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;*
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