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?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(6) radiation instrument calibration;~~

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

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

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

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

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

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

(1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of radiation machines or radiation generating devices;

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

(A) radiation machines and machine components, including the making of diagnostic radiation output ~~measurements;~~ measurements, and performance verification; or

(B) radiation generating devices to include equipment surveys.

(3) Class III - shielding designs for diagnostic radiographic facilities;

(4) Class IV - shielding designs for diagnostic fluoroscopy facilities;

(5) Class V - area radiation surveys and shielding evaluations for diagnostic radiographic and fluoroscopy facilities;

~~(5) manufacturer training for the use of radiation machines or radiation generating devices;~~

(6) Class VI - radiation survey equipment calibrations;

(7) Class VII - therapeutic facility and shielding design, area radiation survey, or ~~calibration.~~ verification;

(8) Class VIII - providing individual monitoring devices;

(9) Class IX - general health and medical physics consulting to include the following services:

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

(B) dose estimates;

(C) radiation output measurements;

(D) radiation safety program development; and

(E) radiation safety program training.

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

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

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

(g) Report of installation

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) room location;

(6) date of sale or installation;

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

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

(9) the date signed.

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

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

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

(1) fluoroscopy machine output measurement; and

(2) radiation generating devices equipment surveys.

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

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

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

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

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)?

In line 25, capitalize "state".

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)?

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)?

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

10A NCAC 15 .0903 is readopted 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:

(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.

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".

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

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

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 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 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.

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

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

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

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

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

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.

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

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

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

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

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

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

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 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., 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.

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

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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".

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

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

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

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

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, 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 when, and 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 high radiation area. This warning device shall be clearly discernible in all high radiation areas and all radiation areas.

(c) 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.

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

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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.

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

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

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

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.

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

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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?

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

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.

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".

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)?

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

10A NCAC 15 .1902 is adopted 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.

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".

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

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

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

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

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

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

10A NCAC 15 .1903 is adopted 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 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 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 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) 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 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) 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 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.

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".

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)?

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

10A NCAC 15 .1904 is adopted 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.

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".

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

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

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

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

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.

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

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

10A NCAC 15 .1905 is adopted 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 that radiation will be administered as directed by the authorized user. 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, 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 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 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.

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".

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)?

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)?

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

10A NCAC 15 .1908 is adopted 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.

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".

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)?

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)?

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

10A NCAC 15 .2008 is adopted 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.