

3701:1-67-02 General administrative requirements.

- (A) The handler shall be responsible for directing the operation of the therapy equipment. The handler shall ensure that the requirements of Chapter 3701:1-67 of the Administrative Code are met in the operation of the therapy equipment.
- (B) Therapy equipment that does not meet the provisions of rules within Chapter 3701:1-67 of the Administrative Code shall not be used for irradiation of patients.
- (C) For any therapy equipment subject to Chapter 3701:1-67 of the Administrative Code, the handler shall require the physician or veterinarian who authorizes use of the therapy equipment to be:
 - (1) Certified in one of the following:
 - (a) Radiation oncology or therapeutic radiology by the "American Board of Radiology" or combined diagnostic and therapeutic radiology program by the "American Board of Radiology" prior to 1976; or
 - (b) Radiation oncology by the "American Osteopathic Board of Radiology"; or
 - (c) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (d) Therapeutic radiology by the "Canadian Royal College of Physicians and Surgeons"; or
 - (e) Radiation oncology by the "American College of Veterinary Radiology"; or
 - (2) In active practice of therapeutic radiology, and has completed two hundred hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred hours of supervised work experience, and supervised clinical experience.
 - (a) To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of ionization radiation; and
 - (iv) Radiation biology.
 - (b) To satisfy the requirement for supervised work experience, training shall be under the supervision of a board certified authorized user who meets the qualifications of paragraph (C)(1) of this rule, and shall include:
 - (i) Review of the calibration measurements and quality assurance performance testing;

- (ii) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
 - (iii) Using administrative controls to prevent misadministrations;
 - (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
 - (v) Checking and using radiation survey meters.
- (c) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user.
- (i) The one year in a formal training program must be approved by either:
 - (A) The "Residency Review Committee" for "Radiology of the Accreditation Council for Graduate Medical Education"; or
 - (B) The "Committee on Postdoctoral Training" of the "American Osteopathic Association."
 - (ii) The additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user shall include:
 - (A) Examining patients and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations or contraindications;
 - (B) Selecting proper dose and how it is to be administered;
 - (C) Calculating the therapy equipment doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and treatment plans as warranted by patients' reaction to radiation; and
 - (D) Post-administration follow-up and review of case histories.
 - (d) For veterinary radiation oncology, completion of a formal training program approved by the "Executive Council" of the "American College of Veterinary Radiology" shall satisfy the requirement for supervised clinical experience.
- (D) For any therapy equipment subject to Chapter 3701:1-67 of the Administrative Code, the handler shall require the qualified medical physicist to:
- (1) Be certified by the "American Board of Radiology" in one of the following:
 - (a) Therapeutic radiological physics;
 - (b) Roentgen-ray and gamma-ray physics;
 - (c) X-ray and radium physics;

- (d) Radiological physics; or
- (2) Be certified by the "American Board of Medical Physics in Radiation Oncology Physics"; or
- (3) Be certified by the "Canadian College of Medical Physics"; or
- (4) Meet all of the following:
 - (a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
 - (b) Have completed one year of full time training in medical physics and an additional year of full time work experience under the supervision of a board certified medical physicist who meets the qualifications of paragraph (D)(1), (D)(2) or (D)(3) of this rule at a medical institution;
 - (i) This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy with photons and electrons with energies greater than or equal to one MV or one MeV; and
 - (ii) The individual shall have performed the tasks listed in rules 3701:1-67-08 and 3701:1-67-09 of the Administrative Code under the supervision of a qualified medical physicist during the year of work experience; and
 - (c) Obtain certification pursuant to paragraph (D)(1), (D)(2), or (D)(3) of this rule within five years of qualifying under paragraph (D)(4) of this rule.
- (E) Every individual who performs radiation therapy procedures on human beings shall be a licensed practitioner or hold a valid radiation therapist license as required by Chapter 3701-72 of the Administrative Code. The names and training of all personnel currently operating therapy equipment shall be kept on file at the facility. Information on former operators shall be retained for a period of at least three years beyond the last date they were authorized to operate the therapy equipment at that facility.
- (F) Written safe operating procedures shall be developed by a qualified medical physicist and shall be available in the control area of the therapy equipment, including any restrictions required for the safe operation of each piece of therapy equipment. The operator shall be able to demonstrate familiarity with these procedures, which shall address at least the following requirements:
 - (1) The therapy equipment shall not be used for irradiation of patients unless the applicable requirements of rule 3701:1-67-09 of the Administrative Code have been met;
 - (2) Therapy equipment shall not be left unattended unless secured to prevent unauthorized use;
 - (3) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

- (4) When only adjustable beam limiting devices are used for patient positioning purposes, the position and shape of the radiation field shall be indicated by a light field. The therapy equipment shall not be used for irradiation of patients unless the light field is operational;
 - (5) The therapy equipment shall not be used for patient irradiation unless at least one viewing system is operational;
 - (6) The therapy equipment shall not be used for irradiation of patients unless continuous two-way aural communication is possible;
 - (7) The equipment shall only be operated as designed by the manufacturer;
 - (8) No individual other than the patient shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes from therapy equipment operating above one hundred fifty kV. At energies less than or equal to one hundred fifty kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of rule 3701:1-38-12 of the Administrative Code; and
 - (9) For equipment operating at less than one megavolt (MV), the tube housing 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 fifty kV. In such cases, the holder shall wear protective gloves and an apron of not less than 0.5 millimeters lead equivalency at one hundred kV.
- (G) Representatives of the department may use interview or observation to determine that the handler assures:
- (1) Every individual who performs radiation therapy procedures on human beings holds a radiation therapist license as required by Chapter 3701-72 of the Administrative Code; and
 - (2) Every individual who performs radiation therapy procedures is adequately instructed in the handler's safe operating procedures and can demonstrate competency in the safe use of the equipment.
- (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 physician authorized to use the therapy equipment. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-medical purposes.
- (I) All individuals associated with the operation of therapy equipment shall be instructed in and shall comply with the provisions of the handler's quality management program. In addition to the requirements in Chapter 3701:1-67 of the Administrative Code, these individuals are also subject to the applicable requirements in Chapter 3701:1-38 and rule 3701:1-66-04 of the Administrative Code.
- (J) The handler shall maintain the following information in a separate file or package for each piece of therapy equipment, for inspection by the department:

- (1) Report of acceptance testing;
 - (2) Records of all surveys, calibrations, and quality assurance performance testing of the therapeutic radiation machine required by Chapter 3701:1-67 of the Administrative Code, as well as the names of people who performed such activities;
 - (3) Records of maintenance and/or modifications performed on each piece of therapy equipment, as well as the names of people who performed such services;
 - (4) Name and signature of the qualified medical physicist or authorized individual, as delineated in the quality assurance manual, authorizing the return of the therapy equipment to clinical use after any service or intervention that significantly affects patient treatment.
- (K) All records required by Chapter 3701:1-67 of the Administrative Code shall be retained until disposal is authorized by the department unless another retention period is specifically authorized in rules found within this chapter. All required records shall be retained in an active file from at least the time of generation until the next department inspection. Any required record generated prior to the last department inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the department authorizes final disposal.
- (L) The safe operating procedures required by paragraph (F) of this rule, shall also specifically address how the qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be contacted.
- (M) The director may, upon application thereof or upon his or her own initiative, grant a variance to the requirements of this rule as he or she determines is authorized by law, provided that the handler shows to the satisfaction of the director that there is good cause for the variance, and that the variance shall not result in any undue hazard or effect on the public health and safety. The terms, conditions, and expiration of the variance shall be set forth in writing by the director. Failure to comply with the terms of the variance may result in immediate revocation of the variance.

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