the agency if used in this State; and
- 12 (B) If the machine or device is energized, it shall only be energized by someone registered in
- 13 accordance with this Section and only to demonstrate that it is operable for sale or transfer.
- 14 (5) No person shall in any advertisement refer to the fact that his or her facility is registered with the
- 15 agency pursuant to the provisions of Rule .0204 or .0205 of this Section, and no person shall state
- 16 or imply that under such registration any activities have been approved by the agency.

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18 *History Note: Authority G.S. 104E-7; 104E-12; 104E-20;*

19 *Eff. February 1, 1980;*

20 *Amended Eff. May 1, 1992;*

21 *Transferred and Recodified from 15A NCAC 11 .0203 Eff. February 1, 2015;*

22 *Readopted Eff. October 1, ~~2025~~ 2025;*

23 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0204 is amended as published in 40:19 NCR 1541-1550 as follows:

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3 **10A NCAC 15 .0204 FACILITY RESPONSIBILITIES**

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

6 (b) Shielding design requirements:

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

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

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

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

18 (C) proposed date of installation.

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

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

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

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

32 (A) dental handheld;

33 (B) dual ~~x-ray~~ X-ray absorptiometry (DEXA);

34 (C) mammography; or

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

37 (c) Facility registration

- 1 (1) Mobile ~~radiation~~ X-ray machines located and used in this ~~State that are fixed in~~ State, and
 2 permanently affixed within a vehicle or ~~trailer~~ trailer, shall meet the following requirements prior to
 3 use:
- 4 (A) have a shielding design ~~submitted~~ acknowledged by the agency in accordance with
 5 Paragraph ~~(a)~~ (b) of this Rule;
- 6 (B) have ~~a Radiation~~ an X-ray Machine Application ~~or a Radiation Generating Devices~~
 7 ~~Application~~ form submitted in accordance with Rule .0203(d) of this Section. ~~Radiation X-~~
 8 ray machines leased or on loan from a registered service provider shall ~~register the radiation~~
 9 ~~machine be registered with the agency~~ if used maintained for more than 30 days;
- 10 (C) have a copy of the operating and safety procedures describing how to protect patients,
 11 operators, and the public from radiation submitted to the ~~agency; agency; and~~
- 12 ~~(D) receive a notice of registration from the agency; and~~
- 13 ~~(E)(D)~~ an individual with administrative control responsible for business operations shall ensure
 14 that ~~radiation~~ X-ray machines are operated in accordance with Section .0600 of this
 15 Chapter.
- 16 (2) Mobile ~~radiation~~ X-ray machines located out-of-state and brought into this State for use, ~~that are~~
 17 ~~fixed in and permanently affixed within~~ a vehicle or trailer, shall meet the following ~~requirements~~
 18 ~~prior to use; requirements:~~
- 19 (A) have the requirements in Parts (c)(1)(A) through (c)(1)(C) of this Rule submitted as a
 20 complete document for agency ~~review; and review;~~
- 21 (B) have a written notice submitted, in accordance with Rule .0208 of this Section, and
 22 maintain it for agency review during ~~inspection; inspection; and~~
- 23 ~~(C) an individual responsible for business operations shall ensure that X-ray machines are~~
 24 ~~operated in accordance with Section .0600 of this Chapter.~~
- 25 (3) Mobile radiation generating devices located out-of-state and brought into this State for use shall
 26 meet the following requirements prior to use:
- 27 (A) have a Radiation Generating Devices Application form submitted in accordance with Rule
 28 .0203(d) of this Section. Radiation generating devices leased or on loan from a registered
 29 service provider shall be registered with the agency if maintained for use for more than 30
 30 days;
- 31 (B) have a copy of the operating and safety procedures describing how to protect operators and
 32 the public from radiation submitted to the agency;
- 33 (C) submit a written notice, in accordance with Rule .0208 of this Section, and maintain it for
 34 agency review during inspection; and
- 35 (D) an individual with administrative control responsible for business operations shall ensure
 36 operators are qualified in accordance with Rule .0800 of this Chapter to use the radiation
 37 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 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) 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 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 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 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 registered pursuant to Paragraph(c) of this Rule shall prohibit any person from furnishing services described in Rule .0205(d) of this Section, at his or her facility, until such person provides evidence they are currently registered with the agency as a provider of such services in accordance with Rule .0205 of this Section.

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

History Note: Authority G.S. 104E-7; 104E-9(a)(3); 104E-12;

Eff. February 1, 1980;

Amended Eff. June 1, 1989;

- 1 *Transferred and Recodified from 15A NCAC 11 .0204 Eff. February 1, 2015;*
- 2 *Readopted Eff. October 1, ~~2025~~, 2025;*
- 3 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0205 is amended as published in 40:19 NCR 1541-1550 as follows:

2
3 **10A NCAC 15 .0205 SERVICE PROVIDER RESPONSIBILITIES**

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

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

9 (c) Each person applying for registration pursuant to Paragraph (a) of this Rule shall certify that he or she has read
10 and understands the requirements of the rules in this Chapter by signing the Company Employee Services Application
11 or Company Services Application form.

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

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

- 14 (1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use
15 of ~~radiation~~ X-ray machines or radiation generating devices;
- 16 (2) Class II - installation, repair, or service of the following:
- 17 (A) ~~radiation~~ X-ray machines and machine components, including the making of diagnostic
18 radiation output measurements, and performance verification; or
- 19 (B) radiation generating devices to include equipment surveys.
- 20 (3) Class III - shielding designs for ~~diagnostic radiographic facilities;~~ X-ray machines;
- 21 (4) Class IV - shielding designs for ~~diagnostic fluoroscopy facilities;~~ fluoroscopic X-ray machines;
- 22 (5) Class V - area radiation surveys and shielding evaluations for ~~diagnostic radiographic and~~
23 ~~fluoroscopy facilities;~~ X-ray machines;
- 24 (6) Class VI - radiation survey equipment calibrations;
- 25 (7) Class VII - therapeutic ~~facility shielding design, area radiation survey, or verification;~~ verification
26 and area surveys;
- 27 (8) Class VIII - providing individual monitoring devices;
- 28 (9) Class IX - general health and medical physics consulting to include the following services:
- 29 (A) equipment surveys and shielding designs for radiation generating devices;
- 30 (B) dose estimates;
- 31 (C) radiation output measurements;
- 32 (D) radiation safety program development; and
- 33 (E) radiation safety program training.

34 (f) Persons registered pursuant to Subparagraph (e)(1) as a Class I service provider to provide mobile ~~radiation~~ X-ray
35 machines that are ~~fixed in~~ permanently affixed within a vehicle or trailer for demonstration purposes or that ~~provides~~
36 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) 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) of this Section.

(g) Report of installation

(1) Persons registered pursuant to Paragraph (a) of this Rule who sell, install, transfer, lease, lend, or dispose of ~~radiation~~ X-ray machines or radiation generating devices 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 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 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.

1 10A NCAC 15 .0206 is amended as published in 40:19 NCR 1541-1550 as follows:

2
3 **10A NCAC 15 .0206 TRAINING AND EDUCATIONAL REQUIREMENTS TO PROVIDE SERVICES**

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

- 7 (1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use
8 of ~~radiation X-ray~~ machines or radiation generating ~~devices~~; devices. The applicant shall certify that
9 all persons providing services are knowledgeable, familiar, and comply with the rules which govern
10 the possession, installation, and use of ~~radiation X-ray~~ machines or radiation generating devices in
11 North Carolina.
- 12 (2) Class II - ~~installation or service to verify~~ installation, service, or performance verification associated
13 with the installation or service:
- 14 (A) manufacturer's equipment school for service, maintenance, and installation for the type of
15 ~~radiation X-ray machine or used for dental hand held, intraoral, and extra-oral, medical~~
16 ~~diagnostic, or medical fluoroscopic~~, radiation generation devices, or equivalent training;
- 17 (B) training in basic principles of radiation protection; and
- 18 (C) three months of experience in the installation and service of ~~radiation X-ray~~ machines,
19 radiation generating devices, and machine components ~~services~~ are required.
- 20 (3) Class III - shielding design for ~~diagnostic radiographic facilities~~; X-ray machine:
- 21 (A) training in basic principles of radiation protection;
- 22 (B) training in shielding design for each modality registering to provide services; and
- 23 (C) one year of experience ~~in diagnostic radiographic facility and shielding~~ for each type of
24 machine ~~application~~; modality.
- 25 (4) Class IV - shielding design for ~~diagnostic fluoroscopic facilities~~; fluoroscopic X-ray machines:
- 26 (A) training in basic principles of radiation protection;
- 27 (B) training in shielding design for each modality registering to provide services; and
- 28 (C) one year of experience ~~in diagnostic fluoroscopic facility and shielding~~ for each type of
29 machine ~~application~~; type.
- 30 (5) Class V - area radiation surveys and shielding evaluation for ~~diagnostic radiographic and~~
31 ~~fluoroscopy facilities~~; X-ray machines:
- 32 (A) training in basic principles of radiation protection;
- 33 (B) training in shielding evaluation for each modality registering to provide services; and
- 34 (C) one year of experience performing area radiation surveys for each type of machine
35 ~~application~~; modality.
- 36 (6) Class VI - radiation instrument calibration: The applicant must possess a current radioactive
37 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: The applicant must hold current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology or use NVLAP-accredited dosimetry.
- (9) Class IX - general health or medical physics consulting shall be performed by a person meeting one of the following requirements:
- (A) certified by the American Board of Health Physics in health physics in the appropriate field or specialties for services provided;
 - (B) certified by the American Board of Medical Physics;
 - (C) certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, ~~x-ray~~ X-ray and radium physics; or
 - (D) hold a master's or doctorate in physics, medical physics, other physical science, engineering, or applied mathematics, from an accredited college or university, and have 40 hours of practical training or supervised experience in ~~x-ray~~ X-ray physics.
- (b) Any person registered to provide Class IX services prior to the effective date of this Rule and holding a baccalaureate degree in physical science of physics, chemistry, or radiologic science, engineering or related field, and having two years of progressive experience in medical or health physics, or two years of graduate training in medical or health physics, is exempt from the requirements in Parts (a)(9)(A) through (D) of this Rule, provided he or she is in good standing with the agency.
- (c) The agency shall initiate action to terminate the registration of any person who fails to meet the requirements of this Rule.

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

1 *Eff. February 1, 1980;*
2 *Transferred and Recodified from 15A NCAC 11 .0206 Eff. February 1, 2015;*
3 *Readopted Eff. October 1, ~~2025~~ 2025;*
4 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0207 is amended as published in 40:19 NCR 1541-1550 as follows:

2
3 **10A NCAC 15 .0207 ADDITIONAL REQUIREMENTS TO PROVIDE SERVICES**

4 (a) A person applying for registration to perform Class II or Class IX services for diagnostic radiation output
5 ~~measurements, measurements and equipment surveys,~~ Class V area radiation surveys and shielding evaluations for
6 ~~diagnostic radiographic and fluoroscopy facilities, fluoroscopic X-ray machines,~~ or Class VII therapeutic area
7 radiation survey or shielding verification services pursuant to Rule .0205 of this Section shall meet the following
8 additional requirements:

- 9 (1) have radiation survey and radiation measurement equipment capable of measuring the radiation
10 energies corresponding to the services requested for authorization;
- 11 (2) ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated annually when a
12 frequency is not recommended by the manufacturer;
- 13 (3) submit the following for agency review prior to registration:
- 14 (A) a description of the procedures that will be used in performing area radiation ~~surveys~~
15 surveys, including a list of all guides and references to the employed;
- 16 (B) a copy of all forms, reports, and documents that will be supplied to registrants;
- 17 (C) samples of surveys for each modality requested for registration;
- 18 (D) samples of reports of diagnostic radiation output measurements for each modality
19 requested for registration; and
- 20 (E) samples of calibration reports for each therapeutic and kV imaging modality requested for
21 registration.

22 (b) A person applying for registration to perform Class VI equipment calibrations shall meet the following
23 requirements:

- 24 (1) ensure such calibrations are current and traceable to the National Institute of Standards and
25 Technology;
- 26 (2) license or register radiation sources used for such calibration as required by the rules in this Chapter;
- 27 (3) label the equipment to indicate the date of calibration; and
- 28 (4) maintain records of the calibration.

29 (c) A person applying for registration to perform Class III shielding designs for ~~diagnostic radiographic facilities, X-~~
30 ~~ray machines,~~ Class IV shielding designs for ~~diagnostic fluoroscopy facilities, fluoroscopic X-ray machines,~~ and Class
31 VII therapeutic ~~facilities and~~ shielding design verification services shall meet the following additional requirements:

- 32 (1) submit examples of the ~~facility and~~ shielding design which will be provided to registrants;
- 33 (2) submit any technical guides, methodology, occupancy factor rationales, and workload estimation
34 rationales that will be used; and
- 35 (3) ensure that the ~~facility and~~ shielding design verification services provided to registrants meet the
36 requirements in this Chapter.

1 *History Note:* *Authority G.S. 104E-7;*
2 *Eff. February 1, 1980;*
3 *Amended Eff. June 1, 1993; June 1, 1989;*
4 *Transferred and Recodified from 15A NCAC 11 .0207 Eff. February 1, 2015.*
5 *Readopted Eff. October 1, ~~2025~~ 2025;*
6 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0211 is amended as published in 40:19 NCR 1541-1550 as follows:

2
3 **10A NCAC 15 .0211 THE INDIVIDUAL RESPONSIBLE FOR RADIATION PROTECTION**
4 **REQUIREMENTS AND RESPONSIBILITIES**

5 (a) A person applying for registration shall designate an individual responsible for radiation protection on the Business
6 Application form pursuant to Rule .0203(c) of this Section. The qualified individual, ~~which~~ who can be an actively
7 registered ~~radiologic technologist~~, Registered Technologist (RT) by the American Registry of Radiologic
8 Technologists (ARRT), shall be on site and be qualified by reason of education, training, and experience. Records of
9 this individual's education, training, and experience shall be available for review during inspections or upon request
10 by the agency. The following are the minimum qualifications that must be met to carry out the job duties:

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

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

- 16 (1) Establishing and overseeing operating and safety procedures:
17 (A) that maintain radiation exposures as low as reasonably achievable (ALARA); and
18 (B) to review the procedures annually, or when changes ~~occur~~ occur, to ensure the procedures
19 are current.
20 (2) Ensuring individual monitoring devices are used in accordance with these Rules by occupationally
21 exposed personnel and records of monitoring results shall be:
22 (A) reviewed;
23 (B) maintained; and
24 (C) notifications made in accordance with Rule .1601 of this Chapter.
25 (3) Ensuring that personnel are complying with:
26 (A) this Chapter;
27 (B) the conditions of the notice of registration; and
28 (C) the operating and safety procedures of the registrant.
29 (4) Knowing:
30 (A) the management policies and administrative procedures of the registrant; and
31 (B) keeping management informed of the registrant's radiation protection program.
32 (5) Assuming control and having the authority to carry out corrective ~~actions~~ actions, including stopping
33 operations in emergencies or unsafe conditions.
34

35 *History Note: Authority G.S. 104E-7;*
36 *Eff. February 1, 1980;*
37 *Amended Eff. June 1, 1989;*

1 *Transferred and Recodified from 15A NCAC 11 .0211 Eff. February 1, 2015;*
2 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,*
3 *2019;*
4 *Amended Eff. October 1, ~~2025~~; 2025; October 1, 2026.*

1 10A NCAC 15 .0212 is amended as published in 40:19 NCR 1541-1550 as follows:

2
3 **10A NCAC 15 .0212 EMERGEING TECHNOLOGIES NOT MEETING EXISTING EQUIPMENT**
4 **REQUIREMENTS**

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

- 11 (1) ~~an application form in accordance with Rule .0203(d) of this Section;~~
12 (2) ~~the manufacturer manual;~~
13 (3) ~~description of intended use;~~
14 (4) ~~operator training provided to the end user;~~
15 (5) ~~an independent equipment survey to include the following:~~
16 (A) ~~all equipment settings available to the operator;~~
17 (B) ~~output at the highest setting; and~~
18 (C) ~~leakage radiation around the radiation machine.~~
19 (6) ~~an area survey to include the following:~~
20 (A) ~~radiation levels in adjacent areas, the operator location, and annual exposure to an operator;~~
21 (B) ~~the survey instrument used; and~~
22 (C) ~~the name and legible signature of the person who performed the survey.~~
23 (7) ~~the hazard level associated with the use of the radiation machine.~~
24 (8) ~~means to achieve radiation protection equivalent to the rules of this Section.~~

25 (b) The user or manufacturer of the X-ray machine shall submit the following to the agency for review:

- 26 (1) an application form in accordance with Rule .0203(d) of this Section;
27 (2) the manufacturer's manual;
28 (3) description of intended use;
29 (4) operator training provided to the end user;
30 (5) an independent equipment survey to include the following:
31 (A) all equipment settings available to the operator;
32 (B) output at the highest setting; and
33 (C) leakage radiation around the X-ray machine.
34 (6) an area survey to include the following:
35 (A) radiation levels in adjacent areas, the operator location, and annual exposure to an operator;
36 (B) the survey instrument used; and
37 (C) the name and legible signature of the person who performed the survey.

1 (7) the hazard level associated with the use of the X-ray machine.

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

3 (c) The user or manufacturer of the radiation generating device shall submit the requirements in Rule .0808 of this
4 Chapter for review.

5 ~~(b)~~(d) After receiving the information in ~~Paragraph (a)~~ Paragraphs (b) and (c) of this Rule, the agency will respond
6 to the applicant in writing within 90 calendar days. Upon review, the agency may require additional information to
7 determine if the ~~radiation~~ X-ray machine or radiation generating device is allowed for use.

8
9 History Note: Authority G.S. 104E-7; 104E-20;

10 Eff. June 1, 1989;

11 Amended Eff. June 1, 1993;

12 Transferred and Recodified from 15A NCAC 11 .0212 Eff. February 1, 2015;

13 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,
14 2019;

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

1 10A NCAC 15 .0214 is repealed as published in 40:19 NCR 1541-1550 as follows:

2
3 **10A NCAC 15 .0214 TRAINING AND EDUCATIONAL REQUIREMENTS FOR EQUIPMENT**
4 **SERVICES**

5
6 *History Note: Authority G.S. 104E-7; 104E-13;*

7 *Eff. June 1, 1989;*

8 *Amended Eff. June 1, 1993;*

9 *Transferred and Recodified from 15A NCAC 11 .0214 Eff. February 1, ~~2015~~.*

10 *Repealed Eff. October 1, 2026.*

1 10A NCAC 15 .0301 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL**
4

5 Codifier's Note: 10 NCAC 03G .2400 was transferred to 15A NCAC 11 .0300 effective January 4, 1990.
6 Recodification pursuant to G.S. 143B-279.3.
7

8 **10A NCAC 15 .0301 GENERAL RULES APPLICABLE TO THE SPECIFIC LICENSING OF**
9 **BYPRODUCT MATERIAL**

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

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

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

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

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

18 (1) 10 CFR 30.1, "Scope;"

19 (2) 10 CFR 30.2, "Resolution of conflict;"

20 (3) 10 CFR 30.3(a), (c), and (d), "Activities requiring license," except that references to 10 CFR
21 30.3(b)(1), (b)(2), and (b)(3) shall not apply;

22 (4) 10 CFR 30.4, "Definitions," except that references in the definitions to common defense and security
23 shall not apply. The term "temporary jobsite" shall mean a location where byproduct materials are
24 used and stored other than those location(s) of use authorized on the license;

25 (5) 10 CFR 30.6, "Communications," except that notices and reports required by this Rule shall be made
26 to the agency at the address shown in Rule .0111 of this Chapter in lieu of the United States Nuclear
27 Regulatory Commission (NRC);

28 (6) 10 CFR 30.9, "Completeness and accuracy of information;"

29 (7) 10 CFR 30.10, "Deliberate misconduct;"

30 (8) 10 CFR 30.11, "Specific exemptions;"

31 (9) 10 CFR 30.12, "Persons using byproduct material under certain Department of Energy and Nuclear
32 Regulatory Commission contracts;"

33 (10) 10 CFR 30.13, "Carriers;"

34 (11) 10 CFR 30.14, "Exempt concentration;"

35 (12) 10 CFR 30.15, "Certain items containing byproduct material;"

36 (13) 10 CFR 30.18, "Exempt quantities;"

37 (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), 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;"

- 1 (39) Appendix C to Part 30, "Criteria Relating to Use of Financial Tests and Self Guarantees for
2 Providing Reasonable Assurance of Funds for Decommissioning;"
- 3 (40) Appendix D to Part 30 "Criteria Relating To Use of Financial Tests and Self-Guarantee for
4 Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That
5 Have no Outstanding Rated Bonds;" and
- 6 (41) Appendix E to Part 30, "Criteria Relating to Use of Financial Tests and Self-Guarantee For
7 Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges,
8 Universities, and Hospitals."
- 9 ~~(b)~~(c) Applications shall be made on forms provided by the agency. One copy of the application and supporting
10 material shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule
11 ~~.0111.0111~~(a) of this Chapter in lieu of the NRC:
- 12 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
13 materials licenses, shall submit an Application for Radioactive Materials License. The following
14 information shall appear on the application:
- 15 (A) legal business name and mailing address;
- 16 (B) physical address(es) where radioactive material shall be used or possessed. The application
17 shall indicate if radioactive materials shall be used at temporary jobsites;
- 18 (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
- 19 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
20 application. If this individual is same as the Radiation Safety Officer, the application shall
21 so state;
- 22 (E) the application shall indicate if the application is for a new license, or for the renewal of an
23 existing license, by marking the corresponding check box;
- 24 (F) if the application is for the renewal of an existing license, the license number shall be
25 provided on the application;
- 26 (G) applicants shall indicate the type and category of license as shown on the form by marking
27 the corresponding check box; and
- 28 (H) the printed name, title, and signature of the certifying official. The certifying official shall
29 be an individual employed by the business or licensee, who is authorized by the licensee
30 to sign license applications on behalf of the business or licensee.
- 31 (2) Persons applying for an amendment to an existing license shall submit an Application for
32 Amendment of Radioactive Materials and Accelerator Licenses. The following information shall
33 appear on the application:
- 34 (A) the license number;
- 35 (B) amendment number of the current license;
- 36 (C) expiration date of the license;
- 37 (D) licensee name as it currently appears on the license;

- 1 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;
- 2 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
- 3 application. If this individual is same as the Radiation Safety Officer, item 5b on the
- 4 application shall be left blank;
- 5 (G) applicants shall provide a description of the action requested by marking the corresponding
- 6 checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
- 7 description of the action requested in the space provided in item 6b;
- 8 (H) explanation of the action requested; and
- 9 (I) the printed name, title, and signature of the certifying official. The certifying official shall
- 10 be an individual employed by the business or licensee who is authorized by the licensee to
- 11 sign license applications on behalf of the business or licensee.

12 (3) Applications specified in this Rule are available at:

13 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

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

15 [rm/doc-collections/cfr/part030/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/).

16

17 *History Note: Authority G.S. 104E-7; 104E-9(8); 104E-10(b);*

18 *Eff. February 1, 1980;*

19 *Amended Eff. October 1, 2013; August 1, 1998; January 1, 1994; May 1, 1992; June 1, 1989; July*

20 *1, 1982;*

21 *Transferred and Recodified from 15A NCAC 11 .0301 Eff. February 1, 2015;*

22 *Readopted Eff. May 1, ~~2024~~2024;*

23 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0302 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .0302 GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL**

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

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

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

8 (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
9 31.12(c)(4), where a reference is made to "an Agreement State", it means "an Agreement State or
10 the NRC;" and

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

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

16 (1) Reports, notifications, and responses to agency requests for information required by this Rule shall
17 be made to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise
18 by the agency;

19 (2) 10 CFR 31.1, "Purpose and scope;"

20 (3) 10 CFR 31.2, "Terms and conditions;"

21 (4) 10 CFR 31.5, "Certain detecting, measuring, gauging, or controlling devices and certain devices for
22 producing light or an ionized atmosphere," except that the fee required by 10 CFR 170.31 shall not
23 apply. Persons using devices described in 31.5(a) shall be registered with the agency. Device
24 registration shall be made in accordance with Paragraph ~~(b)~~(c) of this Rule and shall contain the
25 information required by 31.5(c)(13)(iii);

26 (5) 10 CFR 31.6, "General license to install devices generally licensed in 10 CFR 31.5;"

27 (6) 10 CFR 31.7, "Luminous safety devices in aircraft;"

28 (7) 10 CFR 31.8, "Americium-241 and radium-226 in the form of calibration or reference sources;"

29 (8) 10 CFR 31.9, "General license to own byproduct material;"

30 (9) 10 CFR 31.10, "General license for strontium 90 in ice detection devices;"

31 (10) 10 CFR 31.11, "General license for use of byproduct material for certain in vitro clinical or
32 laboratory testing," except that persons required by 31.11(b) to register devices with the agency shall
33 comply with the provisions of Paragraph ~~(b)~~(c) of this Rule;

34 (11) 10 CFR 31.12, "General license for certain items and self-luminous products containing radium-
35 226;" and

36 (12) 10 CFR 31.21, "Maintenance of records;"

1 ~~(b)~~(c) Persons registering devices shall use General License Application for Registration forms provided by the
2 agency. These forms are available free of charge at: <https://radiation.ncdhhs.gov/rms/rmsgenicforms.htm>.
3 Applications and supporting material shall be submitted to the agency by e-mail at Licensing.ram@dhhs.nc.gov, or at
4 the address shown in Rule ~~0111~~.0111(a) of this Chapter in lieu of the United States Nuclear Regulatory Commission.

5 The following information shall appear on the application:

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

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

19
20 *History Note: Authority G.S. 104E-7; 104E-10(b);*
21 *Eff. February 1, 1980;*
22 *Amended Eff. June 1, 1989; October 1, 1984; October 1, 1980;*
23 *Transferred and Recodified from 15A NCAC 11 .0302 Eff. February 1, 2015;*
24 *Amended Eff. March 1, 2017;*
25 *Readopted Eff. May 1, ~~2024~~.2024;*
26 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0304 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .0304 SPECIFIC LICENSES: MANUFACTURE OR TRANSFER CERTAIN ITEMS**
4 **CONTAINING BYPRODUCT MATERIAL**

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

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

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

9 (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
10 "an Agreement State", it means "an Agreement State or the NRC."

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

17 (1) 10 CFR 32.1(a), (b), and (c)(2), "Purpose and scope;"

18 (2) 10 CFR 32.2, "Definitions," the term "initially transfer" shall mean the "initial commercial transfer
19 of items and devices to an end user or a commercial or retail reseller;"

20 (3) 10 CFR 32.3, "Maintenance of records."

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

23 (1) 10 CFR 32.13, "Same: Prohibition of introduction;"

24 (2) 10 CFR 32.24, "Same: Table of organ doses;" and

25 (3) applications to manufacture, process, produce, prepare, package, re-package, or initially transfer
26 items or devices for commercial distribution containing exempt concentrations or exempt quantities
27 of byproduct material shall be made to the United States Nuclear Regulatory Commission (NRC) in
28 lieu of the agency.

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

32 (1) 10 CFR 32.51, "Byproduct material contained in devices for use under 10 CFR 31.5; requirements
33 for license to manufacture, or initially transfer;"

34 (2) 10 CFR 32.51a, "Same: Conditions of licenses;"

35 (3) 10 CFR 32.52, "Same: Material transfer reports and records;"

36 (4) 10 CFR 32.53, "Luminous safety devices for use in aircraft: Requirements for license to
37 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, 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, or at the address shown in Rule ~~0111.0111(a)~~ of this Chapter in lieu of the NRC:

- 1 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
2 materials licenses, shall submit an Application for Radioactive Materials License. The following
3 information shall appear on the application:
- 4 (A) legal business name and mailing address;
 - 5 (B) physical address(es) where radioactive material shall be used or possessed. The application
6 shall indicate if radioactive materials shall be used at temporary jobsites;
 - 7 (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
 - 8 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
9 application. If this individual is same as the Radiation Safety Officer, the application shall
10 so state;
 - 11 (E) the application shall indicate if the application is for a new license, or for the renewal of an
12 existing license, by marking the corresponding check box;
 - 13 (F) if the application is for the renewal of an existing license, the license number shall be
14 provided on the application;
 - 15 (G) applicants shall indicate the type and category of license as shown on the form by marking
16 the corresponding check box; and
 - 17 (H) the printed name, title, and signature of the certifying official. The certifying official shall
18 be an individual employed by the business or licensee, who is authorized by the licensee
19 to sign license applications on behalf of the business or licensee.
- 20 (2) Persons applying for an amendment to an existing license shall submit an Application for
21 Amendment of Radioactive Materials and Accelerator Licenses. The following information shall
22 appear on the application:
- 23 (A) the license number;
 - 24 (B) amendment number of the current license;
 - 25 (C) expiration date of the license;
 - 26 (D) licensee name as it currently appears on the license;
 - 27 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;
 - 28 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
29 application. If this individual is same as the Radiation Safety Officer, item 5b on the
30 application shall be left blank;
 - 31 (G) applicants shall provide a description of the action requested by marking the corresponding
32 checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
33 description of the action requested in the space provided in item 6b;
 - 34 (H) explanation of the action requested; and
 - 35 (I) the printed name, title, and signature of the certifying official. The certifying official shall
36 be an individual employed by the business or licensee who is authorized by the licensee to
37 sign license applications on behalf of the business or licensee.

1 (3) Applications specified in this Rule are available at:
2 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

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

6
7 *History Note: Authority G.S. 104E-7; 104E-10(b); 104E-20; 10 CFR 30.71;*
8 *Eff. February 1, 1980;*
9 *Amended Eff. October 1, 2013; May 1, 1993;*
10 *Transferred and Recodified from 15A NCAC 11 .0304 Eff. February 1, 2015;*
11 *Amended Eff. March 1, 2017;*
12 *Readopted Eff. May 1, ~~2024~~.2024;*
13 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0305 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .0305 SPECIFIC DOEMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT**
4 **MATERIAL**

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

7 (1) A reference to “NRC” or “Commission” means the “Agency;”

8 (2) A reference to “NRC or agreement state” means the “Agency or agreement state.”

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

13 (1) 10 CFR 33.1, "Purpose and scope;"

14 (2) 10 CFR 33.11(a), "Types of specific licenses of broad scope;"

15 (3) 10 CFR 33.12, "Applications for specific licenses of broad scope," except that the requirements of
16 Paragraph ~~(b)~~(c) of this Rule shall be met;

17 (4) 10 CFR 33.13, "Requirements for the issuance of a Type A specific license of broad scope;"

18 (5) 10 CFR 33.16, "Application for other specific licenses;" and

19 (6) 10 CFR ~~33.17(a)~~33.17(a) and (b), "Conditions of specific licenses of broad scope."

20 ~~(b)~~(c) Applications shall be made on forms provided by the agency. One copy of the application and supporting
21 material shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule
22 ~~.0111.0111(a)~~ of this Chapter in lieu of the United States Nuclear Regulatory Commission:

23 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
24 materials licenses, shall submit an Application for Radioactive Materials License. The instructions
25 for completing the application printed on the application form shall be followed. The following
26 information shall appear on the application:

27 (A) legal business name and mailing address;

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

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

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

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

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

- 1 (G) applicants shall indicate the type and category of license as shown on the form by marking
2 the corresponding check box; and
- 3 (H) the printed name, title, and signature of the certifying official. The certifying official shall
4 be an individual employed by the business or licensee, who is authorized by the licensee
5 to sign license applications on behalf of the business or licensee.
- 6 (2) Persons applying for an amendment to an existing license shall submit an Application for
7 Amendment of Radioactive Materials and Accelerator Licenses. The instructions for completing the
8 application printed on the application form shall be followed. The following information shall
9 appear on the application:
- 10 (A) the license number;
- 11 (B) amendment number of the current license;
- 12 (C) expiration date of the license;
- 13 (D) licensee name as it currently appears on the license;
- 14 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;
- 15 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
16 application. If this individual is same as the Radiation Safety Officer, item 5b on the
17 application shall be left blank;
- 18 (G) applicants shall provide a description of the action requested by marking the corresponding
19 checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
20 description of the action requested in the space provided in item 6b;
- 21 (H) explanation of the action requested; and
- 22 (I) the printed name, title, and signature of the certifying official. The certifying official shall
23 be an individual employed by the business or licensee who is authorized by the licensee to
24 sign license applications on behalf of the business or licensee.
- 25 (3) Applications specified in this Rule are available at:
26 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).
- 27 ~~(e)(d)~~ Copies of the regulations incorporated by this Rule are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part033/)
28 [rm/doc-collections/cfr/part033/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part033/).

29

30 *History Note: Authority G.S. 104E-7; 104E-10(b); 104E-20;*
31 *Eff. February 1, 1980;*
32 *Amended Eff. October 1, 2013; April 1, 1999; June 1, 1993; October 1, 1982; September 1, 1981;*
33 *Transferred and Recodified from 15A NCAC 11 .0305 Eff. February 1, 2015;*
34 *Amended Eff. March 1, 2017;*
35 *Readopted Eff. May 1, ~~2024~~ 2024;*
36 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0306 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .0306 SPECIFIC LICENSES: SEALED SOURCES IN INDUSTRIAL RADIOGRAPHY**
4 **AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL**
5 **RADIOGRAPHIC OPERATIONS**

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

8 (1) A reference to “NRC” or “Commission” means the “Agency;” and,

9 (2) A reference to “NRC or agreement state” means the “Agency or agreement state.”

10 ~~(a)~~(b) Persons conducting industrial radiography using radioactive materials shall comply with the requirements of
11 10 CFR 34, which are hereby incorporated by reference including subsequent amendments and editions, except ~~for~~for
12 10 CFR 34.5, 34.8, 34.121, and 34.123. Copies of these regulations are available free of charge at
13 <https://www.nrc.gov/reading-rm/doc-collections/cfr/part034/>.

14 ~~(b)~~(c) Applications required by 10 CFR 34 shall be made on forms provided by the agency. Applications and
15 supporting material shall be submitted to the agency by e-mail to Licensing.RAM@dhhs.nc.gov, or mailed to the
16 address shown in Rule ~~0111.0111~~(a) of this Chapter in lieu of the NRC:

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

20 (A) legal business name and mailing address;

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

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

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

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

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

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

33 (H) the printed name, title, and signature of the certifying official. The certifying official shall
34 be an individual employed by the business or licensee, who is authorized by the licensee
35 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](http://www.ncradiation.net/rms/rmsforms2.htm(Rev01).htm)

~~(e)~~(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.

~~(4)~~(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 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.

1 10A NCAC 15 .0307 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .0307 MEDICAL USE OF BYPRODUCT MATERIAL IN HUMANS**

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

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

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

8 ~~(a)~~(b) All persons using radioactive materials for medical use in humans shall comply with the general information
9 requirements of Subpart A to 10 CFR 35, as follows:

10 (1) 10 CFR 35.1, "Purpose and scope;"

11 (2) 10 CFR 35.2, "Definitions;"

12 (3) 10 CFR 35.5, "Maintenance of records;"

13 (4) 10 CFR 35.6, "Provisions for the protection of human research subjects;"

14 (5) 10 CFR 35.7, "FDA, other Federal, and State requirements;"

15 (6) 10 CFR 35.10, "Implementation;"

16 (7) 10 CFR 35.11, "License required," except that 35.11(c)(1) shall not apply;

17 (8) 10 CFR 35.12, "Application for license, amendment, or renewal," except that the requirements in
18 Paragraph ~~(m)~~(n) of this Rule shall be met;

19 (9) 10 CFR 35.13, "License amendments," except that 35.13(a)(1) shall not apply;

20 (10) 10 CFR 35.14, "Notifications," except that notifications required by this rule shall be submitted to
21 the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the
22 agency;

23 (11) 10 CFR 35.15, "Exemptions regarding Type A specific licenses of broad scope;"

24 (12) 10 CFR 35.18, "License issuance," except 35.18(a)(2) shall not apply; and

25 (13) 10 CFR 35.19, "Specific exemptions."

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

28 (1) 10 CFR 35.24, "Authority and responsibilities for the radiation safety program;"

29 (2) 10 CFR 35.26, "Radiation protection program changes;"

30 (3) 10 CFR 35.27, "Supervision." Persons using instrumentation for the collection of data to be used by
31 a physician shall hold active nuclear medicine technology (N) certification issued by the American
32 Registry of Radiographic Technologists (ARRT) or hold active certification issued by the Nuclear
33 Medicine Technologist Certification Board (NMTCB) within three (3) years of the effective date of
34 this readopted Rule, or shall be in training and under the supervision of an individual holding active
35 ARRT(N) or NMTCB certification or an authorized user;

36 (4) 10 CFR 35.40, "Written Directives;"

37 (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.
- ~~(e)(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, for each nuclear medicine procedure not requiring a written directive performed at the facility:
- (1) the range of radiopharmaceutical dosages;
 - (2) the method used to determine the dosage;
 - (3) the route of administration;
 - (4) provision of job-specific training and assistance to medical personnel in the administration of radioactive material for purposes including, but not limited to, the evaluation of cardiac ischemia in the emergent setting and localization of seizure foci as an adjunct to epilepsy monitoring; and
 - (5) any other information the licensee determines to be useful for patient care, and to prevent the occurrence of medical events.
- ~~(d)(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. ~~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 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 molybdenum-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."

~~(h)~~(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, 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) where radioactive material shall be used or possessed. The application shall indicate if radioactive materials shall be used at temporary jobsites;
 - (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
 - (D) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, the application shall so state;

- (E) the application shall indicate if the application is for a new license or for the renewal of an existing license by marking the corresponding check box;
- (F) if the application is for the renewal of an existing license, the license number shall be provided on the application;
- (G) applicants shall indicate the type and category of license as shown on the form by marking the corresponding check box; and
- (H) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee, who is authorized by the licensee to sign license applications on behalf of the business or licensee.
- (2) Persons applying for an amendment to an existing license shall submit an Application for Amendment of Radioactive Materials and Accelerator Licenses. The following information shall appear on the application:
- (A) the license number;
- (B) amendment number of the current license;
- (C) expiration date of the license;
- (D) licensee name as it currently appears on the license;
- (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;
- (F) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, item 5b on the application shall be left blank;
- (G) applicants shall provide a description of the action requested by marking the corresponding checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief description of the action requested in the space provided in item 6b;
- (H) explanation of the action requested; and
- (I) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee who is authorized by the licensee to sign license applications on behalf of the business or licensee.
- (3) Applications specified in this Rule are available free of charge at:
[https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).
- ~~(a)~~(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;*

- 1 *Amended Eff. March 1, 2017;*
- 2 *Readopted Eff. May 1, ~~2024~~2014;*
- 3 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0308 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .0308 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS**

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

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

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

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

11 (1) 10 CFR 36.1, "Purpose and scope;"

12 (2) 10 CFR 36.2, "Definitions," except that references to common defense and security shall not apply;

13 (3) 10 CFR 36.11, "Application for a specific license," except that the requirements of Paragraph ~~(b)~~(c)
14 of this Rule shall be met;

15 (4) 10 CFR 36.13, "Specific licenses for irradiators;"

16 (5) 10 CFR 36.15, "Commencement of construction;"

17 (6) 10 CFR 36.17, "Applications for exemptions;"

18 (7) 10 CFR 36.19, "Requests for written statements;"

19 (8) 10 CFR 36.21, "Performance criteria for sealed sources;"

20 (9) 10 CFR 36.23, "Access control;"

21 (10) 10 CFR 36.25, "Shielding;"

22 (11) 10 CFR 36.27, "Fire protection;"

23 (12) 10 CFR 36.29, "Radiation monitors;"

24 (13) ~~10 CFR~~ 10 CFR 36.31, "Control of source movement;"

25 (14) 10 CFR 36.33, "Irradiator pools;"

26 (15) 10 CFR 36.35, "Source rack protection;"

27 (16) 10 CFR 36.37, "Power failures;"

28 (17) 10 CFR 36.39, "Design requirements;"

29 (18) 10 CFR 36.41, "Construction monitoring and acceptance testing;"

30 (19) 10 CFR 36.51, "Training;"

31 (20) 10 CFR 36.53, "Operating and emergency procedures;"

32 (21) 10 CFR 36.55, "Personnel monitoring;"

33 (22) 10 CFR 36.57, "Radiation surveys;"

34 (23) 10 CFR 36.59, "Detection of leaking sources;"

35 (24) 10 CFR 36.61, "Inspection and maintenance;"

36 (25) 10 CFR 36.63, "Pool water quality;"

37 (26) 10 CFR 36.65, "Attendance during operations;"

- 1 (27) 10 CFR 36.67, "Entering and leaving the radiation room;"
- 2 (28) 10 CFR 36.69, "Irradiation of explosive or flammable materials;"
- 3 (29) 10 CFR 36.81, "Records and retention periods;" and
- 4 (30) 10 CFR 36.83, "Reports," except that reports required by this Rule shall be made to the agency at
- 5 the address shown in Rule ~~0111.0111(a)~~ of this Chapter unless directed otherwise by the agency,
- 6 in lieu of the United States Nuclear Regulatory Commission (NRC).
- 7 ~~(b)~~(c) Applications shall be made on forms provided by the agency. One copy of the application and supporting
- 8 material shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule
- 9 ~~0111.0111(a)~~ of this Chapter in lieu of the NRC:
- 10 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
- 11 materials licenses, shall submit an Application for Radioactive Materials License. The following
- 12 information shall appear on the application:
- 13 (A) legal business name and mailing address;
- 14 (B) physical address(es) where radioactive material shall be used or possessed. The application
- 15 shall indicate if radioactive materials shall be used at temporary jobsites;
- 16 (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
- 17 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
- 18 application. If this individual is same as the Radiation Safety Officer, the application shall
- 19 so state;
- 20 (E) the application shall indicate if the application is for a new license, or for the renewal of an
- 21 existing license, by marking the corresponding check box;
- 22 (F) if the application is for the renewal of an existing license, the license number shall be
- 23 provided on the application;
- 24 (G) applicants shall indicate the type and category of license as shown on the form by marking
- 25 the corresponding check box; and
- 26 (H) the printed name, title, and signature of the certifying official. The certifying official shall
- 27 be an individual employed by the business or licensee, who is authorized by the licensee
- 28 to sign license applications on behalf of the business or licensee.
- 29 (2) Persons applying for an amendment to an existing license shall submit an Application for
- 30 Amendment of Radioactive Materials and Accelerator Licenses. The following information shall
- 31 appear on the application:
- 32 (A) the license number;
- 33 (B) amendment number of the current license;
- 34 (C) expiration date of the license;
- 35 (D) licensee name as it currently appears on the license;
- 36 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;

- 1 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
2 application. If this individual is same as the Radiation Safety Officer, item 5b on the
3 application shall be left blank;
- 4 (G) applicants shall provide a description of the action requested by marking the corresponding
5 checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
6 description of the action requested in the space provided in item 6b;
- 7 (H) explanation of the action requested; and
- 8 (I) the printed name, title, and signature of the certifying official. The certifying official shall
9 be an individual employed by the business or licensee who is authorized by the licensee to
10 sign license applications on behalf of the business or licensee.

11 (3) Applications specified in this Rule are available at:
12 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

13 ~~(e)~~(d) Copies of the regulations incorporated by this Rule are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part036/)
14 [rm/doc-collections/cfr/part036/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part036/).

15

16 *History Note: Authority G.S. 104E-7; 104E-10(b);*
17 *Eff. February 1, 1980;*
18 *Amended Eff. January 1, 2005; January 1, 1994;*
19 *Transferred and Recodified from 15A NCAC 11 .0308 Eff. February 1, 2015;*
20 *Amended Eff. March 1, 2017;*
21 *Readopted Eff. May 1, ~~2024~~2024;*
22 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0309 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .0309 DOMESTIC LICENSING OF SOURCE MATERIAL**

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

6 (1) With the exception of the definition of Special Nuclear Material, a reference to "NRC" or
7 "Commission" means the "Agency;"

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

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

12 (4) In 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),
13 where a reference is made to "an Agreement State", it means "an Agreement State or the NRC".

14 ~~(a)~~(b) Persons using source material and byproduct material as defined in this Rule shall comply with the provisions
15 of 10 CFR 40, which are hereby incorporated by reference including subsequent amendments and editions, except that
16 references to importation and exportation of radioactive material and references to and requirements of 10 CFR
17 70.22(b), (c), (f) – (n), and 10 CFR 110 shall not apply, as follows:

18 (1) 10 CFR 40.1, "Purpose;"

19 (2) 10 CFR 40.2, "Scope;"

20 (3) 10 CFR 40.2a, "Coverage of inactive tailings sites;"

21 (4) 10 CFR 40.3, "Licensing requirements;"

22 (5) 10 CFR 40.4, "Definitions," except that the definition of "foreign obligations," "reconciliation," and
23 references in the definitions to common defense and security shall not apply;

24 (6) 10 CFR 40.5, "Communications," except that notices and reports shall be made to the agency at the
25 address shown in Rule .0111 of this Chapter unless directed otherwise by the agency or specified
26 otherwise in this Rule, in lieu of the United States Nuclear Regulatory Commission (NRC);

27 (7) 10 CFR 40.9, "Completeness and accuracy of information;"

28 (8) 10 CFR 40.10, "Deliberate misconduct;"

29 (9) 10 CFR 40.11, "Persons using source material under certain Department of Energy and Nuclear
30 Regulatory Commission contracts;"

31 (10) 10 CFR 40.12(a), "Carriers;"

32 (11) 10 CFR 40.13, "Unimportant quantities of source material," except 10 CFR 40.13(c)(5)(iv);

33 (12) 10 CFR 40.14, "Specific Exemptions;"

34 (13) 10 CFR 40.20, "Types of licenses;"

35 (14) 10 CFR 40.21, "General license to receive title to source or byproduct material;"

36 (15) 10 CFR 40.22, "Small quantities of source material;"

37 (16) 10 CFR 40.25, "General license for use of certain industrial products or devices;"

- 1 (17) 10 CFR 40.26, "General license for possession and storage of byproduct material as defined in this
2 part;"
- 3 (18) 10 CFR 40.31(a), (b), (d), (f) – (i), "Application for specific licenses," except that the requirements
4 of Paragraph ~~(b)(c)~~ of this Rule shall be met, and reports required by 10 CFR 40.31(g) shall be
5 submitted to the NRC in lieu of the agency. In the event an "environmental document," as defined
6 by G.S. 113-9.(2), has been prepared in accordance with 15A NCAC 01C .0206, the agency may
7 base the issuance of a specific license on information and evaluations made in that environmental
8 document;
- 9 (19) 10 CFR 40.32, "General requirements for issuance of specific licenses," except that 10 CFR
10 40.32(d), (g), and references to and requirements for uranium enrichment and uranium hexafluoride
11 facilities shall not apply. In the event an "environmental document," as defined by G.S. 113A-9.(2),
12 has been prepared in accordance with 15A NCAC 01C .0206, the agency may base the issuance of
13 a specific license on information and evaluations made in that environmental document;
- 14 (20) 10 CFR 40.34, "Special requirements for issuance of specific licenses;"
- 15 (21) 10 CFR 40.35, "Conditions of specific licenses issued pursuant to 10 CFR 40.34;"
- 16 (22) 10 CFR 40.36, "Financial assurance and recordkeeping for decommissioning," the initials "DCE"
17 shall mean "detailed cost estimate;"
- 18 (23) 10 CFR 40.41(a) – (c), (e)(2), (e)(4), (f), "Terms and conditions of licenses;"
- 19 (24) 10 CFR 40.42, "Expiration and termination of licenses and decommissioning of sites and separate
20 buildings or outdoor areas;"
- 21 (25) 10 CFR 40.43, "Renewal of licenses;"
- 22 (26) 10 CFR 40.44, "Amendment of licenses at request of licensee;"
- 23 (27) 10 CFR 40.45, "Commission action on application to renew or amend;"
- 24 (28) 10 CFR 40.46, "Inalienability of licenses;"
- 25 (29) 10 CFR 40.51(a), (b)(1) – (b)(5), (b)(7), (c), (d), "Transfer of source or byproduct material;"
- 26 (30) 10 CFR 40.54, "Requirements for license to initially transfer source material for use under the 'small
27 quantities of source material' general license;"
- 28 (31) 10 CFR 40.55, "Conditions of licenses to initially transfer source material for use under the 'small
29 quantities of source material' general license: Quality control, labeling, safety instructions, and
30 records and reports;"
- 31 (32) 10 CFR 40.60, "Reporting requirements;"
- 32 (33) 10 CFR 40.61, "Records;"
- 33 (34) 10 CFR 40.62, "Inspections;"
- 34 (35) 10 CFR 40.63, "Tests;"
- 35 (36) 10 CFR 40.65, "Effluent monitoring reporting requirements;"
- 36 (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, 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) 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;

- 1 (G) applicants shall provide a description of the action requested by marking the corresponding
2 checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
3 description of the action requested in the space provided in item 6b;
4 (H) explanation of the action requested; and
5 (I) the printed name, title, and signature of the certifying official. The certifying official shall
6 be an individual employed by the business or licensee who is authorized by the licensee to
7 sign license applications on behalf of the business or licensee.

8 (3) Applications specified in this Rule are available at:
9 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

10 ~~(e)~~(d) Copies of the regulations incorporated by this Rule are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part040/)
11 [rm/doc-collections/cfr/part040/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part040/).

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13 *History Note: Authority G.S. 104E-7; 104E-10(b);*
14 *Eff. February 1, 1980;*
15 *Amended Eff. October 1, 2013; January 1, 2005; January 1, 1994; June 1, 1989;*
16 *Transferred and Recodified from 15A NCAC 11 .0309 Eff. February 1, 2015;*
17 *Amended Eff. March 1, 2017;*
18 *Readopted Eff. May 1, ~~2024~~2024;*
19 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .0310 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .0310 DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL**

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

6 (1) With the exception of the definition of Special Nuclear Material, a reference to "NRC" or
7 "Commission" means the "Agency".

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

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

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

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

17 (1) 10 CFR 70.1(a) and (b), "Purpose;"

18 (2) 10 CFR 70.2, "Scope;"

19 (3) 10 CFR 70.3, "License requirements;"

20 (4) 10 CFR 70.4, "Definitions," except that references in the definitions to common defense and security
21 shall not apply;

22 (5) 10 CFR 70.5, "Communications," except that notices and reports shall be made to the agency at the
23 address shown in Rule .0111 of this Chapter in lieu of the United States Nuclear Regulatory
24 Commission (NRC) unless otherwise specified by the agency;

25 (6) 10 CFR 70.9, "Completeness and accuracy of information;"

26 (7) 10 CFR 70.10, "Deliberate misconduct;"

27 (8) 10 CFR 70.11, "Persons using special nuclear material under certain DOE and NRC contracts;"

28 (9) 10 CFR 70.12, "Carriers;"

29 (10) 10 CFR 70.17, "Specific exemption;"

30 (11) 10 CFR 70.18, "Types of licenses;"

31 (12) 10 CFR 70.19, "General license for calibration and reference sources;"

32 (13) 10 CFR 70.20, "General license to own special nuclear material;"

33 (14) 10 CFR 70.21(a)(2), (a)(3), (b), "Filing," except that the requirements of Paragraph ~~(b)(c)~~ of this
34 Rule shall be met;

35 (15) 10 CFR 70.22(a), (d), and (e), "Contents of application;"

36 (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, 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) 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](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).
- ~~(e)~~(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.*

1 10A NCAC 15 .0311 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .0311 PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL**

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

6 (1) In 10 CFR 71.0(c), 71.3, 71.5 71.17(a), (b), 71.22, 71.23(a), (b), 10 CFR 71.101(c)(1), a reference
7 to “NRC” or “Commission” means the “Agency;”

8 (2) In 10 CFR 71.8(b), (d), and 71.17(b), the Agency is the “quality assurance program approval
9 holder,” and

10 (3) A reference to “NRC or agreement state” means the “Agency or agreement state.”

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

14 (1) 10 CFR 71.0, "Purpose and scope;"

15 (2) 10 CFR 71.1, "Communications and records;" except that communications, notices, and reports
16 required by this Rule shall be sent to the addresses shown in Rule .0111 of this Chapter unless
17 directed otherwise by the agency, in lieu of the NRC;

18 (3) 10 CFR 71.3, "Requirement for license;"

19 (4) 10 CFR 71.4, "Definitions;"

20 (5) 10 CFR 71.5, "Transportation of licensed material;"

21 (6) 10 CFR 71.7(a), "Completeness and accuracy of information;"

22 (7) 10 CFR 71.8, "~~Deliberate misconduct;~~misconduct.” In 10 CFR 71.8(a)(3), the agency is the
23 “quality assurance program approval holder;”

24 (8) 10 CFR 71.12, "Specific exemptions;"

25 (9) 10 CFR 71.13, "Exemption of Physicians;"

26 (10) 10 CFR 71.14(a), "Exemption for low-level materials;"

27 (11) 10 CFR 71.15, "Exemption from classification as fissile material;"

28 (12) 10 CFR 71.17, "General license: NRC-approved package," except that 10 CFR 71.17(a) applies to
29 any licensee of the agency, and the quality assurance program approval required by 10 CFR 71.17(b)
30 shall be issued by the agency in lieu of the NRC. Notifications required by 10 CFR 71.17(c) shall
31 be made to the agency as required by Subparagraph (2) of this Paragraph and to the NRC in
32 accordance with 71.17(c)(3);

33 (13) 10 CFR 71.21, "General license: Use of foreign approved ~~package;~~package.” except that 10 CFR
34 71.21(a) applies to any licensee of the agency, and the quality assurance program approval required
35 by 10 CFR 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", 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) 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," and
- (8) 10 CFR 150.32, "Funds for reclamation or maintenance of byproduct material;"

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

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0313 Eff. February 1, 2015;
Readopted Eff. May 1, ~~2025~~2025;
Amended Eff. October 1, 2026.*

1 10A NCAC 15 .1203 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **10A NCAC 15 .1203 LICENSE REQUIRED: LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE**
4 **WASTE**

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

7 ~~(a)~~(b) This Rule establishes the procedures, standards, criteria, and terms and conditions upon which the Department
8 issues licenses authorizing land disposal of low-level radioactive waste received from other persons for disposal.

9 (1) No person may receive, possess, and dispose of low-level radioactive waste at a land disposal facility
10 located in North Carolina unless authorized by a license issued by the Department pursuant to this
11 Rule.

12 (2) No low-level radioactive waste shall be received from any source not licensed by the agency except
13 as may be specifically authorized in writing by the agency.

14 (3) The regulations in 10 CFR 61 which are hereby incorporated by reference, including subsequent
15 amendments and editions, except that 10 CFR 61.5, 61.8, 61.16, 61.23(i) and (j), 61.83, and 61.84
16 are not incorporated by reference. Copies of these regulations are available free of charge at
17 <https://www.nrc.gov/reading-rm/doc-collections/cfr/part061/>. Communications, records, reports,
18 and notifications required by 10 CFR 61.4 and 61.80 shall be submitted to the agency at the address
19 shown in Rule .0111 of this Chapter in lieu of the NRC.

20 (4) The requirements found in G.S. 104E-6.1, 104E-10.1(a), (a1), and (b), 104E-10.2, 104E-25(a), (c)
21 through (h), and (j) shall be met.

22 (5) In addition to the definitions found in 10 CFR 61.2, the definitions in G.S. 104E-5 shall apply.

23 (6) The agency may access and inspect any licensed low-level radioactive waste disposal facility on a
24 temporary or emergency basis to determine compliance with the rules in this Chapter or to respond
25 to any emergency which involves possible or actual release of radioactive material.

26 ~~(b)~~(c) This Rule establishes the procedures, criteria, and terms and conditions upon which the agency issues licenses
27 authorizing access to low-level radioactive waste land disposal facilities licensed under Paragraph ~~(a)~~(b) of this Rule.

28 (1) No person shall transport or transfer waste to a low-level radioactive waste land disposal facility
29 licensed under Paragraph ~~(a)~~(b) of this Rule unless licensed by the agency or otherwise specifically
30 authorized in writing by the agency.

31 (2) The definitions of terms in G.S. 104E-5 shall apply.

32 (3) Generators, waste brokers, and waste processors of low-level radioactive waste shall develop
33 procedures and implement practices to prevent, minimize, and reduce the generation of low-level
34 radioactive waste, including segregating radioactive waste by half-life and holding low-level
35 radioactive waste for decay in storage.

36 (4) Upon receipt of an application for a license authorizing access to low-level radioactive waste land
37 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) where radioactive material shall be used or possessed. The application shall indicate if radioactive materials shall be used at temporary jobsites;

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

(3) Application forms specified in this Rule shall be made available by the agency on the agency's public website.

~~(d)(c)~~ 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.

1 10A NCAC 15 .1301 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **SECTION .1300 - REQUIREMENTS FOR WIRELINE-SERVICE OPERATORS AND**
4 **SUBSURFACE-TRACER STUDIES**
5

6 Codifier's Note: 10 NCAC 03G .3400 was transferred to 15A NCAC 11 .1300 effective January 4, 1990.
7 Recodification pursuant to G.S. 143B-279.3.
8

9 **10A NCAC 15 .1301 WELL LOGGING, WIRELINE-SERVICE OPERATIONS, AND SUBSURFACE**
10 **TRACER STUDIES: REQUIREMENTS FOR LICENSEES**

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

13 ~~(a)~~(b) Persons using sources of radiation for well logging, wireline-service operations, mineral logging, radioactive
14 markers, or subsurface tracer studies shall comply with the provisions of 10 CFR Part 39, except that 10 CFR 39.5,
15 39.8, 39.101, and 39.103 shall not apply.

16 ~~(b) In addition to the terms defined in 10 CFR 39.2, the following definitions shall also apply to this Section:~~

17 ~~(1) "Mineral logging" means any logging performed for the purpose of mineral exploration other than~~
18 ~~oil or gas;~~

19 ~~(2) "Well bore" means a drilled hole in which wireline service operations and subsurface tracer studies~~
20 ~~are performed;~~

21 ~~(3) "Wireline" means a cable containing one or more electrical conductors that is used to lower and~~
22 ~~raise logging tools in the well bore; and~~

23 ~~(4) "Wireline service operations" means any evaluation or mechanical service that is performed in the~~
24 ~~well bore using devices on a wireline.~~

25 (c) Applications required by 10 CFR 39.11 shall be made on forms provided by the agency, and the payment of fees
26 required by 10 CFR Part 170 shall not apply. One copy of the application and supporting material shall be submitted
27 to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule ~~.0111.0111(a)~~ of this
28 Chapter in lieu of the NRC:

29 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
30 materials licenses, shall submit an Application for Radioactive Materials License. Items one through
31 five on the application form shall be completed by the applicant, using additional sheets as
32 necessary. The following information shall appear on the application:

33 (A) legal business name and mailing address;

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

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

- (D) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, the application may so state;
- (E) the application shall indicate if the application is for a new license or for the renewal of an existing license by marking the corresponding check box;
- (F) if the application is for the renewal of an existing license, the license number shall be provided on the application;
- (G) applicants shall indicate the type and category of license as shown on the form by marking the corresponding check box; and
- (H) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee, who is authorized by the licensee to sign license applications on behalf of the business or licensee.
- (2) Persons applying for an amendment to an existing license shall submit an Application for Amendment of Radioactive Materials and Accelerator Licenses. Items one through seven on the application form shall be completed by the applicant, using additional sheets as necessary. The following information shall appear on the application:
- (A) the license number;
- (B) amendment number of the current license;
- (C) expiration date of the license;
- (D) licensee name as it currently appears on the license;
- (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;
- (F) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, item 5b on the application may be left blank;
- (G) applicants shall provide a description of the action requested by marking the corresponding checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief description of the action requested in the space provided in item 6b;
- (H) explanation of the action requested; and
- (I) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee who is authorized by the licensee to sign license applications on behalf of the business or licensee.
- (3) Applications specified in this Rule are available free of charge at: [www.ncradiation.net/rms/rmsforms2.htm\(Rev01\).htm](http://www.ncradiation.net/rms/rmsforms2.htm(Rev01).htm).
- (d) Persons conducting subsurface tracer studies using unsealed sources of radiation shall obtain agency approval prior to injecting licensed material into the subsurface. Agency approval shall be obtained by submitting a license application to the agency in accordance with Paragraph (c) of this Rule.

1 (e) Notifications, authorization requests, and reports required by 10 CFR 39.77 shall be made to the agency at the
2 address shown in Rule .0111 of this Chapter in lieu of the NRC.

3 (f) Applications for exemptions to this Rule shall be submitted to the agency at the address shown in Rule
4 ~~.0111~~.0111(a) of this Chapter in lieu of the NRC.

5 (g) The regulations cited in this Rule from 10 CFR Part 39 are hereby incorporated by reference, including subsequent
6 amendments and editions. Copies of these regulations are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part039/)
7 [rm/doc-collections/cfr/part039/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part039/).

8
9 *History Note: Authority G.S. 104E-3; 104E-7;*

10 *Eff. June 1, 1989;*

11 *Amended Eff. January 1, 1994;*

12 *Transferred and Recodified from 15A NCAC 11 .1301 Eff. February 1, 2015;*

13 *Readopted Eff. October 1, ~~2022~~2022;*

14 *Amended Eff. October 1, 2026.*

1 10A NCAC 15 .1601 is amended as published in 40:19 NCR 1516-1541 as follows:

3 **SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION**

5 **10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION**

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

9 (1) Except in 20.1003, a reference to the "Nuclear Regulatory Commission," "NRC" or "Commission"
10 means the "Agency," and

11 (2) In 10 CFR 20.1003, in the definition of "Special Nuclear Material", the sentence "and any other
12 material which the Commission, pursuant to the provisions of section 51 of the Act, determines to
13 be special nuclear material", remains preserved as implemented by G.S. 104E-5.(16).

14 ~~(a)~~(b) Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, and persons licensed
15 pursuant to the rules in Section .0300, .0900, .1200, or .1300 of this Chapter, shall comply with the provisions of 10
16 CFR 20 as follows, which are hereby incorporated by reference including subsequent amendments and editions, except
17 references to and requirements for 10 CFR 50, 52, 60, 63, 72, 73, and 76 shall not apply:

18 (1) 20.1001, "Purpose," except that non-ionizing radiation from radiation machines registered in
19 accordance with the rules in Section .0200 of this Chapter shall also be regulated by this Rule;

20 (2) 20.1002, "Scope;"

21 (3) 20.1003, "Definitions," except that for persons registered with the agency pursuant to the rules in
22 Section .0200 of this Chapter, the following terms used in 10 CFR 20 shall have the following
23 substitutions:

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

26 (B) "licensed" shall have the same meaning as "registered" as defined in Rule .0103(b) of this
27 Chapter;

28 (C) "licensed material" shall have the same meaning as "radiation machine" as defined in Rule
29 .0103(b) of this Chapter, and

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

32 (4) 20.1004, "Units of radiation dose;"

33 (5) 20.1005, "Units of radioactivity;"

34 (6) 20.1007, "Communications," except that licensees and registrants shall address communications
35 regarding these rules, notifications, and reports to the agency as instructed by Rule .0111 of this
36 Chapter in lieu of the NRC;

37 (7) 20.1101, "Radiation protection programs;"

1 (8) 20.1201, "Occupational dose limits for adults;"

2 (9) 20.1202, "Compliance with requirements for summation of external and internal doses;"

3 (10) 20.1203, "Determination of external dose from airborne radioactive material;"

4 (11) 20.1204, "Determination of internal exposure;"

5 (12) 20.1206, "Planned special exposures;"

6 (13) 20.1207, "Occupational dose limits for minors;"

7 (14) 20.1208, "Dose equivalent to an embryo/fetus;"

8 (15) 20.1301, "Dose limits for individual members of the public;"

9 (16) 20.1302, "Compliance with dose limits for individual members of the public;"

10 (17) 20.1401, "General provisions and scope;"

11 (18) 20.1402, "Radiological criteria for unrestricted use;"

12 (19) 20.1403, "Criteria for license termination under restricted conditions;"

13 (20) 20.1404, "Alternate criteria for license termination;"

14 (21) 20.1405, "Public notification and public participation," except the agency shall not publish a notice

15 in the Federal Register;

16 (22) 20.1406, "Minimization of contamination," except that 20.1406(b) shall not apply;

17 (23) 20.1501, "General;"

18 (24) 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose;"

19 (25) 20.1601, "Control of access to high radiation areas;"

20 (26) 20.1602, "Control of access to very high radiation areas;"

21 (27) 20.1701, "Use of process or other engineering controls;"

22 (28) 20.1702, "Use of other controls;"

23 (29) 20.1703, "Use of individual respiratory protection equipment;"

24 (30) 20.1704, "Further restrictions on the use of respiratory equipment;"

25 (31) 20.1705, "Application for use of higher assigned protection factors;"

26 (32) 20.1801, "Security of stored material;"

27 (33) 20.1802, "Control of material not in storage;"

28 (34) 20.1901, "Caution signs;"

29 (35) 20.1902, "Posting requirements;"

30 (36) 20.1903, "Exceptions to posting requirements;"

31 (37) 20.1904, "Labeling containers;"

32 (38) 20.1905, "Exemptions to labeling requirements," except that 20.1905(g) shall not apply;

33 (39) 20.1906, "Procedures for receiving and opening packages;"

34 (40) 20.2001, "General requirements;"

35 (41) 20.2002, "Method for obtaining approval of proposed disposal procedures;"

36 (42) 20.2003, "Disposal by release to sanitary sewerage;"

37 (43) 20.2004, "Treatment or disposal by incineration;"

- (44) 20.2005, "Disposal of specific wastes;"
- (45) 20.2006, "Transfer for disposal and manifests;"
- (46) 20.2007, "Compliance with environmental and health protection regulations;"
- (47) 20.2008, "Disposal of certain byproduct material;"
- (48) 20.2101, "General provisions;"
- (49) 20.2102, "Records of radiation protection programs;"
- (50) 20.2103, "Records of surveys;"
- (51) 20.2104, "Determination of prior occupational dose;"
- (52) 20.2105, "Records of planned special exposures;"
- (53) 20.2106, "Records of individual monitoring results;"
- (54) 20.2107, "Records of dose to individual members of the public;"
- (55) 20.2108, "Records of waste disposal;"
- (56) 20.2110, "Form of records;"
- (57) 20.2201, "Reports of theft or loss of material." Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter shall make telephone reports of the theft or loss of radiation machines in accordance with 20.2201(a)(1)(i);
- (58) 20.2202, "Notifications of incidents;"
- (59) 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits," except that 20.2203(c) shall not apply;
- (60) 20.2204, "Reports of planned special exposures;"
- (61) 20.2205, "Reports to individuals exceeding dose limits;"
- (62) 20.2206, "Reports of individual monitoring," except that 20.2206(a)(1), and 20.2206(a)(3) through (a)(5) shall not apply. The report required by 20.2206(b) shall be submitted upon request by the agency in lieu of the requirements of 20.2206(c);
- (63) 20.2207, "Reports of transactions involving nationally tracked sources." Notwithstanding Subparagraph (a)(6) of this Rule, reports required by this Subparagraph shall be made in accordance with 20.2207(f) and (g);
- (64) 20.2301, "Application for exemptions," except that the request for exemption shall be made on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter, in lieu of the NRC, or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:
- (A) licensee or registrant name;
 - (B) license or registration number;
 - (C) name and contact information for the individual requesting the exemption;
 - (D) a description of the exemption being requested, and
 - (E) an explanation describing why the exemption is necessary;

- 1 (65) 20.2302, "Additional requirements;"
- 2 (66) Appendix A to Part 20, "Assigned Protection Factors for Respirators;"
- 3 (67) Appendix B to Part 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs)
- 4 of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release
- 5 to Sewerage;"
- 6 (68) Appendix C to Part 20, "Quantities of Radioactive Material Requiring Labeling;"
- 7 (69) Appendix E to Part 20, "Nationally Tracked Source Thresholds," and
- 8 (70) Appendix G to Part 20, "Requirements for Transfers of Low-Level Radioactive Waste Intended for
- 9 Disposal at Licensed Land Disposal Facilities and Manifests."
- 10 ~~(b)(c)~~ Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is
- 11 prohibited.
- 12 ~~(e)(d)~~ Licensees and registrants shall continue to perform all activities required by the rules of this Chapter, license
- 13 or registration condition, and shall pay annual fees as instructed on an invoice issued by the agency until the license
- 14 or registration is terminated. Registrants shall maintain registration of all radiation machines under their control until
- 15 those units are disposed.
- 16 ~~(d)(e)~~ Nothing in the rules of this Chapter shall relieve any person of responsibility for complying with other
- 17 applicable North Carolina laws and rules.
- 18 ~~(e)(f)~~ Copies of these regulations are available free of charge at [https://www.nrc.gov/reading-rm/doc-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/)
- 19 [collections/cfr/part020/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/).
- 20
- 21 *History Note: Authority G.S. 104E-7(a)(2);*
- 22 *Eff. January 1, 1994;*
- 23 *Amended Eff. August 1, 1998;*
- 24 *Transferred and Recodified from 15A NCAC 11 .1601 Eff. February 1, 2015;*
- 25 *Readopted Eff. October 1, 2023;*
- 26 *Amended Eff. October 1, 2026; May 1, 2025.*

1 10A NCAC 15 .1701 is amended as published in 40:19 NCR 1516-1541 as follows:

2
3 **SECTION .1700 – PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF**
4 **RADIOACTIVE MATERIAL**

5
6 **10A NCAC 15 .1701 ADDITIONAL REQUIREMENTS FOR LICENSEES POSSESSING CATEGORY**
7 **1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL**

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

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

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

12 ~~(a)~~(b) Licensees possessing an aggregate category 1 or category 2 quantity of radioactive material, as defined in 10
13 CFR 37.5, shall comply with the requirements for the physical protection program listed in 10 CFR Part 37, which is
14 hereby incorporated by reference, including any subsequent amendments and editions, except the following
15 regulations are not incorporated:

16 (1) 10 CFR 37.1;

17 (2) 10 CFR 37.3;

18 (3) 10 CFR 37.7;

19 (4) 10 CFR 37.9;

20 (5) 10 CFR 37.11(a) and (b);

21 (6) 10 CFR 37.13;

22 (7) 10 CFR 37.105;

23 (8) 10 CFR 37.107; and

24 (9) 10 CFR 37.109.

25 ~~(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)
26 through (d), and 37.81 shall use the Agency contact information in Rule .0111 of this Chapter.

27 ~~(c)~~(d) The Code of Federal Regulations incorporated by this Rule are available free of charge at
28 <https://www.ecfr.gov/current/title-10/chapter-I/part-37>.

29
30 *History Note: Authority G.S. 104E-7;*

31 *Eff. June 1, 2016;*

32 *Amended Eff. October 1, 2026; May 1, 2023.*