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.