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.