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 Subparagraph (c)(1) of this Rule but not yet certified by the date of application, certification shall be required within six 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 seven 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 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) 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 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.