

10A NCAC 15 .0201 is amended as published in 39:22 NCR 1469-1480 as follows:

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

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

10A NCAC 15 .0201 PURPOSE AND SCOPE

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

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

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

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

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

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

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

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

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

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

1 *Transferred and Recodified from 15A NCAC 11 .0201 Eff. February 1, 2015;*
2 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,*
3 *~~2019.~~ 2019.*
4 *Amended Eff. October 1, 2025.*

1 10A NCAC 15 .0202 is readopted as published in 39:22 NCR 1469-1480 as follows:

2
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 provided that the dose equivalent rate average over an area
6 of ~~ten~~ 10 square centimeters does not exceed 0.5 mrem per hour at ~~five~~ 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) Radiation machines while in transit or storage incident thereto are exempt from the requirements of this Section.~~

10 The following are exempt from the requirements of this Section:

11 (1) all radioactive materials; and

12 (2) radiation machines while in transit.

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

14
15 *History Note: Authority G.S. 104E-7;*

16 *Eff. February 1, 1980;*

17 *Transferred and Recodified from 15A NCAC 11 .0202 Eff. February 1, ~~2015~~ 2015;*

18 *Readopted Eff. October 1, 2025.*

10A NCAC 15 .0203 is readopted as published in 39:22 NCR 1469-1480 as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 (2) The application form requires the following:

8 (A) indication if the application is for a new facility, a change of ownership, relocation of a
9 facility, or to update information by marking the corresponding checkbox;

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

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

13 (D) the name of the individual on-site who is responsible for radiation protection. The training
14 and experience qualifying him or her to perform the job duties and responsibilities in Rule
15 .0211 of this Section, shall be documented on the application;

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

17 (F) description of facility use;

18 (G) description of service provider equipment;

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

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

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

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

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

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

31 (2) The application requires the following information:

32 (A) registration number;

33 (B) machine or device location;

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

36 (D) location of machine or device not in use;

37 (E) installer information; and

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

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

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

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

- (1) The application shall be submitted by any person engaged in:
 - (A) direct sales, demonstration, leasing, or transfer of radiation machines or radiation generating devices;
 - (B) providing individual monitoring devices; and
 - (C) radiation survey equipment calibrations, except when calibrations are performed by the manufacturer of the equipment.
- (2) The application requires the following information:
 - (A) registration number;
 - (B) business name, facility physical address;
 - (C) identify if the application is for a new service provider, for a change of ownership, relocation of the facility, or to update information;
 - (D) identify each class and modality of services requested to be provided in the State;
 - (E) submit the requirements listed on the agency form for each class and modality requesting to provide services in the State;
 - (F) list any class or modality not listed on this form;
 - (G) description of service provider equipment used for output measurements and surveys; and
 - (H) signature of the individual with administrative control.

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

- (1) The application shall be submitted by any person engaged in providing the following services:
 - (A) area radiation surveys for diagnostic radiographic and fluoroscopy facilities;

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

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

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

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

(F) radiation protection expert;

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

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

(2) The application requires the following information:

(A) name of the employee to be registered;

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

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

(D) class identification and modality of services to be provided;

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

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

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

(H) additional information the agency determines is necessary for evaluating the application for registration.

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

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

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

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

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

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

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

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

(B) submit to the agency, a Disposal of a Radiation Machine or Radiation Generating Device Form in accordance with Paragraph(e) of this Rule; and

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

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

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

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

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

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

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

10A NCAC 15 .0204 is readopted as published in 39:22 NCR 1469-1480 as follows:

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

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

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

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

(b) Shielding design requirements:

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

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

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

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

(C) proposed date of installation.

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

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

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

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

(A) dental handheld;

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

2 (C) mammography; or

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

5 (c) Facility registration

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

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

9 (B) have a Radiation Machine Application or a Radiation Generating Devices Application form
10 submitted in accordance with Rule .0203(d) of this Section. Radiation machines leased or
11 on loan from a registered service provider shall register the radiation machine if used for
12 more than 30 days;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16
17 *History Note: Authority G.S. 104E-7; 104E-9(a)(3); 104E-12;*

18 *Eff. February 1, 1980;*

19 *Amended Eff. June 1, 1989;*

20 *Transferred and Recodified from 15A NCAC 11 .0204 Eff. February 1, ~~2015~~. 2015;*

21 *Readopted Eff. October 1, 2025.*

10A NCAC 15 .0205 is readopted as published in 39:22 NCR 1469-1480 as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) ~~radiation instrument calibration;~~

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

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

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

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

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

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

- (1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of radiation machines or radiation generating devices;
- (2) Class II - ~~installation or service repair~~ installation, repair, or service ~~to include~~ of the following:
 - (A) radiation machines and machine components, including the making of diagnostic radiation output ~~measurements~~; measurements, and performance verification; or
 - (B) radiation generating devices to include equipment surveys.
- (3) Class III - shielding designs for diagnostic radiographic facilities;
- (4) Class IV - shielding designs for diagnostic fluoroscopy facilities;
- (5) Class V - area radiation surveys and shielding evaluations for diagnostic radiographic and fluoroscopy facilities;
- ~~(5) manufacturer training for the use of radiation machines or radiation generating devices;~~
- (6) Class VI - radiation survey equipment calibrations;
- ~~(7) Class VII - therapeutic facility and shielding design, area radiation survey, or calibration.~~
- verification;
- (8) Class VIII - providing individual monitoring devices;
- (9) Class IX - general health and medical physics consulting to include the following services:
 - (A) equipment surveys and shielding designs for radiation generating devices;
 - (B) dose estimates;
 - (C) radiation output measurements;
 - (D) radiation safety program development; and
 - (E) radiation safety program training.

(f) Persons registered pursuant to Subparagraph (e)(1) as a Class I service provider to provide mobile radiation machines that are fixed in a vehicle or trailer for demonstration purposes or that provides leasing services shall meet the following requirements prior to use:

- (A) mobile radiation machines located and used in this State shall meet the requirements of Rules .0204(c)(1)(A) through (E) of this Section; and
- (B) mobile radiation machines located out of state and brought into this State for use shall meet the requirements of Rules .0204(c)(2)(A) and (B) of this Section.

(g) Report of installation

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

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

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

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

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

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

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

(B) for radiation machines for nonhuman use and radiation generating devices, when a Report of Sale and Installation Form prepared in accordance with Paragraph (i) of this Rule is received by the agency.

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

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

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

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

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

(5) room location;

(6) date of sale or installation;

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

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

(9) the date signed.

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

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

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

1 (1) fluoroscopy machine output measurement; and

2 (2) radiation generating devices equipment surveys.

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

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

7 (2) be provided to the registrant for agency review during inspection.

8
9 *History Note: Authority G.S. 104E-7; 104E-12; 104E-20;*

10 *Eff. February 1, 1980;*

11 *Amended Eff. June 1, 1993; May 1, 1992; June 1, 1989;*

12 *Transferred and Recodified from 15A NCAC 11 .0205 Eff. February 1, ~~2015~~; 2015;*

13 *Readopted Eff. October 1, 2025.*

10A NCAC 15 .0206 is readopted as published in 39:22 NCR 1469-1480 as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) training in basic principles of radiation protection;

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

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

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

(A) training in basic principles of radiation protection;

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

- 1 (C) one year of experience in diagnostic fluoroscopic facility and shielding for the specific
2 each type of machine application.
- 3 (5) Class V - area radiation surveys and shielding evaluation for diagnostic radiographic and
4 fluoroscopy facilities:
- 5 (A) training in basic principles of radiation protection;
- 6 (B) training in shielding evaluation for each modality registering to provide services; and
- 7 (C) one year of experience performing area radiation surveys for the specific each type of
8 machine application.
- 9 (6) Class VI - radiation instrument calibration: The applicant must possess a current radioactive
10 materials license or registration authorizing radiation instrument calibration.
- 11 (7) Class VII - therapeutic facility and shielding design, area radiation survey, or verification:
- 12 (A) certification by the American Board of Radiology in therapeutic radiological physics,
13 radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics;
- 14 (B) certification by the American Board of Medical Physics;
- 15 (C) doctorate degree in medical physics or related field; or
- 16 (D) have a master's degree in physics, biophysics, radiological physics, nuclear engineering, or
17 health physics, one year of full-time training in therapeutic radiological physics, one year
18 of full-time experience in a therapeutic facility including personal calibration and
19 spot-check of at least one machine, submit a description of the procedures that will be
20 utilized in performing therapeutic calibrations including a list of all guides and references
21 to be employed, submit a copy of all forms, reports, and documents that will be supplied
22 to customers; and submit one sample of each type of therapy modality service provided.
- 23 (8) Class VIII - providing individual monitoring dosimetry: The applicant must hold current personnel
24 dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP)
25 of the National Institute of Standards and Technology or use NVLAP-accredited dosimetry.
- 26 (9) Class IX - general health or medical physics consulting shall be performed by a person meeting one
27 of the following requirements:
- 28 (A) certified by the American Board of Health Physics in health physics in the appropriate field
29 or specialties for services provided;
- 30 (B) certified by the American Board of Medical Physics;
- 31 (C) certified by the American Board of Radiology in therapeutic radiological physics,
32 radiological physics, roentgen-ray and gamma ray physics, x-ray and radium physics; or
- 33 (D) hold a master's or doctorate in physics, medical physics, other physical science,
34 engineering, or applied mathematics, from an accredited college or university, and have 40
35 hours of practical training or supervised experience in x-ray physics.
- 36

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

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

8
9 *History Note: Authority G.S. 104E-7; ~~104E-12~~; 104E-13;*

10 *Eff. February 1, 1980;*

11 *Transferred and Recodified from 15A NCAC 11 .0206 Eff. February 1, ~~2015~~; 2015;*

12 *Readopted Eff. October 1, 2025.*

10A NCAC 15 .0207 is readopted as published in 39:22 NCR 1469-1480 as follows:

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

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

- ~~(1) — is qualified by reason of education, training or experience in the use and hazards of radiation sources described in the application for registration;~~
- ~~(2) — has facilities and equipment which meet the requirements in these Rules;~~
- ~~(3) — has established a radiation protection program, appropriate to the registered activities, which assures compliance with radiation protection requirements in these Rules; and~~
- ~~(4) — meets the applicable requirements in this Chapter.~~

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

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

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

- (1) have radiation survey and radiation measurement equipment capable of measuring the radiation energies corresponding to the services requested for authorization;
- (2) ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated annually when a frequency is not recommended by the manufacturer;
- (3) submit the following for agency review prior to registration:
 - (1) a description of the procedures that will be used in performing area radiation surveys including a list of all guides and references to the employed;
 - (2) a copy of all forms, reports, and documents that will be supplied to registrants;
 - (3) samples of surveys for each modality requested for registration;
 - (4) samples of reports of diagnostic radiation output measurements for each modality requested for registration; and
 - (5) samples of calibration reports for each therapeutic and kV imaging modality requested for registration.

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

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

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

- 11 (1) submit examples of the facility and shielding design which will be provided to registrants;
- 12 (2) submit any technical guides, methodology, occupancy factor rationales, and workload estimation
13 rationales that will be used; and
- 14 (3) ensure that the facility and shielding design services provided to registrants meet the requirements
15 in this Chapter.

16
17 *History Note: Authority G.S. 104E-7;*

18 *Eff. February 1, 1980;*

19 *Amended Eff. June 1, 1993; June 1, 1989;*

20 *Transferred and Recodified from 15A NCAC 11 .0207 Eff. February 1, 2015.*

21 *Readopted Eff. October 1, 2025.*

10A NCAC 15 .0208 is amended as published in 39:22 NCR 1469-1480 as follows:

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

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

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

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

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

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

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

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

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

(3) comply with the Rules of this Chapter.

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

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

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

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

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

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

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

Eff. February 1, 1980;

Transferred and Recodified from 15A NCAC 11 .0208 Eff. February 1, 2015;

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

1

Amended Eff. October 1, 2025.

1 10A NCAC 15 .0209 is readopted as published in 39:22 NCR 1469-1480 as follows:

2
3 **10A NCAC 15 .0209 ~~REPORT OF CHANGES~~ ISSUANCE OF NOTICE OF REGISTRATION**

4
5 ~~Any registrant shall notify the agency in writing when any change will render the information contained in the~~
6 ~~application for registration or notice of registration no longer accurate.~~

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

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

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

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

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

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

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

22
23 *History Note: Authority G.S. 104E-7; ~~104E-12~~;*

24 *Eff. February 1, 1980;*

25 *Transferred and Recodified from 15A NCAC 11 .0209 Eff. February 1, ~~2015~~. 2015;*

26 *Readopted Eff. October 1, 2025.*

10A NCAC 15 .0210 is readopted as published in 39:22 NCR 1469-1480 as follows:

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

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

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

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

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

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

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

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

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

(2) because of a decision made by the agency to refuse to grant registration on the original application revealed by:

(A) the application;

(B) any statement of fact;

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

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

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

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

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

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

History Note: Authority G.S. 104E-7; ~~104E-20~~; 104E-13;

1 *Eff. February 1, 1980;*
2 *Amended Eff. May 1, 1993; June 1, 1989;*
3 *Transferred and Recodified from 15A NCAC 11 .0210 Eff. February 1, ~~2015~~. 2015;*
4 *Readopted Eff. October 1, 2025.*

10A NCAC 15 .0211 is amended as published in 39:22 NCR 1469-1480 as follows:

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

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

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

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

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

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

(1) training in basic radiation protection principles;

(2) completed educational courses relating to ionizing radiation;

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

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

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

(1) Establishing and overseeing operating and safety procedures:

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

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

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

(A) reviewed;

(B) maintained; and

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

(3) Ensuring that personnel are complying with:

(A) this Chapter;

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

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

(4) Knowing:

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

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

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

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

7 *Eff. February 1, 1980;*

8 *Amended Eff. June 1, 1989;*

9 *Transferred and Recodified from 15A NCAC 11 .0211 Eff. February 1, 2015;*

10 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,*
11 ~~*2019; 2019;*~~

12 *Amended Eff. October 1, 2025.*

10A NCAC 15 .0212 is amended as published in 39:22 NCR 1469-1480 as follows:

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

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

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

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

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

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

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

~~(A) the application;~~

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

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

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

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

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

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

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

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

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

(1) an application form in accordance with Rule .0203(d) of this Section;

(2) the manufacturer manual;

(3) description of intended use;

1 (4) operator training provided to the end user;

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

3 (A) all equipment settings available to the operator;

4 (B) output at the highest setting; and

5 (C) leakage radiation around the radiation machine.

6 (6) an area survey to include the following:

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

8 (B) the survey instrument used; and

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

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

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

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

15
16 *History Note: Authority G.S. 104E-7; ~~104E-13~~; 104E-20;*

17 *Eff. June 1, 1989;*

18 *Amended Eff. June 1, 1993;*

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

20 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,*

21 *~~2019~~. 2019;*

22 *Amended Eff. October 1, 2025.*

1 10A NCAC 15 .0213 is repealed through readoption as published in 39:22 NCR 1469-1480 as follows:

2

3 **10A NCAC 15 .0213 ADDITIONAL REQUIREMENTS: REGISTERED SERVICES**

4

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

6 *Eff. June 1, 1989;*

7 *Amended Eff. June 1, 1993;*

8 *Transferred and Recodified from 15A NCAC 11 .0213 Eff. February 1, 2015.*

1 10A NCAC 15 .0501 is amended as published in 39:19 NCR 1225-1262 as follows:

2
3 **SECTION .0500 - INDUSTRIAL RADIOGRAPHY X-RAY MACHINES**
4

5 Codifier's Note: 10 NCAC 03G .2600 was transferred to 15A NCAC 11 .0500 effective January 4, 1990.
6 Recodification pursuant to G.S. 143B-279.3.
7

8 **10A NCAC 15 .0501 INDUSTRIAL RADIOGRAPHIC OPERATIONS OF ELECTRONIC RADIATION**
9 **MACHINES FOR NON-HUMAN USE**

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

13 (1) 10 CFR 34.1, "Purpose and Scope;"

14 (2) 10 CFR 34.3, "Definitions;" except that the definition of becquerel, control (drive) cable, control
15 drive mechanism, control tube, exposure head, field station, guide tube (projection sheath), S-tube,
16 source assembly, source changer, and storage container, shall not apply. Prior to using industrial
17 radiography all persons shall be registered in accordance with rules in Section .0200 of this Chapter.
18 The following terms apply:

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

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

22 (C) "licensed" shall have the same meaning as "registered" pursuant to the rules in Section
23 .0200 of this Chapter;

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

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

27 (F) "radiographic exposure device" shall have the same meaning as "radiation machine" in G.S.
28 104E-5(13); and

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

30 (3) 10 CFR 34.25, "Radiation survey instruments." The term "radioactive material" used in 10 CFR
31 34.25 shall have the same meaning as "radiation machine" in G.S. 104E-5(13);

32 (4) 10 CFR 34.31(a), (b)(1), and (c), "Inspection and maintenance of radiographic exposure devices,
33 transport and storage containers, associated equipment, source changers, and survey instruments;"

34 (5) 10 CFR 34.33, "Permanent radiographic installations." The term "radioactive source" used in 10
35 CFR 34.33 shall have the same meaning as "radiation machine" in G.S. 104E-5(13);

36 (6) 10 CFR 34.35(c), "Labeling, storage, and transportation;"

37 (7) 10 CFR 34.41, "Conducting industrial radiographic operations;"

- (8) 10 CFR 34.42, "Radiation Safety Officer for industrial radiograph;"
- (9) 10 CFR 34.43, "Training;"
- (10) 10 CFR 34.45(a)(1) through (a)(3), (a)(5), (a)(7) through (a)(11), (a)(13), and (b), "Operating and emergency procedure;"
- (11) 10 CFR 34.46, "Supervision of radiographers' assistants;"
- (12) 10 CFR 34.47, "Personnel monitoring;"
- (13) 10 CFR 34.49, "Radiation surveys;"
- (14) 10 CFR 34.51, "Surveillance;"
- (15) 10 CFR 34.53, "Posting;"
- (16) 10 CFR 34.61, "Records of the specific license for industrial radiography;"
- (17) 10 CFR 34.65, "Records of radiation survey instrument;"
- (18) 10 CFR 34.71, "Utilization logs;"
- (19) 10 CFR 34.73, "Records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments;"
- (20) 10 CFR 34.75, "Record of alarm system and entrance control checks at permanent radiographic installations;"
- (21) 10 CFR 34.79, "Records of training and certification;"
- (22) 10 CFR 34.81, "Copies of operating and emergency procedures;"
- (23) 10 CFR 34.83, "Records of personnel monitoring procedures;"
- (24) 10 CFR 34.85, "Records of radiation surveys;"
- (25) 10 CFR 34.87, "Form of records;"
- (26) 10 CFR 34.89(a), (b)(1 through 10), "Location of documents and records;" and
- (27) Appendix A to 10 CFR 34-Radiographer Certification.
- (b) Copies of these regulations are available free of charge at <https://www.nrc.gov/reading-rm/doc-collections/cfr/part034/index.html>.

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

Eff. February 1, 1980;

Amended Eff. May 1, 1993;

Transferred and Recodified from 15A NCAC 11 .0501 Eff. February 1, 2015;

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

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

1 10A NCAC 15 .0608 is repealed through readoption as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0608 THERAPEUTIC X-RAY INSTALLATIONS: LESS THAN ONE MEV**

4
5 *History Note: Authority G.S. 104E-7; 104E-12(a);*

6 *Eff. February 1, 1980;*

7 *Amended Eff. January 1, 1994; May 1, 1992; November 1, 1989;*

8 *Transferred and Recodified from 15A NCAC 11 .0608 and .0609 Eff. February 1, ~~2015~~ 2015;*

9 *Repealed Eff. October 1, 2025.*

1 10A NCAC 15 .0609 is repealed through readoption as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0609 X-RAY AND ELECTRON THERAPY INSTALLATIONS ONE MEV AND**
4 **ABOVE**

5
6 *History Note: Authority G.S. 104E-7; 104E-12(a);*

7 *Eff. February 1, 1980;*

8 *Amended Eff. January 1, 1994; May 1, 1992; November 1, 1989;*

9 *Transferred and Recodified from 15A NCAC 11 .0608 and .0609 Eff. February 1, ~~2015~~ 2015;*

10 *Repealed Eff. October 1, 2025.*

1 10A NCAC 15 .0802 is amended as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0802 DEFINITIONS**

4 In addition to terms found in Rule ~~104.0103~~ of this Chapter, the following definitions shall apply to this Section:

- 5 (1) "Accredited bomb squad" means a law enforcement agency utilizing certified bomb technicians.
- 6 (2) "Accessible surface" means the external or outside surface of the enclosure or housing provided by
7 the manufacturer or designer of the RGD. This includes the high-voltage generator, doors, access
8 panels, latches, control knobs, and other permanently mounted hardware, and including the plane
9 across the exterior edge of any opening.
- 10 (3) "Analytical RGD equipment" means equipment that uses electronic means to generate ionizing
11 radiation for the purpose of examining the microstructure of materials using direct x-ray
12 transmission, x-ray diffraction, x-ray fluorescence, and x-ray spectroscopy.
- 13 (4) "Analytical RGD system" means a group of local and remote components utilizing x-rays to
14 determine the elemental composition or to examine the microstructure of materials.
- 15 (5) "Certified bomb technician" means a member of an accredited bomb squad who has successfully
16 completed the FBI Hazardous Devices School. Information pertaining to this program can be found
17 at <http://www.fbi.gov/about-us/cirg/hazardous-devices>.
- 18 (6) "Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to
19 meet the certification requirements specified in 21 C.F.R. 1020.40, as incorporated by reference in
20 Rule ~~117.0104~~ of this Chapter.
- 21 (7) "Certified cabinet x-ray system" means an RGD utilized in an enclosed, interlocked cabinet, such
22 that the radiation machine will not operate unless all openings are securely closed. These systems
23 shall be certified in accordance with 21 CFR 1010.2, as incorporated by reference in Rule
24 ~~117.0104~~ of this Chapter, as being manufactured and assembled pursuant to the provisions of 21
25 C.F.R. 1020.40, as incorporated by reference in Rule ~~117.0104~~ of this Chapter.
- 26 (8) "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.
- 27 (9) "Control panel" means the part of the x-ray control where the switches, knobs, pushbuttons, and
28 other hardware are, located for manually setting the technique factors.
- 29 (10) "Electron Beam Device" means any device using electrons below 1MeV to heat, join, or otherwise
30 irradiate materials.
- 31 (11) "Enclosed beam RGD" means an RGD with all possible x-ray beam paths contained in a chamber,
32 coupled chambers, or other beam-path-confinement devices, to prevent any part of the body from
33 intercepting the beam during normal operations. Normal access to the primary beam path, such as a
34 sample chamber door, shall be interlocked with the high voltage of the x-ray tube or the shutter for
35 the beam to be considered "enclosed." An open-beam device placed in an interlocked enclosure is
36 considered an "enclosed beam" unless there are provisions for routine bypassing of the interlocks.

- (12) "Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected radiation exposure of an individual exceeding administrative or regulatory limits found in Rule 10A NCAC 15 .1601(a)(8) and .1601(a)(15). This procedure shall include the names and telephone numbers of individuals to be contacted, as well as directives for processing individual monitoring devices.
- (13) "Fail-safe characteristics" means a design feature that causes the radiation beam to terminate, port shutters to close, or otherwise prevents emergence of the primary beam upon the failure of a safety or warning device. For example, if an "X-ray On" light indicator, shutter indicator, or interlock fails, the radiation beam shall terminate.
- (14) "Gauging device" means a mechanism containing a source of ionizing radiation that is designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative composition of materials. It may include components such as radiation shields, useful-beam controls, and other safety features in order to meet the requirements or specifications of the device.
- (15) "General-use system" means a security screening system that delivers an effective dose of 25 microrem (0.25 microSv) or less per screening.
- (16) "Hand-held x-ray system" means any device or equipment that is portable and used for similar purposes as analytical RGD equipment.
- (17) "Individual responsible for radiation protection" means a person who has the knowledge and responsibility to apply appropriate radiation rules, for persons registered with the agency in accordance with Section .0200 of this Chapter, commensurate with the scope of the activities authorized by the registrant.
- (18) "Inspection Zone" means the area established for the purpose of controlling access where screening is performed. Areas controlled due to the presence of radiation shall include areas of ingress, egress, gates, portals, and traffic paths. The area outside of the inspection zone shall not exceed the limits of Rule .1601(a)(13) of this Chapter.
- (19) "Interlock" means a feature designed to prevent access to an area of radiation hazard by preventing entry or by automatically removing the hazard.
- (20) "Ion implantation equipment, low-energy" means any enclosed device operating below 1MeV used to accelerate elemental ions and implant them in other materials.
- (21) "Leakage radiation" means radiation emanating from the source assembly housing except for:
- (A) the primary beam;
 - (B) scatter radiation emanating from other components; and
 - (C) radiation produced when the "beam on" switch or timer is not activated.
- (22) "Limited-use system" means a screening system that is capable of delivering an effective dose greater than 25 microrem (0.25 microSv) per screening, but shall not exceed an effective dose of 1 mrem (10 microSv) per screening,

- (23) "Local components" means part of an RGD x-ray system and include areas that are struck by x rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.
- (24) "Mobile RGD" means RGD equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
- (25) "Normal operating procedures" means step-by-step instructions necessary to accomplish a task. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures that are related to radiation safety.
- (26) "Open-beam RGD" means a device or system designed in such a way that the primary beam is not completely enclosed during normal operation, when used for analysis, gauging, or imaging, an individual could accidentally place some part of their body in the primary beam or stray radiation path during normal operation.
- (27) "Portable RGD" means RGD equipment designed to be carried by hand.
- (28) "Primary beam" means radiation that passes through an aperture of the source assembly housing by a direct path from the radiation source.
- (29) "Radiation generating device (RGD)" means any system, device, subsystem, or machine component that may generate, by electronic means, x-rays or particle radiation above 5 keV, but below 1 MeV, and not used for healing parts on humans or animals. RGDs may be used as a:
- (A) mobile RGD;
 - (B) portable RGD; or
 - (C) stationary RGD.
- (30) "Remote components" means parts of an RGD x-ray system that are not struck by x-rays, such as power supplies, transformers, amplifiers, readout devices, and control panels.
- (31) "Safety Device" means a device, interlock or system that prevents the entry of any portion of an individual's body into the primary x-ray beam or that will cause the beam to shut off upon entry into its path.
- (32) "Scattered radiation" means radiation, other than leakage radiation, that during passage through matter, has been deviated in direction or has been modified by a decrease in energy.
- (33) "Screening" means the sum of scans necessary for a security screening system to image concealed objects as intended by the system design under normal operating conditions.
- (34) "Security screening device" means a non-human use open-beam device designed for the detection of contraband or weapons concealed in baggage, mail, packages, or other structures. These devices include bomb detection devices used for the sole purpose of detecting explosive devices.
- (35) "Security screening system" means a system specifically designed to detect contraband and weapons concealed on a person and is used for the sole purpose of public safety and security evaluation by law enforcement.

- 1 (36) "Shutter" means an adjustable device, generally made of lead or other high atomic number material,
2 fixed to a source assembly housing to intercept, block, or collimate the primary beam.
- 3 (37) "Source" means the point of origin of the radiation, such as the focal spot of an x-ray tube.
- 4 (38) "Stationary RGD" means RGD equipment that is installed or placed in a fixed location.
- 5 (39) "Stray radiation" means the sum of leakage and scatter radiation emanating from the source
6 assembly or other components, except for the primary beam, and radiation produced when the beam
7 on switch or timer is not activated.
- 8 (40) "Warning device" means an audible or visible signal that warns individuals of a potential radiation
9 hazard.
- 10 (41) "X-ray generator" means the part of an x-ray system that provides the accelerating (high) voltage
11 and current for the x-ray tube.
- 12 (42) "X-ray source housing" means the portion of an RGD system which contains the x-ray tube and
13 emitting target. The housing often contains radiation shielding material or inherently provides
14 shielding.

15
16 *History Note:* *Authority G.S. 104E-7;*
17 *Eff. February 1, 1980;*
18 *Transferred and Recodified from 15A NCAC 11 .0802 Eff. February 1, 2015;*
19 *Amended Eff. October 1, 2015;*
20 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,*
21 *2019;*
22 *Amended Eff. October 1, 2025; November 1, 2024.*
23
24

10A NCAC 25 .0803 is amended as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .0803 PERSONNEL REQUIREMENTS

(a) The registrant, as defined in 10A NCAC 15 ~~.0104(130)~~.0103, shall document the scope of training and instruction required for the RGD in use.

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

(1) Basic principles of radiation protection:

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

(2) Device specific training for each RGD:

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

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

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

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

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

- (1) operating open-beam RGDs; and
- (2) performing maintenance on an RDG, if the maintenance procedures require the presence of a primary x-ray beam when any local component in the RGD is disassembled or removed.

1 *History Note:* *Authority G.S. 104E-7;*
2 *Eff. February 1, 1980;*
3 *Transferred and Recodified from 15A NCAC 11 .0803 Eff. February 1, 2015;*
4 *Amended Eff. October 1, 2015;*
5 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,*
6 *2019;*
7 *Amended Eff. October 1, 2025; November 1, 2024.*

1 10A NCAC 15 .0901 is readopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **SECTION .0900 - REQUIREMENTS FOR PARTICLE ACCELERATORS**
4

5 Codifier's Note: 10 NCAC 03G .3000 was transferred to 15A NCAC 11 .0900 effective January 4, 1990.
6 Recodification pursuant to G.S. 143B-279.3.
7

8 **10A NCAC 15 .0901 PURPOSE AND SCOPE**

9 (a) This Section establishes procedures for the licensing and the use of particle accelerators.

10 (b) In addition to the requirements of this Section, all licensees are subject to the requirements of Sections .0100,
11 .0200, .1000, and .1600 of this Chapter. ~~Chapter, and: Licensees engaged in industrial radiographic operations are~~
12 ~~subject to the requirements of Section .0500 of this Chapter, and licensees engaged in the healing arts are subject to~~
13 ~~Rule .0350 of this Chapter and the applicable requirements of Section .0600 of this Chapter. Licensees engaged in~~
14 ~~the production of radioactive material or possessing radioactive material incidental to an accelerator are subject to the~~
15 ~~requirements of Section .0300 of this Chapter.~~

16 (1) Licensees engaged in the production of radioactive material or possessing radioactive material
17 incidental to operating an accelerator are subject to the requirements of Section .0300 of this
18 Chapter;

19 (2) Licensees engaged in the treatment of humans are subject to the requirements of Section .1900 of
20 this Chapter, and

21 (3) Licensees engaged in the veterinary treatment of animals are subject to the requirements of Section
22 .2000 of this Chapter.

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

25 ~~(e)(d)~~ In addition to the requirements of this Section, all particle accelerator licensees are subject to the annual fee
26 provisions contained in Section .1100 of this Chapter.
27

28 *History Note: Authority G.S. 104E-7; 104E-9(a)(8); 104E-19(a);*

29 *Eff. February 1, 1980;*

30 *Amended Eff. January 1, 1994; June 1, 1989; July 1, 1982;*

31 *Transferred and Recodified from 15A NCAC 11 .0901 Eff. February 1, ~~2015~~ 2015;*

32 *Readopted Eff. October 1, 2025.*

1 10A NCAC 15 .0902 is readopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0902 LICENSING REQUIREMENTS**

4 No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a license
5 issued pursuant to these Rules or as otherwise provided for in these Rules. The general procedures for licensing of
6 particle accelerator facilities are included in ~~Section~~Rule .0903 of this ~~Chapter~~Section.

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

9 *Eff. February 1, 1980;*

10 *Amended Eff. May 1, 1993;*

11 *Transferred and Recodified from 15A NCAC 11 .0902 Eff. February 1, ~~2015~~, 2015;*

12 *Readopted Eff. October 1, 2025.*

10A NCAC 15 .0903 is readopted with changes as published in 39:19 NCR 1225-1262 as follows:

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

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

- (1) The applicant and the applicant's particle accelerator operators are qualified by reason of training and experience to use the accelerator in such a manner as to minimize danger to public health and safety or property;
- (2) The applicant's proposed equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or ~~property; property, and~~
- (3) ~~The applicant has appointed a radiation safety officer;~~ The applicant's management has appointed a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The applicant, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and the requirements of this Section.
- ~~(4) The applicant has established a radiation safety committee to approve that the operation of the particle accelerator is in accordance with applicable radiation protection Sections of this Chapter; and~~
- ~~(5) The applicant for the use of a particle accelerator in the healing arts shall be a physician licensed to practice medicine in the state of North Carolina. The individuals designated on the application as users shall have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans.~~
- ~~(4) The applicant for therapeutic use of a particle accelerator for medical use on humans shall meet the additional requirements of Section .1900 of this Chapter and shall:~~
 - ~~(A) [be]have a board-certified physician licensed as outlined in Rule .1903(c)(1) of Section .1900 of this Chapter and licensed to practice medicine in the State of North Carolina; and,~~
 - ~~(B) have a board-certified physicist outlined in Rule .1903(d) of Section .1900 of this Chapter.~~
- ~~(5) The applicant for therapeutic use of a particle accelerator for veterinary use on animals shall meet the additional requirements of Section .2000 of this Chapter.~~

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

- ~~(1) Persons applying for new accelerator licenses, or for the renewal of existing accelerator licenses, shall submit an Application for Accelerator License. The instructions for completing the application printed on the application form shall be followed. The following information shall appear on the application:~~
 - ~~(A) legal business name and mailing address;~~

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

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

1 10A NCAC 15 .0904 is readopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0904 LIMITATIONS**

4 (a) No licensee shall permit any person to act as a particle accelerator operator until such person:

5 (1) has been instructed in radiation safety and shall have demonstrated an understanding thereof;

6 (2) has received copies of, and instruction in, this Section and the applicable requirements of this
7 Chapter, pertinent licensing ~~conditions~~ conditions, and the licensee's operating and emergency
8 procedures; and

9 (3) has demonstrated competence to use the particle accelerator, related equipment, and survey
10 instruments which will be employed in ~~his~~ their assignment.

11 (b) ~~Either the radiation safety committee or the The radiation safety officer~~ Radiation Safety Officer shall have the
12 authority to terminate the operations at a particle accelerator facility if this action is deemed necessary to minimize
13 danger to public health and safety or property.

14
15 *History Note: Authority G.S. 104E-7;*

16 *Eff. February 1, 1980;*

17 *Transferred and Recodified from 15A NCAC 11 .0904 Eff. February 1, ~~2015~~ 2015;*

18 *Readopted Eff. October 1, 2025.*

1 10A NCAC 15 .0905 is readopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0905 SHIELDING AND SAFETY DESIGN**

4 (a) ~~A~~For medical use, a qualified expert registered to provide Class VII services by the **agency Agency** pursuant to
5 Rule .0205 of this Chapter, or an Authorized Medical Physicist named on the licensee's license, shall be consulted in
6 the design of a particle accelerator ~~installation. A qualified expert installation and~~ shall perform a radiation survey
7 when the accelerator is first capable of producing radiation to verify that radiation levels and shielding effectiveness
8 meet the applicable requirements in this Chapter. ~~A copy of the survey shall be submitted to the agency by the licensee~~
9 ~~prior to its use for its licensed purpose.~~

10 (b) For Veterinary use, a qualified expert registered to provide Class VII services pursuant to Rule .0205 of this
11 Chapter by the **agency Agency** or an Authorized Medical Physicist named on the licensee's license, shall be consulted
12 in the design of a particle accelerator installation and shall perform a radiation survey when the accelerator is first
13 capable of producing radiation to verify that radiation levels and shielding effectiveness meet the applicable
14 requirements in this Chapter.

15 (c) For non-medical use, a qualified expert registered to provide Class VII or Class IX services by the **agency Agency**
16 pursuant to Rule .0205 of this Chapter, an individual with a Master's Degree in physics or higher, or the licensee's
17 Radiation Safety Officer shall be consulted in the design of a particle accelerator and shall perform a radiation survey
18 when the accelerator is first capable of producing radiation to verify that radiation levels and shielding effectiveness
19 meet the applicable requirements in this Chapter. The Radiation Safety Officer may delegate performing the radiation
20 survey to another individual provided the Radiation Safety Officer reviews the final survey results.

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

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

26 ~~(b)(f)~~ Plans for construction of accelerator installations shall be submitted to the **agency- Agency.**

27 ~~(e)(g)~~ Each particle accelerator installation shall be provided with such primary and secondary barriers as are
28 necessary to assure compliance with ~~Rules .1604 and .1614~~ Rule .1601 of this Chapter.

29
30 *History Note: Authority G.S. 104E-7;*
31 *Eff. February 1, 1980;*
32 *Amended Eff. January 1, 1994;*
33 *Transferred and Recodified from 15A NCAC 11 .0905 Eff. February 1, 2015; 2015;*
34 *Readopted Eff. October 1, 2025.*

1 10A NCAC 15 .0906 is readopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0906 CONTROLS AND INTERLOCK SYSTEMS**

4 (a) Instrumentation, ~~readouts~~ readouts, and controls on the particle accelerator control console shall be clearly
5 identified and easily discernible.

6 (b) All entrances into a target room or other high radiation area shall conform to the requirements of Rule ~~4615.1601~~
7 of this Chapter.

8 (c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by
9 manually resetting ~~controls at the position where the interlock that has been tripped~~ tripped, and, subsequently at the
10 ~~main control console.~~

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

12 (e) All safety interlocks shall be fail-safe, ~~i.e.,~~ meaning that safety interlocks are designed so that any defect or
13 component failure in the interlock system prevents operation of the accelerator.

14 (f) A "Scram button" or other emergency power cut-off switch shall be located and easily identifiable in all high
15 radiation areas and at the control console. Such a cut-off switch shall include a manual reset so that the accelerator
16 cannot be restarted from the accelerator control console without first manually resetting the cut-off switch.

17
18 *History Note: Authority G.S. 104E-7;*

19 *Eff. February 1, 1980;*

20 *Amended Eff. January 1, 1994;*

21 *Transferred and Recodified from 15A NCAC 11 .0906 Eff. February 1, ~~2015~~ 2015;*

22 *Readopted Eff. October 1, 2025.*

1 10A NCAC 15 .0907 is readopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0907 WARNING DEVICES**

4 (a) ~~All~~ Except in facilities designed for human exposure, all locations designated as high radiation areas, areas and
5 entrances to such locations shall be equipped with easily observable warning lights that operate ~~when, and only when,~~
6 when radiation is being produced. Facilities designed for human exposure shall be equipped with easily observable
7 warning lights outside the entrances to high radiation areas that operate only when radiation is being produced.

8 (b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device
9 which shall be activated for 15 seconds prior to ~~the possible creation of such~~ operating equipment capable of creating
10 a high radiation area. This warning device shall be clearly discernible in all high radiation areas and all radiation
11 areas.

12 (c) ~~Barriers, All barriers temporary or otherwise,~~ and pathways leading to high radiation areas shall be identified in
13 accordance with Rule ~~1624.1601~~ of this Chapter.

14
15 *History Note: Authority G.S. 104E-7;*

16 *Eff. February 1, 1980;*

17 *Amended Eff. January 1, 1994;*

18 *Transferred and Recodified from 15A NCAC 11 .0907 Eff. February 1, 2015, 2015;*

19 *Readopted Eff. October 1, 2025.*

1 10A NCAC 15 .0908 is readopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0908 OPERATING PROCEDURES**

4 (a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

5 (b) Only a switch on the accelerator control console shall be ~~routinely~~ used to turn the accelerator beam "on" and
6 "off". The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

7 (c) All safety and warning devices, including interlocks shall be checked for proper operability at least every six
8 months unless more frequent checks are required by the ~~agency.~~ **Agency.** Results of such tests shall be maintained for
9 two years at the accelerator facility for inspection by the ~~agency.~~ **Agency.**

10 ~~(d) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and~~
11 ~~maintained for inspection by the agency.~~

12 ~~(e)(d)~~ If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

13 (1) authorized by the ~~radiation safety officer;~~ **Radiation Safety Officer;**

14 (2) recorded in a permanent log and a notice posted at the accelerator control console and at the location
15 of the bypassed interlock; and

16 (3) terminated as soon as possible.

17 ~~(f)(c)~~ A copy of the current operating and the emergency procedures shall be maintained at the accelerator control
18 panel.

19
20 *History Note: Authority G.S. 104E-7;*

21 *Eff. February 1, 1980;*

22 *Transferred and Recodified from 15A NCAC 11 .0908 Eff. February 1, ~~2015~~ 2015;*

23 *Readopted Eff. October 1, 2025.*

1 10A NCAC 15 .0909 is readopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0909 RADIATION MONITORING REQUIREMENTS**

4 (a) ~~Portable~~ Except for persons licensed for activities authorized by Section .1900 of this Chapter possessing non-
5 portable therapeutic radiation machines, portable monitoring equipment shall be available at each particle accelerator
6 facility. Such equipment shall be tested for proper operation monthly and calibrated at intervals not to exceed one
7 year, and after each servicing and repair.

8 (b) A radiation protection survey shall be performed and documented by a qualified expert registered by the ~~agency~~
9 Agency pursuant to Rule .0205 of this ~~Chapter~~ Chapter for the provision of Class VII, Class IX services or an
10 Authorized Medical Physicist named on the licensee's license when changes have been made in shielding, operation,
11 equipment, or occupancy of adjacent areas. The licensee shall submit the report or a copy of the report of the qualified
12 expert to the ~~agency~~ Agency by email to licensing.ram@dhhs.nc.gov or at one of the address addresses found in Rule
13 ~~.0111.0111(a)~~ of this Chapter.

14 (c) Except for facilities designed for human exposure, radiation levels in all high radiation areas shall be continuously
15 monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems
16 and capable of providing a remote and local readout with visual or audible alarms at the control panel and other
17 appropriate locations.

18 (d) All area monitors shall be tested for proper operation at least every six months unless more frequent checks are
19 required by the ~~agency~~ Agency.

20 (e) ~~Whenever applicable, periodic surveys~~ Surveys shall be performed to determine the amount of airborne particulate
21 radioactivity present in areas of airborne ~~hazards~~ hazards at least annually.

22 (f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target
23 and other pertinent areas.

24 (g) All area surveys shall be made in accordance with ~~the~~ written procedures ~~established by a qualified expert~~
25 ~~registered by the agency pursuant to Rule .0205 of this Chapter, or approved by the~~ radiation safety officer Radiation
26 Safety Officer of the accelerator facility.

27 (h) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be
28 kept current and on file at each accelerator facility for two years for inspection by the ~~agency~~ Agency.

29
30 *History Note: Authority G.S. 104E-7; 104E-12(a);*

31 *Eff. February 1, 1980;*

32 *Amended Eff. October 1, 1980;*

33 *Transferred and Recodified from 15A NCAC 11 .0909 Eff. February 1, 2015; 2015;*

34 *Readopted October 1, 2025.*

1 10A NCAC 15 .0910 is readopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .0910 VENTILATION SYSTEMS**

4 (a) Adequate ventilation shall be provided in areas where airborne radioactivity may be produced to comply with
5 Rule ~~1604~~.1601 of this Chapter.

6 (b) The licensee shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area in
7 excess of the limits specified in Rule ~~1614~~.1601 of this Chapter.

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

10 *Eff. February 1, 1980;*

11 *Amended Eff. January 1, 1994; May 1, 1992;*

12 *Transferred and Recodified from 15A NCAC 11 .0910 Eff. February 1, ~~2015~~.2015;*

13 *Readopted Eff. October 1, 2025.*

Rule 10A NCAC 15 .1001 is amended as published in 39:19 NCR 1225-1262 as follows:

SECTION .1000 - NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS

Codifier's Note: 10A NCAC 03G .3100 was transferred to 15A NCAC 11 .1000 effective January 4, 1990.

Recodification pursuant to G.S. 143B-279.3.

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

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

- (1) 10 CFR 19.1, "Purpose;"
- (2) 10 CFR 19.2, "Scope;"
- (3) 10 CFR 19.3, "Definitions," except that the definition of "regulated activities" and "regulated entities" shall not apply. For persons registered with the ~~agency~~ **Agency** pursuant to the rules in Section .0200 of this Chapter, the following terms used in 10 CFR 19 shall have the following substitutions:
 - (A) "license" shall have the same meaning as "registration" as defined in Rule ~~.0104(131)~~ **.0103(b)** of this Chapter;
 - (B) "licensed" means "registered" as defined in Rule ~~.0104(131)~~ **.0103(b)** of this Chapter;
 - (C) "licensee" shall have the same meaning as "registrant" as defined in Rule ~~.0104(130)~~ **.0103(b)** of this Chapter;
 - (D) "materials" shall have the same meaning as "radiation machine" as defined in Rule ~~.0104(122)~~ **.0103(b)** of this Chapter;
 - (E) "NRC-licensed" means "registered"; and
 - (F) "radioactive material" shall have the same meaning as "radiation machine" as defined in Rule ~~.0104(122)~~ **.0103(b)** of this Chapter.
- (4) 10 CFR 19.5, "Communications," except that licensees and registrants shall address communications and reports to the ~~agency~~ **Agency** as instructed by Rule .0111 of this Chapter in lieu of the NRC;
- (5) 10 CFR 19.11, "Posting of notices to workers," except that 19.11(b) and (c) shall not apply;
 - (A) NRC Form 3 shall not be used in lieu of the Notice to Employees issued by the ~~agency~~ **Agency**, except as authorized by the ~~agency~~ **Agency** in writing;
 - (B) licensees and registrants shall not post other notices, postings, notes, or other materials over the Notice to Employees, nor shall equipment be placed in such a manner that the Notice to Employees is obscured or hidden by that equipment; and

- (C) additional copies of the Notice to Employees may be obtained free of charge from the ~~agency~~ Agency by contacting the ~~agency~~ Agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC, or online at <https://radiation.ncdhhs.gov/>;
- (6) 10 CFR 19.12, "Instructions to workers;"
- (7) 10 CFR 19.13, "Notifications and reports to individuals;"
- (8) 10 CFR 19.14, "Presence of representatives of licensees and regulated entities, and workers during inspections," except that 19.14(a) shall not apply;
- (9) 10 CFR 19.15, "Consultation with workers during inspections;"
- (10) 10 CFR 19.16, "Requests by workers for inspections." Requests for inspections shall be mailed or delivered to the ~~agency~~ Agency as instructed by Rule .0111(a) of this Chapter in lieu of the NRC;
- (11) 10 CFR 19.17, "Inspections not warranted; informal review." Communications regarding the agency's decisions with respect to a request for inspection submitted to the ~~agency~~ Agency under Subparagraph (a)(10) shall be mailed or delivered to the ~~agency~~ Agency as instructed by Rule .0111(a) of this Chapter in lieu of the NRC;
- (12) 10 CFR 19.18, "Sequestration of witnesses and exclusion of counsel in interviews conducted under subpoena;"
- (13) 10 CFR 19.20, "Employee protection;"
- (14) 10 CFR 19.31, "Application for exemptions," except that the request for exemption shall be made on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the ~~agency~~ Agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the ~~agency~~ Agency. To request an exemption, the following information shall be submitted to the ~~agency~~ Agency:
- (A) licensee or registrant name;
- (B) license or registration number;
- (C) name of the individual requesting the exemption;
- (D) contact information for the individual requesting the exemption;
- (E) a description of the exemption being requested; and
- (F) an explanation describing why the exemption is necessary.
- (b) Notwithstanding Subparagraph (a)(5) of this Rule, registrants temporarily working in North Carolina and licensees working in North Carolina under reciprocity may post the Notice to Employees, NRC Form 3, or an equivalent form issued under the authority of the regulatory agency issuing the registration or license.
- (c) Copies of these regulations are available free of charge at <https://www.nrc.gov/reading-rm/doc-collections/cfr/part019/>.

*History Note: Authority G.S. 104E-7; 104E-12;
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989;*

1 *Transferred and Recodified from 15A NCAC 11 .1001 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; October 1, 2023.*

10A NCAC 15 .1601 is amended as published in 39:19 NCR 1225-1262 as follows:

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION

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

- (1) 20.1001, "Purpose," except that non-ionizing radiation from radiation machines registered in accordance with the rules in Section .0200 of this Chapter shall also be regulated by this Rule;
- (2) 20.1002, "Scope;"
- (3) 20.1003, "Definitions," except that for persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following terms used in 10 CFR 20 shall have the following substitutions:
 - (A) "license" shall have the same meaning as "registration" as defined in Rule ~~.0104(131)~~ .0103(b) of this Chapter;
 - (B) "licensed" ~~means registered pursuant to the rules in Section .0200~~ shall have the same meaning as "registered" as defined in Rule .0103(b) of this Chapter;
 - (C) "licensed material" shall have the same meaning as "radiation machine" as defined in Rule ~~.0104(122)~~ .0103(b) of this Chapter, and
 - (D) "licensee" shall have the same meaning as "registrant" as defined in Rule ~~.0104(130)~~ .0103(b) of this Chapter;
- (4) 20.1004, "Units of radiation dose;"
- (5) 20.1005, "Units of radioactivity;"
- (6) 20.1007, "Communications," except that licensees and registrants shall address communications regarding these rules, notifications, and reports to the agency Agency as instructed by Rule .0111 of this Chapter in lieu of the NRC;
- (7) 20.1101, "Radiation protection programs;"
- (8) 20.1201, "Occupational dose limits for adults;"
- (9) 20.1202, "Compliance with requirements for summation of external and internal doses;"
- (10) 20.1203, "Determination of external dose from airborne radioactive material;"
- (11) 20.1204, "Determination of internal exposure;"
- (12) 20.1206, "Planned special exposures;"
- (13) 20.1207, "Occupational dose limits for minors;"
- (14) 20.1208, "Dose equivalent to an embryo/fetus;"
- (15) 20.1301, "Dose limits for individual members of the public;"

- 1 (16) 20.1302, "Compliance with dose limits for individual members of the public;"
- 2 (17) 20.1401, "General provisions and scope;"
- 3 (18) 20.1402, "Radiological criteria for unrestricted use;"
- 4 (19) 20.1403, "Criteria for license termination under restricted conditions;"
- 5 (20) 20.1404, "Alternate criteria for license termination;"
- 6 (21) 20.1405, "Public notification and public participation," except the ~~agency~~ Agency shall not publish
- 7 a notice in the Federal Register;
- 8 (22) 20.1406, "Minimization of contamination," except that 20.1406(b) shall not apply;
- 9 (23) 20.1501, "General;"
- 10 (24) 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose;"
- 11 (25) 20.1601, "Control of access to high radiation areas;"
- 12 (26) 20.1602, "Control of access to very high radiation areas;"
- 13 (27) 20.1701, "Use of process or other engineering controls;"
- 14 (28) 20.1702, "Use of other controls;"
- 15 (29) 20.1703, "Use of individual respiratory protection equipment;"
- 16 (30) 20.1704, "Further restrictions on the use of respiratory equipment;"
- 17 (31) 20.1705, "Application for use of higher assigned protection factors;"
- 18 (32) 20.1801, "Security of stored material;"
- 19 (33) 20.1802, "Control of material not in storage;"
- 20 (34) 20.1901, "Caution signs;"
- 21 (35) 20.1902, "Posting requirements;"
- 22 (36) 20.1903, "Exceptions to posting requirements;"
- 23 (37) 20.1904, "Labeling containers;"
- 24 (38) 20.1905, "Exemptions to labeling requirements," except that 20.1905(g) shall not apply;
- 25 (39) 20.1906, "Procedures for receiving and opening packages;"
- 26 (40) 20.2001, "General requirements;"
- 27 (41) 20.2002, "Method for obtaining approval of proposed disposal procedures;"
- 28 (42) 20.2003, "Disposal by release to sanitary sewerage;"
- 29 (43) 20.2004, "Treatment or disposal by incineration;"
- 30 (44) 20.2005, "Disposal of specific wastes;"
- 31 (45) 20.2006, "Transfer for disposal and manifests;"
- 32 (46) 20.2007, "Compliance with environmental and health protection regulations;"
- 33 (47) 20.2008, "Disposal of certain byproduct material;"
- 34 (48) 20.2101, "General provisions;"
- 35 (49) 20.2102, "Records of radiation protection programs;"
- 36 (50) 20.2103, "Records of surveys;"
- 37 (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~~ 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~~ Agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the ~~agency~~ Agency. To request an exemption, the following information shall be submitted to the ~~agency~~ Agency:
- (A) licensee or registrant name;
 - (B) license or registration number;
 - (C) name and contact information for the individual requesting the exemption;
 - (D) a description of the exemption being requested, and
 - (E) an explanation describing why the exemption is necessary;
- (65) 20.2302, "Additional requirements;"
- (66) Appendix A to Part 20, "Assigned Protection Factors for Respirators;"
- (67) Appendix B to Part 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage;"
- (68) Appendix C to Part 20, "Quantities of Radioactive Material Requiring Labeling;"
- (69) Appendix E to Part 20, "Nationally Tracked Source Thresholds," and

1 (70) Appendix G to Part 20, "Requirements for Transfers of Low-Level Radioactive Waste Intended for
2 Disposal at Licensed Land Disposal Facilities and Manifests."

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

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

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

10 (e) 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/)
11 [collections/cfr/part020/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/).

12
13 *History Note: Authority G.S. 104E-7(a)(2);*

14 *Eff. January 1, 1994;*

15 *Amended Eff. August 1, 1998;*

16 *Transferred and Recodified from 15A NCAC 11 .1601 Eff. February 1, 2015;*

17 *Readopted Eff. October 1, ~~2023~~ 2023;*

18 *Amended Eff. October 1, 2025.*

1 10A NCAC 15 .1901 is adopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **SECTION .1900 – THERAPEUTIC RADIATION MACHINES**
4

5 **10A NCAC 15 .1901 PURPOSE AND SCOPE**

6 (a) This Section establishes requirements for use of therapeutic radiation machines to treat disease in humans. The
7 requirements of this Section are in addition to the requirements of Sections .0100, .0200, .0900, .1000, and .1600 of
8 this Chapter.

9 (b) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the
10 healing arts who meets the training and experience criteria established by Rule .1903(c).

11 (c) In addition to the requirements of this Section, all therapeutic radiation machine licensees are subject to the annual
12 fee provisions contained in Section .1100 of this Chapter.

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

15 Eff. October 1, 2025.

10A NCAC 15 .1902 is adopted with changes as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .1902 DEFINITIONS

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

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

- (18) "Kilovolt," "kV," "kilo electron volt," and "keV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. Current convention is to use kV for photons and keV for electrons.
- (19) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.
- (20) "Licensee" means any person who is licensed by the agency pursuant to the rules of this Section .0900 of this Chapter.
- (21) "Light field" means the area illuminated by light, simulating the radiation field.
- (22) "Megavolt," "MV," "mega electron volt," and "MeV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.
- (23) "Method of Delivery" means mode of radiation to be used during treatment, which may include photons, electrons, or protons.
- (24) "Patient" means an individual, for whom a written directive is intended, subjected to machine produced radiation for the purposes of medical therapy.
- (25) "Periodic quality assurance check" means a procedure which is performed to ensure that a previous parameter or condition continues to be valid.
- (26) "Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. 90, Article 1.
- (27) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive.
- (28) "Primary protective barrier" (see "Protective barrier").
- (29) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:
- (A) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.
- (B) "Secondary protective barrier" means the material which attenuates stray radiation.
- (30) "Qualified Expert" means a person registered by the agency pursuant to Rule .0205 of this Chapter for the provision of Class VII services and who meets the training and experience requirements listed in Rule [0206(a)(7)(A)] 0214(a)(7)(A) or (B) of this Chapter.
- [30][31] "Quarterly" means at intervals not to exceed 13 consecutive weeks, plus or minus 7 consecutive days.
- [31][32] "Radiation oncology safety team" means, minimally, a group of individuals consisting of an authorized user, authorized medical physicist, medical dosimetrist, radiation therapist and oncology nurse whose purpose is to work together to deliver radiation safely and reproducibly.
- [32][33] "Referring physician" means the physician whom referred the patient or human research subject to the licensee for specialized care.

1 ~~(33)~~(34) "Semiannually" means at intervals not to exceed 6 consecutive months, plus or minus 15
2 consecutive days.

3 ~~(34)~~(35) "Sievert" and "Sv" mean the SI unit of dose equivalent measured as joule per kilogram.

4 ~~(35)~~(36) "Supervision" shall be defined as follows:

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

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

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

15 ~~(36)~~(37) "Therapeutic radiation machine" means equipment that is designed and used for external beam
16 radiation therapy in the healing arts. For these regulations, devices used to administer electronic
17 brachytherapy shall also be considered therapeutic radiation machines.

18 ~~(37)~~(38) "Therapeutic radiation machine medical event" means an event that meets the criteria in Rule
19 .1905(a)(4).

20 ~~(38)~~(39) "Treatment room shielding" means a location which contains fixed protective barriers to limit
21 radiation exposures to members of the public and occupationally exposed workers to within
22 regulatory limits.

23 ~~(39)~~(40) "Weekly" means at least once per calendar week.

24 ~~(40)~~(41) "Written directive" means an order in writing for the administration of radiation to a specific
25 patient or human research subject, as specified in .1905(a)(1).

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

28
29 *History Note: Authority G.S. 104E-7;*

30 *Eff. October 1, 2025.*

10A NCAC 15 .1903 is adopted with changes as published in 39:19 NCR 1225-1262 as follows:

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

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

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

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

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

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

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

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

(1) Be certified and ~~maintaining~~ maintain certification by the American Board of Radiology in:

(A) Therapeutic ~~radiological physics~~ Radiological Physics; or

(B) Therapeutic ~~medical physics~~ Medical Physics; or

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

- (3) ~~Be certified and maintaining~~ maintain certification by the Canadian College of Medical Physics in Radiation Oncology Physics; or,
- (4) Be an individual listed on an Agency or an Agreement State medical accelerator license as an authorized medical physicist on or before the effective date of this Rule. Individuals listed on an Agency or Agreement State medical accelerator license need not comply with Subparagraphs (d)(1) through (d)(3) of this Paragraph, except they must meet the training requirements defined in other Paragraphs of this Rule for any uses for which they were not authorized on or before the effective date of this Rule, and shall document 75 hours of accredited continuing education every three ~~(3)~~ years that is acceptable to the certifying organizations identified in (d)(1) through (d)(3).
- (e) Training for Therapeutic Radiation Machine Radiation Safety Officer: The licensee for any therapeutic radiation machine subject to Rules within this subpart Subpart shall require the Radiation Safety Officer:
- (1) Be listed as an Authorized User or Authorized Medical Physicist on the license; or,
- (2) Be certified by the American Board of Health Physics in Health Physics; or,
- (3) Be certified by the American Board of Science in Nuclear Medicine in Radiation Protection; or,
- (4) Be certified by the American Board of Radiology in:
- (A) Diagnostic Radiologic Physics;
- (B) Diagnostic Medical Physics;
- (C) Medical Nuclear Physics;
- (D) Nuclear Medical Physics; or,
- (5) Be certified by the American Board of Medical Physics in Medical Health Physics; or,
- (6) Be an individual listed on an Agency or an Agreement State medical accelerator license as a Therapeutic Radiation Machine Radiation Safety Officer on or before the effective date of this Rule. Individuals listed on an Agency or Agreement State medical accelerator on or before the effective date of this Rule need not comply with Subparagraphs (e)(1) through (e)(5) of this Paragraph, except they must meet the training requirements in radiation safety, regulatory issues, and emergency procedures for the types of use for which they were not authorized on or before the effective date of this Rule, and shall document 60 hours of accredited continuing education every three ~~(3)~~ years that is acceptable to the certifying organizations identified in (e)(2) through (e)(5).
- (f) Qualifications of Operators:
- (1) Direct Human Use – Operators: Individuals who will be operating a therapeutic radiation machine on humans or irradiation of products to be used by humans, shall:
- (A) Be a registered Radiation Therapy Technologists by the American Registry of Radiologic Technologists; or,
- (B) Be American Registry of Radiologic Technologists registry-eligible as Radiation Therapy Technologists provided the individual is under the personal supervision of an individual that meets the requirements of Subparagraph (A) of this Paragraph; and,

- (C) Successfully complete a licensee-developed initial and ongoing competency program in the use of the therapeutic radiation machine as well as other ancillary systems used by the operator in medical use applications. This competency program shall be documented, and records shall include the list of topics evaluated, and each individual's completion of the competency program shall be approved, signed, and dated. Records required by this Subparagraph shall be maintained for a minimum of three years.
- (2) Non-direct Human Use – Operators: Individuals who will be operating a therapeutic radiation machine for the purposes of quality assurance and/or non-human research, shall:
- A) Comply with Paragraph (d) of this Rule; or,
- B) Comply with Subparagraph (1)(A) of this Paragraph; or,
- C) Comply with the requirements of Section .0900 of this Chapter; and,
- (D) Successfully complete a licensee-developed initial and ongoing competency program in the use of the therapeutic radiation machine as well as other ancillary systems used by the operator for quality assurance or non-human research. The competency program shall be documented, and records shall include the list of topics evaluated, and each individual's completion of the competency program shall be approved, signed, and dated. Records required by this subparagraph shall be maintained for a minimum of three years.
- (g) Documented safety procedures shall be developed by an Authorized Medical Physicist and shall be readily accessible in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.
- (h) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a therapeutic radiation machine authorized user. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing-arts purposes.
- (i) Visiting Authorized User: A licensee may permit any physician to act as a visiting authorized user under the term of the licensee's license for a total of ~~sixty (60)~~60 days per calendar year under the following conditions:
- (1) The visiting authorized user has the prior approval of the licensee's facility management; and
- (2) The visiting authorized user meets the requirements established for authorized user(s) in Subparagraph (c) of this Rule; and
- (3) The licensee shall maintain copies of the documentation of the approval and that the visiting authorized user met the requirements of Subparagraph (i)(2) of this Paragraph for three ~~(3)~~ years from the date of the last visit.
- (j) Visiting Authorized Medical Physicist: A licensee may permit any medical physicist to act as a visiting authorized medical physicist under the term of the licensee's license for a total of ~~sixty (60)~~ 60 days per calendar year under the following conditions:
- (1) The visiting qualified medical physicist has the prior approval of the licensee's facility management; and

- 1 (2) The visiting authorized medical physicist meets the requirements established for ~~authorized user(s)~~
2 authorized medical physicists in Subparagraphs (d) of this Rule; and
- 3 (3) The licensee shall maintain copies of the documentation of the approval and proof that the visiting
4 authorized medical physicist met the requirements of Subparagraph (j)(2) of this Rule for three ~~(3)~~
5 years from the date of the last visit.
- 6 (k) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall
7 comply with the provisions of the licensee's quality management program. In addition to the requirements of this
8 Section, these individuals are also subject to the requirements of Rules .1601(a)(8), (a)(24) and (a)(51) of this Chapter.
- 9 (l) Unless otherwise specified by license condition, whenever patients or human research subjects are being treated
10 by a therapeutic radiation machine, a physician shall be accessible. This physician does not need to be an authorized
11 user.
- 12 (m) A licensee that permits supervised activities within this subpart Subpart is responsible for the acts and omissions
13 of the supervised individual.
- 14 (n) Information and Maintenance Record and Associated Information: The licensee shall maintain the following
15 information in a separate file or package for each therapeutic radiation machine for inspection by the Agency:
- 16 (1) Report of acceptance testing and commissioning;
- 17 (2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic
18 radiation machine required by this Section, as well as the names of persons who performed such
19 activities;
- 20 (3) Records of maintenance and/or modifications performed on the therapeutic radiation machine after
21 the effective date of this Rule as well as the names of persons who performed such services;
- 22 (4) Assessments performed by an Authorized Medical Physicist, prior to the return of a therapeutic
23 radiation machine to clinical use, after significant service, repair, or upgrade that may result in
24 variances of machine functions more than the thresholds established within the quality management
25 program.
- 26 (o) Records Retention: All records required by this Section shall be retained until disposal is authorized by the
27 Agency unless another retention period is specifically authorized in this Section.
- 28
- 29 History Note: Authority G.S. 104E-7;
30 Eff. October 1, 2025.

10A NCAC 15 .1904 is adopted with changes as published I 39:19 NCR 1225-1262 as follows:

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

(a) Protection Surveys:

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

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

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

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

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

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

(C) After relocating the therapeutic radiation machine;

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

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

(3) The survey record shall include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one ~~(4)~~ week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

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

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

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

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

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

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

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

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

13 (c) Radiation Measuring Equipment. The licensee shall have, when required, appropriate and operable radiation
14 measuring equipment available for use and calibrated in accordance with Rule [0927-]1908. Radiation measuring
15 equipment includes, but is not limited to, dosimetry systems, survey instruments, and other radiation measuring
16 devices used in planning, guiding, and administering radiation.

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

21
22 History Note: Authority G.S. 104E-7;

23 Eff. October 1, 2025.

10A NCAC 15 .1905 is adopted with changes as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .1905 QUALITY MANAGEMENT PROGRAM

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

(1) Written Directives:

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

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

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

(D) The licensee shall retain a copy of the written directive for three ~~(3)~~ years.

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

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

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

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

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

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

- 1 (F) The licensee retains a copy of the procedures for administrations for the duration of the
2 license.
- 3 (3) New Procedures on Established Equipment: Licensees possessing established and commissioned
4 therapeutic radiation machines shall reevaluate equipment parameters, pursuant to this Section,
5 when new procedures are to be performed [that] if the parameters, including dose rate, field size,
6 imaging accuracy, maximum dose, fall outside of the original commissioned parameters.
- 7 (4) Documentation, Reports, and Notifications of Medical Events:
- 8 (A) Any unintended treatment deviation from the written directive or approved treatment plan
9 shall be identified, evaluated, and documented. Licensees shall document the corrective
10 action taken by the licensee as a result of any unintended deviation from the written
11 directive or approved treatment plan.
- 12 (B) A licensee shall report any medical event resulting from intervention of a patient or human
13 research subject in which the administration of radiation from therapy equipment results,
14 or will result, in unintended permanent functional damage to an organ or a physiological
15 system as determined by a physician.
- 16 (C) Except as required by Part (B) of this Subparagraph, licensees shall report any treatment
17 deviation as a medical event, except for a treatment deviation that results from intervention
18 by a patient or human research subject, when the treatment deviation is caused by any of
19 the conditions listed in Parts (D), (E), or (F) of this Subparagraph.
- 20 (D) Treatment deviations in which the administration of radiation from therapy equipment
21 involves the administration of radiation to an individual using a treatment plan intended
22 for another patient or human research subject;
- 23 (E) Treatment deviations in which the administration of radiation to a patient or human
24 research subject does not conform to the written directive and the approved treatment plan,
25 and the administered dose over the entire treatment course differs from the prescribed dose
26 as stated in the written directive by twenty percent or more; or,
- 27 (F) Treatment deviations in which the administered dose delivered differs from the prescribed
28 dose, for a single fraction, by an overdose of 50 percent or more.
- 29 (G) The licensee shall notify the Agency by telephone no later than the next calendar day after
30 the licensee determines that a medical event occurred.
- 31 (5) The licensee shall submit a written report to the Agency within fifteen days after the initial report
32 of the medical event. The written report must include:
- 33 (A) The licensee name;
- 34 (B) The name of the prescribing physician;
- 35 (C) A brief description of the event;
- 36 (D) Why the event occurred;
- 37 (E) The effect, if any, on the individual who received the medical event;

- (F) Actions, if any, that have been taken, or are planned, to prevent recurrence;
- (G) Certification that the licensee notified the patient, or the patient's responsible relative or guardian, and if not, why not, and
- (H) The report shall not contain the patient's name or any other information that could lead to the identification of the patient;
- (6) The licensee shall provide notification of the medical event to the referring physician no later than twenty-four hours after its discovery. The licensee shall also notify the individual who is the subject of the medical event no later than twenty-four hours after the initial notification, unless the authorized user or referring physician determines that, based on their medical judgment, informing the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within ~~twenty-four~~24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care because of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.
- (7) Aside from the notification requirement, nothing in this section Section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.
- (8) The licensee shall retain a record of each unintended deviation in accordance with Part (4)(A) of this Paragraph. If the unintended deviation is a medical event, a copy of the record shall be provided to the referring physician if other than the licensee within ~~fifteen~~ 15 days after its discovery.
- (9) The licensee shall retain a record of each unintended deviation for three years. The record must contain the following:
- (A) The licensee name and the names of the individuals involved;
- (B) A unique identification number, if one has been assigned, of the individual who is the subject of the unintended deviation;
- (C) A brief description of the event; why it occurred; the effect, if any, on the individual;
- (D) The actions, if any, taken or planned to prevent recurrence; and
- (E) Whether the licensee notified the individual, or the individual's responsible relative or guardian; and, if not, whether such failure to notify was based on guidance from the referring physician.

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

10A NCAC 15 .1906 is adopted as published in 39:19 NCR 1225-1262 as follows:

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

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

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

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

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

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

(1) All protective barriers shall be fixed except for entrance doors or beam interceptors;

(2) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(4) When any door referred to in Subparagraph (3) of this Paragraph is opened while the x-ray tube is activated, the air kerma rate at a distance of **±one** meter from the source shall be reduced to less than **±one** mGy (100 mrad) per hour.

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

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

- 1 and commissioning shall be conducted before the first medical use following installation or
2 reinstallation of the therapeutic radiation machine.
- 3 (2) A licensee authorized to use a therapeutic radiation machine for medical use shall perform
4 calibration measurements on each therapeutic radiation machine:
- 5 (A) Before the first medical use of the unit; and
6 (B) Before medical use whenever spot-check measurements indicate that the output, for each
7 specific mode and energy, differs by more than five percent from the output obtained at the
8 last calibration, following reinstallation of the therapeutic radiation machine in a new
9 location, following any repair of the therapeutic radiation machine that would likely impact
10 the radiation output beyond the normal range of expected fluctuation, and
11 (C) At intervals not to exceed annually.
- 12 (3) To satisfy the requirement of Paragraph (a) of this Rule, an authorized medical physicist shall design
13 and implement a calibration procedure for each radiation therapy machine which is consistent with
14 the specifications recommended by the manufacturer of the equipment and consistent with
15 nationally recognizable standards. The calibration procedure shall be designed to ensure accurate
16 patient or human research subject treatments, in accordance with the written directive and treatment
17 plan. The calibration procedure shall include, but not be limited to, the following:
- 18 (A) Accuracy of output measurements to within $\pm$ five percent of radiations used medically;
19 and
20 (B) Evaluation and accuracy of auxiliary systems, such as motion tracking or gating and image
21 guidance, used during patient or human research subject treatments.
- 22 (4) A licensee shall use the dosimetry system described in Rule .1908 of this Section to measure the
23 output for one set of exposure conditions. The remaining radiation measurements required in Part
24 (3)(A) of this Paragraph may be made using a dosimetry system that indicates relative dose rates.
- 25 (5) The evaluations and measurements for:
- 26 (A) Acceptance, commissioning, and calibration measurements in Part (3)(A) of this Paragraph
27 shall be performed under the direct supervision of an authorized medical physicist;
28 (B) full calibration measurements in Part (3)(B) of this Paragraph shall be performed by an
29 authorized medical physicist or under the general supervision of an authorized medical
30 physicist.
- 31 (6) A licensee shall maintain a record of each therapeutic radiation machine calibration for three years.
32 The record must include:
- 33 (A) The date of the calibration;
34 (B) The manufacturer's name, model number, and serial number of the therapeutic radiation
35 machine, auxiliary systems, and the instruments used to calibrate the unit(s);
36 (C) The results and an assessment of the calibrations; and
37 (D) The name of the authorized medical physicist who approves the calibration.

(7) A licensee shall maintain a record of each therapeutic radiation machine acceptance testing and commissioning for the lifetime of the machine. The record must include:

(A) The date of the acceptance testing or commissioning;

(B) The manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to evaluate the unit(s);

(C) The results and an assessment of acceptance testing and/or commissioning; and

(D) The name of the authorized medical physicist who approves the acceptance testing and/or commissioning.

(e) Independent Verification of Therapeutic Radiation Machine Output:

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

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

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

(C) Biennially, thereafter.

(2) Verification may be obtained by:

(A) irradiating dosimeters from an AAPM Accredited Dosimetry Calibration Laboratory; or

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

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

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

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

(f) Quality Assurance Checks:

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

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

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

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

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

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

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

(6) The licensee shall maintain a record of each quality assurance check required by this Paragraph for **3 three** years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

(g) Operating Procedures:

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

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

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

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

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

(6) No individual other than the patient or human research subject shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient or human research subject, in the treatment

1 room shall be protected by a barrier sufficient to meet the requirements of Rule .1601(a)(8) of this
2 Chapter.

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

5
6 History Note: Authority G.S. 104E-7;
7 Eff. October 1, 2025.

10A NCAC 15 .1907 is adopted as published in 39:19 NCR 1225-1262 as follows:

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

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

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

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

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

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

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

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

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

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

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

(7) Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without activating the access control and reinitiating irradiation by manual action at the control panel;

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

- (9) Emergency Cutoff Switches. At least ~~+~~one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch; and
- (10) Safety Interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.
- (c) Authorized Medical Physicist Support.
- (1) The services of an Authorized Medical Physicist shall be required in facilities having therapeutic radiation machines. The Authorized Medical Physicist shall be responsible for:
- (A) Calibrations required by Paragraph (d) of this Rule and radiation safety surveys required by Rule .1904(a) of this Section;
- (B) Beam data acquisition and configuration for treatment planning, and supervision of its use;
- (C) Quality assurance, including quality assurance check review required by Paragraph (f) of this Rule.
- (D) Consultation with the authorized user in treatment planning, as needed; and
- (E) Perform calculations/assessments regarding medical events.
- (2) The operating procedures required by Paragraph (d) of this Rule shall also specifically address how the Authorized Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Authorized Medical Physicist can be contacted.
- (d) Operating Procedures.
- (1) No individual, other than the patient or human research subject, shall be in the treatment space during treatment or during any irradiation for testing or calibration purposes;
- (2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of Rule .1904(a) of this Section, and Paragraphs (e), (f) and (g) of this Rule have been met;
- (3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use pursuant to Rules .1601(a)(32) and (33) of this Chapter;
- (4) When a patient or human research subject must be held in position for radiation therapy, mechanical supports or immobilization devices shall be used;
- (5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.
- (e) Acceptance Testing, Commissioning and Calibration Measurements. Acceptance testing, commissioning, and calibration of a therapeutic radiation machine subject to this Rule shall be performed by, or under the direct supervision of, an Authorized Medical Physicist:
- (1) Acceptance testing and commissioning shall be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies, that includes the American Association of Physicists in Medicine

- (AAMP), the American College of Radiology and the American Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.
- (2) A licensee authorized to use a therapeutic radiation machine for medical use shall perform calibration measurements on each therapeutic radiation machine:
- (A) Before the first medical use of the unit; and
- (B) Before medical use under the following conditions: Whenever spot-check measurements indicate that the output, for each specific mode and energy, differs by more than five percent from the output obtained at the last calibration, following reinstallation of the therapeutic radiation machine in a new location, following any repair of the therapeutic radiation machine that would likely impact the radiation output beyond the normal range of expected fluctuation; and
- (C) At intervals not to exceed annually.
- (3) To satisfy the requirement of Paragraph (d) of this Rule, an authorized medical physicist shall design and implement a calibration procedure for each radiation therapy machine which is consistent with the specifications recommended by the manufacturer of the equipment and consistent with nationally recognizable standards. The calibration procedure shall be designed to ensure accurate patient or human research subject treatments, in accordance with the written directive and treatment plan. The calibration procedure shall include, but not be limited to, the following:
- (A) Accuracy of output measurements to within $\pm$ five percent of radiations used medically; and
- (B) Evaluation and accuracy of auxiliary systems, such as motion tracking or gating and image guidance, used during patient or human research subject treatments.
- (f) Independent Verification of Therapeutic Radiation Machine Output
- (1) In addition to the calibration required by Paragraph (e) of this Rule, the licensee shall have the outputs, for all clinically used radiations, independently verified:
- (A) Within 90 days of first clinical use of a new installation;
- (B) Within 90 days of first clinical use following a reinstallation in a new location; and
- (C) Biennially, thereafter.
- (2) Verification may be obtained by:
- (A) the authorized medical physicist irradiating dosimeters from an AAPM Accredited Dosimetry Calibration Laboratory; or
- (B) evaluation by an independent registered qualified expert using an independent dosimetry system meeting Rule .1908 of this Section.
- (3) A licensee shall maintain a record of each independent verification of therapeutic radiation machine output for three years. The record must include:

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

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

10 (g) Quality Assurance Checks.

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

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

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

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

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

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

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

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

1

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

3 *Eff. October 1, 2025.*

1 10A NCAC 15 .1908 is adopted with changes as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .1908 CALIBRATION OF SURVEY INSTRUMENTS AND DOSIMETRY SYSTEMS**

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

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

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

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

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

13 (3) To satisfy the requirements of Subparagraph (a)(2) of this Rule, the licensee ~~[shall:]~~ shall consider
14 a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than
15 20 percent.

16 ~~[(A) Consider a point as calibrated if the indicated dose rate differs from the calculated dose~~
17 ~~rate by not more than 10 percent; and~~

18 ~~(B) Consider a point as calibrated if the indicated dose rate differs from the calculated dose~~
19 ~~rate by not more than 20 percent if a correction factor or graph is conspicuously attached~~
20 ~~to the instrument.]~~

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

23 (A) A description of the calibration procedure; and

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

28 (5) The licensee may obtain the services of individuals licensed by the Agency, the US Nuclear
29 Regulatory Commission or an Agreement State to perform calibrations of survey instruments.
30 Records of calibrations that contain information required by Paragraph ~~(4)~~(c) of this Rule shall be
31 maintained by the licensee.

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

34 (b) Dosimetry system:

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

- 1 (A) The system must have been calibrated using a system or source traceable to the National
2 Institute of Standards and Technology and published protocols accepted by nationally
3 recognized bodies; or by a calibration laboratory accredited by the American Association
4 of Physicists in Medicine. The calibration must have been performed within the previous
5 2 two years and after any servicing that may have affected system calibration; or
6 (B) The system must have been intercompared with another dosimetry system that was
7 calibrated within the previous 2 two years by the National Institute of Standards and
8 Technology or by a calibration laboratory accredited by the American Association of
9 Physicists in Medicine. The results of the intercomparison must indicate that the calibration
10 factor of the licensee's system had not changed by more than 2 two percent.
11 (2) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry
12 equipment done for three years after the record is made. For each calibration, intercomparison, or
13 comparison, the record must include:
14 (A) The date;
15 (B) The manufacturer's name, model numbers and serial numbers of the instruments that were
16 calibrated, intercompared, or compared as required by Parts (1)(A) or (1)(B) of this
17 Paragraph;
18 (C) The correction factor that was determined from the calibration or comparison or the
19 apparent correction factor that was determined from an intercomparison; and
20 (c) The names of the individuals who performed the calibration, intercomparison, or comparison.

21
22 History Note: Authority G.S. 104E-7;
23 Eff. October 1, 2025.

1 10A NCAC 15 .1909 is adopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .1909 SHIELDING AND SAFETY DESIGN REQUIREMENTS**

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

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

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

16
17 History Note: Authority G.S. 104E-7;

18 Eff. October 1, 2025.

1 10A NCAC 15 .1910 is adopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .1910 OTHER USE OF ELECTRONICALLY-PRODUCED RADIATION TO DELIVER**
4 **THERAPEUTIC RADIATION DOSAGE**

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

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

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

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

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

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

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

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

21 (8) Radiation safety precautions and instructions; and

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

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

26
27 *History Note: Authority G.S. 104E-7;*

28 *Eff. October 1, 2025.*

10A NCAC 15 .1911 is adopted as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .1911 EMERGING TECHNOLOGIES

(a) Each registrant shall develop, implement, and maintain a dedicated quality management program to control the processes used to administer therapeutic radiation with US Food and Drug Administration cleared emerging technologies or previously unused features of a future or existing technology system.

(b) Implementation and on-going clinical use of the technology dated before the technology arrives at the facility or the new features are used:

(1) Must include an explicit strategy to ensure quality of processes and patient or human research subject safety.

(2) Must include approval from facility management and the radiation oncology safety team before the technology arrives or new features are used.

(c) The quality management program shall be developed by the radiation oncology safety team.

(d) The quality management program shall address, at a minimum:

(1) Education and training about the new technology or features;

(2) A system and timeline for on-going competency assessment;

(3) A system for real-time recording of on-going issues related to the technology and clinical use of the new technology or features;

(4) A strategy for timely investigation and adjudication of accidents and process deviations that may be captured in the system developed in Subparagraph (b)(1) of this Rule;

(5) A strategy for routine review at intervals not to exceed 13 months of the clinical use of the new technology or features which includes an assessment of the current use compared to Paragraph (b) of this Rule and plan to either update the clinical use plan or steps to bring the clinical use back into alignment with Paragraph (b) of this Rule;

(6) A strategy to ensure quality of equipment functions;

(7) A strategy for ensuring quality after hardware and software updates and after equipment repair.

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

(f) New technology issues should be reported through the vendor or manufacturer, applicable regulatory agency alerts, or customer service bulletins and be reviewed and addressed via a documented reporting system.

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

Eff. October 1, 2025.

1 10A NCAC 15 .2001 is adopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **SECTION .2000 - VETERINARY USES OF THERAPEUTIC RADIATION MACHINES**

4
5 **10A NCAC 15 .2001 PURPOSE AND SCOPE**

6 (a) This Section establishes requirements for licensing and use of veterinary therapeutic radiation machines to treat
7 disease in animals other than humans. In addition to the requirements of this Section, all licensees are subject to the
8 rules in Sections .0100, .0200, .0900, .1000, and .1600 of this Chapter.

9 (b) The use of veterinary therapeutic radiation machines shall be authorized by a licensed practitioner of veterinary
10 medicine who meets the training and experience criteria established by Rule .2003(b) of this Section.

11 (c) In addition to the requirements of this Section, all veterinary therapeutic radiation machine licensees are subject
12 to the annual fee provisions contained in Section .1100 of this Chapter.

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

15 Eff. October 1, 2025.

10A NCAC 15 .2002 is adopted as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .2002 DEFINITIONS

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

- (1) "Acceptance testing" means an evaluation of equipment and systems to confirm they meet the specifications stated by the manufacturer.
- (2) "Animal" means any mammal other than human, and includes birds, fish, and reptiles, wild or domestic, living or dead.
- (3) "Annually" means at intervals not to exceed 12 consecutive months, plus or minus 30 days.
- (4) "Authorized Medical Physicist" means an individual authorized in accordance with Rule .2003(c) of this Section.
- (5) "Authorized user" means a veterinarian who meets the training requirements of Rule .2003(b) of this Section and is authorized by license condition to use a therapeutic radiation machine covered by this Section.
- (6) "Barrier" see "Protective barrier".
- (7) "Biennially" means at intervals not to exceed 24 consecutive months, plus or minus 30 days.
- (8) "Commissioning" means an intricate and methodical process designed to:
 - (A) acquire needed machine-specific beam data;
 - (B) validate the safe, accurate, and effective operation of a therapeutic radiation machine, treatment planning systems, ancillary systems, and associated procedural protocols; and,
 - (C) set baseline for future measurements for performance constancy.
- (9) "Dosimetry systems" means radiation detecting equipment that may be used to characterize the radiation beam and quantify the energy it may deposit within a medium.
- (10) "Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.
- (11) "Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.
- (12) "Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.
- (13) "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
- (14) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.
- (15) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
- (16) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

- (17) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.
- (18) "Kilovolt," "kV," "kilo electron volt," and "keV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. Current convention is to use kV for photons and keV for electrons
- (19) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.
- (20) "Licensee" means any person who is licensed by the agency pursuant to the Rules of Section .0900 of this Chapter.
- (21) "Light field" means the area illuminated by light, simulating the radiation field.
- (22) "Megavolt," "MV," "mega electron volt," and "MeV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.
- (23) "Method of Delivery" means mode of radiation to be used during treatment, which may include photons, electrons, or protons.
- (24) "Patient" means an animal, for whom a written directive is intended, subjected to machine produced radiation for the purposes of medical therapy.
- (25) "Periodic quality assurance check" means a procedure which is performed to ensure that a previous parameter or condition continues to be valid.
- (26) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive.
- (27) "Primary protective barrier" see "Protective barrier".
- (28) "Protective barrier" means a barrier of radiation absorbing materials used to reduce radiation exposure. The types of protective barriers are as follows:
- (A) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.
- (B) "Secondary protective barrier" means the material which attenuates stray radiation.
- (29) "Qualified Expert" means a person registered by the agency pursuant to Rule .0205 of this Chapter for the provision of either Class VII or IX services.
- (30) "Quarterly" means at intervals not to exceed 13 consecutive weeks, plus or minus 7 days.
- (31) "Radiation oncology safety team" means, minimally, a group of individuals consisting of an authorized user, authorized medical physicist, and veterinary therapeutic radiation machine operator whose purpose is to work together to deliver radiation safely and reproducibly.
- (32) "Restricted area" means an area, access to which is controlled by the licensee or registrant for purposes of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.
- (33) "Semiannually" means at intervals not to exceed 6 consecutive months, plus or minus 15 days.

1 (34) "Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per
2 kilogram.

3 (35) "Supervision" shall be defined as follows:

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

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

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

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

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

19 (38) "Veterinarian" means a person licensed to practice medicine in North Carolina pursuant to G.S.
20 Chapter 90, Article 11.

21 (39) "Veterinary therapeutic radiation machine," also known as a "Therapeutic radiation machine,"
22 means equipment that is designed and used for external beam radiation therapy in the healing arts.
23 For these regulations, devices used to administer electronic brachytherapy shall also be considered
24 therapeutic radiation machines.

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

26 (41) "Written directive" means an order in writing for the administration of radiation to a specific patient,
27 as specified in Rule .2005(b)(1) of this Section.

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

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

32 *Eff. October 1, 2025.*

10A NCAC 15 .2003 is adopted as published in 39:19 NCR 1225-1262 as follows:

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

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

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

- (1) Certification in Radiation Oncology by the American College of Veterinary Radiology; or
- (2) Satisfactory completion of a radiation oncology residency program approved by the American College of Veterinary Radiology. For radiation oncologists who are eligible for certification by the American College of Veterinary Radiology in accordance with Subparagraph (c)(1) of this Rule but not yet certified by the date of application, certification shall be required within six years of initial certification eligibility; and
- (3) Recentness of Training: The training and experience specified within Paragraph (c) of this Rule must have been obtained within the seven years preceding the date of hire or the individual must have had related continuing education and experience since the required training and experience was completed.

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

- (1) Be certified and maintaining certification by the American Board of Radiology in:
 - (A) Therapeutic radiological physics; or
 - (B) Therapeutic medical physics; or
- (2) Be certified and maintaining certification by the American Board of Medical Physics in Radiation Oncology Physics; or
- (3) Be certified and maintaining certification by the Canadian College of Medical Physics in Radiation Oncology Physics; or
- (4) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and
 - A) Completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide external beam therapy with photons and electrons with energies greater than or equal to **four** million electron volts and brachytherapy services and must

1 include: Performing full calibration and periodic spot checks of external beam treatment
2 units, stereotactic radiosurgery units, and remote afterloading units as applicable to the
3 veterinary practice, and conducting radiation surveys around external beam treatment units,
4 stereotactic radiosurgery units, and remote afterloading units as applicable to the veterinary
5 practice; and

6 (B) Completed training for the types of use for which authorization is sought that includes
7 hands-on device operation, safety procedures, clinical use, and the operation of a treatment
8 planning system. This training requirement may be satisfied by satisfactorily completing
9 either a training program provided by the vendor or by training supervised by an authorized
10 medical physicist authorized for the types of use for which the individual is seeking
11 authorization; or, be a qualified expert registered by the agency to provide Class VII or
12 Class IX services in accordance with Rule .0205(c) of this Chapter.

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

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

20 (1) Be listed as an Authorized User or Authorized Medical Physicist on the license; or
21 (2) Be certified by the American Board of Health Physics in Health Physics; or,
22 (3) Be certified by the American Board of Science in Nuclear Medicine in Radiation Protection; or
23 (4) Be certified by the American Board of Radiology in:
24 (A) Diagnostic Radiologic Physics;
25 (B) Diagnostic Medical Physics;
26 (C) Medical Nuclear Physics;
27 (D) Nuclear Medical Physics; or
28 (5) Be certified by the American Board of Medical Physics in Medical Health Physics; or
29 (6) Has completed a structured educational program consisting of both:
30 (A) 200 Two hundred hours of classroom and laboratory training in the following areas:
31 Radiation physics and instrumentation, radiation protection, radiation biology, and
32 radiation dosimetry, and
33 (B) One year of full-time radiation safety experience under the supervision of the individual
34 identified as the Radiation Safety Officer on an Agreement State license or permit that
35 authorizes similar type(s) of use(s) of radiation sources;
36 (7) An individual identified on an Agency or an Agreement State medical accelerator license as an
37 Therapeutic Radiation Machine Radiation Safety Officer on or before the effective date of this Rule

1 need not comply with Subparagraphs (1) through (6) of this Paragraph, except they must meet the
2 training requirements in radiation safety, regulatory issues, and emergency procedures for the types
3 of use which they were not authorized on or before this date; and
4 (8) Receive training in the requirements of the rules in Sections .1000 and .1600 of this Chapter and the
5 Rules of this Section.
6 (e) Qualifications of Operators: Individuals who will be operating therapeutic radiation machines on patients or
7 irradiation of products to be used by patients, shall:
8 (1) Comply with the requirements of Section .0900 of this Chapter; and
9 (2) Successfully complete a licensee-developed initial and ongoing competency program in the use of
10 the therapeutic radiation machine as well as other ancillary systems used by the operator in
11 veterinary medical use applications. The competency program shall be documented, and
12 documentation of training shall include the list of topics evaluated, and shall be approved by the
13 licensee, signed, and dated. Records required by this subparagraph shall be maintained for three
14 years from the completion date of the approved competency program.
15 (f) Documented safety procedures shall be developed by an Authorized Medical Physicist and shall be readily
16 accessible in the control area of a therapeutic radiation machine, including any restrictions required for the safe
17 operation of the therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these Rules.
18 (g) Patients shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure
19 has been ordered in writing by a therapeutic radiation machine authorized user. This provision specifically prohibits
20 deliberate exposure of a patient for training, demonstration, or other non-healing-arts purposes.
21 (h) Visiting Veterinary Authorized User: A licensee may permit any veterinarian to act as a visiting authorized user
22 under the term of the licensee's license for a total of 60 days per calendar year under the following conditions:
23 (1) The visiting authorized user has the prior approval of the licensee's management; and
24 (2) The visiting authorized user meets the requirements established for authorized users in Paragraph
25 (b) of this Rule; and
26 (3) The licensee shall maintain copies of the documentation of the approval and that the visiting
27 authorized user met the requirements of this rule for three years from the date of the last visit.
28 (i) Visiting Veterinary Authorized Medical Physicist: A licensee may permit any medical physicist to act as a
29 visiting authorized medical physicist under the term of the licensee's license for a total of 60 days per calendar year
30 under the following conditions:
31 (1) The visiting authorized medical physicist has the prior approval of the licensee's management; and
32 (2) The visiting authorized medical physicist meets the requirements established for authorized user(s)
33 in Subparagraphs (c)(1) through (c)(5) of this Rule; and
34 (3) The licensee shall maintain copies of the documentation of the approval and that the visiting
35 authorized medical physicist met the requirements of this rule for three years from the date of the
36 last visit.

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

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

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

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

10 (1) Report of acceptance testing and commissioning;

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

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

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

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

21
22 History Note: Authority G.S. 104E-7;

23 Eff. October 1, 2025.

1 10A NCAC 15 .2004 is adopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .2004 GENERAL TECHNICAL REQUIREMENTS FOR FACILITIES USING**
4 **VETERINARY THERAPEUTIC RADIATION MACHINES**

5 (a) Protection Surveys:

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

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

13 (B) Radiation levels in unrestricted areas do not exceed the limits specified in Rule
14 .1601(a)(15) of this Chapter.

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

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

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

20 (C) After relocating the therapeutic radiation machine;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 Eff. October 1, 2025.

10A NCAC 15 .2005 is adopted as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .2005 QUALITY MANAGEMENT PROGRAM

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

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

(1) Written Directives:

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

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

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

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

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

(A) Prior to the administration of each course of radiation treatments, the patient's identity is verified.

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

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

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

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

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

3 (c) New Procedures on Established Equipment. Established and commissioned therapeutic radiation machines shall
4 reevaluate equipment parameters, pursuant to this Section, when new procedures are to be performed [that] if the
5 parameters, including dose rate, field size, imaging accuracy, maximum dose, falls outside of the original
6 commissioned parameters.

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

10A NCAC 15 .2006 is adopted as published in 39:19 NCR 1225-1262 as follows:

**10A NCAC 15 .2006 VETERINARY THERAPEUTIC RADIATION MACHINES OF LESS THAN 500
KV**

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

(b) Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV shall meet the requirements of Rule .2009 of this Section and shall permit continuous observation of the patient subject during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

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

(1) All protective barriers shall be fixed except for entrance doors or beam interceptors;

(2) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(4) When any interlocked door is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 1 mGy or 100 mrad per hour.

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

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

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

- (A) Before the first medical use of the unit;
- (B) Whenever spot-check measurements indicate that the output, for each specific mode and energy, differs by more than five percent from the output obtained at the last calibration;
- (C) Following reinstallation of the therapeutic radiation machine in a new location;
- (D) Following any repair of the therapeutic radiation machine that would likely impact the radiation output beyond the normal range of expected fluctuation; and
- (E) at intervals not exceeding annually.
- (3) To satisfy the requirement of Paragraph (a) of this Rule, an authorized medical physicist shall design and implement a calibration procedure for each radiation therapy machine which is consistent with the specifications recommended by the manufacturer of the equipment and consistent with nationally recognizable standards. The calibration procedure shall be designed to ensure accurate patient treatments, in accordance with the written directive and treatment plan. The calibration procedure shall include, but not be limited to, the following:
- (A) Accuracy of output measurements to within $\pm$ five percent of radiations used medically; and,
- (B) Evaluation and accuracy of auxiliary systems, such as motion tracking or gating and image guidance, used during patient treatments.
- (4) A licensee shall use the dosimetry system described in Rule .2008 of this Section to measure the output for one set of exposure conditions. The remaining radiation measurements required in Part (3)(A) of this Paragraph may be made using a dosimetry system that indicates relative dose rates.
- (5) The evaluations and measurements for:
- (A) Acceptance, commissioning, and calibration measurements required by Part (3)(A) of this Paragraph shall be performed under the direct supervision of an authorized medical physicist;
- (B) Full calibration measurements required by Part (3)(B) of this Paragraph shall be performed by an authorized medical physicist or under the general supervision of an authorized medical physicist.
- (6) A licensee shall maintain a record of each therapeutic radiation machine calibration for three years. The record must include:
- (A) The date of the calibration;
- (B) The manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to calibrate the units;
- (C) The results and an assessment of the calibrations; and
- (D) The name of the authorized medical physicist who approves the calibration.
- (7) A licensee shall maintain a record of each therapeutic radiation machine acceptance testing and commissioning for the lifetime of the machine. The record must include:
- (A) The date of the acceptance testing or commissioning;

- (B) The manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to evaluate the units;
- (C) The results and an assessment of acceptance testing or commissioning; and
- (D) The name of the authorized medical physicist who approves the acceptance testing or commissioning.

(e) Independent Verification of Therapeutic Radiation Machine Output

- (1) In addition to the full calibration required by Paragraph (a) of this Rule, the licensee shall have the outputs, for all clinically used radiations, independently verified:
 - (A) Within 90 days of first clinical use of a new installation;
 - (B) Within 90 days of first clinical use following a reinstallation in a new location; and
 - (C) Biennially, thereafter.
- (2) Verification may be obtained by:
 - (A) irradiating dosimeters from an American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory; or
 - (B) evaluation by a registered qualified expert using an independent dosimetry system meeting the requirements of Rule .0947 of this Chapter.
- (3) A licensee shall maintain a record of each independent verification of therapeutic radiation machine output for three years. The record must include:
 - (A) If obtained by Part (2)(A) of this Paragraph: The date of the irradiation, the date of the analysis by the dosimetry center, name, address and contact information for the American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory, and the results of the independent verification.
 - (B) If obtained by Part (2)(B) of this Paragraph: the date of the calibration, the manufacturer's name, model number, and serial number of the therapeutic radiation machine, auxiliary systems, and the instruments used to calibrate the units. The results and an assessment of the independent verification, and the name of the registered qualified expert who provided the independent verification.

(f) Quality Assurance Checks.

- (1) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to this Rule, which are capable of operation at greater than or equal to 50 kV.
- (2) To satisfy the requirement of Subparagraph (1) of this Paragraph, quality assurance checks shall meet the following requirements:
 - (A) The licensee shall perform quality assurance checks, to include ensuring the proper function of requirements outlined in Paragraphs (d) and (e) of this Rule, in accordance with written procedures established by the Authorized Medical Physicist; and
 - (B) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify

- that the quality assurance check shall be performed during the calibration specified in Paragraph (d) of this Rule. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in Paragraph (d) of this Rule shall be stated.
- (3) The cause for a parameter exceeding a tolerance set by the Authorized Medical Physicist shall be investigated and corrected before the system is used for patient irradiation;
 - (4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Authorized Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in Subparagraph (d)(2) of this Rule;
 - (5) The licensee shall use the dosimetry system described in Rule .2008 of this Section to make the quality assurance check required in Subparagraph (2) of this Paragraph;
 - (6) The licensee shall maintain a record of each quality assurance check required by this Paragraph for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.
- (g) Operating Procedures.
- (1) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of Paragraphs (d) and (e) of this Rule have been met;
 - (2) Therapeutic radiation machines shall not be left unattended unless secured pursuant to Rules .1601(a)(32) and (33) of this Chapter;
 - (3) When a patient must be held in position for radiation therapy, mechanical supports or immobilization devices shall be used;
 - (4) The tube housing or any other part of the imaging assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;
 - (5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and
 - (6) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of Rule .1601(a)(8) of this Chapter.
- (h) Electronic brachytherapy devices are subject to the requirements of Rule .2011 of this Chapter and are exempt from the requirements of this Rule.

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

10A NCAC 15 .2007 is adopted as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .2007 VETERINARY THERAPEUTIC RADIATION MACHINES OF 500 KEV AND ABOVE

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

(b) Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of Rule .2009 of this Section, the following design requirements are made:

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

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

(A) Be located outside the treatment space and shall comply with the dose limits required by Rules .1601(a)(8) and .1601(a)(15) of this Chapter; and

(B) Provide a visual indication of when radiation is being produced;

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

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

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

(6) Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without activating the access control and reinitiating irradiation by manual action at the control panel;

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

(8) Emergency Cutoff Switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. All emergency power cutoff switches shall include a manual reset so that the

- 1 therapeutic radiation machine cannot be restarted from the unit's control console without resetting
2 the emergency cutoff switch; and
- 3 (9) Safety Interlocks. All safety interlocks shall be designed so that any defect or component failure in
4 the safety interlock system prevents or terminates operation of the therapeutic radiation machine.
- 5 (c) Authorized Medical Physicist Support.
- 6 (1) The services of an Authorized Medical Physicist shall be required in facilities having therapeutic
7 radiation machines. The Authorized Medical Physicist shall be responsible for:
- 8 (A) Calibrations required by Paragraph (d) of this Rule and the protection surveys required by
9 Rule .2004(a) of this Section;
- 10 (B) Beam data acquisition and configuration for treatment planning, and supervision of its use;
- 11 (C) Quality assurance, including quality assurance check review required by Paragraph (f) of
12 this Rule.
- 13 (D) Consultation with the authorized user in treatment planning, as needed; and
- 14 (E) Perform calculations and assessments regarding medical events.
- 15 (2) The operating procedures required by Paragraph (c) of this Rule shall also address how the
16 Authorized Medical Physicist is to be contacted for problems or emergencies, as well as the specific
17 actions, if any, to be taken until the Authorized Medical Physicist can be contacted.
- 18 (d) Operating Procedures.
- 19 (1) No person shall be in the treatment space during treatment or during any irradiation for testing or
20 calibration purposes;
- 21 (2) Therapeutic radiation machines shall not be made available for medical use unless the requirements
22 of Rule .2004(a), and Paragraphs (d), (e) and (f) of this rule have been met;
- 23 (3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use
24 pursuant to Rules .1601(a)(32) and (33) of this Chapter;
- 25 (4) When a patient must be held in position for radiation therapy, mechanical supports or
26 immobilization devices shall be used;
- 27 (5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic
28 radiation machine control console.
- 29 (e) Acceptance Testing, Commissioning and Calibration Measurements. Acceptance testing, commissioning, and
30 calibration of a therapeutic radiation machine subject to this Rule shall be performed by, or under the direct supervision
31 of, an Authorized Medical Physicist:
- 32 (1) Acceptance testing and commissioning shall be performed in accordance with current published
33 recommendations from a recognized national professional association with expertise in the use of
34 therapeutic radiation technologies, that includes the American Association of Physicists in
35 Medicine, the American College of Radiology and the American Society for Radiation Oncology.
36 In the absence of a protocol published by a national professional association, the manufacturer's
37 protocol or equivalent quality, safety, and security protocols, shall be followed.

- 1 (2) A licensee authorized to use a therapeutic radiation machine for medical use shall perform
2 calibration measurements on each therapeutic radiation machine:
- 3 (A) Before the first medical use of the unit; and
- 4 (B) Before medical use under the following conditions: Whenever spot-check measurements
5 indicate that the output, for each specific mode and energy, differs by more than five
6 percent from the output obtained at the last calibration, following reinstallation of the
7 therapeutic radiation machine in a new location, or following any repair of the therapeutic
8 radiation machine that would likely impact the radiation output beyond the normal range
9 of expected fluctuation, and at intervals not exceeding annually.
- 10 (3) To satisfy the requirement of Paragraph (d) of this Rule, an authorized medical physicist shall design
11 and implement a calibration procedure for each radiation therapy machine which is consistent with
12 the specifications recommended by the manufacturer of the equipment and consistent with
13 nationally recognizable standards. The calibration procedure shall be designed to ensure accurate
14 patient treatments, in accordance with the written directive and treatment plan. The calibration
15 procedure shall include, but not be limited to, the following:
- 16 (A) Accuracy of output measurements to within $\pm$ five percent of radiations used medically;
17 and,
- 18 (B) Evaluation and accuracy of auxiliary systems, such as motion tracking or gating and image
19 guidance, used during patient treatments.
- 20 (f) Independent Verification of Therapeutic Radiation Machine Output
- 21 (1) In addition to the calibration required by Paragraph (d) of this Rule, the licensee shall have the
22 outputs, for all clinically used radiations, independently verified:
- 23 (A) Within 90 days of first clinical use of a new installation;
- 24 (B) Within 90 days of first clinical use following a reinstallation in a new location; and
- 25 (C) Biennially, thereafter.
- 26 (2) Verification may be obtained by:
- 27 (A) the authorized medical physicist irradiating dosimeters from an American Association of
28 Physicists in Medicine Accredited Dosimetry Calibration Laboratory; or
- 29 (B) evaluation by an independent registered qualified expert using an independent dosimetry
30 system meeting the requirements of Rule .2008 of this Chapter.
- 31 (3) A licensee shall maintain a record of each independent verification of therapeutic radiation machine
32 output for three years. The record must include:
- 33 (A) If obtained by Part (e)(2)(A) of this Rule: The date of the irradiation, the date of the analysis
34 by the dosimetry center, name, address and contact information for the American
35 Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory, and
36 the results of the independent verification.

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

(g) Quality Assurance Checks.

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

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

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

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

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

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

(5) The licensee shall use the dosimetry system described in Rule .2008 of this Section to make the quality assurance check required in Paragraph (f) of this rule;

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

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

1 10A NCAC 15 .2008 is adopted with changes as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .2008 CALIBRATION OF SURVEY INSTRUMENTS AND DOSIMETRY SYSTEMS**

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

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

8 (2) To satisfy the requirements of Subparagraph (1) of this Paragraph, the licensee shall:

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

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

14 (3) To satisfy the requirements of Subparagraph (a)(2) of this Rule, the licensee ~~[shall]~~ shall consider
15 a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than
16 10 percent.

17 ~~[(A) Consider a point as calibrated if the indicated dose rate differs from the calculated dose~~
18 ~~rate by not more than 10 percent; and~~

19 ~~(B) Consider a point as calibrated if the indicated dose rate differs from the calculated dose~~
20 ~~rate by not more than 20 percent if a correction factor or graph is conspicuously attached~~
21 ~~to the instrument.]~~

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

24 (A) A description of the calibration procedure; and

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

29 (5) The licensee may obtain the services of individuals licensed by the Agency, the US Nuclear
30 Regulatory Commission or an Agreement State to perform calibrations of survey instruments.
31 Records of calibrations that contain information required by Paragraph (d) of this rule shall be
32 maintained for three years by the licensee.

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

35 (b) Dosimetry system:

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

1 (A) The system must have been calibrated using a system or source traceable to the National
2 Institute of Standards and Technology and published protocols accepted by nationally
3 recognized bodies; or by a calibration laboratory accredited by the American Association
4 of Physicists in Medicine. The calibration must have been performed within the previous
5 2 two years and after any servicing that may have affected system calibration; or

6 (B) The system must have been intercompared with another dosimetry system that was
7 calibrated within the previous 2 two years by National Institute of Standards and
8 Technology or by a calibration laboratory accredited by the American Association of
9 Physicists in Medicine. The results of the intercomparison must indicate that the calibration
10 factor of the licensee's system had not changed by more than 2 two percent.

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

14 (A) The date;

15 (B) The manufacturer's name, model numbers and serial numbers of the instruments that were
16 calibrated, intercompared, or compared as required by paragraphs (b)(1) and (b)(2);

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

19 (D) The names of the individuals who performed the calibration, intercomparison, or
20 comparison.

21
22 History Note: Authority G.S. 104E-7;

23 Eff. October 1, 2025.

1 10A NCAC 15 .2009 is adopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .2009 SHIELDING AND SAFETY DESIGN REQUIREMENTS**

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

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

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

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

18 Eff. October 1, 2025.

1 10A NCAC 15 .2010 is adopted as published in 39:19 NCR 1225-1262 as follows:

2
3 **10A NCAC 15 .2010 OTHER USE OF ELECTRONICALLY-PRODUCED RADIATION TO DELIVER**
4 **THERAPEUTIC RADIATION DOSAGE**

5 (a) A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to
6 deliver therapeutic radiation dosage, and which is not regulated under any existing category of therapeutic radiation
7 machine, until the applicant or licensee has, at a minimum, provided the Agency with:

8 (1) Documentation that equipment to be licensed conforms to the relevant International Electrotechnical
9 Commission standard, documentation of US Food and Drug Administration clearance, or
10 documentation of participation in a clinical research study approved by the licensee's Institutional
11 Animal Care and Use Committee.

12 (2) A detailed description of the device and its intended applications;

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

14 (4) Documentation of appropriate training for authorized users, authorized medical physicists, and other
15 personnel who will be involved in performing quality assurance tasks and setting up patients for
16 treatment or delivering treatment;

17 (5) Methodology for measurement of dosages to be administered to patients;

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

20 (7) Radiation safety precautions and instructions; and

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

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

24
25 History Note: Authority G.S. 104E-7;

26 Eff. October 1, 2025.

1 10A NCAC 15 .2011 is adopted as published in 39:19 NCR 1225-1262 as follows:

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3 **10A NCAC 15 .2011 EMERGING TECHNOLOGIES**

4 (a) Each registrant shall develop, implement, and maintain a dedicated quality management program to control the
5 processes used to administer therapeutic radiation with US Food and Drug Administration cleared emerging
6 technologies or previously unused features of a future or existing technology system.

7 (b) Implementation and on-going clinical use of the technology dated before the technology arrives at the facility or
8 the new features are used:

9 (1) Must include an explicit strategy to ensure quality of processes and patient safety.

10 (2) Must include approval from facility management and the radiation oncology safety team before the
11 technology arrives or new features are used.

12 (c) The quality management program shall be developed by the radiation oncology safety team.

13 (d) The quality management program shall address, at a minimum:

14 (1) Education and training about new technologies and features;

15 (2) A system and timeline for on-going competency assessment;

16 (3) A system for real-time recording of on-going issues related to the technology and clinical use of the
17 new technology or features;

18 (4) A strategy for timely investigation and adjudication of accidents and process deviations that may be
19 captured in the system developed in Subparagraph (b)(1) of this Rule;

20 (5) A strategy for routine review at intervals not to exceed 13 months of the clinical use of the new
21 technology or features which includes an assessment of the current use compared to Paragraph (b)
22 of this Rule and a plan to either update the clinical use plan or steps to bring the clinical use back
23 into compliance with Paragraph (b) of this Rule;

24 (6) A strategy to ensure quality of equipment functions;

25 (7) An strategy for ensuring quality after hardware and software updates and after equipment repair.

26 (e) The quality management program shall be developed and maintained in accordance with current published
27 recommendations from a recognized national professional association with expertise in the use of therapeutic radiation
28 technologies, such as the American Association of Physicists in Medicine, the American College of Radiology, and
29 the American Society for Radiation Oncology. In the absence of a protocol published by a national professional
30 association, the manufacturer's protocol or equivalent quality, safety, and security protocol shall be followed.

31 (f) New technology issues should be reported through the vendor or manufacturer, applicable regulatory agency alerts,
32 and customer service bulletins and be reviewed and addressed via a documented reporting system.

33
34 *History Note: Authority G.S. 104E-7;*

35 *Eff. October 1, 2025.*