Burgos, Alexander N

Subject: FW: Sept 25 RRC meeting

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Tuesday, September 23, 2025 10:01 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

Any requested speakers have until 5pm today to comply with 26 NCAC 05. 0105.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Tuesday, September 23, 2025 10:00 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: Re: Sept 25 RRC meeting

Then James will not need to speak. Thanks for your help.

Burgos, Alexander N

Subject: FW: Sept 25 RRC meeting

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Tuesday, September 23, 2025 9:47 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

We have not received any requests to speak for Thursday.

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Tuesday, September 23, 2025 9:46 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: Re: Sept 25 RRC meeting

I thought Jennifer O'Daniel was going to speak on the radiation protection rules. If she isn't, James will not need to speak.

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Tuesday, September 23, 2025 9:43:47 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

All requested speakers must comply with 26 NCAC 05. 0105. We have currently have no requested speakers on the agenda for Thursday.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Tuesday, September 23, 2025 7:45 AM

To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

Good morning,

Louis Brayboy, section chief of the Radiation Protection section, emailed me to let me know that James Albright would like to speak in rebuttal to Jennifer O'Daniels at the RRC meeting. Sorry for such short notice, I just saw it this morning,

I hope that is ok.

Thanks and have a great week.

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Wednesday, September 3, 2025 11:38 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

Shanah,

Please make sure to comply with 26 NCAC 05.0106 for the requested speaker.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Wednesday, September 3, 2025 11:13 AM
To: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

Great, thanks!

From: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Sent: Wednesday, September 3, 2025 11:12 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

Hello Shanah, they can speak on Webex or come in person. The request to speak should be sent to Travis and copy me.

Alexander Burgos
Paralegal
Office of Administrative Hearings
1711 New Hope Church Road
Raleigh NC, 27609

(984) 236-1940
Alexander.burgos@oah.nc.gov

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Wednesday, September 3, 2025 11:10 AM
To: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Subject: Sept 25 RRC meeting

Hey,

Hope you had a great weekend. I know of a professor that wants to speak at the Sept. 25 RRC meeting about the proposed Radiation Protection rules.

Does this person have to speak in person on can it be on Webex?

Who does she need to contact about wanting to participate?

Thanks for your help on this.

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

Work Cell: 919-896-9371
Office: 919-855-3481
Fax: 919-733-2757
shanah.black@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: 10A NCAC 15 phase 9 responses

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Tuesday, September 16, 2025 11:27 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 15 phase 9 responses

Thank you and have a great week.

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Tuesday, September 16, 2025 11:27 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 15 phase 9 responses

Good morning,

I'm satisfied with the changes to these rules. Please email all the submitted rules, as revised, to oah.rules@oah.nc.gov by September 19th at 5pm for RRC review. Please copy me and alexander.burgos@oah.nc.gov to the email.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: 10A NCAC 15 phase 9 responses
Attachments: 10A NCAC 15 .0903.docx; 10A NCAC 15 .0905.docx; 10A NCAC 15 .0908.docx; 10A NCAC 15 .0909.docx; 10A NCAC 15 .1001.docx; 10A NCAC 15 .1601.docx; 10A NCAC 15 .1903.docx; 10A NCAC 15 .1904.docx; 10A NCAC 15 .1905.docx; 10A NCAC 15 .1906.docx; 10A NCAC 15 .1907.docx; 10A NCAC 15 .1908.docx; 10A NCAC 15 .2003.docx; 10A NCAC 15 .2008.docx

---

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Tuesday, September 16, 2025 9:31 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 15 phase 9 responses

Good morning,

Attached are changes to the rules, highlighted in yellow.

Thanks

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.

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

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

10A NCAC 15 .0905 SHIELDING AND SAFETY DESIGN

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

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

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

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

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

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

~~(c)~~(g) Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with ~~Rules .1604 and .1611~~Rule .1601 of this Chapter.

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

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

10A NCAC 15 .0908 OPERATING PROCEDURES

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

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

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

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

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

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

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

(3) terminated as soon as possible.

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0908 Eff. February 1, ~~2015.~~2015;
Readopted Eff. October 1, 2025.

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

10A NCAC 15 .0909 RADIATION MONITORING REQUIREMENTS

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

(b) A radiation protection survey shall be performed and documented by a qualified expert registered by the ~~agency~~ Agency pursuant to Rule .0205 of this ~~Chapter,~~Chapter for the provision of Class VII, Class IX services or an Authorized Medical Physicist named on the licensee's license when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas. The licensee shall submit the report or a copy of the report ~~of the qualified expert~~ to the ~~agency~~ Agency by email to licensing.ram@dhhs.nc.gov or at one of the ~~address~~ addresses found in Rule ~~.0111~~.0111(a) of this Chapter.

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

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

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

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

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

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

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0909 Eff. February 1, ~~2015.~~2015;
Readopted 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 (e) 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;

Transferred and Recodified from 15A NCAC 11 .1001 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. October 1, 2025; October 1, 2023.

10A NCAC 15 .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;"

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

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

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

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

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

(21) 20.1405, "Public notification and public participation," except the ~~agency~~ Agency shall not publish a notice in the Federal Register;

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

(23) 20.1501, "General;"

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

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

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

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

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

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

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

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

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

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

(34) 20.1901, "Caution signs;"

(35) 20.1902, "Posting requirements;"

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

(37) 20.1904, "Labeling containers;"

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

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

(40) 20.2001, "General requirements;"

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

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

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

(44) 20.2005, "Disposal of specific wastes;"

(45) 20.2006, "Transfer for disposal and manifests;"

(46) 20.2007, "Compliance with environmental and health protection regulations;"

(47) 20.2008, "Disposal of certain byproduct material;"

(48) 20.2101, "General provisions;"

(49) 20.2102, "Records of radiation protection programs;"

(50) 20.2103, "Records of surveys;"

(51) 20.2104, "Determination of prior occupational dose;"

(52) 20.2105, "Records of planned special exposures;"

(53) 20.2106, "Records of individual monitoring results;"

(54) 20.2107, "Records of dose to individual members of the public;"

(55) 20.2108, "Records of waste disposal;"

(56) 20.2110, "Form of records;"

(57) 20.2201, "Reports of theft or loss of material." Persons registered with the ~~agency~~ 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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Report of acceptance testing and commissioning;

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

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

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

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

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

10A NCAC 15 .1904 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 ~~(1)~~ 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.

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

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

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

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

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

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

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

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

10A NCAC 15 .1905 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

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

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

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

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

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

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

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

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

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

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

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

(A) The licensee name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the individual who received the medical event;

(F) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(G) Certification that the licensee notified the patient, or the patient's responsible relative or guardian, and if not, why not, and

(H) The report shall not contain the patient's name or any other information that could lead to the identification of the patient;

(6) The licensee shall provide notification of the medical event to the referring physician no later than twenty-four hours after its discovery. The licensee shall also notify the individual who is the subject of the medical event no later than twenty-four hours after the initial notification, unless the authorized user or referring physician determines that, based on their medical judgment, informing the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within ~~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;*

Eff. October 1, 2025.

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 ~~1~~ one meter from the source shall be reduced to less than ~~1~~ one mGy (100 mrad) per hour.

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

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

and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

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

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

(B) Before medical use whenever spot-check measurements indicate that the output, for each specific mode and energy, differs by more than five percent from the output obtained at the last calibration, following reinstallation of the therapeutic radiation machine in a new location, following any repair of the therapeutic radiation machine that would likely impact the radiation output beyond the normal range of expected fluctuation, and

(C) At intervals not to exceed annually.

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

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

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

(4) A licensee shall use the dosimetry system described in Rule .1908 of this Section to measure the output for one set of exposure conditions. The remaining radiation measurements required in Part (3)(A) of this Paragraph may be made using a dosimetry system that indicates relative dose rates.

(5) The evaluations and measurements for:

(A) Acceptance, commissioning, and calibration measurements in Part (3)(A) of this Paragraph shall be performed under the direct supervision of an authorized medical physicist;

(B) full calibration measurements in Part (3)(B) of this Paragraph shall be performed by an authorized medical physicist or under the general supervision of an authorized medical physicist.

(6) A licensee shall maintain a record of each therapeutic radiation machine calibration for three years. The record must include:

(A) The date of the calibration;

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

(C) The results and an assessment of the calibrations; and

(D) The name of the authorized medical physicist who approves the calibration.

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

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

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

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

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

(e) Independent Verification of Therapeutic Radiation Machine Output:

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

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

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

(C) Biennially, thereafter.

(2) Verification may be obtained by:

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

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

(3) A licensee shall maintain a record of each independent verification of therapeutic radiation machine output for three ~~(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

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

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

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

10A NCAC 15 .1907 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 ~~1~~ one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch; and

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

(c) Authorized Medical Physicist Support.

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

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

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

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

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

(E) Perform calculations/assessments regarding medical events.

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

(d) Operating Procedures.

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

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

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

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

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

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

(1) Acceptance testing and commissioning shall be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies, that includes the American Association of Physicists in Medicine

(AAMP), the American College of Radiology and the American Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.

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

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

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

(C) At intervals not to exceed annually.

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

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

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

(f) Independent Verification of Therapeutic Radiation Machine Output

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

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

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

(C) Biennially, thereafter.

(2) Verification may be obtained by:

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

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

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

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

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

(g) Quality Assurance Checks.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[~~(A) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than10 percent; and~~

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

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

(A) A description of the calibration procedure; and

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

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

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

(b) Dosimetry system:

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

(A) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous ~~2~~ two years and after any servicing that may have affected system calibration; or

(B) The system must have been intercompared with another dosimetry system that was calibrated within the previous ~~2~~ two years by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than ~~2~~ two percent.

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

(A) The date;

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

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

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

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

10A NCAC 15 .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 ~~1~~one million electron volts and brachytherapy services and must

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

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

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

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

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

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

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

(4) Be certified by the American Board of Radiology in:

(A) Diagnostic Radiologic Physics;

(B) Diagnostic Medical Physics;

(C) Medical Nuclear Physics;

(D) Nuclear Medical Physics; or

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

(6) Has completed a structured educational program consisting of both:

(A) ~~200~~ Two hundred hours of classroom and laboratory training in the following areas: Radiation physics and instrumentation, radiation protection, radiation biology, and radiation dosimetry, and

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

(7) An individual identified on an Agency or an Agreement State medical accelerator license as an Therapeutic Radiation Machine Radiation Safety Officer on or before the effective date of this Rule

need not comply with Subparagraphs (1) through (6) of this Paragraph, except they must meet the training requirements in radiation safety, regulatory issues, and emergency procedures for the types of use which they were not authorized on or before this date; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Report of acceptance testing and commissioning;

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

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

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

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

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

10A NCAC 15 .2008 is adopted with changes as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .2008 CALIBRATION OF SURVEY INSTRUMENTS AND DOSIMETRY SYSTEMS

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

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

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

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

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

(3) To satisfy the requirements of Subparagraph (a)(2) of this Rule, the licensee [~~shall:~~] shall consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent.

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

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

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

(A) A description of the calibration procedure; and

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

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

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

(b) Dosimetry system:

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

(A) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous ~~2~~ two years and after any servicing that may have affected system calibration; or

(B) The system must have been intercompared with another dosimetry system that was calibrated within the previous ~~2~~ two years by National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than ~~2~~ two percent.

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

(A) The date;

(B) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (b)(1) and (b)(2);

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

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

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

Burgos, Alexander N

Subject: FW: 10A NCAC 15 phase 9 responses

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Monday, September 15, 2025 3:46 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 15 phase 9 responses

Thanks, will send them shortly.

Burgos, Alexander N

Subject: FW: 10A NCAC 15 phase 9 responses

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Monday, September 15, 2025 3:45 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 15 phase 9 responses

Good afternoon,

Thank you for the changes and responses. Please see below.

10A NCAC 15 .0908-.0909

- In (c), line 8 and elsewhere, please capitalize "agency" when referring to your specific agency.

10A NCAC 15 .1903

- On pg. 2, now line 8, you've deleted "three (3)" but not in other sections of the Rule (pg. 1, line 29; pg. 3, line 17; pg. 4, line 4). Numbers under 10 should be spelled out. Please be consistent with putting "(3)" after spelling it.

10A NCAC 15 .1907

- On pg. 3, line 1, add "(AAMP)" after "Medicine".

Please reply to this email at your earliest convenience.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: 10A NCAC 15 phase 9 responses
Attachments: 09.2025-Radiation Protection Commission-Request for Technical Changes Phase 9.docx; 10A NCAC 15 .0501.docx; 10A NCAC 15 .0608.docx; 10A NCAC 15 .0609.docx; 10A NCAC 15 .0802.docx; 10A NCAC 15 .0803.docx; 10A NCAC 15 .0901.docx; 10A NCAC 15 .0902.docx; 10A NCAC 15 .0903.docx; 10A NCAC 15 .0904.docx; 10A NCAC 15 .0905.docx; 10A NCAC 15 .0906.docx; 10A NCAC 15 .0907.docx; 10A NCAC 15 .0908.docx; 10A NCAC 15 .0909.docx; 10A NCAC 15 .0910.docx; 10A NCAC 15 .1001.docx; 10A NCAC 15 .1601.docx; 10A NCAC 15 .1901.docx; 10A NCAC 15 .1902.docx; 10A NCAC 15 .1903.docx; 10A NCAC 15 .1904.docx; 10A NCAC 15 .1905.docx; 10A NCAC 15 .1906.docx; 10A NCAC 15 .1907.docx; 10A NCAC 15 .1908.docx; 10A NCAC 15 .1909.docx; 10A NCAC 15 .1910.docx; 10A NCAC 15 .1911.docx; 10A NCAC 15 .2001.docx; 10A NCAC 15 .2002.docx; 10A NCAC 15 .2003.docx; 10A NCAC 15 .2004.docx; 10A NCAC 15 .2005.docx; 10A NCAC 15 .2006.docx; 10A NCAC 15 .2007.docx; 10A NCAC 15 .2008.docx; 10A NCAC 15 .2009.docx; 10A NCAC 15 .2010.docx; 10A NCAC 15 .2011.docx

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Monday, September 15, 2025 8:45 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 10A NCAC 15 phase 9 responses

Good morning,

Hope you both had good weekends. I am attaching the rest of the technical change response for the radiation protection rules.

Thanks for you help on these.

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

Work Cell: 919-896-9371
Office: 919-855-3481
Fax: 919-733-2757
shanah.black@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

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

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

The imposition of a question implies that the rule as written is unclear or there is some ambiguity. If the request includes questions and you do not understand the question, please contact the reviewing attorney to discuss. Failure to respond may result in a staff opinion recommending objection.

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

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

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

Note the following general instructions:

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

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0903

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In line 1, add "with changes" after "readopted".

Response: Updated in text.

In (a)(4), lines 22-23, "medical use" and "shall meet the additional requirements of Section .1900 of this Chapter" were not published in the Register. Why does this not constitute a "substantial change" pursuant to G.S. 150B-21.2(g)?

Response: Deleted the text and updated the rule. The term "medical use" is redundant since the rule states "therapeutic use," which is a medical use. Likewise, the partial sentence "shall meet the additional requirements of Section .1900 of this Chapter" is redundant because Rule .0901(b)(2) states that licensees for the treatment of humans (medical use) use must comply with the rules in Section .1900. This additional text was intended to clarify the rule but it is unnecessary.

In line 25, capitalize "state".

Response: Updated in text.

All of paragraph (a)(5) was not published in the Register. Why does this not constitute a "substantial change" pursuant to G.S. 150B-21.2(g)?

Response: Deleted the text and updated the rule. This was intended to be a clarifying paragraph, but it is redundant because Rule .0901(b)(3) states that veterinary users must comply with the requirements of Section .2000.

On pg. 2, in (b)(3), line 36, the website address was not published in the Register. Why does this not constitute a "substantial change" pursuant to G.S. 150B-21.2(g)?

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

Response: Page 2, (b)(3), line 35, shows www.ncradiation.net/rms/rmsforms2.htm as the web address to obtain copies of applications to be submitted to the agency for licensing purposes. This web address is no longer active as was pointed out by a member of the public in their comments during the public comment period. The correct web address is https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm as it appears on pg. 2, line 36, in (b)(3).

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0904

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In (a)(2), line 7, add a comma after "conditions".

Response: Updated in text.

In (b), line 10, capitalize "radiation safety officer".

Response: Updated in text.

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0905

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In lines 4 and 10, add a comma after "use".

Response: Updated in text.

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0906

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In (a), line 4, add a comma after "readouts".

Response: Updated in text.

In (e), line 12, avoid using "i.e.", per the OAH Style Guide (2.8).

Response: Deleted the Latin abbreviation "i.e" from (e), line 12, on page 4, and substituted the text that the Latin abbreviation was intended to substitute for, '…meaning that safety interlocks are…'

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0907

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In (a), line 5, consider deleting "when, and" and deleting the comma after the second "when".

Response: Updated in text.

In (a), line 7, consider deleting "when, and" and deleting the comma after the second "when".

Response: Updated in text.

In (b), line 9, what is the meaning of "possible creation" as it appears unclear and ambiguous.

Response: Deleted "the possible creation of such" from the rule text in (b) line 9, because it may be unclear as you noted, and added clarifying text. That part of the sentence in (b) line 9 and 10 now reads "…operating equipment capable of creating a…"

In (c), consider adding "All" to the beginning and deleting "temporary or otherwise".

Response: Updated in text.

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0908

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In (b), line 5, consider deleting "routinely" or be more specific since it's vague and amorphous.

Response: Deleted and updated in text

In (c), line 8 and elsewhere, what "agency" is being referred to? Is "agency" defined as the "Radiation Protection Commission" in a different rule?

Response: The term "agency" is defined as "the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section" in 10A NCAC 15 .0103(a)(2). The Radiation Protection Section is responsible for licensing and inspecting licensees for compliance with 10A NCAC 15.

In (b), line 9, what is the meaning of "possible creation" as it appears unclear and ambiguous.

Response: I cannot find this item in Rule .0908. I think this may have been inadvertently carried over from your comment on Rule .0907.

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0909

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In (b), line 8 and elsewhere, what "agency" is being referred to? Is "agency" defined as the "Radiation Protection Commission" in a different rule?

Response: The term "agency" is defined as "the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section" in 10A NCAC 15 .0103(a)(2).

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1902

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In line 1, add "with changes" after "adopted".

Response: Updated in text.

On pg. 2, in (30), line 29, "~~(.0206(a)(7)(A))~~" was published in the Register, but ".0214(a)(7)(A)" was not published in the Register. Why does this not constitute a "substantial change" pursuant to G.S. 150B-21.2(g)?

Response: The citation appearing on pg. 2, in (30), line 29, [~~.0206(a)(7)(A)~~] is incorrect and was identified by a member of the public during the public comment period. The correct rule citation is .0214(a)(7)(A) as it appears on pg. 2, in (30), line 29. The definition of a "Qualified Expert" in (30) on pg. 2, line 28 includes individuals who meet the "training and experience requirements of…" The title of Rule .0214 is "Training And Educational Requirements For Equipment Services," and the rule contains those items. The title of Rule .0206 is "Reports of Installation" and the rule does not contain training and education requirements.

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1903

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In line 1, add "with changes" after "adopted".

Response: Updated in text.

In (b), line 8, replace "regulations" with "rules".

Response: Updated in text.

In (c), line 11, capitalize "subpart". Do the same on pg. 2, (e), line 11, and on pg. 4, (m), line 12.

Response: Updated in text.

In (d), line 33 and 36, consider deleting "ing" at the end of "maintaining". Do the same on pg. 2, line 1.

Response: Updated in text.

In (d)(1)(A)-(B), lines 34-35, should "radiological physics" and "medical physics" be capitalized as was done in (e)(4)(A)-(D)?

Response: Updated in text.

On pg. 2, (C), line 6, you've added "(3)" after some references to "three years" but not in others. Please be consistent.

Response: Updated in text.

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1904

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In line 1, add "with changes" after "adopted".

Response: Updated in text.

On pg. 2, (c), line 14, ~~"(.0927)"~~ was published in the Register, but ".1908" was not published in the Register. Why does this not constitute a "substantial change" pursuant to G.S. 150B-21.2(g)?

Response: The correction to this rule to cite rule .1908 on pg. 2, (c), line 14, was made in response to the public comment that identified the error. Rule .0927 does not exist, and the citation was made in error on page 2, (c), line 14, prior to publication of the rules. The rules in Section .0900 are numbered from .0901 to .0910. This error occurred during rule development when the working group initially attempted to place all the accelerator rules for licensing, industrial use, medical use, and veterinary use in Section .0900. This effort quickly became convoluted and confusing, so the working group focused on writing Section .0900 for licensing all accelerators and for the industrial use of accelerators and developed Sections .1900 and .2000 for medical use and veterinary use, respectively. I attempted to find and correct all these errors prior to publication but missed the one that the public identified during the public comment period.

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1905

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In line 1, add "with changes" after "adopted".

Response: Updated in text.

In line 5, consider deleting "to provide high confidence" and add "ensures" before "radiation". The phrase "high confidence" is unclear and ambiguous.

Response: Updated in text.

In line 6, delete "as a minimum" because it's unnecessary.

Response: Updated in text.

In (a)(1)(A), line 9, delete the comma after "If". On line 11, replace "will be" with "shall".

Response: Updated in text. "Shall" is also correct – it works as well as "will be" and it is an item the agency inspects against.

In (2)(E), line 26, what is the definition of "table-shift policy"?

Response: The term "table-shift policy" (in (2)(E), on line 28) refers to the set of instructions given to staff who administer therapeutic radiation (therapists) to patients using accelerators. Patients are placed in a supine position on the "table," a bed-like structure that is part of the accelerator. The table is positioned and moved during treatment according to the treatment plan to deliver the therapeutic dose to the correct region of the patient's body. Minor differences in patient morphology, positioning on the table and other small factors affect the delivery of the prescribed dose every time the patient is treated. To account for these minor differences, therapists adjust (shift) the position of the table prior to treatment. The term "table-

shift policy" is such a part of therapeutic radiation oncology lexicon that nobody thought it needed a separate definition when on lines 28 – 29, the rule states that the table-shift policy describes the "action to be taken by staff in the event shifts are used for patient or human research subject setup".

On pg. 2, (5), line 29, you've added "(15)" after some numerical references "three (3) years" but not in others. Please be consistent throughout the Rule.

Response: Updated in text.

On pg. 3, line 19, capitalize "section".

Response: Updated in text.

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1908

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In line 1, add "with changes" after "adopted".

Response: Updated in text.

In (a)(3), lines 13-15, "shall consider" through "20 percent" was not published in the Register. Why does this not constitute a "substantial change" pursuant to G.S. 150B-21.2(g)?

Response: (a)(3), lines 13 – 15, were revised based upon comments received from the public during the public comment period after the rule was published. The public felt that the 10 percent expectation on (a)(3)(A), line17, was too restrictive and not in alignment with similar requirements for the therapeutic use of radioactive material for external radiation exposure in the treatment of cancer. The public also opined that having different expectations for a single accelerator calibration requirement would lead licensees to make unnecessary mistakes while complying with (a)(3) and that the less restrictive requirement will not negatively impact patient care.

All of paragraphs (3)(A) and (B) were not published in the Register. Why does this not constitute a "substantial change" pursuant to G.S. 150B-21.2(g)?

Response: Refer also to the explanation for the change made to (a)(3), lines 13 – 15. Both (a)(3)(A) and (B) deal with accelerator calibration requirements. Because the public comment to change the expectation from 10 percent to 20 percent was made to (a)(3)(A), it is more concise to delete (a)(3)(A) and (B) than to change (a)(3)(A), line 17, to 20 percent and to keep (a)(3)(B) as published. Although there appears to be a 'real' difference between (a)(3)(A) and (a)(3)(B), in practice there isn't. (a)(3)(A) and (a)(3)(B) are both means to achieve the same goal as stated in (a)(3) on lines 13 – 15. Once the expectation for (a)(3)(A) matched the expectation for (a)(3)(B) there was no reason to differentiate between either Part, so the subparagraph (a)(3) was developed.

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .2008

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

In line 1, add "with changes" after "adopted".

Response: Updated in text.

In (a)(3), lines 14-16, "shall consider" through "20 percent" was not published in the Register. Why does this not constitute a "substantial change" pursuant to G.S. 150B-21.2(g)?

Response: Please refer to the explanation for .1908(a)(3), above. The explanation for the change made to .2008(a)(3) is identical to the explanation made for .1908, with the exception that it applies to .2008.

All of paragraphs (3)(A) and (B) were not published in the Register. Why does this not constitute a "substantial change" pursuant to G.S. 150B-21.2(g)?

Response: Please refer to the explanation for .1908(a)(3)(A) and (B), above. The explanation for the change made to .2008(a)(3)(A) and (B) is identical to the explanation made for .1908, with the exception that it applies to .2008.

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

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

SECTION .0500 - INDUSTRIAL RADIOGRAPHY X-RAY MACHINES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(9) 10 CFR 34.43, "Training;"

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

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

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

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

(14) 10 CFR 34.51, "Surveillance;"

(15) 10 CFR 34.53, "Posting;"

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

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

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

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

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

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

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

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

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

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

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

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

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0501 Eff. February 1,2015;
Pursuant to G.S.150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. <u>*October 1, 2025;*</u> *May 1, 2024.*

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

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

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

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

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

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

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

10A NCAC 15 .0802 DEFINITIONS

In addition to terms found in Rule ~~.0104~~.0103 of this Chapter, the following definitions shall apply to this Section:

(1) "Accredited bomb squad" means a law enforcement agency utilizing certified bomb technicians.

(2) "Accessible surface" means the external or outside surface of the enclosure or housing provided by the manufacturer or designer of the RGD. This includes the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware, and including the plane across the exterior edge of any opening.

(3) "Analytical RGD equipment" means equipment that uses electronic means to generate ionizing radiation for the purpose of examining the microstructure of materials using direct x-ray transmission, x-ray diffraction, x-ray fluorescence, and x-ray spectroscopy.

(4) "Analytical RGD system" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

(5) "Certified bomb technician" means a member of an accredited bomb squad who has successfully completed the FBI Hazardous Devices School. Information pertaining to this program can be found at http://www.fbi.gov/about-us/cirg/hazardous-devices.

(6) "Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to meet the certification requirements specified in 21 C.F.R. 1020.40, as incorporated by reference in Rule ~~.0117~~.0104 of this Chapter.

(7) "Certified cabinet x-ray system" means an RGD utilized in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed. These systems shall be certified in accordance with 21 CFR 1010.2, as incorporated by reference in Rule ~~.0117~~.0104 of this Chapter, as being manufactured and assembled pursuant to the provisions of 21 C.F.R. 1020.40, as incorporated by reference in Rule ~~.0117~~.0104 of this Chapter.

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

(9) "Control panel" means the part of the x-ray control where the switches, knobs, pushbuttons, and other hardware are, located for manually setting the technique factors.

(10) "Electron Beam Device" means any device using electrons below 1MeV to heat, join, or otherwise irradiate materials.

(11) "Enclosed beam RGD" means an RGD with all possible x-ray beam paths contained in a chamber, coupled chambers, or other beam-path-confinement devices, to prevent any part of the body from intercepting the beam during normal operations. Normal access to the primary beam path, such as a sample chamber door, shall be interlocked with the high voltage of the x-ray tube or the shutter for the beam to be considered "enclosed." An open-beam device placed in an interlocked enclosure is considered an "enclosed beam" unless there are provisions for routine bypassing of the interlocks.

(12) "Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected radiation exposure of an individual exceeding administrative or regulatory limits found in Rule 10A NCAC 15 .1601(a)(8) and .1601(a)(15). This procedure shall include the names and telephone numbers of individuals to be contacted, as well as directives for processing individual monitoring devices.

(13) "Fail-safe characteristics" means a design feature that causes the radiation beam to terminate, port shutters to close, or otherwise prevents emergence of the primary beam upon the failure of a safety or warning device. For example, if an "X-ray On" light indicator, shutter indicator, or interlock fails, the radiation beam shall terminate.

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

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

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

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

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

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

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

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

(A) the primary beam;

(B) scatter radiation emanating from other components; and

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

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

(23) "Local components" means part of an RGD x-ray system and include areas that are struck by x rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

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

(25) "Normal operating procedures" means step-by-step instructions necessary to accomplish a task. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures that are related to radiation safety.

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

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

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

(29) "Radiation generating device (RGD)" means any system, device, subsystem, or machine component that may generate, by electronic means, x-rays or particle radiation above 5 keV, but below 1 MeV, and not used for healing parts on humans or animals. RGDs may be used as a:

(A) mobile RGD;

(B) portable RGD; or

(C) stationary RGD.

(30) "Remote components" means parts of an RGD x-ray system that are not struck by x-rays, such as power supplies, transformers, amplifiers, readout devices, and control panels.

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

(32) "Scattered radiation" means radiation, other than leakage radiation, that during passage through matter, has been deviated in direction or has been modified by a decrease in energy.

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

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

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

(36) "Shutter" means an adjustable device, generally made of lead or other high atomic number material, fixed to a source assembly housing to intercept, block, or collimate the primary beam.

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

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

(39) "Stray radiation" means the sum of leakage and scatter radiation emanating from the source assembly or other components, except for the primary beam, and radiation produced when the beam on switch or timer is not activated.

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

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

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0802 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. October1, 2025; November 1, 2024.

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.

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

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

SECTION .0900 - REQUIREMENTS FOR PARTICLE ACCELERATORS

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

10A NCAC 15 .0901 PURPOSE AND SCOPE

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

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

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

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

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

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

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

History Note: *Authority G.S. 104E-7; 104E-9(a)(8); 104E-19(a);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1989; July 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0901 Eff. February 1, ~~2015.~~2015;
Readopted Eff. October 1, 2025.

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

10A NCAC 15 .0902 LICENSING REQUIREMENTS

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0902 Eff. February 1, ~~2015.~~2015;
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. Applications and supporting material shall be submitted to the agency via email to Licensing.ram@dhhs.nc.gov unless directed otherwise by the agency:

(1) Persons applying for new accelerator licenses, or for the renewal of existing accelerator licenses, shall submit an Application for Accelerator License. The instructions for completing the application printed on the application form shall be followed. The following information shall appear on the application:

(A) legal business name and mailing address;

(B) physical address(es) where accelerators shall be used or possessed. The application shall indicate if accelerators shall be used at temporary jobsites;

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

(3) Applications specified in this Rule are available at: [~~www.ncradiation.net/rms/rmsforms2.htm(Rev01).htm~~] https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

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

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

10A NCAC 15 .0904 LIMITATIONS

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

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

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

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

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0904 Eff. February 1, ~~2015.~~2015;
Readopted Eff. October 1, 2025.

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

10A NCAC 15 .0905 SHIELDING AND SAFETY DESIGN

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

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

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

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

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

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

~~(c)~~(g) Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with ~~Rules .1604 and .1611~~Rule .1601 of this Chapter.

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

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

10A NCAC 15 .0906 CONTROLS AND INTERLOCK SYSTEMS

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

(b) All entrances into a target room or other high radiation area shall conform to the requirements of Rule ~~.1615~~.1601 of this Chapter.

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

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

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

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0906 Eff. February 1, ~~2015.~~2015;
Readopted Eff. October 1, 2025.

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

10A NCAC 15 .0907 WARNING DEVICES

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

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

(c) ~~Barriers,~~ All barriers ~~temporary or otherwise,~~ and pathways leading to high radiation areas shall be identified in accordance with Rule ~~.1624~~.1601 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0907 Eff. February 1, ~~2015.~~2015;
Readopted Eff. October 1, 2025.

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

10A NCAC 15 .0908 OPERATING PROCEDURES

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

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

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

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

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

(1) authorized by the radiation safety officer;

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

(3) terminated as soon as possible.

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0908 Eff. February 1, ~~2015.~~2015;
Readopted Eff. October 1, 2025.

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

10A NCAC 15 .0909 RADIATION MONITORING REQUIREMENTS

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

(b) A radiation protection survey shall be performed and documented by a qualified expert registered by the agency pursuant to Rule .0205 of this ~~Chapter,~~Chapter for the provision of Class VII, Class IX services or an Authorized Medical Physicist named on the licensee's license when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas. The licensee shall submit the report or a copy of the report ~~of the qualified expert~~ to the agency by email to licensing.ram@dhhs.nc.gov or at one of the ~~address~~ addresses found in Rule ~~.0111~~.0111(a) of this Chapter.

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

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

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

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

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

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

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0909 Eff. February 1, ~~2015.~~2015;
Readopted October 1, 2025.

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

10A NCAC 15 .0910 VENTILATION SYSTEMS

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

(b) The licensee shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area in excess of the limits specified in Rule ~~.1611~~.1601 of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0910 Eff. February 1, ~~2015.~~2015;
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 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 as instructed by Rule .0111 of this Chapter in lieu of the NRC;

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) licensee or registrant name;

(B) license or registration number;

(C) name of the individual requesting the exemption;

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

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

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

(b) Notwithstanding Subparagraph (a)(5) of this Rule, registrants temporarily working in North Carolina and licensees working in North Carolina under reciprocity may post the Notice to Employees, NRC Form 3, or an equivalent form issued under the authority of the regulatory agency issuing the registration or license.

(c) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part019/.

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

Transferred and Recodified from 15A NCAC 11 .1001 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. October 1, 2025; October 1, 2023.

10A NCAC 15 .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 as instructed by Rule .0111 of this Chapter in lieu of the NRC;

(7) 20.1101, "Radiation protection programs;"

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

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

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

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

(12) 20.1206, "Planned special exposures;"

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

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

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

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

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

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

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

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

(21) 20.1405, "Public notification and public participation," except the agency shall not publish a notice in the Federal Register;

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

(23) 20.1501, "General;"

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

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

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

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

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

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

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

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

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

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

(34) 20.1901, "Caution signs;"

(35) 20.1902, "Posting requirements;"

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

(37) 20.1904, "Labeling containers;"

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

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

(40) 20.2001, "General requirements;"

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

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

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

(44) 20.2005, "Disposal of specific wastes;"

(45) 20.2006, "Transfer for disposal and manifests;"

(46) 20.2007, "Compliance with environmental and health protection regulations;"

(47) 20.2008, "Disposal of certain byproduct material;"

(48) 20.2101, "General provisions;"

(49) 20.2102, "Records of radiation protection programs;"

(50) 20.2103, "Records of surveys;"

(51) 20.2104, "Determination of prior occupational dose;"

(52) 20.2105, "Records of planned special exposures;"

(53) 20.2106, "Records of individual monitoring results;"

(54) 20.2107, "Records of dose to individual members of the public;"

(55) 20.2108, "Records of waste disposal;"

(56) 20.2110, "Form of records;"

(57) 20.2201, "Reports of theft or loss of material." Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter shall make telephone reports of the theft or loss of radiation machines in accordance with 20.2201(a)(1)(i);

(58) 20.2202, "Notifications of incidents;"

(59) 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits," except that 20.2203(c) shall not apply;

(60) 20.2204, "Reports of planned special exposures;"

(61) 20.2205, "Reports to individuals exceeding dose limits;"

(62) 20.2206, "Reports of individual monitoring," except that 20.2206(a)(1), and 20.2206(a)(3) through (a)(5) shall not apply. The report required by 20.2206(b) shall be submitted upon request by the agency in lieu of the requirements of 20.2206(c);

(63) 20.2207, "Reports of transactions involving nationally tracked sources." Notwithstanding Subparagraph (a)(6) of this Rule, reports required by this Subparagraph shall be made in accordance with 20.2207(f) and (g);

(64) 20.2301, "Application for exemptions," except that the request for exemption shall be made on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:

(A) licensee or registrant name;

(B) license or registration number;

(C) name and contact information for the individual requesting the exemption;

(D) a description of the exemption being requested, and

(E) an explanation describing why the exemption is necessary;

(65) 20.2302, "Additional requirements;"

(66) Appendix A to Part 20, "Assigned Protection Factors for Respirators;"

(67) Appendix B to Part 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage;"

(68) Appendix C to Part 20, "Quantities of Radioactive Material Requiring Labeling;"

(69) Appendix E to Part 20, "Nationally Tracked Source Thresholds," and

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

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

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

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

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

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

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

SECTION .1900 – THERAPEUTIC RADIATION MACHINES

10A NCAC 15 .1901 PURPOSE AND SCOPE

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

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

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

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

10A NCAC 15 .1902 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.

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

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

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

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

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

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

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

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

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

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

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

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

History Note: *Authority G.S. 104E-7;*
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)~~ 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)~~ 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) 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) days per calendar year under the following conditions:

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

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

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

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

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

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

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

(1) Report of acceptance testing and commissioning;

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

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

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

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

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

10A NCAC 15 .1904 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 (1) 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.

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

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

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

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

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

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

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

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

10A NCAC 15 .1905 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

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

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

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

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

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

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

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

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

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

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

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

(A) The licensee name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the individual who received the medical event;

(F) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(G) Certification that the licensee notified the patient, or the patient's responsible relative or guardian, and if not, why not, and

(H) The report shall not contain the patient's name or any other information that could lead to the identification of the patient;

(6) The licensee shall provide notification of the medical event to the referring physician no later than twenty-four hours after its discovery. The licensee shall also notify the individual who is the subject of the medical event no later than twenty-four hours after the initial notification, unless the authorized user or referring physician determines that, based on their medical judgment, informing the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four 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 days after its discovery.

(9) The licensee shall retain a record of each unintended deviation for three years. The record must contain the following:

(A) The licensee name and the names of the individuals involved;

(B) A unique identification number, if one has been assigned, of the individual who is the subject of the unintended deviation;

(C) A brief description of the event; why it occurred; the effect, if any, on the individual;

(D) The actions, if any, taken or planned to prevent recurrence; and

(E) Whether the licensee notified the individual, or the individual's responsible relative or guardian; and, if not, whether such failure to notify was based on guidance from the referring physician.

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

Eff. October 1, 2025.

10A NCAC 15 .1906 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 1 meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

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

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

and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

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

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

(B) Before medical use whenever spot-check measurements indicate that the output, for each specific mode and energy, differs by more than five percent from the output obtained at the last calibration, following reinstallation of the therapeutic radiation machine in a new location, following any repair of the therapeutic radiation machine that would likely impact the radiation output beyond the normal range of expected fluctuation, and

(C) At intervals not to exceed annually.

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

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

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

(4) A licensee shall use the dosimetry system described in Rule .1908 of this Section to measure the output for one set of exposure conditions. The remaining radiation measurements required in Part (3)(A) of this Paragraph may be made using a dosimetry system that indicates relative dose rates.

(5) The evaluations and measurements for:

(A) Acceptance, commissioning, and calibration measurements in Part (3)(A) of this Paragraph shall be performed under the direct supervision of an authorized medical physicist;

(B) full calibration measurements in Part (3)(B) of this Paragraph shall be performed by an authorized medical physicist or under the general supervision of an authorized medical physicist.

(6) A licensee shall maintain a record of each therapeutic radiation machine calibration for three years. The record must include:

(A) The date of the calibration;

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

(C) The results and an assessment of the calibrations; and

(D) The name of the authorized medical physicist who approves the calibration.

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

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

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

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

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

(e) Independent Verification of Therapeutic Radiation Machine Output:

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

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

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

(C) Biennially, thereafter.

(2) Verification may be obtained by:

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

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

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

(g) Operating Procedures:

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

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

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

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

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

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

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

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

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

10A NCAC 15 .1907 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 1 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, the American College of Radiology and the American Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.

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

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

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

(C) At intervals not to exceed annually.

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

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

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

(f) Independent Verification of Therapeutic Radiation Machine Output

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

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

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

(C) Biennially, thereafter.

(2) Verification may be obtained by:

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

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

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

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

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

(g) Quality Assurance Checks.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[~~(A) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than10 percent; and~~

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

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

(A) A description of the calibration procedure; and

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

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

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

(b) Dosimetry system:

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

(A) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(B) The system must have been intercompared with another dosimetry system that was calibrated within the previous 2 years by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent.

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

(A) The date;

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

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

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

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

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

10A NCAC 15 .1909 SHIELDING AND SAFETY DESIGN REQUIREMENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(8) Radiation safety precautions and instructions; and

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

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

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

10A NCAC 15 .1911 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.

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

SECTION .2000 - VETERINARY USES OF THERAPEUTIC RADIATION MACHINES

10A NCAC 15 .2001 PURPOSE AND SCOPE

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

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

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

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

10A NCAC 15 .2002 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.

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

(35) “Supervision” shall be defined as follows:

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

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

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

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

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

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

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

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

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

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

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

10A NCAC 15 .2003 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 1 million electron volts and brachytherapy services and must

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

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

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

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

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

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

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

(4) Be certified by the American Board of Radiology in:

(A) Diagnostic Radiologic Physics;

(B) Diagnostic Medical Physics;

(C) Medical Nuclear Physics;

(D) Nuclear Medical Physics; or

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

(6) Has completed a structured educational program consisting of both:

(A) 200 hours of classroom and laboratory training in the following areas: Radiation physics and instrumentation, radiation protection, radiation biology, and radiation dosimetry, and

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

(7) An individual identified on an Agency or an Agreement State medical accelerator license as an Therapeutic Radiation Machine Radiation Safety Officer on or before the effective date of this Rule need not comply with Subparagraphs (1) through (6) of this Paragraph, except they must meet the

training requirements in radiation safety, regulatory issues, and emergency procedures for the types of use which they were not authorized on or before this date; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Report of acceptance testing and commissioning;

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

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

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

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

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

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

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

(a) Protection Surveys:

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

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

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

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

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

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

(C) After relocating the therapeutic radiation machine;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10A NCAC 15 .2005 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

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

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

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

10A NCAC 15 .2006 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 ± five percent of radiations used medically; and,

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

(4) A licensee shall use the dosimetry system described in Rule .2008 of this Section to measure the output for one set of exposure conditions. The remaining radiation measurements required in Part (3)(A) of this Paragraph may be made using a dosimetry system that indicates relative dose rates.

(5) The evaluations and measurements for:

(A) Acceptance, commissioning, and calibration measurements required by Part (3)(A) of this Paragraph shall be performed under the direct supervision of an authorized medical physicist;

(B) Full calibration measurements required by Part (3)(B) of this Paragraph shall be performed by an authorized medical physicist or under the general supervision of an authorized medical physicist.

(6) A licensee shall maintain a record of each therapeutic radiation machine calibration for three years. The record must include:

(A) The date of the calibration;

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

(C) The results and an assessment of the calibrations; and

(D) The name of the authorized medical physicist who approves the calibration.

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

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

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

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

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

(e) Independent Verification of Therapeutic Radiation Machine Output

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

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

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

(C) Biennially, thereafter.

(2) Verification may be obtained by:

(A) irradiating dosimeters from an American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory; or

(B) evaluation by a registered qualified expert using an independent dosimetry system meeting the requirements of Rule .0947 of this Chapter.

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

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

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

(f) Quality Assurance Checks.

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

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

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

(B) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify

that the quality assurance check shall be performed during the calibration specified in Paragraph (d) of this Rule. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in Paragraph (d) of this Rule shall be stated.

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

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

(5) The licensee shall use the dosimetry system described in Rule .2008 of this Section to make the quality assurance check required in Subparagraph (2) of this Paragraph;

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

(g) Operating Procedures.

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

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

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

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

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

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

(h) Electronic brachytherapy devices are subject to the requirements of Rule .2011 of this Chapter and are exempt from the requirements of this Rule.

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

10A NCAC 15 .2007 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

therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch; and

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

(c) Authorized Medical Physicist Support.

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

(A) Calibrations required by Paragraph (d) of this Rule and the protection surveys required by Rule .2004(a) of this Section;

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

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

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

(E) Perform calculations and assessments regarding medical events.

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

(d) Operating Procedures.

(1) No person shall be in the treatment space during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of Rule .2004(a), and Paragraphs (d), (e) and (f) of this rule have been met;

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

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

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

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

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

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

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

(B) Before medical use under the following conditions: Whenever spot-check measurements indicate that the output, for each specific mode and energy, differs by more than five percent from the output obtained at the last calibration, following reinstallation of the therapeutic radiation machine in a new location, or following any repair of the therapeutic radiation machine that would likely impact the radiation output beyond the normal range of expected fluctuation, and at intervals not exceeding annually.

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

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

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

(f) Independent Verification of Therapeutic Radiation Machine Output

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

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

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

(C) Biennially, thereafter.

(2) Verification may be obtained by:

(A) the authorized medical physicist irradiating dosimeters from an American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory; or

(B) evaluation by an independent registered qualified expert using an independent dosimetry system meeting the requirements of Rule .2008 of this Chapter.

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

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

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

(g) Quality Assurance Checks.

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

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

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

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

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

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

(5) The licensee shall use the dosimetry system described in Rule .2008 of this Section to make the quality assurance check required in Paragraph (f) of this rule;

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

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

10A NCAC 15 .2008 is adopted with changes as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .2008 CALIBRATION OF SURVEY INSTRUMENTS AND DOSIMETRY SYSTEMS

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

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

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

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

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

(3) To satisfy the requirements of Subparagraph (a)(2) of this Rule, the licensee [~~shall:~~] shall consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent.

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

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

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

(A) A description of the calibration procedure; and

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

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

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

(b) Dosimetry system:

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

(A) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(B) The system must have been intercompared with another dosimetry system that was calibrated within the previous 2 years by National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent.

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

(A) The date;

(B) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (b)(1) and (b)(2);

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

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

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

10A NCAC 15 .2009 is adopted as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .2009 SHIELDING AND SAFETY DESIGN REQUIREMENTS

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

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

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

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

10A NCAC 15 .2010 is adopted as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .2010 OTHER USE OF ELECTRONICALLY-PRODUCED RADIATION TO DELIVER THERAPEUTIC RADIATION DOSAGE

(a) A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not regulated under any existing category of therapeutic radiation machine, until the applicant or licensee has, at a minimum, provided the Agency with:

(1) Documentation that equipment to be licensed conforms to the relevant International Electrotechnical Commission standard, documentation of US Food and Drug Administration clearance, or documentation of participation in a clinical research study approved by the licensee's Institutional Animal Care and Use Committee.

(2) A detailed description of the device and its intended applications;

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

(4) Documentation of appropriate training for authorized users, authorized medical physicists, and other personnel who will be involved in performing quality assurance tasks and setting up patients for treatment or delivering treatment;

(5) Methodology for measurement of dosages to be administered to patients;

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

(7) Radiation safety precautions and instructions; and

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

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

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

10A NCAC 15 .2011 is adopted as published in 39:19 NCR 1225-1262 as follows:

10A NCAC 15 .2011 EMERGING TECHNOLOGIES

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

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

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

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

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

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

(1) Education and training about new technologies and features;

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

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

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

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

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

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

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

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

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

Burgos, Alexander N

Subject: FW: September RRC Meeting

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Monday, September 8, 2025 2:55 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: September RRC Meeting

Great! Thanks Travis. Will hopefully get the other technical changes to you this week.

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Monday, September 8, 2025 2:54 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: September RRC Meeting

Good afternoon,

The change made to Form 0400 for 10A NCAC 15 .0205 is sufficient.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: September RRC Meeting

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Monday, September 8, 2025 2:55 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: September RRC Meeting

Great! Thanks Travis. Will hopefully get the other technical changes to you this week.

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Monday, September 8, 2025 2:54 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: September RRC Meeting

Good afternoon,

The change made to Form 0400 for 10A NCAC 15 .0205 is sufficient.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: September RRC Meeting
Attachments: 09.2025-Radiation Protection Commission-Request for Technical Changes Phase 8.docx; Form0400PermRule 10 NCAC 15 .0205 (002).docx

---

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Thursday, September 4, 2025 1:05 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: September RRC Meeting

Good afternoon,

These are the changes for the phase 8 radiation protection rules. Please let me know if this is sufficient.

Thanks

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

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0205

DEADLINE FOR RECEIPT: September 17, 2025

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

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

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

The Permanent Rule Form 0400, Section 9B says "the federal regulations in 21 CFR 1020.30(d) are proposed for incorporation by reference…into Rule 10A NCAC 15 .0205(f)(2)(A)". Where in this Rule are the federal regulations incorporated?

Response:
The Permanent Rule Form 0400, Section 9B where is says " Rule 10ANCAC 15 .0205(f)(2)(A)", should read 10A NCAC .0205(g)(2)(B). The form has been updated and submitted with this document.

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

Travis Wiggs
Commission Counsel
Submitted to agency: September 3, 2025

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: N.C. Radiation Protection Commission

2. Rule citation & name (name not required for repeal): 10A NCAC 15 .0205/SERVICE PROVIDER REPSONSIBILITIES

3. Action:
☐ **ADOPTION** ☐ **AMENDMENT** ☐ **REPEAL** ☒ **READOPTION** ☐ **REPEAL through READOPTION**

4. Rule exempt from RRC review?
☐ **Yes. Cite authority:**
☒ **No**

5. Rule automatically subject to legislative review?
☒ **Yes. Cite authority: SL 2023-91 .S.2**
☐ **No**

6. Notice for Proposed Rule:

☒ **Notice Required**
Notice of Text published on: 5/15/2025
Link to Agency notice: https://info.ncdhhs.gov/dhsr/ruleactions.html
Hearing on: 6/2/2025
☒ **The requirements listed in G.S. 150B-19.1(c)(1)-(5) were posted on the agency's Web site no later than the publication date of the notice of text in the N.C. Register.**
Adoption by Agency on: 7/25/2025
☐ **Notice not required under G.S.:**
Adoption by Agency on:

7. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

8. Fiscal impact. Check all that apply.

☒ **This Rule was part of a combined analysis.**
☒ **State funds affected**
☒ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☒ **Approved by OSBM**
☐ **No fiscal note required**

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:

☒ **Agency**
☐ **Court order / cite:**
☐ **Federal statute / cite:**
☐ **Federal regulation / cite:**
☒ **Legislation enacted by the General Assembly**
Cite Session Law: 2023-91
☐ **Petition for rule-making**
☒ **Other: 150B-21.3A.(c)(2)(g)**

9B. Explain: The rules in 10A NCAC 15 regulate the use of radioactive machines in NC pursuant to G.S. 104E. Rules in Section .0200 of Chapter 15 regulate all registrants who use radiation machines, radiation generating devices, and who provide radiological services in NC. Four rules, .0201, .0208, .0211, and .0212 are amended with this rulemaking action. Nine rules, 10A NCAC 15 .0202 - .0207, .0209, and .0210 will be readopted and rule .0213 will be repealed through readoption. As mandated by G.S. 150B-19(4) the agency may not adopt a rule that repeats the content of a law, a rule, or a federal regulation. To comply with this mandate, the federal regulations in 21 CFR 1020.30(d) are proposed for incorporation by reference, including subsequent amendments and editions. The federal regulations are incorporated by reference into Rule 10A NCAC 15 .0205(g)(2)(A).

10. Rulemaking Coordinator: Shanah Black

Phone: 919-855-3481
E-Mail: shanah.black@dhhs.nc.gov

Additional agency contact, if any: Regina Kissinger

Phone: 919-814-2335
E-Mail: regina.kissinger@dhhs.nc.gov

11. Signature of Agency Head* or Rule-making Coordinator:
Shanah F Black

By signing, I have verified that the information contained on this form is true and accurate to the best of my knowledge.

***If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: Shanah Black
Title: Rule-making Coordinator

RRC AND OAH USE ONLY

Action taken:
☐ RRC extended period of review:
☐ RRC determined substantial changes:
☐ Withdrawn by agency
☐ Subject to Legislative Review
☐ Other:

Burgos, Alexander N

From: Black, Shanah
Sent: Wednesday, September 3, 2025 3:54 PM
To: Wiggs, Travis C
Cc: Burgos, Alexander N
Subject: RE: September RRC Meeting

Just to let you know, these are 2 different phases of rules for RP so I am going to break them up into 2 packages. The first set was phase 8 – 15.0201-15.0213. The second set was phase 9 of the radiation protection rules. They had 2 different drafters involved.

Thanks

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Wednesday, September 3, 2025 3:47 PM
To: Black, Shanah <shanah.black@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: September RRC Meeting

Good afternoon,

I'm the attorney who reviewed the rules submitted by the Radiation Protection Commission for the September 2025 RRC meeting. The RRC will formally review these rules at its meeting on Thursday, September 25, 2025, at 10:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get close to the meeting. If there are any other representatives from your agency who want to attend virtually, please let me know prior to the meeting, and we will get evites out to them as well.

Attached is the Request for Changes Pursuant to G.S. 150B-21.10. Please submit the revised rules to me via email, no later than 5 p.m. on September 17, 2025. Let me know if you have any questions.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: Sept 25 RRC meeting

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Wednesday, September 3, 2025 11:38 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

Will do, thank you.

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Wednesday, September 3, 2025 11:38 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

Shanah,

Please make sure to comply with 26 NCAC 05.0106 for the requested speaker.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Wednesday, September 3, 2025 11:13 AM
To: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

Great, thanks!

From: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Sent: Wednesday, September 3, 2025 11:12 AM
To: Black, Shanah <shanah.black@dhhs.nc.gov>; Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Subject: RE: Sept 25 RRC meeting

Hello Shanah, they can speak on Webex or come in person. The request to speak should be sent to Travis and copy me.

Alexander Burgos
Paralegal
Office of Administrative Hearings
1711 New Hope Church Road

Raleigh NC, 27609
(984) 236-1940
Alexander.burgos@oah.nc.gov

From: Black, Shanah <shanah.black@dhhs.nc.gov>
Sent: Wednesday, September 3, 2025 11:10 AM
To: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Subject: Sept 25 RRC meeting

Hey,

Hope you had a great weekend. I know of a professor that wants to speak at the Sept. 25 RRC meeting about the proposed Radiation Protection rules.

Does this person have to speak in person on can it be on Webex?

Who does she need to contact about wanting to participate?

Thanks for your help on this.

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

Work Cell: 919-896-9371
Office: 919-855-3481
Fax: 919-733-2757
shanah.black@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701