Fiscal Impact Analysis of
Permanent Rule Readoption and Permanent Rule Amendment
without Substantial Economic Impact

Agency Proposing Rule Change
DHHS/Division of Health Service Regulation
Radiation Protection Commission

Contact Persons
Shanah Black, DHSR Rules Review Manager – (919) 855-3811
Louis Brayboy, Radiation Protection Section Chief – (919) 814-2304
James Albright, Radioactive Materials Branch Manager – (919) 814-2251 (cell: (919) 604-4037)

Impact Summary

Federal Government:	No Impact
State Government:	Minimal Impact
Local Government:	No Impact
Regulated Community:	Minimal Impact
Substantial Impact:	No

Rules with Proposed Changes

Rule Readoption with substantive changes:

10A NCAC 15 .0901	Purpose and Scope
10A NCAC 15 .0902	Licensing Requirements
10A NCAC 15 .0903	Requirements for Issuance of a License for Accelerators
10A NCAC 15 .0904	Limitations
10A NCAC 15 .0905	Shielding and Safety Design
10A NCAC 15 .0906	Controls and Interlock Systems
10A NCAC 15 .0907	Warning Devices
10A NCAC 15 .0908	Operating Procedures
10A NCAC 15 .0909	Radiation Monitoring Requirements
10A NCAC 15 .0910	Ventilation Systems

Rule Readoption without substantive changes:

10A NCAC 15 .0501	Industrial Radiographic Operations of Electronic Radiation Machines for Non-Human Use
10A NCAC 15 .0802	Definitions
10A NCAC 15 .0803	Personnel Requirements
10A NCAC 15 .1001	Notices, Instructions, and Reports to Employees
10A NCAC 15 .1601	Standards for Protection Against Radiation

Rules Proposed for Adoption

10A NCAC 15 .1901	Purpose and Scope
10A NCAC 15 .1902	Definitions
10A NCAC 15 .1903	General Administrative Requirements for Facilities Using Therapeutic Radiation Machines
10A NCAC 15 .1904	General Technical Requirements for Facilities Using Therapeutic Radiation Machines
10A NCAC 15 .1905	Quality Management Program
10A NCAC 15 .1906	Therapeutic Radiation Machines Less Than 500keV
10A NCAC 15 .1907	Therapeutic Radiation Machines of 500keV and Above
10A NCAC 15 .1908	Calibration of Survey Instruments and Dosimetry Systems
10A NCAC 15 .1909	Shielding and Safety Design Requirements
10A NCAC 15 .1910	Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage
10A NCAC 15 .1911	Emerging Technologies
10A NCAC 15 .2001	Purpose and Scope
10A NCAC 15 .2002	Definitions
10A NCAC 15 .2003	General Administrative Requirements for Facilities Using Therapeutic Radiation Machines
10A NCAC 15 .2004	General Technical Requirements for Veterinary Facilities Using Therapeutic Radiation Machines
10A NCAC 15 .2005	Quality Management Program
10A NCAC 15 .2006	Veterinary Therapeutic Radiation Machines Less Than 500kV
10A NCAC 15 .2007	Veterinary Therapeutic Radiation Machines of 500keV and Above
10A NCAC 15 .2008	Calibration of Survey Instruments and Dosimetry Systems
10A NCAC 15 .2009	Shielding and Safety Design Requirements
10A NCAC 15 .2010	Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage
10A NCAC 15 .2011	Emerging Technologies

*See text in Appendix

Rules Proposed for Repeal

Rule Repeals Through Readoption: 10A NCAC 15 .0608 and .0609

*See text in Appendix

Authorizing Statutes

G.S. 104E-7, 104E-7(a)(2), 104E-9(a)(8), 104E-12, 104E-12(a), and 104E-19(a).

Background

Under authority of G.S. 150B-21.3A, Periodic review and expiration of existing rules, DHHS/DHSR and the Radiation Protection Commission submitted a report to the Rules Review Commission and the Joint Legislative Administrative Procedure Oversight Committee. This report was approved and the readoption schedule set at the July 18, 2019, meeting of the Rules Review Commission. Rules 10A NCAC 15 .0501, .0802, .0803, and .1001 were determined to be "Necessary Without Substantive Public Interest" and were readopted on June 22, 2019. These Rules are being amended during this rulemaking action. Rules 10A NCAC 15 .0608, .0609, and .0901 - .0911 were determined to be "Necessary With Substantive Public Interest" and will be readopted or readopted as repeals with this rulemaking action.

Rule 10A NCAC 15 .0501 is being amended during this rulemaking action to correct regulatory references found in this Rule.

Rules 10A NCAC 15 .0608 and .0609 are being repealed during this rulemaking because they have become redundant. The requirements in these two Rules have been moved to the Rules in Section .0900, so these two Rules are no longer necessary.

Rules 10A NCAC 15 .0802, .0803, and .1001 are being amended during this rulemaking action to correct regulatory references found in this Rule.

Rules 10A NCAC 15 .0901 through .0911 are being readopted this rulemaking and are being revised to address general requirements for licensing all accelerators. Accelerators are also referred to as radiation generating devices, radiation generating machines, or electronic devices. Accelerators are used for treating disease in humans and animals, producing radioactive drugs for diagnosing disease in humans and animals, education and research, and manufacturing goods used in everyday life. Examples include treating breast cancer in women, producing positron emitting radioactive drugs for diagnosing disease in humans and their pets using positron emitting tomography, discovering new subatomic particles in high energy physics, physics and medical education at universities, and annealing the rubber used in automotive tires so they last longer and are safer on the road. The readoption of the rules in Section .0900 will affect all one hundred accelerator licensees in North Carolina because these general requirements apply to the licensing of an accelerator for any use.

Rule 10A NCAC 15 .1601 was readopted effective on October 1, 2023. This Rule is being amended during this rulemaking action to correct regulatory references found in this Rule.

Rules 10A NCAC 15 .1901 - .1911 and .2001 - .2011 are new rules for adoption and are necessary to protect the health and safety of patients, the public, and the environment from unnecessary exposure to radiation from licensed electronic sources of radiation used for therapy. Rules .1901 - .1911 address the therapeutic use of radiation for the medical treatment of humans using electronic devices such as high energy accelerators, electronic brachytherapy, and superficial radiation therapy using low energy x-rays to treat skin cancer. Rules .2001 - .2011 address the therapeutic use of radiation for the medical treatment of non-human, veterinary patients for those same types of electronic devices.

The adoption of the therapeutic radiation machine (i.e., medical accelerator) rules in Section .1900 will affect:

- four University of North Carolina licensees [East Carolina University, UNC-Chapel Hill (two licenses), and UNC-Charlotte] and
- 76 privately owned medical licensees.

The adoption of the veterinary accelerator rules in Section .2000 will affect:

- one University of North Carolina licensee (NCSU) and
- two privately owned veterinary licensees.

Neither Section .1900 nor .2000 will affect the remaining two UNC system isotope production accelerator licensees, two UNC system research accelerator licensees, five privately owned isotope production licensees, two privately owned research accelerator licensees, or six privately owned manufacturing accelerator licensees. These licensees are subject to the particle accelerator rules in Section .0900 which are being readopted.

There are no local government accelerator licensees (municipal or county). As such, local government will not be impacted by the proposed rules. The agency does not regulate activities that occur at federal government facilities, therefore these rules do not impact the federal government.

Rule Changes and Anticipated Fiscal Impact

10A NCAC 15 .0501 Industrial Radiographic Operations of Electronic Radiation Machines for Non-Human Use

The Radiation Protection Commission is proposing to amend this Rule to correct regulatory citations appearing within the Rule. Definitions of terms used in Chapter 15 of 10A NCAC were moved from Rule .0104 to .0103. This change requires that Rule .0501 be amended to refer to the correct Rule defining terms used in Rule .0501. Specifically: .0501(a)(2)(B) and (D) both reference Rule .0104 as the rule that contains definitions of terms used in Rule .0501. However, Rule .0103 is anticipated to replace Rule .0104 when Rule .0103 becomes effective on May 1, 2025.

None of the proposed changes to Rule 10A NCAC 15 .0501 impose burdens on the regulated community that are not already required by Rule .0501, or require any changes to the operations of federal, state or local government. The only changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0608 Therapeutic X-Ray Installations: Less Than One MeV
10A NCAC 15 .0609 X-Ray and Electron Therapy Installations One MeV and Above

The Radiation Protection Commission is proposing to readopt these two Rules as repeals. The requirements found in Rule .0608 are found in Rule .1906, and the requirements found in Rule .0609 are found in Rule .1907. In addition, some of the requirements found in Rule .0608 and .0609 are outdated or no longer applicable to these devices because of advances in technology since these rules were last amended in 1994, over thirty years ago.

The repeal of these two Rules will impose no additional burdens on the regulated community or require changes to the operations of federal, state or local government. The removal of the outdated elements of these Rules should reduce the cost of compliance for the regulated community because equipment specifications and performance standards have changed in the intervening thirty-one years since these rules were last amended. Repealing these Rules will provide clarity to the regulated community thereby making compliance easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0802 Definitions
10A NCAC 15 .0803 Personnel Requirements

The Radiation Protection Commission is proposing to amend these two Rules to correct regulatory citations appearing within both Rules due to rule changes that are anticipated to become effective May 1, 2025. Definitions of terms used in Chapter 15 of 10A NCAC will be moved from Rule .0104 to Rule .0103, and the Rule incorporating the federal requirements referred to in Rule .0802 is anticipated to change from Rule .0117 to Rule .0104. Rule .0117 is anticipated to be repealed through readoption when Rule .0104 becomes effective. The changes to Rules .0103, .0104, and .0117 require that Rules .0802 and .0803 be amended to implement these changes. Specifically:

- The first sentence in Rule .0802 references Rule .0104 and needs to refer to Rule .0103;
- Items (6) and (7) of Rule .0802 references Rule .0117, and need to refer to Rule .0104, and
- Paragraph (a) of Rule .0803 references Rule .0104 and needs to refer to Rule .0103.

None of the proposed changes to Rule 10A NCAC 15 .0802 or .0803 impose burdens on the regulated community that are not already required by the rules in Section .0800, or require any changes to the operations of federal, state or local government. The only changes of note to these two Rules are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0901 Purpose and Scope

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The amended rule reorganizes the Rule into Paragraphs with subdivisions to improve readability. The Rule also introduces our licensees to two new Sections of rules that apply exclusively to the possession and use of radiation generating machines for therapy: Section .1900 that provides rules for the therapeutic use of radiation generating machines for treating humans, and Section .2000 that provides rules for the therapeutic use of radiation generating machines for treating animals. Rule .0901 also exempts persons conducting industrial radiography using radiation generating machines from the Rules in Section .0900 and instead refers them to 10A NCAC 15 .0501.

None of the proposed changes to Rule 10A NCAC 15 .0901 impose burdens on the regulated community that are not already required by this Rule, or requires any changes to the operations of federal, state or local government. The only changes of note to this Rule are administrative changes that will provide

clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0902 Licensing Requirements

The Radiation Protection Commission is proposing to readopt this rule without substantive changes. The Rule is identical to the existing Rule except that the text in the second sentence of the existing Rule is corrected to refer to 'Rule .0903 of this Section' and not 'Section .0903 of this Chapter.' There is no 'Section .0903' in 10A NCAC 15, but there is the Rule: 10A NCAC 15 .0903.

The proposed change to Rule 10A NCAC 15 .0902 imposes no burdens on the regulated community that are not already required by this Rule, or requires any changes to the operations of federal, state or local government. The only changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0903 Requirements for Issuance of a License for Accelerators

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. Rule .0903 has been amended to subdivide .0903 into Paragraphs (a) and (b):

- Subparagraphs (a)(1) and (a)(2) are identical to Items (1) and (2) from the former Rule;
- Subparagraph (a)(3), formerly Item (3), has been amended to require the Radiation Safety Officer appointed by the applicant to agree <u>in writing</u> to be responsible for implementing the licensee's radiation safety program. The requirement for this person to agree in writing to be responsible for implementing the licensee's radiation safety program is a requirement that has been implemented by policy but not previously expressed in Rule for accelerator licensees. The purpose for requiring written acknowledgement of responsibility for implementing the radiation safety program is two-fold:

    - It serves to notify management that the Radiation Safety Officer has sole authority for compliance with the rules and operational safety.
    - It reinforces to the individual proposed to act as the Radiation Safety Officer that compliance with the rules and operational safety is their responsibility.

    This requirement existed more-or-less verbatim since 2002 in 10A NCAC 15 .0318(o) and is presently found in Rule .0307(b)(1) (Medical Use of Byproduct Material in Humans) incorporating 10 CFR 35.24(b) by reference. Both Rules are radioactive materials rules designating lines of authority and responsibility for medical licensees using radioactive materials that the agency 'borrowed' and applied to accelerator licensees. Rule .0318 was repealed through readoption when Rule .0307 was readopted effective May 1, 2024.

The Radiation Protection Commission has proposed to codify the requirement for written acknowledgement of responsibility for the particle accelerator licensee's radiation safety program in rule. This is clearly stated in Subparagraph (a)(3) of this proposed Rule without reference to the federal regulation to avoid confusion because the 10 CFR regulations apply only to radioactive materials and not electronically produced sources of radiation. This amendment to the Rule codifies a longstanding policy to comply with G.S. 150B-18.

This written agreement can be any electronic or hard-copy document developed by the applicant, licensee, or the applicant's or licensee's proposed or designated Radiation Safety Officer containing a statement that the individual named as the Radiation Safety Officer acknowledges responsibility for implementing the applicant's or licensee's radiation safety program. The cost to create, sign, and maintain copies of the written agreement is minimal, and does not add a noticeable cost to the application package submitted to the agency for review for licensing purposes. Likewise, reviewing this documentation does not add a noticeable cost to the agency during the review of an accelerator application to add or change the Radiation Safety Officer. All of our accelerator licensees have consistently complied with the policy to provide this written agreement. As such, this change to the rule will not impose any additional burdens as compared to the ongoing practice. Even compared to the regulatory baseline -- which would not include requirements implemented solely through policy – there would be a de minimis impact to applicants.

- Item (4) of the existing Rule .0903 is being removed from the Rule because the agency determined through 40 years of operational experience that accelerator licensees with an established and active Radiation Safety Committee are no safer and patient health and medical outcomes are no better than for accelerator licensees with a committee formed just to comply with the rule.

  Typically, accelerator licensees associated with hospitals with radioactive materials licenses or licensees with multiple accelerators have established the Radiation Safety Committee required by this Rule. Many accelerator licensees serving rural areas only have one or two authorized users, a single authorized medical physicist, and one or two therapists. These licensees do not have the means to create a committee as required by Item (4) because the staff requirements set by Rule .0307(b)(1) cannot be met. For example, the practice manager is often an authorized user who also serves as the Radiation Safety Officer. This 'management mix' is prohibited by 10 CFR 35.24(f), incorporated by reference in Rule .0307(b)(1). The agency recognizes that this requirement is burdensome and difficult for many accelerator licensees to comply with and has exercised regulatory discretion during licensing and inspections to relax this requirement in policy.

  During this rulemaking action, the Radiation Protection Commission also recognized that not all accelerator licensees have the staff to support a Radiation Safety Committee as that requirement exists in Rule .0903(a)(4) and Rule .0307(b)(1), and that such a committee is not a value-added element to accelerator programs. Prior to the readoption of Rule .0307 in May 2024, this requirement was found in Rule .0319(b)(2) and (3), last amended in October 1984. Rule .0319 was repealed when Rule .0307 became effective.

- Item (4) of the proposed Rule requires that applicants for an accelerator license for human use meet the additional requirements of Section .1900, be a board certified physician licensed to practice medicine in North Carolina, and have a board certified medical physicist listed on the application.

- Item (5) of the existing Rule is being removed from the Rule because it repeats the essence of Item (4) as proposed and is being repurposed to require that applicants for an accelerator license for veterinary use meet the additional requirements of Section .2000.

- Paragraph (b) clarifies and describes the process to apply for an accelerator license and is required to be in Rule by G.S. 150B-18. The process to apply for a license is a requirement of the agency prior to being issued a license to possess an accelerator. Paragraph (b) also describes the content of the application form (referencing G.S. 150B-2(8a).

Removing the requirement to have a Radiation Safety Committee is a substantive change to the Rule that reduces the regulatory burden and subsequent opportunity costs for licensees and state government. Because the agency has exercised regulatory discretion in applying the requirement through policy, removing this from the rule is required by G.S. 150B-18 and clarifies the rule. These changes will require no change to the operations of federal or local government entities and will result in minor changes to the procedures used by state government entities. While voluntary for current licensees, to remove the current requirement for a Radiation Safety Committee, licensees will be required to amend their procedures and to submit a license application to the agency to remove the commitment from their license. The agency is opting to not enforce those commitments and giving licensees the opportunity to make these changes during other routine license amendment actions to reduce the cost of compliance to the regulated community. For accelerator licensees considering the dissolution of their Radiation Safety Committees, the potential for cost savings is largely theoretical and likely minimal in practice. While there may be a nominal reduction in time spent on committee-related activities, several factors mitigate these savings:

- Most accelerator licensees operate with a small number of authorized users, which means they would be unlikely to maintain a full-fledged “committee” in the traditional sense.
- The time dedicated to these Radiation Safety Committees, when they do exist, is already minimal.
- Even if the formal committee structure is disbanded, safety oversight duties will still need to be performed.

Licensees that opt to keep a Radiation Safety Committee may do so and will not experience a net cost or net benefit for doing so as compared to the regulatory baseline. The removal of the requirement to establish a committee will provide a comparatively larger potential opportunity cost savings for future licensees versus current licensees.

The requirements of Items (4) and (5) are administrative in nature. They require the applicant to comply with the requirements of Section .1900 for medical use and Section .2000 for veterinary use of accelerators. Item (4) further stipulates that the applicant for a medical license be a board certified physician licensed to practice in North Carolina and that the applicant have a medical physicist. The purpose of Items (4) and (5) is to tie the licensing issuance requirements to the requirements for use in Sections .1900 and .2000 as appropriate for the licensed activities. The requirement that a medical use accelerator applicant be a board certified physician licensed to practice medicine in North Carolina and that there be a board certified medical physicist is added to the license issuance rule for clarity. Neither Item (4) not (5) adds an additional burden to applicants seeking an accelerator license that is not already required by the Rules in 10A NCAC 15 (Radiation Protection).

The proposed changes to Rule 10A NCAC 15 .0903 imposes no new burdens on the regulated community that are not already required by this Rule or agency practices. The new requirement requiring the individual designated as the licensee’s Radiation Safety Officer to sign a written acknowledgement of

responsibility for the licensee's compliance program is a substantive change to the Rule. It is expected, however, to add an insignificant cost burden to licensees and state government. Other changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0904 Limitations

The Radiation Protection Commission is proposing to readopt this rule with substantive changes.

- Rule .0904 has been amended to make the rule gender neutral in (a)(3) by changing "his" to "their."
- Paragraph .0904(b) has been amended to remove authorization from a licensee's radiation safety committee to order the cessation of licensed activities for health and safety reasons. This responsibility and the authority to issue a 'stop work' will rest with the radiation safety officer once this rule is effective. Historically, the requirement for accelerator licensees to have a radiation safety committee is a requirement that nearly all non-hospital-based accelerator licensees have not been complying with, and the agency has historically not required compliance with this part of the Rule for non-hospital-based accelerator licensees. In addition, the requirement for an accelerator licensee to have a radiation safety committee predates 2002 and was based on the requirement in 10A NCAC 15 .0319 for medical licensees using radioactive materials for medical use. This requirement is now codified in Rule .0307(b)(1) that incorporates 10 CFR 35.24 by reference, however, Rule .0307 does not apply to accelerator licensees. The Radiation Protection Commission is removing the requirement for a radiation safety committee from the accelerator rules, as previously discussed, so this provision in the existing rule becomes moot when the rules in this rulemaking become effective.

The proposed changes to Rule 10A NCAC 15 .0904 impose no new burdens on the regulated community that are not already required by this Rule or agency practices, or requires any changes to the operations of federal, state or local government. The only changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0905 Shielding and Safety Design

The Radiation Protection Commission is proposing to readopt this rule with substantive changes.

- Rule 10A NCAC 15 .0905(a), is being expanded into three Paragraphs ((a), (b), and (c)) and revised to clarify the training and experience requirements for registered service providers (i.e., "qualified experts") to provide shielding design and survey services for therapeutic medical, therapeutic veterinary, and non-medical use of accelerators. These training and experience requirements already apply to particle accelerators via Rules 10A NCAC 15 .0205 (Application for Registration of Services) and 10A NCAC 15 .0214 (Training and Educational Requirements for Equipment Services). The proposed rule consolidates the service provider registration requirements from Section .0200 with the licensing requirements in Section .0900 and clarifies the requirements for accelerator license applicants:
    - There are nine types of service classes listed in Rule .0205(d): Class I through Class IX. Class VII service providers are authorized to design accelerator vaults used for medical

purposes, to survey these vaults after construction to ensure that radiation exposures outside the vault are safe, to evaluate changes made to a vault or equipment inside the vault, or changes in workload, etc. Accelerators used for medical therapy are very high energy machines and there is a danger of real physical harm if the vault or the equipment is inadequately shielded. This is the reason for the existing rigorous training and educational requirements for Class VII services (which are not changing with this proposed rulemaking).

  - The proposed Rule .0905 also allows an Authorized Medical Physicist named on an accelerator license to perform these services for the license that they are named on. Prior to this rulemaking, the Agency allowed Authorized Medical Physicists named on the licensee's license to perform these services by policy, but confusion was caused by the requirement for registration as a service provider beforehand. The proposed rule removes this confusion by stating that Authorized Medical Physicists can provide vault design, shielding design, and post installation surveys for the license that they are named on without needing to be registered by the agency to do so. These activities are not considered 'being in the business of' as noted in Rule .0205 because the Authorized Medical Physicist is an employee of the licensee.
  - Note that the training and experience requirements for Class VII service providers found in existing Rule .0214 are less restrictive than the requirements for authorized medical physicists found in the proposed Rule .0903(d): Both accept American Board of Radiology (ABR) certification in therapeutic radiologic physics. However, Class VII service providers can use an alternate pathway relying on education and work experience that is not permitted for medical physicists: A Masters degree in physics and one year experience in therapeutic physics under an authorized medical physicist and one year on the job experience. Since the training and experience requirements for Class VII service registration are less stringent than the requirements for authorized medical physicists, the agency determined that a medical physicist named on an accelerator license is qualified to provide the services a 'qualified expert' registered as a Class VII service provider could provide for that license. Medical physicists are not permitted to provide Class VII services for other accelerator licenses because the agency registers these individuals to ensure uniformity of practice between service providers and this activity is considered 'being in the business of' as noted in Rule .0205.

- Paragraph (d), as proposed, allows individuals registered to provide Class VII services to continue providing vault and shielding design services and to conduct vault surveys to document compliance with the dose limits in this Rule .1601 but removes the ability to conduct accelerator calibration from the list of permitted service activities. This is expected to increase safety and improve medical outcomes for patients because of the more stringent training and education requirements for Authorized Medical Physicists. The restriction on this activity for Class VII services providers is not anticipated to have a significant cost. The Joint Commission, a non-profit organization that sets standards and accredits healthcare organizations across the United States, mandates high levels of patient care. The standard set by the Joint Commission, in cooperation with the American Board of Radiology, is that Medical Physicists calibrate accelerator outputs and perform machine QA/QC checks. Because of this, there are no Class VII service providers calibrating accelerators for medical use.

The proposed changes to Rule .0905 do not add an appreciable cost to private or state government licensees or to individuals registered as Class VII service providers during conduct of the activities authorized by this rule. Rule changes will improve rule clarity, align the rules with ongoing agency practices, and update the scope of Class VII services to better align with current industry best practices for calibrating accelerators for medical use. The streamlined process for Authorized Medical Physicists could

offer nominal time savings from the reduced administrative burden and confusion. The additional rule clarity and reduced scope of Class VII services could result in incremental improvements to worker safety and improve patient outcomes in medical and veterinary settings.

10A NCAC 15 .0906 Controls and Interlock Systems

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The rule is an equipment specification that requires accelerators that are shut down by manually pushing (tripping) an emergency interlock button, by opening a radiation barrier such as the door to the treatment vault, or because of a machine malfunction or an improper treatment setting, need to be reset at the position where the trip occurred and at the treatment console. The language in Paragraph (c) paraphrases the requirement in Paragraph (f) of this Rule, so Paragraph (c) has been amended to require resetting the interlocks before the accelerator can produce radiation and the repetitive language removed. No other changes have been made to this Rule.

None of the proposed changes to Rule 10A NCAC 15 .0906 impose burdens on the regulated community that are not already required by this rule or the agency, or require any changes to the operations of federal, state or local government. The only changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0907 Warning Devices

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. Paragraph (a) of the former Rule requires warning lights outside and inside areas where high radiation exposures occur when the accelerator unit is energized, and radiation is produced. In practice the agency recognizes that patients are often anxious and the appearance of a green light turning red during patient treatment can be discomfiting to those patients. Some licensees have dealt with this by placing the warning light outside of the patient's view inside the vault. This Rule is a legacy Rule based on the agency's experience with teletherapy units using radioactive materials where long exposure times are required to deliver a prescribed dose to the patient and the source continuously emits radiation. Removing the requirement for warning lights inside the treatment vault where high radiation exposures occur does not impact safety because the lights are required when radiation is produced and not beforehand, limiting the usefulness of these lights to warn individuals inside the vault of the exposure. The Rule has also been revised to require warning lights outside the vault where human medical therapy takes place to remove any ambiguity over the placement of these warning lights in medical facilities.

None of the proposed changes to Rule 10A NCAC 15 .0907 impose burdens on the regulated community that are not already required by this rule or the agency, or require any changes to the operations of federal, state or local government. The only changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0908 Operating Procedures

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. This Rule is being amended to remove the requirement to keep electrical diagrams for inspection by the agency. This is a legacy requirement from when radiation therapy was delivered using teletherapy machines using radioactive materials that are always "on" so to speak. Radioactive materials continually emit radiation while electronic radiation generating devices stop emitting radiation when the electrical power is shut off. Electrical diagrams were required for teletherapy machines because they could not by turned "off" and it was necessary to ensure that all safety and control interfaces worked properly to protect the health and safety of the public and occupationally exposed workers. In addition, the complexity of vault and accelerator wiring has grown so much that reviewing these diagrams during inspection is not a value-added item protecting health and safety.

None of the proposed changes to Rule 10A NCAC 15 .0908 impose burdens on the regulated community that are not already required by this rule or the agency, or require any changes to the operations of federal, state or local government. The only changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0909 Radiation Monitoring Requirements

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The agency is proposing a new Section in 10A NCAC 15 for rules that apply specifically to the medical use of radiation from radiation generating devices.

- Paragraph (a) of this Rule exempts licensees performing therapy for medical uses on humans from the requirement to possess portable radiation monitoring equipment. This requirement is a legacy item from teletherapy units containing radioactive materials that continuously emit radiation, and this equipment was necessary to protect occupationally exposed workers from exposure to radiation while entering or working in the exposure vault. Modern accelerators have radiation detection equipment installed on the accelerator and portable radiation monitoring equipment is no longer necessary.
- Paragraph (b) clarifies the training and experience requirements for individuals authorized to perform radiation surveys after changes are made to the vault or equipment inside the vault impacting the delivery of radiation. The agency has interpreted the prior language to mean qualified experts registered to provide Class VII or Class IX services, and not individuals registered to provide other classes of services who are registered under the provisions of 10A NCAC 15 .0205. The Rule also explicitly allows Authorized Medical Physicists to provide these services that the agency allowed through policy and practice based on the training and certification requirements for medical physicists. Authorized Medical Physicists are held to stricter training and experience standards than Class VII or IX service providers and every accelerator licensee is required to have at least one medical physicist on staff to help create treatment plans for patients on an accelerator, and to quality check and calibrate the radiation beam and accelerator device controls for performance. Conducting surveys of the radiation beam and areas outside the vault to ensure compliance with the dose limits in Rule .1601 when necessary are part of their everyday job requirements. The agency has determined that it is more efficient with no loss in safety to allow medical physicists named on the license to conduct these activities than to require these individuals to be registered as service providers when they are only performing these activities for the license they are named on. The agency also determined that this activity is not captured under Rule .0205 as "in the business of" providing these services.

Medical physicists providing services reserved for Class VII or IX service providers for licenses other than those they are named on are required to register as Class VII or IX service providers because at that point they are "in the business of" providing these services.

- Paragraph (b) also provides guidance as to where reports of accelerator vault surveys should be sent for review by the agency for licensing purposes.
- Paragraph (g) places the responsibility for approving procedures used by a licensee with the licensee's Radiation Safety Officer instead of a qualified expert who may or may not be associated with the licensee. The Radiation Safety Officer is responsible for compliance with the Rules and safe operation of the facility on behalf of the licensee, and this change is made to reflect that responsibility.

None of the proposed changes to Rule 10A NCAC 15 .0909 impose burdens on the regulated community that are not already required by this rule or the rules in this Chapter, or require any changes to the operations of state or local government. The rule permits medical physicists authorization to conduct vault and shielding design and surveys to document compliance with the dose limits of Rule .1601. This activity is not considered a business activity when it is done for the license that the medical physicists are listed on. The principle changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0910 Ventilation Systems

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The only change being made to this Rule is to correct the regulatory citation from Rule .1611 of this Chapter to Rule .1601. Rule .1601 incorporates the health and safety requirements found in 10 CFR 20 formerly found in Rule .1611.

None of the proposed changes to Rule 10A NCAC 15 .0910 impose burdens on the regulated community that are not already required by this rule or the agency, or require any changes to the operations of federal, state or local government. The only changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

Introduction to Sections .1900 and .2000 of 10A NCAC 15:

The Radiation Protection Commission is proposing to adopt Rules for two new Sections in 10A NCAC 15. Section .1900 is added to provide rules and guidance for the medical use of radiation from radiation generating devices in the treatment of disease in human patients. This will impact four state government and 76 privately owned medical accelerator licensees. Section .2000 is added to provide rules and guidance for the use of radiation from radiation generating devices in the treatment of disease in non-human (veterinary) patients. This will impact one state licensee and both private veterinary accelerator licensees. The rules in both Sections are very similar and reflect the agency's practices and implementation of existing radioactive materials rules regulating the use of teletherapy devices for

human-use and non-human-use of radiation from electronic devices in therapy in medical and veterinary practices. Since the rules are similar, they are discussed in pairs to avoid unnecessary repetition. Dissimilarities between the paired rules will be outlined in the discussion that follows each paired set of rules for clarity.

These two new Sections are necessary because prior to this rulemaking, the agency interpreted the rules controlling the use of radioactive materials for teletherapy to regulate electronically produced sources of radiation in therapeutic settings. Historically, these rules are found in 10A NCAC 15 .0117(a)(2)(E) incorporating subpart H of 10 CFR 35 and Rule .0318, both last amended in October 2013; Rule .0319, last amended in October 1984; Rule .0320, last amended in November 2007; and Rules .0321 and .0322, both last amended in October 2013. Currently, these requirements are found in Rules .0117(a)(2)(E) and .0307(i). Note that Rule .0307(i) is a readoption that became effective May 2024, and it incorporates the teletherapy regulations in Subpart H of 10 CFR 35 through incorporation by reference. Rule .0307 replaced Rules .0318 through .0322 and those rules were repealed.

The 2015 version of 10A NCAC 15 is the last set of rules predating the readoption period that began in 2018 and is available upon request.

Specific examples and the crosswalk between Rule .0307, other rules in 10A NCAC 15, and the proposed new rules are provided in the discussion following each set of paired rules to demonstrate that although the rules themselves are new, the requirements of the agency are not new. That said, the proposed rules in Sections .1900 and .2000 will regulate therapeutic machines with output energies less than 500 kilo electron volts (keV) and greater than 500 keV. Under the current rules in Section .0600, Rule .0608 applies to therapeutic installations using therapeutic machines with output energies less than one million electron volts (MeV) and Rule .0609 applies to therapeutic installations using therapeutic machines with outputs energies greater than 1 MeV. The current and proposed rules in Section .0900 apply to all accelerators without regard to output energies. The choice of energy cutoff is arbitrary and the focus of the rules in Sections .0900, .1900, and .2000 is on use: therapy and research. There are no licensees using radiation generating machines for therapy with output energies less than 1MeV, but the rules are developed to accommodate lower energies to be ‘forward facing’ as technologies change.

The facility design and machine requirements found in Rules .0608 and .0609 are being transferred to the proposed Rules in Sections .0900, .1900, and .2000 to make compliance with the requirements easier to find. As noted previously, Rules .0608 and .0609 will be readopted as repeals during this rulemaking.

10A NCAC 15 .1901 Purpose and Scope
10A NCAC 15 .2001 Purpose and Scope

The Radiation Protection Commission is proposing to adopt these two rules. Rule .1901 applies to the use of accelerators to treat human patients in the practice of medicine, and Rule .2001 applies to the use of accelerators to treat non-human patients in veterinary medicine. Paragraphs (a) and (b) of both Rules are nearly identical in every other respect and reflect the agency’s application of the medical use rules in Rule .0117 and formerly in Sections .0300, .0600, and .0900 of Chapter 10A NCAC 15 to human and veterinary uses of machine generated radiation used for therapy. Paragraph (c) is identical in both Rules. Much of the language in these two Rules is borrowed from Rule 10A NCAC 15 .0901, last amended in 1994, that the agency uses to regulate both types of medical activities.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less

time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1902 Definitions
10A NCAC 15 .2002 Definitions

The Radiation Protection Commission is proposing to adopt these two rules. Rule .1902 provides definitions of terms that apply to the use of accelerators to treat human patients, and Rule .2002 provides definitions of terms that apply to the use of accelerators to treat non-human (veterinary) patients. The majority of the terms defined in both rules are the same, but there are some differences in the terms being defined because of the areas being regulated. For instance, the definition of an Authorized User differs between both Rules. Rule .1902(a)(2) defines an authorized user as a physician meeting the training requirements of Rule .1903(d), while Rule .2002(a)(5) defines an authorized user as a veterinarian meeting the training requirements of Rule .2003(b). In all cases where terms are common between human use and veterinary use the terms are the same. For example, there are no or very few differences between common terms used in the Rules in both Sections such as 'barrier,' 'external beam radiation therapy,' 'isocenter,' 'licensee,' etc. Terms such as 'physician,' defined in 10A NCAC 15 .0104(103) and 'prescribed dose,' defined in Rule .0104(108) are the same or nearly the same as they appear in Rule .1902(a)(26) and (27). The term 'prescribed dose' appearing in Rule .2002(a)(26) is nearly the same as it appears in Rule .0104(108). Just for the record, Rule .0104 was last amended in 2013. Other terms such as 'veterinarian,' 'isocenter,' 'interlock,' are new in Rule and exist for clarity because the agency and the regulated communities use these terms to describe people, places, or things related to the use of electronic devices producing radiation for therapy.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1903 General Administrative Requirements for Facilities Using Therapeutic Radiation Machines
10A NCAC 15 .2003 General Administrative Requirements for Veterinary Facilities Using Therapeutic Radiation Machines

Proposed Rules .1903 and .2003 provide general requirements for licensing medical use and veterinary use of radiation generating machines for therapy, respectively.

- Paragraphs .1903(a) and .2003(a) state that a license is required to authorize the use of radiation generating machines for medical use or veterinary use, respectively. Currently, the agency uses the requirement from Rule .0902, last amended in 1993, for this purpose. The requirement that licensees only use radiation generating machines meeting the minimum requirements of the rules in Section .1900 and .2000, found in Rule .1903(b) and .2003(a) is an agency requirement modified from Rule .0307(i)(1), readopted in 2024, and Rule .0117(a)(2)(E), last amended in 2013. Both Rule .0307 and Rule .0117 are teletherapy rules for devices containing radioactive materials that the agency is applying to licensed activities authorizing the use of accelerators.

- Paragraphs .1903(c) and .2003(b) address the training and experience requirements for authorized users for medical use in humans and veterinary use, respectively. Historically, the agency interpreted the training and experience requirements for authorized users for teletherapy machines using radioactive materials to address these requirements for accelerator authorized users. These requirements are currently found in Rule .0307(b)(10) for authorized users listed on another accelerator license or possessing certain specific certifications, and .0307(i)(17) for authorized users who are not listed on another accelerator license. Rule .0307 was readopted in 2024. Prior to 2024 these requirements were codified in Rules .0117(a)(2)(E) and .0318(c). Both Rules .0117 and .0318 were last amended in 2013.
- Paragraphs .1903(d) and .2003(c) address the training and experience requirements for authorized medical physicists for medical use and veterinary use, respectively. As with authorized users, discussed above, the agency used the requirements for teletherapy machines using radioactive materials, modified to apply to accelerators, for this purpose. The requirements for medical physicists are currently found in Rule .0307(b)(8) and (10), readopted in 2024. These requirements were previously codified in Rules .0117(a)(2)(E) and .0318(a), last amended in 2013.
- Paragraphs .1903(e) and .2003(d) address the training and experience requirements for radiation safety officers. As with both authorized users and authorized medical physicists for medical use and veterinary use, the agency interpreted the teletherapy rules for radioactive materials use to apply to the training and experience requirements for these individuals. The training and experience requirements are currently found in Rule .0307(b)(7) and (10), readopted in 2024. Prior to the readoption of Rule .0307, these requirements were found in Rules .0117(a)(2)(E) and .0318(d), both last amended in 2013.
- Paragraphs .1903(f) and .2003(e) address the training and experience requirements for therapeutic radiation machine operators (therapists) for medical use and veterinary use, respectively. Currently, the agency uses Rule .0904 to require therapists to be trained and interprets Rule .0307(b)(3) in such a manner that it applies to therapists for the content of this training. Rule .0904 was last amended in 1980. Prior to the readoption of Rule .0307 in 2024, these requirements were found in Rule .0318(h) and (i), last amended in 2013.
- Paragraphs .1903(g) and .2003(f) require the development of safety procedures to be used at accelerator facilities for medical use and veterinary use, respectively. Currently the agency interprets the licensing requirement found in Rule .0903(2) to apply for this purpose. A license cannot be issued for an accelerator facility without procedures and this requirement assures that the quality of these procedures will meet the minimum needs for licensed activities. These Paragraphs clarify the safety-related licensing requirements developed by licensees for licensees conducting licensed activities for the practice of medicine and the veterinary arts. Rule .0903 was last amended in 1980 when the Rule first became effective.
- Paragraphs .1903(h) and .2003(g) prohibit the intentional exposure of an individual or an animal to radiation produced by an accelerator without a medical or veterinary purpose. Both Rules .0608(c)(6) and .0609(e)(2) prohibit anyone other than the patient being in the treatment room during use of the radiation generating device for therapy. The use of restraints is required if the patient must be restrained during treatment. Both Rules .0608 and .0609 were last amended in 1994. These rules are based on the ALARA principle to keep exposures ‘as low as reasonably achievable’ that comes into consideration with these rules. The ALARA principle is defined in Rules .0104(11) and .1601(a)(3) and is a regulatory requirement in Rule .1601(a)(7). ALARA is also a consideration in several rules where it is an item to be addressed during reports of radiation exposures exceeding the various limits in Rule .1601. Rule .0104 was last amended in 2013, but the ALARA concept predates the rule. For instance, the ALARA principle appears twenty times in the health and safety rules: Rule .1203 last amended in 1993, .1206 and .1225, last amended in 1994, .1512 last amended in 1995, .1603(b) that was last amended in 1998, etc.

- Paragraphs .1903(i) and (j) and Paragraphs .2003(h) and (i) allow accelerator licensees to hire temporary authorized users and temporary medical physicists to fill gaps in coverage at their licensed locations. Prior to 1997 the Radioactive Materials Branch permitted radioactive materials and accelerator licensees to approve individuals listed on a different radioactive materials or accelerator license to act as "locum tenens" authorized users or authorized medical physicists for medical use of radioactive materials under the auspices of Rule .0318(f)(4)(B). However, the USNRC objected to this practice and the agency subsequently determined that the supervision required by .0318(f)(4) was not met for temporary authorized users and authorized medical physicists in light of guidance from USNRC. Some licensees worked around this by adding physicians and medical physicists to their licenses to fulfill the need for "locum tenens," others amended their licenses to comply with Rule .0318(f)(4) by providing plans and procedures for supervising physicians and medical physicists to fill the need for "locum tenens" while not mentioning that these individuals provided services on a temporary basis. As a compliance issue, the topic has largely faded away since 1997. Please note that Rule .0318 cited in this discussion was last amended in 2013 and the rule was repealed when Rule .0307 became effective in 2024. The supervisory relationship noted in Rule .0318 is carried over into the rules currently in use by Rule .0307(b)(3).

  In light of this history, the Radiation Protection Commission desires the ability for accelerator licensees to utilize services from temporary authorized users and medical physicists without resorting to manipulating records or bending the rule to meet the intent of a rule, and these four proposed rules provides this ability. The costs or cost savings for this ability are difficult to quantify: the low risk of being found out of compliance because it is a record-keeping issue, the savings to the patient and the licensee for not having to reschedule appointments, travel time and expense for all involved, the financial and mental health cost to the patient due to delayed cancer treatments, the cost to the licensee to hire and then supervise a physician to act as a temporary authorized user and so forth. These costs or cost savings are not expected to be significant because most patients' treatment regimens are scheduled around expected staff absences to account for vacations, etc., so this provision is most likely to be used during unplanned, unexpected absences at licensed accelerator facilities.
- Paragraphs .1903(k) and .2003(j) both require licensees to provide training to therapists and other accelerator operators that is specific to the medical use and veterinary use activities licensed at these facilities. These requirements are worded differently but are essentially the same requirements appearing in Rule .0904(a). .0904(a) was last amended in 1980. Training in all of the licensees operating procedures includes training in quality management and is required by the agency for licensing and compliance. This is specifically stated in Rule .0307(b)(3) for radioactive materials licensees. Prior to the readoption of Rule .0307 in 2024, this requirement appeared in Rule .0318(g) and (h). Please note that Rule .0318 was last amended in 2013 and was repealed when Rule .0307 was readopted.
- Paragraph .1903(l) requires medical use licensees to have a physician on call and Paragraph .2003(k) requires veterinary use licensees to have a veterinarian on call to provide medical care to patients in the event of a health emergency. This requirement is nearly identical to the requirement for radioactive materials licensees administering radiopharmaceuticals for medical use in Rule .0307(b)(12), readopted in 2024, and is identical to the previous requirement found in Rule .0318(k). Please note that Rule .0318 was last amended in 2013 and was repealed when Rule .0307 was readopted.
- Paragraphs .1903(m) and .2003(l) both hold licensees responsible for the acts and omissions of their employees. This requirement is identical to the requirement for radioactive materials licensees appearing in Rule .0307(b)(3) and has been in rule since at least 2013 where the

requirement appears in Rule .0318(n). Rule .0318 was repealed in 2024 when Rule .0307 was readopted.

- Paragraphs .1903(n) and (o) and Rules .2003(m) and (n) contain recordkeeping requirements for medical use and veterinary use licensees, respectively. These four requirements codify the record retention requirements currently required by Rules .0307(k)(14), (19) – (23), and (27), readopted in 2024, and in Rule .0117(a)(2)(E), last amended in 2013. As noted previously, Rules .0307 and .0117 are radioactive materials rules that the agency interprets to apply to activities using radiation generating devices to regulate those devices in the absence of rules specifically applying to radiation generating devices. Prior to 2024 these requirements could be found in Rule .0117(a)(2)(E), and in the general sense in Rules .1635 (last amended in 2002), .1636 and .1637 (last amended in 1994). Rules .1635, .1636, and .1637 were readopted as repeals when Rule .0307 was readopted.

Neither of these proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1904 General Technical Requirements for Facilities Using Therapeutic Radiation Machines

10A NCAC 15 .2004 General Technical Requirements for Facilities Using Veterinary Therapeutic Radiation Machines

Proposed Rules .1904 and .2004 provide general technical requirements the agency has established in other rules and guidance governing the use of radiation generating machines used for medical and veterinary uses, respectively.

- Parts .1904(a)(1) – (3) and .2004(a)(1) – (3) establish requirements for licensees authorized to possess and use radiation generating devices for medical use and veterinary use to conduct, record, and submit surveys to document the exposure rate in occupationally exposed and public areas outside the vault to the agency. Radiation surveys are required whenever a new accelerator is installed, a vault has not been previously surveyed, when any changes are made to the treatment room shielding, after making any change in the location of the therapeutic radiation machine within the treatment room, after relocating the therapeutic radiation machine in the same treatment room or in another treatment room, after changes in occupancy in surrounding areas, or before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the treatment room. These requirements are carried over from Rules .0608(c)(1) and .0609(e)(1), which are specific to accelerator facilities, and refined for clarity in Rules .1904 and .2004. Rules .0608 and .0609 were last amended in 1994 and will be repealed during this rulemaking action.
- Parts .1904(a)(4) and .2004(a)(4) require that the radiation generating device be locked out of service if the surveys required by Parts .1904(a)(1) – (3) or .2004(a)(1) – (3) demonstrate that radiation exposure rates are in excess of the limits set by Rule .1601. The agency has interpreted Rule .0307(i)(10) which applies to periodic surveys of teletherapy units using radioactive materials to apply to surveys of accelerators conducted under Rules .0608 and .0609. 10 CFR 35.642(e), incorporated by reference in .0307(i)(10) and in Rule .0117(a)(E)(2), requires that teletherapy units be locked out if the survey reveals an unsafe condition until the unit can be

repaired. This rulemaking action clarifies the requirements regarding this situation for users of radiation generating devices.

- Paragraphs .1904(b) and .2004(b) provide options for licensees possessing radiation generating devices to resolve any issues caused by excessive dose rates outside the accelerator vault if the surveys required by Rules .1904(a) or .2004(a) reveal dose rates in excess of the regulatory limits in Rule .1601. These two rules codify agency practices and advice the agency gives to accelerator licensees when and if such circumstances occur. The agency has always permitted licensees using any source of radiation to 'fix' problems by a variety of means and these rules give clarification and guidance to accelerator licensees in addition to any advice the agency may offer.
- Paragraphs .1904(c) and .2004(c) clarify the requirement that accelerator licensees possess radiation detection equipment without specifying the type of equipment required. The current requirement, found in Rules .0909(a) and (d) was promulgated and last amended in 1980 when the agency was relying heavily on teletherapy rules to regulate the use of accelerators and had no experience with accelerators. Unlike teletherapy units which contain radioactive materials and always emit radiation, the radiation generated by accelerators can be 'turned off' by deenergizing the radiation generating machine. The requirement for portable radiation detection equipment found in Rule .0909(a) was created out of a misunderstanding of how accelerators work and an overabundance of caution. Radiation detection equipment required by Rule .0909(d) is still useful for ensuring that radiation is being generated by the accelerator and specialized portable survey equipment used for conducting various surveys and machine calibrations required by 10A NCAC 15 is still useful, but portable radiation detection equipment for use upon entering the treatment room is not necessary. This rule recognizes that fact and provides for radiation detection equipment that is more appropriate for accelerator uses and to modernize the rule.
- Paragraphs .1904(d) and .2004(d) clarify the requirement that medical use and veterinary use accelerator licensees send the results of surveys conducted to determine dose rates around accelerator vaults to the agency. This is a requirement found in Rule .0909(b) that applies to all accelerator licensees but not specifically to medical users and veterinary users of radiation generating machines. As noted earlier, Rule .0909 was last amended in 1980. Rules .0608(c)(1) and .0609(e)(1)(B), both last amended in 1994, also require that the licensee send reports of vault surveys to the agency, but the agency has generally relied on Rule .0909 for this purpose simply because the rules in Section .0900 are better understood by the regulated community. Rules .0608 and .0609 will be repealed through readoption during this rulemaking, further clarifying the record reporting requirements for users of radiation generating devices.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1905 Quality Management Program
10A NCAC 15 .2005 Quality Management Program

Proposed Rules .1905 and .2005 require the establishment of a program to ensure that radiation delivered to patients during medical and veterinary uses of radiation generating devices meet minimum standards of care established by the medical and veterinary communities. The requirement for a Quality Management Program is expressed through the requirement for written directives prescribing therapeutic doses of radiation exposure found in Rule .0307(b)(5). Rule .0307(b)(5) was readopted in 2024, but the

requirement for licensees to develop, maintain, and implement a quality management program for both diagnostic and therapeutic administrations of radioactive materials or radiation from a licensed source (electronic or radioactive material) is much older. The definitions in Rule .0104(25) addresses a document called the 'clinical procedures manual' that applies to diagnostic administration of radioactive materials that don't require a written directive. Rule .0104(109)(a) defines a "prescribed dose" in terms of a written directive for teletherapy and accelerator radiation. Rule .0104(164) defines a "treatment site" in terms of where a radiation dose is to be delivered during therapy. Rule .0104(178) defines what a "written directive" is and Subitem (c) of Rule .0104(178) delineates the information that must be on a written directive for teletherapy or accelerator radiation therapy. Rule .0318(l) requires that radiation be administered in accordance with a written directive if one is required. Rule .0356 describes written directives and the requirements for a quality management program in terms of how written directives are created, modified, and used to control the administration of radiation to patients. Rule .0364 requires that licensees report "medical events" where a radiation dose is not delivered in accordance with a written directive and the dose exceeds certain limits. Rule .0104 was last amended in 2013, Rules .0356 and .0364 were last amended in 2007. Rules .1905 and .2005 clarify the requirements for Quality Management Programs and is specifically tailored to accelerator users, unlike the requirements in Rules .0104, .0356, and .0364 that rely upon teletherapy device rules using radioactive materials and inaccurately reflect the needs of accelerator licensees.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1906 Therapeutic Radiation Machines of Less Than 500 kV
10A NCAC 15 .2006 Veterinary Therapeutic Radiation Machines of Less Than 500 kV

Proposed Rules .1906 and .2006 apply to the medical use and veterinary use of radiation generating devices, respectively. The requirements in both rules are updated and are nearly identical to the requirements found in Rule .0608. Rule .0608 was last amended in 1994 and will be repealed through readoption during this rulemaking. This Rule provides clarity to medical users and veterinary users using radiation from radiation generating devices with energies less than 500 keV by locating the requirements found in Section .0600 to Sections .1900 and .2000 that are proposed specifically for both communities of users of radiation generating devices for therapeutic purposes in patients. Most accelerator licensees are familiar with the rules in Section .0900, but few were fully aware of the requirements in Section .0600 that don't appear to apply to accelerator licensees but to which they are held responsible for complying with by the agency.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1907 Therapeutic Machines of 500keV and Above
10A NCAC 15 .2007 Veterinary Therapeutic Machines of 500keV and Above
Proposed Rules .1907 and .2007 apply to the medical use and veterinary use of radiation generating devices, respectively. The requirements in both rules are updated and are nearly identical to the requirements found in Rule .0609. Rule .0609 was last amended in 1994 and will be repealed through readoption during this rulemaking. This Rule provides clarity to medical users and veterinary users using radiation from radiation generating devices with energies of 500 keV and above by locating the requirements found in Section .0600 to Sections .1900 and .2000 that are proposed specifically for both communities of users of radiation generating devices for therapeutic purposes in patients. Most accelerator licensees are familiar with the rules in Section .0900, but few were fully aware of the requirements in Section .0600 that don't appear to apply to accelerator licensees but to which they are held responsible for complying with by the agency.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1908 Calibration of Survey Instruments and Dosimetry Systems
10A NCAC 15 .2008 Calibration of Survey Instruments and Dosimetry Systems
Proposed Rules .1908 and .2008 provide the requirements for calibrating survey instrumentation and using dosimetry systems to quantify radiation measurements during medical use and veterinary use of radiation generating devices.

- Paragraphs .1908(a) and .2008(a) provide the calibration requirements for instruments used to quantify levels of radiation in the environment for medical uses and veterinary uses of radiation generating devices, respectively. Quantifying radiation surveys measure the amount of radiation in a given area, while qualitative measurements only determine if radiation is or is not present in a given area. Quantifying levels of radiation is critical to determining dose and requires a rigorous calibration program to ensure that exposures are measured accurately. Survey instruments used to measure dose rates around accelerator vaults to demonstrate compliance with the dose limits in Rule .1601 currently must be calibrated in accordance with Rule .0307(d)(2) and records kept as required by .0307(k)(6). Rule .0307 was readopted in 2024. Prior to the readoption of Rule .0307, the requirements for calibrating survey instruments and recordkeeping were found in Rules .0360(e), (f) and (h). Rule .0360 was last amended in 2007. Both Rules .0307 and .0360 are radioactive materials rules adapted by the agency for regulating activities using accelerators.
- Paragraphs .1908(b) and (c) and Paragraphs .2008(b) and (c) provide the requirements for dosimetry systems used to measure doses delivered by radiation generating machines used for therapy in human and veterinary patients, respectively. The requirements for dosimetry systems are found in Rule .0307(i)(6) incorporating the dosimetry system requirements for teletherapy devices using radioactive materials by reference. Record keeping requirements for his activity are found in Rule .0307(k)(21) which are also radioactive materials requirements for teletherapy dosimetry systems. Rule .0307 became effective in 2024. Prior to 2024, these requirements were found in Rule .0117(a)(2)(E) and the agency applied these requirements to accelerator licensees

in the absence of rules specifically created for accelerator licensees. Rule .0117 was last amended in 2013.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1909 Shielding and Safety Design Requirements
10A NCAC 15 .2009 Shielding and Safety Design Requirements
Proposed Rules .1909 and .2009 specify the shielding and safety design requirements for accelerator vaults for medical use and veterinary use of radiation generating machines, respectively.

- Paragraphs .1909(a) and .2009(a) require primary or primary and secondary barriers that act as shielding to reduce exposures to meet the requirements of the dose limits in Rule .1601 and are very similar to the requirements in Rules .0608(b), .0609(c), and .0905(a). Rules .0608(b)(4)(A), .0609(d)(1) both require fixed barriers, and .0905(c) requires primary and secondary barriers to reduce doses to meet the exposure limits in Rule .1601. Both proposed rules clearly state the requirements for these barriers and combine them into rules that are easy to find, read, and understand. Rules .0608, .0609, and .0905 were last amended in 1994. Rules .0608 and .0609 will be readopted as repeals during this rulemaking, which will make the requirements both clearer and easier to comply with because most members of the regulated community are unfamiliar with the requirements found in Section .0600. Also, placing these requirements in rules specific to medical users and veterinary users will make compliance easier for our licensees.
- Paragraphs .1909(b) and Rules .2009(b) codify the requirement that authorized medical physicists and qualified experts use the most up-to-date recommendations and guidance to design and construct accelerator vaults for medical users and veterinary users of radiation generating devices. This is implied in Rule .0903(2) and in the requirement to use a qualified expert to design the vault in Rule .0905(a), but it is not explicitly stated as it is in both proposed rules. Rule .0903 became effective in 1980 and has never been amended; Rule .0905 was last amended in 1994. These two Paragraphs will make compliance easier for licensees
- Paragraphs .1909(c) and .2009(c) require that shielding plans be submitted to the agency for new accelerator vaults, if changes are made to equipment inside the vault, if the energies used for therapeutic radiation are increased, or if the workload using the radiation generating devices installed inside the vault increases above that used during the initial vault survey reviewed and approved by the agency. This requirement is stated in Rule .0909(b) in the general requirements for licensing accelerators, but not explicitly stated for medical or veterinary users of radiation generating machines. Rule .0909 became effective in 1980 and has not been amended since then. These two rules clarify this requirement and placing it in the rules specifically for those uses makes the requirement easier to find.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will

be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1910 Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage
10A NCAC 15 .2010 Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage

Proposed Rules .1910 and .2010 prohibit the use of radiation generating devices capable of producing therapeutic radiation doses for medical use or veterinary use, respectively, that are not otherwise regulated under the rules in Sections .1900 or .2000 without prior approval by the agency. These two rules reflect the risks posed by radiation generating devices used for therapy are that are not properly regulated as mirrored by the agency's application of the concepts behind Rule .0307(i)(1), incorporating 10 CFR 35.360(b) by reference, to accelerator licensees. Rule .0307(i)(1) requires that teletherapy units containing radioactive materials be used in accordance with the unit's sealed source and device registry sheet or in a manner that meets the requirements for safe use stated in the sealed source and device registry sheet, or for research under a device exemption issued by the Food and Drug Administration. Use of a teletherapy device under these conditions requires agency approval, and that concept is applied to users of radiation generating devices in the proposed rules. Rule .0307 was readopted in 2024. Prior to the readoption of Rule .0307, Rule .0117(a)(2)(E), incorporating Subpart H to 10 CFR was used for this purpose. Rule .0117 was last amended in 2013. These proposed rules clearly state the agency's requirements for the use of radiation generating devices for therapeutic uses other than those approved by the other rules in Sections .1900 or .2000.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15 or require any change to the operations of federal, state or local government. The only item of note in these Rules is administrative in nature that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1911 Emerging Technologies
10A NCAC 15 .2011 Emerging Technologies

Proposed Rules .1911 and .2011 apply to new technologies and technologies under development that are not foreseen by the existing rules regulating the use of radiation generating devices in Sections .1900 and .2000 for medical or veterinary use, respectively. These two proposed rules are based upon the emerging technology rules for radioactive materials found in Rule .0307(j) incorporating the regulations in Subpart K to 10 CFR 35 and in Rule .0117(a)(2)(E) incorporating 10 CFR 35.1000. As noted previously, Rule .0307 was readopted in 2024, and Rule .0117 was last amended in 2013. Both of the proposed rules codify the agency's requirements for new and developing technologies for radiation generating devices and clarify these requirements for the regulated community.

The aim of these proposed rules is to create a more efficient regulatory framework for new and innovative radiation generating device technologies for medical and veterinary applications in North Carolina. These rules balance innovation with safety. Currently, new technologies that don't quite fit into the existing regulatory framework would likely be evaluated for 'regulating by exemption.' Regulating by exemption refers to a regulatory process whereby the agency evaluates the technology as it would any other application for a license but then specifies the particular rule requirements to which the licensee is

exempt. This allows the new technology to be brought to market more quickly and cost effectively, but with a somewhat less rigorous set of requirements than is ideal. At best, regulating by exemption is an inefficient process. At worst, allowing for exclusions from certain radiation safety and training requirements may increase the potential risks to the health and safety of the public and occupationally exposed workers. In cases where regulating by exemption is not a palatable option for either the agency or the licensee, the licensee would have to delay launch of the new technology pending the outcome of a lengthy rulemaking process. The largest drawback to waiting for the adoption of new rules is that it delays the use of new technologies that could have significant benefits for patients in the near term. The proposed rules will fill this regulatory gap by allowing new technologies to be licensed in an efficient manner but with a more tailored, flexible set of guardrails than is currently available via existing regulations. This would eliminate the need for "regulating by exemption" and offer enhanced health and safety protections as compared to the existing process.

While there are currently no known emerging technologies that would immediately benefit from these rules, they would create a structure to handle future innovations more efficiently. As new technologies emerge, the agency may adopt additional regulations tailored to specific technologies, but only after initial deployment under these broader rules. Further impact analysis would be completed as part of any future rulemaking.

In other radiation protection areas, there have been examples of the flexibility currently available to the agency and the need for a more efficient regulatory process. For example, there are two North Carolina radioactive materials licensees where the application of the concept behind these two Rules impact patient care and made technology available that may have otherwise been delayed or not implemented. The first is a medical research and development (R&D) licensee who successfully brought three products to market for treating cancer. During research and development and the clinical trial phase the agency regulated all three products under 10 CFR 35 .1000. The agency determined that there were simply too many unknown factors to be resolved before regulatory requirements could be relaxed. After the clinical trials were completed and before the products were marketed the safety requirements for each of the products were reevaluated. The agency and the USNRC determined that the three products could be safely used under the regulations in 10 CFR 35 .400 as manual brachytherapy devices. Subsequently all three are sold worldwide and are regulated in the United States under 10 CFR 35 .400.

The second licensee is a major medical center in the state. This licensee possesses and treats patients with a device that ordinarily is regulated under 10 CFR 35 .600. However, the manufacturer made engineering changes to the device to enhance its features. The resulting changes in QA/QC and how the device functions differ so much from other devices of this type the USNRC regulates the device under 10 CFR 35 .1000. Unlike the R&D licensee's products, it is unlikely that the device at the medical center will ever be regulated under 10 CFR 35 .600 unless the USNRC amends its regulations to accommodate the device.

The cost to the agency for the enhanced flexibility associated with the proposed rules is no greater than with the current regulatory schema. In fact, it is likely that the proposed rules will result in modest opportunity cost savings for agency staff involved in evaluating applications since they will not need to spend time to identify specific concessions or exclusions that would be needed. The Rules specify what information is needed for licensing and inspections; it becomes a matter of determining if that information and the licensees' practices comply with maintaining doses ALARA. As new information is available regulatory requirements can be lightened or tightened to protect the health and safety of the public and occupationally exposed workers.

Neither of the proposed Rules impose burdens on the regulated community that are not already required by other rules in 10A NCAC 15. The rules should offer several key benefits to the regulated community such as the potential for faster market entry, reduced development time and associated costs, and reduced

regulatory uncertainty. Allowing for innovative technologies to reach the market faster could benefit the public by giving them faster access to the potentially life-saving medical technologies. The rules could also potentially improve safety protections which should minimize unnecessary radiation doses to patients and healthcare workers. Lastly, faster development and deployment of new technologies could stimulate economic growth in the medical and veterinary technology sectors, potentially leading to job creation. Because there are currently no known emerging technologies in these areas, the timing, magnitude and likelihood of realizing these impacts is highly uncertain.

Summary

The proposed changes to Sections .0900, .1900, and .2000 in 10A NCAC 15 aim to:

1. Update and readopt rules for therapeutic radiation generating devices, aligning them with existing rules and longstanding practices that currently apply to accelerator licensees in general.
2. Create new rules that clarify the regulatory framework specific to medical and veterinary accelerator licensees, including rules that will apply to emerging technologies.

Key points:

- Most requirements for accelerator licensees are not new but are adapted from teletherapy rules using radioactive materials in 10 CFR Part 35.
- Rules have been in use for over a decade, some since 1980.
- Changes resolve inconsistencies between radioactive materials and electronically produced radiation regulations.

Benefits include:

- Clearer guidance and reduced confusion for regulators and licensees
- Potentially smoother license application and license application review processes
- Greater consistency between inspections, licensing, and licensee performance
- Improved compliance with the rules
- Improved radiation safety standards

Expected impacts:

- Minimal time savings for accelerator licensees and regulators due to improved clarity.
- Little to no change in compliance costs compared to the baseline of continuing the current practice of applying radioactive materials rules to radiation generating devices.
- Potential incremental improvement in the safety of facilities and the operation of radiation generating devices. It is unknown to what extent the proposed rule changes will directly result in these types of improvement. Any improvement to radiation safety and the therapeutic use of radiation, however, can result in meaningful improvement in patient health outcomes, avoided radiation injury, and inadvertent radiation exposure to the public and occupationally exposed workers.

Appendix

10A NCAC 15 .0501 is proposed for amendment 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. May 1, ~~2024.~~2024; October 1, 2025.

10A NCAC 15 .0802 is proposed for amendment 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. November 1, ~~2024.~~2024; October 1, 2025.

10A NCAC 25 .0803 is proposed for amendment 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. November 1, ~~2024.~~2024; October 1, 2025.

10A NCAC 15 .0901 is proposed for readoption with substantive changes 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 proposed for readoption with substantive changes 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 proposed for readoption with substantive changes 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 on humans shall comply with the additional requirements of Section .1900 of this Chapter, and:

(A) be a board-certified physician licensed as outlined in Rule .1903(c)(1) of Section .1900 and licensed to practice medicine in the state of North Carolina; and,

(B) have a board-certified physicist outlined in Rule .1903(d)(1) – (3) of Section .1900.

(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

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 proposed for readoption with substantive changes 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.

10A NCAC 15 .0905 is proposed for readoption with substantive changes 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 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 (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.~~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 proposed for readoption with substantive changes 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.

10A NCAC 15 .0907 is proposed for readoption with substantive changes 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.

10A NCAC 15 .0908 is proposed for readoption with substantive changes 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 proposed for readoption with substantive changes 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 proposed for readoption with substantive changes 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; Effective October 1, 2025.

Rule 10A NCAC 15 .1001 is proposed for amendment 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, ~~2023.~~2023; October 1, 2025.

10A NCAC 15 .1601 is proposed for amendment 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 proposed for adoption 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 proposed for adoption 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) or (B) of this Chapter.

(30) "Quarterly" means at intervals not to exceed 13 consecutive weeks, plus or minus 7 consecutive days.

(31) "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) "Referring physician" means the physician whom referred the patient or human research subject to the licensee for specialized care.

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

(34) "Sievert" and "Sv" mean the SI unit of dose equivalent measured as 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) "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) "Therapeutic radiation machine medical event" means an event that meets the criteria in Rule .1905(a)(4).

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

(40) "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 proposed for adoption 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) 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.

10A NCAC 15 .1904 is proposed for adoption 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. 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 proposed for adoption 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 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.

10A NCAC 15 .1906 is proposed for adoption 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 Part (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 5 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 ± 5% 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 (3) 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 (a), 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 (f)(2) of this Rule;

(6) The licensee shall maintain a record of each quality assurance check required by this Paragraph for three (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 Subparagraphs (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 Chapter 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 proposed for adoption 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 5 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 ± 5% 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 (3) 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 Chapter 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 rule for three (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.

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

10A NCAC 15 .1908 is proposed for adoption 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:

(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 (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) 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 proposed for adoption 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 proposed for adoption 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 proposed for adoption 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 thirteen (13) months of the clinical use of the new technology or features which includes an assessment of the current use compared to Subparagraph (b) of this Rule and plan to either update the clinical use plan or steps to bring the clinical use back into alignment with Subparagraph (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.

(e) 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 proposed for adoption 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 proposed for adoption 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 proposed for adoption 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 Paragraph (c)(1) of this Rule but not yet certified by the date of application, certification shall be required within 6 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 7 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 subpart 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 sixty (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 proposed for adoption 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 (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 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 Subparagraph (a) 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 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. 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 .2005 is proposed for adoption 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 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. May 1, 2025.

10A NCAC 15 .2006 is proposed for adoption 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 5 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 ± 5% 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 paragraph (d)(3)(A) of this section 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. May 1, 2025.

10A NCAC 15 .2007 is proposed for adoption 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 5 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 ± 5% 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. May 1, 2025.

10A NCAC 15 .2008 is proposed for adoption 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:

(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. May 1, 2025.

10A NCAC 15 .2009 is proposed for adoption 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. May 1, 2025.

10A NCAC 15 .2010 is proposed for adoption 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. May 1, 2025.

10A NCAC 15 .2011 is proposed for adoption 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. May 1, 2025.