

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 rules 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 Paragraph 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 Rule 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 Rule 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 Rule, 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 years that is acceptable to the certifying organizations identified in Subparagraphs (c)(1) through (c)(2) of this Rule.

(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 maintain certification by the American Board of Radiology in:
 - (A) Therapeutic Radiological Physics; or
 - (B) Therapeutic Medical Physics; or
- (2) Be certified and maintain certification by the American Board of Medical Physics in Radiation Oncology Physics; or
- (3) Be certified and maintain 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 Rule, 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 years that is acceptable to the certifying organizations identified in Subparagraphs (d)(1) through (d)(3) of this Rule.

(e) Training for Therapeutic Radiation Machine Radiation Safety Officer: The licensee for any therapeutic radiation machine subject to Rules within this Paragraph 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 Rule, 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 years that is acceptable to the certifying organizations identified in Subparagraphs (e)(2) through (e)(5) of this Rule.
- (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 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 Rule for three 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 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 medical physicists 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 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 Section 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;
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