MEMORANDUM

Date: January 13, 2020

To: Interested Parties

From: James Castle, X-ray Program Administrator
       Bureau of Environmental Health and Radiation Protection

Subject: Draft Amendments to Ohio Administrative Code (OAC) Rules 3701:1-67-01, 02, 04, 05, 06, 07, 08, 09, 10, 11 and 12

The amendments to OAC rules 3701:1-67-01, 02, 04, 05, 06, 07, 08, 09, 10, 11 and 12 are being proposed as part of the five-year review. The rules set forth radiation safety and quality assurance requirements for facilities with radiation therapy equipment.

The proposed revisions were reviewed by the Radiation-Generating Equipment Committee (REC) and other members of the public attending the REC meeting on August 16, 2019. Please see the attached summary of amendments.

Please review the draft rule amendments and provide any comments you may have by February 13, 2020 to the address below. Please include the words “Comments to Proposed Amendments to Ohio Administrative Code Chapter 3701:1-67” in the subject line of all comments sent via regular mail or e-mail. The Ohio Department of Health will review and consider the comments received before the rule is submitted for formal rule proposal and adoption proceedings. Thank you.

Office of the General Counsel [Draft Revisions Chapter 3701:1-67]
Ohio Department of Health
246 N. High St.
Columbus, Ohio 43215
ODHRules@odh.ohio.gov
## ATTACHMENT

### SUMMARY OF REVISIONS TO CHAPTER 3701:1-67

<table>
<thead>
<tr>
<th>Rule 3701:1-67-01</th>
<th>Revisions to rule</th>
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</thead>
<tbody>
<tr>
<td>3701:1-67-01(B)</td>
<td>Removed unnecessary wording.</td>
</tr>
<tr>
<td>3701:1-67-01(B)(1)</td>
<td>Removed the typo &quot;D.&quot;</td>
</tr>
<tr>
<td>Old 3701:1-67-01(B)(4)</td>
<td>Removed. The definition of &quot;annually&quot; is already defined in Ohio Administrative Code 3701:1-38-01. This definition follows the national standards from the Nuclear Regulatory Commission and the Code of Federal Regulations.</td>
</tr>
<tr>
<td>3701:1-67-01(B)(9)</td>
<td>Modified to rule writing convention.</td>
</tr>
<tr>
<td>3701:1-67-01(B)(33)</td>
<td>Replaced old term &quot;misadministration&quot; with new term &quot;medical event.&quot;</td>
</tr>
<tr>
<td>3701:1-67-01(B)(34)</td>
<td>Modified to rule writing convention.</td>
</tr>
<tr>
<td>Old 3701:1-67-01(B)(36)</td>
<td>Removed old term &quot;misadministration&quot; that is no longer used in the Chapter.</td>
</tr>
<tr>
<td>3701:1-67-01(B)(56)</td>
<td>Modified to rule writing convention.</td>
</tr>
<tr>
<td>3701:1-67-01(B)(58)</td>
<td>Modified to rule writing convention.</td>
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<table>
<thead>
<tr>
<th>Rule 3701:1-67-02</th>
<th>Revisions to rule</th>
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<tbody>
<tr>
<td>3701:1-67-02(A)</td>
<td>Modified wording in paragraph for clarity.</td>
</tr>
<tr>
<td>3701:1-67-02(B)</td>
<td>Added the actor (handler) that must comply with the rule and modified wording in paragraph for clarity.</td>
</tr>
<tr>
<td>3701:1-67-02(C)(b)(iii)</td>
<td>Updated term to “medical event.”</td>
</tr>
<tr>
<td>3701:1-67-02(E)</td>
<td>Combined language with old paragraph (G) of this rule as the content is covering the same topic. Also, modified paragraph for clarity.</td>
</tr>
<tr>
<td>3701:1-67-02(F)</td>
<td>Modified paragraph for clarity.</td>
</tr>
<tr>
<td>3701:1-67-02(F)(10)</td>
<td>Combined old paragraph (L) into this rule as the content is covering the same topic.</td>
</tr>
<tr>
<td>Old 3701:1-67-02(G)</td>
<td>Removed and combined language with paragraph (E) as the content is covering the same topic.</td>
</tr>
<tr>
<td>New 3701:1-67-02(G)</td>
<td>Modified paragraph for consistency with other radiation protection regulations.</td>
</tr>
<tr>
<td>3701:1-67-02(I)</td>
<td>Explicitly identified the qualifications of the IRRP to meet the definition’s intent of having radiation safety knowledge.</td>
</tr>
<tr>
<td>Old 3701:1-67-02(K)</td>
<td>Removed this rule as it is arbitrary. Retention periods are already addressed in the rules as needed.</td>
</tr>
</tbody>
</table>
Combined language with paragraph (F)(10) of this rule as the content is covering the same topic. Referenced “chapter” so it encompasses the entire chapter which is consistent with other radiation-generating equipment rules.

**Rule 3701:1-67-04**

<table>
<thead>
<tr>
<th>Revisions to rule</th>
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<tbody>
<tr>
<td>3701:1-67-04(A)</td>
</tr>
<tr>
<td>Removed the word “registrant” for consistency with other radiation-generating equipment rules. The word “handler” is a broader term that includes registrants and unregistered facilities.</td>
</tr>
</tbody>
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**Rule 3701:1-67-08**

<table>
<thead>
<tr>
<th>Revisions to rule</th>
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<tbody>
<tr>
<td>Opening Paragraph</td>
</tr>
<tr>
<td>3701:1-67-08(G)</td>
</tr>
<tr>
<td>Removed the word &quot;protection&quot; and replaced with common term “area radiation survey.” Also incorporated the actor who performs the area radiation survey.</td>
</tr>
<tr>
<td>Old 3701:1-67-08(H)</td>
</tr>
<tr>
<td>Removed this rule as the amendments in paragraphs (G) and (I) now incorporate the actor who performs the area radiation survey.</td>
</tr>
<tr>
<td>New 3701:1-67-08(H)</td>
</tr>
<tr>
<td>Refined paragraph for clarity.</td>
</tr>
<tr>
<td>3701:1-67-08(I)</td>
</tr>
<tr>
<td>Updated rule reference and incorporated the actor (qualified medical physicist) who performs the area radiation survey.</td>
</tr>
<tr>
<td>3701:1-67-08(J)</td>
</tr>
<tr>
<td>Used common term &quot;area radiation survey” and updated rule reference.</td>
</tr>
<tr>
<td>3701:1-67-08(K)</td>
</tr>
<tr>
<td>Updated to common term &quot;area radiation survey.&quot;</td>
</tr>
<tr>
<td>3701:1-67-08(M)</td>
</tr>
<tr>
<td>Removed redundant language as it is now covered by the opening paragraph and used common term ‘area radiation survey.”</td>
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</table>

**Appendix 3701:1-67-08**

<table>
<thead>
<tr>
<th>Revisions to appendix</th>
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<tbody>
<tr>
<td>Opening Paragraph</td>
</tr>
<tr>
<td>Removed unnecessary sentence with incorrect rule reference.</td>
</tr>
<tr>
<td>Section II Item C</td>
</tr>
<tr>
<td>Corrected typo by adding hyphen in the referenced rule.</td>
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**Rule 3701:1-67-09**

<table>
<thead>
<tr>
<th>Revisions to rule</th>
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<tbody>
<tr>
<td>Opening Paragraph</td>
</tr>
<tr>
<td>3701:1-67-09(A)(2)</td>
</tr>
<tr>
<td>Identified the actor performing the action for this requirement.</td>
</tr>
<tr>
<td>3701:1-67-09(B)</td>
</tr>
<tr>
<td>Removed redundant language as it is now addressed by the opening paragraph.</td>
</tr>
<tr>
<td>3701:1-67-09(B)(2)</td>
</tr>
<tr>
<td>Removed redundant language as it is now addressed by the opening paragraph.</td>
</tr>
<tr>
<td>3701:1-67-09(B)(3)</td>
</tr>
<tr>
<td>Removed redundant language as it is now addressed by the opening paragraph.</td>
</tr>
<tr>
<td>3701:1-67-09(B)(4)</td>
</tr>
<tr>
<td>Removed redundant language as it is now addressed by the opening paragraph.</td>
</tr>
<tr>
<td>3701:1-67-09(C)</td>
</tr>
<tr>
<td>Identified the actor performing the action for this requirement.</td>
</tr>
<tr>
<td>3701:1-67-09(E)(1)</td>
</tr>
<tr>
<td>Updated address for the American Association in Physicists in Medicine.</td>
</tr>
<tr>
<td>3701:1-67-09(E)(2)(a)</td>
</tr>
<tr>
<td>Updated address for the American Association inPhysicists in Medicine.</td>
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<tr>
<td>3701:1-67-09(E)(2)(b)</td>
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<tr>
<td>Updated address for the American Association in Physicists in Medicine.</td>
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<tr>
<td>3701:1-67-09(E)(2)(c)</td>
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<tr>
<td>Updated address for the American Association in Physicists in Medicine.</td>
</tr>
<tr>
<td>3701:1-67-09(E)(2)(d)</td>
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<tr>
<td>Updated address for the American Association in Physicists in Medicine.</td>
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<tr>
<td>Rule 3701:1-67-10</td>
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<tr>
<td>Opening Paragraph</td>
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<tr>
<th>Rule 3701:1-67-12</th>
<th>Revisions to rule</th>
</tr>
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<tbody>
<tr>
<td>3701:1-67-12(J)</td>
<td>[Rationale: Updated rule reference.</td>
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(A) Terms defined in rule 3701:1-38-01 of the Administrative Code shall have the same meaning when used in Chapter 3701:1-67 of the Administrative Code except for:

(1) Terms redefined within this rule which shall be used within Chapter 3701:1-67 of the Administrative Code; and

(2) Terms redefined in specific rules in Chapter 3701:1-67 of the Administrative Code, are for use within that specific rule only.

(B) As used in this chapter, the following definitions apply:

(1) "Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

(2) "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

(3) "Air kerma" means the sum of the initial kinetic energy of all charged ionizing particles liberated by uncharged ionizing radiation in a given mass of air. The unit for air kerma is joules per kilogram which is given the special name of gray (Gy). To determine air kerma in Gy from exposure in units of roentgens (R) multiply exposure by the conversion factor 0.00876 Gy/R.

(4) "Annual" means at least once a year, not to exceed fourteen months.

(5) "Authorized user" means an individual qualified in accordance with paragraph (C) of rule 3701:1-67-02 of the Administrative Code.

(6) "Beam axis" means the axis of rotation of the beam limiting device.

(7) "Beam-limiting device" means a field defining collimator, integral to the therapy equipment, which provides a means to restrict the dimensions of the useful beam.

(8) "Beam monitoring system" means a system installed in the radiation head to detect and measure the radiation present in the useful beam.

(9) "Beam scattering foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

(10) "Computed tomography" or "(CT)" means an imaging procedure that uses multiple x-ray transmission measurements and a computer program to generate tomographic images of a patient or material.

(11) "Contact therapy system" means a therapeutic radiation machine that is a type of electronic brachytherapy device.
"Control panel" means that part of the radiation-generating equipment control system used to initiate and terminate the beam.

"Control system" means the collective hardware and software components used for determining and selecting the treatment parameters and monitor the course of treatment.

"Conventional simulator" means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

"Daily" means each treatment day before the evaluated equipment component is used clinically.

"Direct supervision" means to be physically present at the same address and available to respond to the needs of something or someone.

"Dose monitoring system" means

(a) "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

(b) "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Dose rate" means absorbed dose per unit time, for machines with timers, or monitor unit per unit time for linear accelerators.

"Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

"Electronic brachytherapy device" means the system used to deliver electronic brachytherapy including the x-ray tube, the control mechanism, the cooling system, and the power source.

"Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to preferentially attenuate selected radiations.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

"Handler" means a facility that handles radiation-generating equipment unless possession is solely for the purpose of transportation.

"Individual responsible for radiation protection (IRRP)" means an individual designated by the registrant who has the knowledge and responsibility for overall radiation safety and the quality
assurance program at the facility, to include daily radiation safety operations and compliance with the rules.

(28)-(26) "Intensity Modulated Radiation Therapy (IMRT)" means radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

(29)-(27) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(30)-(28) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions via the control system.

(31)-(29) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

(32)-(30) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

(33)-(31) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.

(34)-(32) "Light field" means the area illuminated by light, simulating the radiation field.

(33) "Medical Event" means an event that meets the criteria in paragraph (B) or (C) of rule 3701:1-67-12 of the Administrative Code.

(35)-(34) "Megavolt" or "(MV)" or "mega electron volt (MeV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.

(36) "Misadministration" means an event that meets the criteria in paragraph (A) or (B) of rule 3701:1-67-12 of the Administrative Code.

(37)-(35) "Mobile Electronic Brachytherapy Service" means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

(38)-(36) "Monitor unit" or "(MU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(39)-(37) "Monthly" means at least once each calendar month, not to exceed forty-five days from previous event.

(40)-(38) "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

(41)-(39) "Nominal treatment distance" means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
(b) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

(42)-(40) "Patient" means an individual or animal subjected to radiation from therapy equipment for the purposes of medical therapy.

(43)-(41) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(44)-(42) "Phantom" means an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

(45)-(43) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a piece of therapy equipment using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

(46)-(44) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

(b) "Secondary protective barrier" means the material which attenuates stray radiation.

(47)-(45) "Qualified Medical Physicist" means an individual qualified in accordance with paragraph (D) of rule 3701:1-67-02 of the Administrative Code.

(48)-(46) "Radiation detector or detector" means a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(49)-(47) "Radiation head" means the structure from which the useful beam emerges.

(50)-(48) "Redundant beam monitoring system" means a combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

(51)-(49) "Shutter" means a device attached to the tube housing assembly which can intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

(52)-(50) "Signature" or "sign" means an identifier that authenticates the person who made it.

(53)-(51) "Simulator" or "radiation therapy simulation system" means any x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field.

(54)-(52) "Source" means the point of origin of the useful radiation beam.

(55)-(53) "Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(56)-(54) "Stray radiation" means the sum of leakage and scattered radiation.
"Target" means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

"Target-skin distance" or "(TSD)" means the distance measured along the beam axis from the center of the front surface of the x-ray target and/or electron virtual source to the surface of the irradiated object or patient.

"Technique factors" means any combination of the following which determines the exposure rate: kVp, mA, time, x-ray pulses, or the product of tube current and exposure time in mAs.

"Tenth-value layer" or "(TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions via the control system.

"Therapy equipment" means x-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of these regulations, devices used to administer electronic brachytherapy or contact therapy shall also be considered therapy equipment.

"Treatment site" means the description of the specific tissue volume intended to receive a radiation dose, as described in the written directive and treatment plan.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

"Useful beam" or "radiation field" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapy equipment to produce radiation.

"Virtual Simulator" means a computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine; and that allows import, manipulation, display, and storage of images from CT and/or other imaging modalities.

"Virtual source" means a point from which radiation appears to originate.

"Wedge" means a device which effects continuous change in transmission over all or a part of the useful beam.

"Weekly" means once per calendar week in which the evaluated equipment component has or will be used clinically, unless the equipment component was not evaluated during the prior week. If the equipment component was not evaluated during the prior week, “weekly” means once per calendar week before the evaluated equipment component is used clinically.

"Written directive" means a documented order for the administration of radiation to a specific patient or human research subject, as specified in paragraph (B) of rule 3701:1-67-04 of the
(72)-(70) "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.
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) The handler shall not use 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 misadministration medical events;
(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. For any therapy equipment subject to
Chapter 3701:1-67 of the Administrative Code, the handler shall require:

(1) Every individual who performs radiation therapy procedures on human beings holds a valid radiation
therapist license as required by Chapter 3701-72 of the Administrative Code;

(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; and

(3) The names and training of all personnel currently operating the therapy equipment shall be kept on file at
the facility. The names and training of 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 The handler's written safe operating procedures shall be developed by a qualified medical physicist to
include any operation restrictions for the therapy equipment, and The written safe operating procedures 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 and the operator shall be able to demonstrate familiarity
with these procedures, which The written safe operating procedures 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.

(10) How to contact the qualified medical physicist for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be contacted.

(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) (G) 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 licensed practitioner acting within his or her scope of practice for dental, medical or radiation therapy purposes. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-medical purposes is prohibited unless otherwise specified in rules promulgated under Chapter 4773 or 3748 of the Revised Code.

(I) (H) 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.

(I) The handler shall assure the individual responsible for radiation protection (IRRP) is qualified as one of the following:

(1) Ohio licensed to operate radiation-generating equipment excluding general x-ray machine operators;
(2) Registered veterinary technician and trained to operate veterinary radiation-generating equipment;

(3) Certified by the American Registry of Radiologic Technologists in a pathway involving ionizing radiation or certified by the Nuclear Medicine Technologist Certification Board;

(4) A radiation expert as defined in rule 3701:1-66-01 of the Administrative Code;

(5) A health physicist certified by the American Board of Health Physics; or

(6) An associate's degree or higher in health physics, radiologic science, nuclear medicine or nuclear engineering.

(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) (K) 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.
3701:1-67-04 Quality management program.

(A) Each registrant or handler of therapy equipment subject to the requirements of Chapter 3701:1-67 of the Administrative Code, shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the physician or veterinarian authorizing its use.

(B) The quality management program shall address, as a minimum, the following specific objectives regarding written directives:

1. A written directive must be dated and signed by a physician or veterinarian authorizing its use prior to the administration of radiation. If because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by an authorized user within forty-eight hours of the oral revision;

2. The written directive must contain the patient or human research subject’s name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions;

3. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the therapy equipment dose, or the next fractional dose; and

4. The handler shall retain a copy of the written directive for seven years.

(C) The handler shall develop, implement, and maintain for the duration of the registration, written procedures to provide high confidence that:

1. Prior to the administration of each radiation treatment, the patient’s or human research subject's identity is verified by more than one method as the individual named in the written directive;

2. Each administration is in accordance with the written directive;

3. The final plans of treatment and related calculations are in accordance with the respective written directives by:

   a. Checking the parameters and the results of the primary calculation with a secondary method to verify they are correct and in accordance with the written directive; and

   b. Verifying that the planned parameters are correctly transferred to the treatment charts; and

4. Any unintended deviation from the written directive is identified, documented, evaluated and appropriate action is taken.
3701:1-67-05 Standards for therapy equipment operating at less than one megavolt (MV).

As used in this rule, "therapy equipment" means therapy equipment operating below one megavolt (MV). In addition to the rules in Chapters 3701:1-38 and 3701:1-67 of the Administrative Code, handlers of therapy equipment shall comply with the following:

(A) When the x-ray tube is operated at its maximum rated tube current for the maximum kilovoltage (kV), the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapy equipment.

(1) For five kV to fifty kV systems, the leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one milligray (one hundred millirad) in any one hour.

(2) For greater than fifty kV and less than one MV systems, the leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed one centigray (one rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than one hundred square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed thirty centigrays (thirty rad) per hour.

(3) For each piece of therapy equipment, the handler shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraphs (A)(1) and (A)(2) of this rule for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the department.

(B) Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(C) Requirements for adjustable or removable beam limiting devices include:

(1) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five per cent of the useful beam for the most penetrating beam used; and

(2) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(D) The filter system shall be so designed that:

(1) Filters can not be accidentally displaced at any possible tube orientation;

(2) An interlock system prevents irradiation if the proper filter is not in place;

(3) The air kerma rate escaping from the filter slot shall not exceed one centigray (one rad) per hour at one meter under any operating conditions; and

(4) Each filter shall be marked as to its material of construction and its thickness.

(E) Requirements for tube immobilization include:

(1) The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

(2) The tube housing assembly shall be capable of being immobilized for stationary portal treatments unless
the unit is designed to be hand-held and the peak tube potential of the system does not exceed fifty kV.

(F) The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

(G) Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at one hundred kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(H) A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

   (1) A timer with a display shall be provided by the treatment control system. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

   (2) The timer shall be a cumulative timer that activates with an indication of "beam-on" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

   (3) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

   (4) The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

   (5) The timer shall not permit an exposure if set at zero;

   (6) The timer shall not activate until the shutter is opened if irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

   (7) The timer shall be accurate to within one per cent of the selected value or one second, whichever is greater.

(I) The control system, in addition to the displays required by other provisions in this rule, shall have:

   (1) An indication of whether electrical power is available to the control system and if activation of the x-ray tube is possible;

   (2) An indication of whether x-rays are being produced;

   (3) A means for indicating x-ray tube potential and current;

   (4) The means for terminating an exposure at any time;

   (5) A locking device which will prevent unauthorized use of the therapy equipment;

   (6) A positive display of specific filter(s) in the beam; and

   (7) A warning label which cautions individuals that radiation is produced when the therapy equipment is energized.

(J) When a control system may energize more than one x-ray tube:

   (1) It shall be possible to activate only one x-ray tube at any time;
(2) There shall be an indication at the control panel identifying which x-ray tube is selected to enable irradiation; and

(3) There shall be an indication at the tube housing assembly when that tube is selected to enable irradiation.

(K) There shall be a means of determining the central axis target-to-skin distance (TSD) to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(L) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "on" switch is energized, the beam shall be attenuated by a shutter. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(M) Therapy equipment having a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.
As used in this rule, "therapy equipment" means photon therapy systems and electron therapy systems operating at or above one megavolt (MV). In addition to the rules in Chapters 3701:1-38 and 3701:1-67 of the Administrative Code, handlers of therapy equipment shall comply with the following:

(A) Upon installation of therapy equipment, acceptance testing shall be performed to verify that the equipment complies with all manufacturer specifications. In the event that manufacturer specifications are unavailable for reference, all therapy equipment shall be tested to ensure compliance with the standards of this rule. Any modification of equipment that occurs pursuant to initial acceptance testing shall entail appropriate retesting in order to re-determine compliance with applicable manufacturer standards or standards of this rule.

(B) Leakage radiation outside the maximum useful beam in photon and electron modes shall not exceed the manufacturer specifications, or in the absence of the manufacturer specifications:

1. The absorbed dose due to leakage radiation, excluding neutrons, at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance, such as patient plane, shall not exceed a maximum of 0.2 per cent and an average of 0.1 per cent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters at a minimum of sixteen points uniformly distributed in the plane;

2. Except for the area defined in paragraph (B)(1) of this rule, the absorbed dose due to leakage radiation, excluding neutrons, at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 per cent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters;

3. For equipment manufactured after July 21, 2014, the neutron absorbed dose outside the useful beam shall be in compliance with "International Electrotechnical Commission Document 60601-2-1:2009/AMD1:2014 (IEC 60601-2-1:2009/AMD1:2014)," (IEC) documents which, may be purchased from the "IEC National Committee of United States of America, ANSI, 25 West 43rd Street, 4th Floor, New York, New York, 10036," telephone (212) 642-4900, http://www.iec.ch/. Evidence of a product conformity assessment (CA) showing the parameter referenced in this rule is in compliance with IEC 60601-2-1:2009/AMD1:2014 shall be considered adequate to meet the requirements of this rule; and

4. For each piece of therapy equipment, the handler shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraphs (B)(1) and (B)(2) of this rule for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the department.

(C) Leakage radiation through beam limiting devices shall not exceed the manufacturer specifications, or in the absence of the manufacturer specifications, shall meet the following:

1. Using photon radiation, all adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed two per cent of the maximum absorbed dose on the central axis of the useful beam measured in a one hundred square centimeter radiation field, or
(2) Using electron radiation, all adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(a) A maximum of two per cent and average of 0.5 per cent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(b) A maximum of ten per cent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam; and

(3) Measurements of leakage radiation for:

(a) Photon radiation shall have measurements through the beam limiting devices made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters; and

(b) Electron radiation shall have measurements through the electron applicators made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

(D) Filters and wedges shall comply with the following:

(1) Each wedge that is removable from the system shall be clearly marked with an identification number. For removable wedges, the nominal wedge angle shall appear on the wedge or wedge tray, if it is permanently mounted to the tray. If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

(2) If the absorbed dose rate information required by paragraph (I) of this rule relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by authorized service personnel; and

(3) For equipment manufactured after June 01, 2013, which utilizes wedges, interchangeable field flattening filters, or interchangeable beam scattering foils:

(a) Irradiation shall not be possible until a selection of a wedge or a positive selection to use "no wedge" has been made via the treatment control system, either manually or automatically;

(b) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(c) A display shall be provided by the treatment control system showing the wedges, interchangeable
field flattening filter(s), or interchangeable beam scattering foil(s) in use; and

(d) An interlock shall be provided to prevent irradiation if any filter or beam scattering foil selection operation carried out in the treatment room does not agree with the filter or beam scattering foil selection operation carried out via the treatment control system.


(F) All therapy equipment subject to the requirements of this rule shall be provided with redundant beam monitoring systems. The detectors for these systems shall be fixed in the useful beam during treatment to indicate the dose rate.

(1) Each redundant beam monitoring system shall be provided with an independently powered integrating dose meter. Alternatively, dose meters with shared components may be used if the production of radiation is terminated upon failure of any common components.

(2) The detector and the system into which that detector is incorporated shall meet the following requirements:

(a) Each detector shall form part of a beam monitoring system from whose readings the absorbed dose at a reference point can be calculated;

(b) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation;

(c) For equipment manufactured after June 01, 2013, the design of the beam monitoring systems shall ensure that the:

(i) Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

(ii) Failure of either system shall terminate irradiation or prevent the initiation of radiation; and

(d) Each beam monitoring system shall have a legible treatment control system display. For therapy equipment manufactured after February 15, 2001, each display shall:

(i) Maintain a reading until intentionally reset;

(ii) Have only one scale and no electrical or mechanical scale multiplying factors;

(iii) Utilize a design such that increasing dose is displayed by increasing numbers; and

(iv) In the event of power failure, the beam monitoring information required in paragraph (F)(2)(d)(iii) of this rule, displayed by the control system at the time of failure shall be retrievable in at least one system for a twenty minute period of time.
(G) The following requirements shall be met for beam symmetry:

(1) A bent-beam linear accelerator with beam flattening filter(s) subject to the requirements of this rule shall be provided with auxiliary device(s) to monitor beam symmetry;

(2) The device(s) referenced in paragraph (G)(1) of this rule, shall be able to detect field asymmetry greater than ten per cent; and

(3) The device(s) referenced in paragraph (G)(1) of this rule, shall be configured to terminate irradiation if the specifications in paragraph (G)(2) of this rule, cannot be maintained.

(H) The following requirements shall be met for the selection and display of monitor units:

(1) Irradiation shall not be possible until a new selection of a number of monitor units has been made via the treatment control system;

(2) The pre-selected number of monitor units shall be displayed by the treatment control system until reset manually for the next irradiation;

(3) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(4) For therapy equipment manufactured after June 01, 2013, it shall be necessary for the operator to reset the pre-selected monitor units after each termination of an irradiation and before a new irradiation can be initiated.

(I) For therapy equipment manufactured after June 01, 2013, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in paragraph (F) of this rule may form part of this system. In addition:

(1) The monitor unit rate shall be displayed by the treatment control system;

(2) If the therapy equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the handler;

(3) If the therapy equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four gray (four hundred rad); and

(4) For each piece of therapy equipment, the handler shall determine, or obtain from the manufacturer, the maximum value(s) specified in paragraphs (I)(2) and (I)(3) of this rule, for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the department.

(J) During stationary beam radiation therapy, termination of irradiation by the beam monitoring systems shall meet the following requirements:
(1) The primary system shall terminate irradiation when the pre-selected number of monitor units set via the control system has been detected by the system; 

(2) The secondary system shall be capable of terminating irradiation when not more than fifteen per cent or forty monitor units above the pre-selected number of monitor units set via the control system has been detected by the system; and 

(3) For equipment manufactured after February 15, 2001, a treatment control system indicator shall show which monitoring system has terminated irradiation.

(K) It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(L) If the therapy equipment has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(M) A suitable irradiation control system shall be provided to terminate the irradiation after a pre-set time interval and shall meet the following requirements:

(1) A timer shall be provided which has a treatment control system display. The timer shall have a pre-set time selector and an elapsed time indicator; 

(2) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator; and

(3) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(N) Therapy equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made via the treatment control system; 

(2) The radiation type selected shall be displayed by the treatment control system before and during irradiation; 

(3) An interlock system shall be provided to ensure that the therapy equipment can principally emit only the radiation type that has been selected; 

(4) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted; 

(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and 

(6) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the operations selected via the treatment control system.
(O) Therapy equipment capable of generating radiation beams of different energies shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of energy has been made via the treatment control system;

(2) The nominal energy value selected shall be displayed by the treatment control system until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

(3) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.


(P) Therapy equipment capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made via the treatment control system;

(2) The mode of operation shall be displayed by the treatment control system;

(3) An interlock system shall be provided to ensure that the therapy equipment can operate only in the mode that has been selected;

(4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the parameter displayed by the treatment control system;

(5) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental monitor units and incremental movement. For therapy equipment manufactured after June 01, 2013:

(a) An interlock system shall be provided to terminate irradiation if the number of monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than twenty per cent from the selected value;

(b) Where angle terminates the irradiation in moving beam radiation therapy, the monitor units delivered shall differ by less than five per cent from the monitor unit value selected;

(c) An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;

(d) An interlock shall be provided to require that a selection of direction be made via the treatment control system in all units which are capable of both clockwise and counter-clockwise moving beam
radiation therapy; and

(e) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental monitor units and incremental movement;

(6) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by paragraph (J) of this rule; and

(7) For equipment manufactured after the effective date of this rule, an interlock system shall be provided to terminate irradiation if movement:

(a) Occurs during stationary beam radiation therapy; or

(b) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

(Q) The control panel shall have a warning label which cautions individuals that radiation is produced when the therapy equipment is energized.
3701:1-67-07 Survey and dosimetry instruments.

(A) The handler shall ensure each facility location authorized to use therapy equipment shall have available appropriately calibrated portable survey equipment, which is capable of measuring doses over the range ten microsievert (one mrem) per hour to ten millisievert (one thousand mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with rule 3701:1-67-07 of the Administrative Code.

(B) The handler shall ensure that the survey instruments used to show compliance with Chapter 3701:1-67 of the Administrative Code have been calibrated before first use, at intervals not to exceed twelve months, and following repair.

(C) To satisfy the requirements of paragraph (B) of this rule, the handler shall ensure that the survey instruments are:

1. Calibrated on all required scale readings up to ten millisieverts (one thousand millirem) per hour with an appropriate radiation source that is traceable to the "National Institute of Standards and Technology" (NIST); and

2. Calibrated on at least two points on each scale to be calibrated. These points should be at approximately one-third and two-thirds of full-scale.

(D) To satisfy the requirements of paragraph (C) of this rule, the handler shall:

1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten per cent; and

2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty per cent if a correction factor or graph is conspicuously attached to the instrument.

(E) The handler may obtain the services of individuals licensed by the department, the United States nuclear regulatory commission, or agreement state to perform calibrations of survey instruments.

(F) The handler shall retain a record of each calibration for three years. The record shall include:

1. A description of the calibration procedure; and

2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the name and signature of the individual who performed the calibration, and the date of calibration.

(G) The handler shall have a calibrated primary dosimetry system available for use. The system shall have been calibrated by the "National Institute for Standards and Technology" (NIST) or by an "American Association of Physicists in Medicine" (AAPM) "Accredited Dosimetry Calibration Laboratory" (ADCL). The calibration shall have been performed within the previous twenty-four months and after any servicing that may have affected system calibration.

1. For beams with energies greater than one MV (one MeV), the dosimetry system shall have been calibrated for cobalt-60; or

2. For beams with energies equal to or less than one MV (one MeV), the dosimetry system shall have been calibrated at an energy or energy range appropriate for the radiation being measured.
(H) The handler may have a secondary dosimetry system for quality assurance check measurements available for use. The system may either be calibrated according to the requirements of paragraph (G) of this rule or compared with a system that has been calibrated in accordance with paragraph (G) of this rule. If compared, the comparison shall have been performed within the previous twelve months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in paragraph (G) of this rule.

(I) The handler shall maintain a record of each dosimetry system calibration or comparison required by paragraph (G) and paragraph (H) of this rule for the duration of the registration. For each calibration or comparison, the record shall include:

1. The date;
2. The manufacturers' names, model numbers, and serial numbers of the instruments that were calibrated or compared;
3. The correction factors that were determined;
4. The names of the individuals who performed the calibration or comparison; and
5. Evidence that any comparison was performed by, or under the direct supervision and in the physical presence of, a qualified medical physicist.
3701:1-67-08   Shielding design and survey requirements.

In addition to the rules in Chapters 3701:1-38 and 3701:1-67 of the Administrative Code, handlers shall comply with paragraphs (A) through (L) of this rule.

(A) Therapy equipment subject to the rules in Chapter 3701:1-67 of the Administrative Code shall be provided with such primary and secondary barriers as are necessary to ensure compliance with rules 3701:1-38-12 and 3701:1-38-13 of the Administrative Code which prescribe occupational and public dose limits respectively. Specifically:

(1) All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers; and

(2) Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

(B) Treatment room design shall provide for:

(1) Continuous two-way aural communication between the patient and the operator at the control panel; and

(2) Continuous observation of the patient during irradiation. This viewing system shall be so located that the operator can observe the patient from the control panel. Therapy equipment shall not be used for patient irradiation unless at least one viewing system is operational.

(C) For therapy equipment operating above 150kV, treatment rooms shall meet the following:

(1) All protective barriers shall be fixed, except for entrance access doors to the treatment room or movable 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; and

(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths if applicable, 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.

(D) For therapy equipment operating at or above one MV, treatment rooms shall meet the following:

(1) In addition to other requirements specified in Chapter 3701:1-67 of the Administrative Code, the control panel shall:

(a) Be located outside the treatment room;

(b) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(c) Provide an indication of whether radiation is being produced; and

(d) Include an access control or locking device that will prevent unauthorized use of the therapy equipment;

(2) Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will state in words when the useful beam is on;
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 therapy equipment to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with paragraph (A) and paragraph (B) of rule 3701:1-38-13 of the Administrative Code, 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 barrier(s);

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. This switch is in addition to the termination switch required on the treatment control panel. All emergency power cutoff switches shall include a manual reset so that the therapy equipment cannot be restarted from the unit's control console without resetting the emergency cutoff switch; and

All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapy equipment.

A qualified medical physicist shall design shielding, verify shielding design or verify that the existing shielding is adequate for installation of therapy equipment.

The facility design information for all new installations of therapy equipment or installations of equipment of higher energy or capable of producing a larger maximum useful beam into a room not previously designed for that energy or beam size shall be submitted to the department prior to installation of the therapy equipment. The minimum facility design information that shall be submitted is listed in the appendix to this rule.

The handler shall ensure that an area radiation protection survey of all new facilities, and existing facilities not previously surveyed, are performed by, or under the direct supervision of a qualified medical physicist with an operable radiation measurement survey instrument calibrated in accordance with rule 3701:1-67-07 of the Administrative Code.

The radiation protection survey shall be performed by, or under the direct supervision of a qualified medical physicist.

With the area radiation survey shall be performed with the therapy equipment in the "beam-on" condition using the largest clinically available treatment field and with a scattering phantom in the useful beam when evaluating secondary protective barriers and no phantom in the useful beam when evaluating primary protective barriers, and with the therapy equipment in a "beam-on" condition, the qualified medical physicist shall verify that:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in rule 3701:1-38-12 of the Administrative Code; and
2. Radiation levels in unrestricted areas do not exceed the limits specified in rule 3701:1-38-13 of the Administrative Code.

In addition to the requirements of paragraphs (G) to (I) of this rule, an area radiation protection
survey shall also be performed by a qualified medical physicist or directly supervised by a qualified medical physicist prior to any subsequent medical use and:

(1) After making any change in the treatment room shielding;

(2) After making any change in the location of the therapy equipment within the treatment room except for portable contact therapy equipment, electronic brachytherapy equipment or portable external beam radiation therapy equipment capable of electron production only;

(3) After relocating the therapy equipment except for portable contact therapy equipment, electronic brachytherapy equipment or portable external beam radiation therapy equipment capable of electron production only;

(4) Before using the therapy equipment in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room; or

(5) After changes are made to the therapy equipment, the therapy equipment shielding, or the treatment room shielding following a survey that failed to ensure compliance with the requirements of this rule.

(6) Determination of residual activity for all therapy equipment capable of generating photon and electron energies above ten MV shall be performed to determine compliance with occupational dose limits prior to machining, removing, or working on therapy equipment components which may have become activated due to photo-neutron production.

(K)-(J) If the results of the area radiation surveys required by paragraphs (G) to (J)(I) of this rule indicate any radiation levels in excess of the respective limits, the handler shall lock the control in the "off" position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the therapy equipment, the therapy equipment shielding, or the treatment room shielding;

(2) Until either the equipment is provided with appropriate beam directional interlocks or additional radiation shielding is added to ensure compliance with rules 3701:1-38-12 and 3701:1-38-13 of the Administrative Code;

(3) Until implementation of administrative controls to reduce radiation levels below the respective limits; or

(4) Until the handler has requested and received a variance from the department that authorizes radiation levels in unrestricted areas greater than those permitted by rules 3701:1-38-12 and 3701:1-38-13 of the Administrative Code.

(L)-(K) The area radiation survey record shall indicate:

(1) All instances where the facility, in the opinion of the qualified medical physicist, is in violation of applicable regulations;

(2) The date of the measurements;

(3) The reason the survey is required;

(4) The manufacturer's name, model number and serial number of the therapy equipment;
(5) The manufacturers' names, model numbers, serial numbers, and dates of calibration of the instruments used to measure radiation levels;

(6) A plan of the areas surrounding the treatment room that were surveyed;

(7) The measured dose rate at a representative number of points in each area expressed in microsieverts (millirem) per hour;

(8) The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and

(9) The name and signature of the individual responsible for conducting the survey.

(M) (L) The handler shall maintain a record of each shielding design and area radiation survey for the duration of the registration and make the records and measurements available upon request during an inspection.
In accordance with paragraph (B) of rule 3701:1-67-08 of the Administrative Code, the following facility design requirements shall be met.

I. For all therapy equipment, the facility design plan shall include the following basic information: registration name and number, telephone number, and the name of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address and room number of the therapy equipment facility. The plan should also indicate whether this is a new structure or a modification to existing structure.

II. Therapy equipment operating at 150 kV or below (photons only).

In addition to the requirements listed in Section I above, therapy equipment which produce only photons with a maximum energy at or below 150 kV shall submit facility design information which contains, as a minimum, the following:

A. Equipment specifications, including the manufacturer and model number of the therapy equipment, as well as the maximum technique factors;

B. Maximum design workload for the facility including total weekly radiation output at the nominal treatment distance, the total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. A facility blueprint/drawing indicating: scale [0.25 inch equals 1 foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapy equipment treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with rules 3701:1-38-12 and 3701:1-38-13 of the Administrative Code;

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present; and

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s)] and shielding material in the facility:
1. If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

2. If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

III. Therapy equipment operating above 150 kV.

In addition to the requirements listed in Section I above, therapy equipment that produce photons with a maximum energy above 150 kV or electrons shall submit facility design information which contains, as a minimum, the following:

A. Equipment specifications including the manufacturer and model number of the therapy equipment, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced;

B. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze;

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy, source to isocenter distance, work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and "allowed" radiation exposure in both restricted and unrestricted areas; and

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility:

1. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date; and
2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron Shielding

In addition to the requirements listed in Sections I and III above, therapy equipment that are capable of operating above 10 MV shall submit facility design information which contain, as a minimum, the following:

A. The structural composition, thickness, minimum density and location of all neutron shielding material;

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, the combined photon and neutron contributions, total neutron absorbed dose and total neutron dose equivalent in both restricted and unrestricted areas, using the "National Council of Radiation Protection (NCRP) report 151, Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities" or equivalent acceptable to the department as a basis;

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e.: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility:

1. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date; and

2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

VI. References


C. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).

3701:1-67-09 Quality assurance for radiation therapy, simulation and image guidance equipment.

In addition to the rules in Chapters 3701:1-38 and 3701:1-67 of the Administrative Code, handlers shall comply with paragraphs (A) through (H) of this rule.

(A) For therapy equipment subject to this chapter, a qualified medical physicist shall develop a documented quality assurance (QA) program using the appropriate “American Association of Physicists in Medicine” (AAPM) reports or the “National Council of Radiation Protection” (NCRP) report as a basis.

(1) The quality assurance program shall:

(a) Identify each QA performance test to be performed;

(b) Describe the procedures used to complete each QA performance test;

(c) Describe the method used to document the results of each QA performance test;

(d) Identify the frequency of each QA performance test; and

(e) Specify the acceptable action limits and safety tolerance limits for each QA performance test result and the action to be taken when exceeded.

(2) Any variation from the identified tests, frequency or tolerance limits specified in the appropriate AAPM or NCRP reports shall be based on a documented history of therapy equipment performance or inherent therapy equipment design and be justified by the qualified medical physicist in the quality assurance program.

(3) Any QA performance test result exceeding a factor of two from the tolerances in AAPM or NCRP documents shall require immediate action prior to further treatment.

(B) The handler shall perform QA performance tests in accordance with the written procedures established by the qualified medical physicist and comply with the following:

(1) The authorized user and qualified medical physicist shall be immediately notified if any QA performance test result exceeds a safety tolerance limit set by the qualified medical physicist. The cause for a parameter exceeding the safety tolerance limit shall be investigated before the system is used for patient irradiation. The medical physicist in collaboration with the authorized user shall determine whether medical treatment may continue safely or be interrupted until corrected;

(2) The handler shall use a dosimetry system described in rule 3701:1-67-07 of the Administrative Code to perform absolute-dose related QA performance tests required by this rule;

(3) The handler shall have the qualified medical physicist review and sign the results of each QA performance test within a month of the date that the test was performed, by an individual other than the qualified medical physicist;

(4) The handler shall ensure that safety QA tests are performed monthly on the following:

(a) Electrical interlocks at each external beam radiation therapy room entrance;
(b) The "beam-on" and termination switches;
(c) All beam indicator lights;
(d) Patient audio visual viewing system; and
(e) If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(C) As used in this rule, “calibration” means the determination of the exposure or dose per unit time or absorbed dose per monitor unit (MU) under specified conditions as described by the qualified medical physicist in the quality assurance program. Calibration shall be performed:

1. Before the first medical use following installation or reinstallation;
2. Annually; and
3. Before medical use under the following conditions:
   (a) Whenever QA performance test results indicate the radiation output differs by more than five per cent from the calibration value obtained during the most recent annual QA performance tests and the difference cannot be reconciled. Calibration of therapy equipment with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and
   (b) Following any major mechanical, electrical or software based alterations affecting the radiation source, its housing, power supply or controls or after replacement of the radiation source. If an alteration or replacement does not affect all energies, calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in paragraph (C)(3)(a) of this rule.

(D) For therapy equipment operating at less than one megavolt (MV):

1. The qualified medical physicist shall use NCRP report 69, Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50MeV (1981) for commissioning, initial QA performance testing and to meet the requirements of paragraph (A) of this rule. The term “QA performance test”, as used in paragraph (D) of this rule, shall have the same meaning as the term “check” in the NCRP report.
2. Commissioning and initial QA performance testing shall be completed prior to medical use following installation or reinstallation.
3. Commissioning, initial and annual QA performance tests shall be performed by or under direct supervision of a qualified medical physicist.

(E) For therapy equipment operating at or above one megavolt (MV):

1. The qualified medical physicist shall use the "AAPP Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47 (AAPM report 47)," prepared by "Radiation Therapy Task Group 45" (this publication can be obtained from the American association of physicists in medicine, One Physics-Ellipse, College Park, MD 207401631 Prince St, Alexandria, VA 22314, telephone (301) 209-3350, http://www.aapm.org/pubs/reports) and the manufacturer's contractual specifications as a basis for
acceptance testing and commissioning.

(2) To meet the requirements of paragraph (A) of this rule, the qualified medical physicist shall use:


(b) "Task Group 142 report: Quality assurance of medical accelerators" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740 1631 Prince St, Alexandria, VA 22314, telephone (301) 209-3350, http://www.aapm.org/pubs/reports) for therapy equipment provided with asymmetric jaws, multileaf collimation, dynamic or virtual wedges, planar imaging devices, tomographic imaging devices or those used for stereotactic radiosurgery, stereotactic body radiation therapy, total body photon irradiation or intensity-modulated radiotherapy.

(c) The "Intraoperative radiation therapy using mobile electron linear accelerators: Report of AAPM Radiation Therapy Committee Task Group No. 72" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740 1631 Prince St, Alexandria, VA 22314, telephone (301) 209-3350, http://www.aapm.org/pubs/reports) for mobile electron linear accelerator therapy equipment.

(d) The "Report of AAPM TG 135: Quality assurance for robotic radiosurgery" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740 1631 Prince St, Alexandria, VA 22314, telephone (301) 209-3350, http://www.aapm.org/pubs/reports) for robotic radiosurgery therapy equipment.

(e) The "QA for helical tomotherapy: Report of the AAPM Task Group 148" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740 1631 Prince St, Alexandria, VA 22314, telephone (301) 209-3350, http://www.aapm.org/pubs/reports) for helical tomotherapy equipment.

(f) The "Comprehensive proton therapy machine quality assurance AAPM Task Group 224" (this publication can be obtained from the American association of physicists in medicine, 1631 Prince St, Alexandria, VA 22314, telephone (301) 209-3350, http://www.aapm.org/pubs/reports) for proton therapy equipment.

(3) Acceptance testing, commissioning and baseline QA performance testing shall be completed prior to medical use following installation or reinstallation.

(4) Acceptance testing, commissioning, baseline and annual QA performance tests shall be performed by or under direct supervision of a qualified medical physicist.

(5) An independent verification of the calibration of all photon beams and a sample of available electron
beams shall be performed annually by:

(a) A second radiation expert using a dosimetry system other than the dosimetry system that was used during the annual calibration; or

(b) A national institute of science and technology traceable third-party dosimetry service or an equivalent method which is capable of measuring doses with an accuracy within five percent.

(6) Proper operation of each emergency power cutoff switch shall be verified annually. If more than one switch is installed, they may be evaluated on a rotating basis throughout the year.

(F) For image guidance systems and conventional or virtual simulation:

(1) The qualified medical physicist shall use the "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group No. 40: AAPM Report No. 46 (AAPM report 46)" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 207401631 Prince St, Alexandria, VA 22314, telephone (301) 209-3350, http://www.aapm.org/pubs/reports) to meet the requirements of paragraph (A) of this rule for a conventional simulator.

(2) The qualified medical physicist shall use the "Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83 (AAPM report 83)" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 207401631 Prince St, Alexandria, VA 22314, telephone (301) 209-3350, http://www.aapm.org/pubs/reports) for acceptance testing, commissioning and to meet the requirements of paragraph (A) of this rule for a virtual simulator.

(3) The qualified medical physicist shall use the "Quality assurance for image-guided radiation therapy utilizing CT-based technologies AAPM Task Group 179" (this publication can be obtained from the American association of physicists in medicine, 1631 Prince St, Alexandria, VA 22314, telephone (301) 209-3350, http://www.aapm.org/pubs/reports) to meet the requirements of paragraph (A) of this rule for CT-based image guidance systems.

(3)(4) Acceptance testing, commissioning, initial QA performance testing, annual QA performance testing and semiannual (if appropriate) QA performance testing shall be performed by or under the direct supervision of a qualified medical physicist.

(G) For therapy equipment used for IMRT, patient specific treatment QC shall be performed before the first fraction is delivered unless extenuating circumstances are documented by the medical physicist. If a direct measurement for individual plans is not performed, the checks shall include both a dose calculation second check and a method to validate patient plan transfer and deliverability to the treatment unit.

(H) The handler shall maintain a record of each QA performance test result for three years and acceptance testing, commissioning and each calibration for the duration of the registration. The records shall include:

(1) The date of the QA test or calibration;
(2) The manufacturer's name, model number, and serial number of the therapy equipment;

(3) The manufacturer's name, model numbers and serial numbers for the instrument(s) used to measure the radiation output of the therapy equipment; and

(4) The signature of the individual who performed the QA performance test or calibration.
3701:1-67-10  Electronic brachytherapy.

In addition to the rules in Chapters 3701:1-38 and 3701:1-67 of the Administrative Code, handlers of electronic brachytherapy equipment shall comply with paragraphs (A) through (N) of this rule.

(A) Electronic brachytherapy devices shall be subject to the requirements of this rule, and shall be exempt from the requirements of rule 3701:1-67-05 of the Administrative Code.

(1) An electronic brachytherapy device that does not meet the requirements of this rule shall not be used for irradiation of patients; and

(2) An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the United States food and drug administration unless participating in a research study approved by the handler's institutional review board.

(B) Each facility location authorized to use an electronic brachytherapy device in accordance with the requirements of this rule, shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsievert (one millirem) per hour to ten millisievert (one rem) per hour. Each survey instrument shall be operable and calibrated in accordance with rule 3701:1-67-07 of the Administrative Code for the applicable electronic brachytherapy source energy.

(C) In addition to shielding adequate to meet requirements of rule 3701:1-67-08 of the Administrative Code, the treatment room shall meet the following design requirements:

(1) If applicable, provisions shall be made to prevent simultaneous operation of more than one piece of therapy equipment in a treatment room;

(2) Access to the treatment room shall be controlled by a door at each entrance;

(3) Each treatment room shall have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed;

(4) For electronic brachytherapy devices capable of operating below fifty kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield or as localized shielded material around the treatment site; and

(5) For electronic brachytherapy devices capable of operating at greater than one hundred fifty kV:

   (a) The control panel shall be located outside the treatment room; and

   (b) Electrical interlocks shall be provided for all door(s) to the treatment room that will:

      (i) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

      (ii) Cause the source to be shielded when an entrance door is opened; and

      (iii) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.
(D) Electrical safety for electronic brachytherapy devices shall include the following:

(1) The high voltage transformer shall be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

(2) The high voltage transformer shall be isolated from personnel, including the operator, and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

(3) The high voltage transformer shall have appropriate safety labels warning personnel of potential electrical shock and/or heat related injuries.

(4) Electronic brachytherapy devices shall be in compliance with the following "International Electrotechnical Commission" (IEC) documents which, may be purchased from the "IEC National Committee of United States of America, ANSI, 25 West 43rd Street, 4th Floor, New York, New York, 10036, telephone (212) 642-4900, http://www.iec.ch/":

(a) IEC 60601-1:2005, "General requirements for basic safety and essential performance;"

(b) IEC 60601-1-2:2007, "General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests;"

(c) IEC 60601-2-8:2010, "Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV;" and

(d) IEC 60601-2-17:2013, "Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment."

(E) The control panel, in addition to the displays required by other provisions in this rule, shall:

(1) Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

(2) Provide an indication of whether x-rays are being produced;

(3) Provide a means for indicating electronic brachytherapy source potential and current;

(4) Provide the means for terminating an exposure at any time;

(5) Include an access control or locking device that will prevent unauthorized use of the electronic brachytherapy device; and

(6) Bear a warning label indicating that radiation is produced when the therapy equipment is energized and that the equipment may be dangerous to patients and operators unless safety and operating instructions are observed.

(F) A suitable irradiation control device or timer shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor and satisfy the following:

(1) A timer shall be provided at the treatment control panel and shall indicate planned setting and the time elapsed or remaining;
(2) The timer shall not permit an exposure if set at zero;

(3) The timer shall be a cumulative device that activates with an indication of "BEAM ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(4) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation;

(5) The timer shall permit setting of exposure times as short as 0.1 second; and

(6) The timer shall be accurate to within one per cent of the selected value or 0.1 second, whichever is greater.

(G) The services of a qualified medical physicist shall be required in facilities having electronic brachytherapy devices.

(1) The qualified medical physicist shall be responsible for:

(a) Evaluation of the output from the electronic brachytherapy source;

(b) Generation of the necessary dosimetric information;

(c) Supervision and review of treatment calculations prior to initial treatment of any treatment site;

(d) Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in paragraph (K) of this rule;

(e) Consultation with the authorized physician or veterinarian in treatment planning, as needed;

(f) Performing calculations/assessments regarding patient treatments that may constitute a misadministration; and

(g) Developing a quality assurance program.

(2) If the qualified medical physicist is not a full-time employee of the handler, the operating procedures required by paragraph (H) 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.

(H) Operating procedures for electronic brachytherapy devices subject to the requirements of this rule shall include:

(1) Only individuals approved by the authorized physician or veterinarian, individual responsible for radiation protection, or qualified medical physicist shall be present in the treatment room during treatment;

(2) Electronic brachytherapy devices shall not be made available for medical use unless the requirements of paragraph (G) of rule 3701:1-67-08 of the Administrative Code, and paragraphs (I) and (J) of this rule have been met;

(3) The electronic brachytherapy device shall be inoperative, either by hardware or password, when unattended by qualified staff or service personnel;
(4) During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam;

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

(6) Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

(a) Instructions for responding to electronic brachytherapy device failures and the names of the individuals responsible for implementing corrective actions; and

(b) The names and telephone numbers of the authorized physicians or veterinarians, the designated qualified medical physicist, and the individual responsible for radiation protection to be contacted if the device or console operates abnormally.

(7) A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console. If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation;

(8) Instructions shall be posted at the electronic brachytherapy device control console or alternate location identified in paragraph (H)(7) of this rule, to inform the operator of the names and telephone numbers of the authorized physicians or veterinarians, the qualified medical physicist, and the individual responsible for radiation protection to be contacted if the device or console operates abnormally; and

(9) The individual responsible for radiation protection, or his/her designee, and an authorized physician or veterinarian shall be notified as soon as possible if the patient has a medical emergency, suffers injury or dies. The individual responsible for radiation protection or the qualified medical physicist shall inform the manufacturer of the event.

(I) Safety precautions for electronic brachytherapy devices subject to the requirements of this rule, shall include:

(1) A qualified medical physicist shall determine which persons in the treatment room require monitoring when the beam is energized;

(2) An authorized physician or veterinarian and a qualified medical physicist shall be physically present during the entire duration of all patient treatments involving the electronic brachytherapy device;

(3) When shielding is required by paragraph (C)(4) of this rule, a qualified medical physicist shall designate shield locations sufficient to meet the requirements of rule 3701:1-38-12 of the Administrative Code, for any individual, other than the patient, in the treatment room; and

(4) All personnel in the treatment room are required to remain behind shielding during treatment. A qualified medical physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

(J) Electronic brachytherapy source calibration measurements for an electronic brachytherapy device subject to the requirements of this rule shall include the following:
1) Calibration of the electronic brachytherapy source output shall be performed by, or under the direct supervision of, a qualified medical physicist;

2) Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

3) Calibration of the electronic brachytherapy source output shall utilize a dosimetry system described in paragraph (G) of rule 3701:1-67-07 of the Administrative Code;

4) Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:
   (a) The output within two per cent of the expected value, if applicable, or determination of the output if there is no expected value;
   (b) Timer and linearity over the typical range of use;
   (c) Proper operation of back-up exposure control devices;
   (d) Evaluation that the relative dose distribution about the source is within five per cent of that expected; and
   (e) Source positioning accuracy to within one millimeter within the applicator;

5) Calibration of the x-ray source output required by paragraphs (J)(1) to (J)(4) of this rule shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed; and

6) The handler shall maintain a record of each calibration in an auditable form for as long as the therapy facility exists. The record shall include:

   [Rationale: Removed language as it is now addressed in the opening paragraph.]

   (a) The date of the calibration;
   (b) The manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source;
   (c) The model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and
   (d) The name and signature of the qualified medical physicist responsible for performing the calibration.

(K) Periodic and day-of-use quality assurance checks for electronic brachytherapy devices subject to the requirements of this rule shall include the following:

1) Quality assurance checks shall be performed on each electronic brachytherapy device:
   (a) At the beginning of each day of use;
(b) Each time the device is moved to a new room or site, where site is intended to include each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer; and

(c) After each x-ray tube installation.

(2) The handler shall perform periodic quality assurance checks required by paragraph (K)(1) of this rule in accordance with procedures established by the qualified medical physicist;

(3) To satisfy the requirements of paragraph (K)(1) of this rule, radiation output quality assurance checks shall include, as a minimum:

(a) Verification that output of the electronic brachytherapy source falls within three per cent of expected values, as appropriate for the device, as determined by;

   (i) Output as a function of time, or

   (ii) Output as a function of setting on a monitor chamber.

(b) Verification of the consistency of the dose distribution to within three per cent of that found during calibration required by paragraph (J) of this rule; and

(c) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one millimeter; and

(4) The handler shall use a dosimetry system that has been intercompared within the previous twelve months with the dosimetry system described in paragraph (B) of rule 3701:1-67-07 of the Administrative Code to make the quality assurance checks required in paragraph (K)(3) of this rule;

(5) The handler shall review the results of each radiation output quality assurance check according to the following procedures:

   (a) An authorized physician or veterinarian and qualified medical physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within their acceptable tolerances;

   (b) If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized physician or veterinarian or qualified medical physicist within two days; and

   (c) The qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty days.

(6) To satisfy the requirements of paragraph (K)(1) of this rule, safety device quality assurance checks shall, at a minimum, assure:

   (a) Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;

   (b) Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;
(c) Proper operation of radiation monitors, if applicable;

(d) The integrity of all cables, catheters or parts of the device that carry high voltages; and

(e) Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

(7) If the results of the safety device quality assurance checks required in paragraph (K)(6) of this rule indicate the malfunction of any system, the handler shall secure the control console in the "OFF" position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

[Rationale: Correct typo.]

(8) The handler shall maintain a record of each quality assurance check required by paragraphs (K)(3) and (K)(7) of this rule in an auditable form for three years.

(a) The record shall include:

  (i) The date of the quality assurance check;

  (ii) The manufacturer's name, model number, and serial number for the electronic brachytherapy device;

  (iii) The name and signature of the individual who performed the periodic quality assurance check; and

  (iv) The date, name and signature of the qualified medical physicist who reviewed the quality assurance check;

(b) For radiation output quality assurance checks required by paragraph (K)(3) of this rule, the record shall also include:

  (i) The unique identifier for the electronic brachytherapy source; and

  (ii) The manufacturer's name, model number, and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

(L) The handler shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

(1) Acceptance testing shall be performed by, or under the direct supervision of, a qualified medical physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

  (a) The source-specific input parameters required by the dose calculation algorithm;

  (b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

  (c) The accuracy of isodose plots and graphic displays;
(d) The accuracy of the software used to determine radiation source positions from radiographic images; and

(e) If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(2) The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

(3) Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the authorized physician or veterinarian and the qualified medical physicist for correctness through means independent of that used for the determination of the parameters.

(M) Training for electronic brachytherapy devices subject to the requirements of this rule shall include the following:

(1) A handler shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in paragraph (H) of this rule. If the interval between patients exceeds one year, retraining of the individuals shall be provided.

(2) In addition to the requirements of paragraph (C) of rule 3701:1-67-02 of the Administrative Code, for authorized physicians or veterinarians of electronic brachytherapy equipment and paragraph (D) of rule 3701:1-67-02 of the Administrative Code, for qualified medical physicists, these individuals shall also receive device specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:

(a) Device-specific radiation safety requirements;

(b) Device operation;

(c) Clinical use for the types of use approved by the United States food and drug administration;

(d) Emergency procedures, including an emergency drill; and

(e) The handler's quality assurance program.

(3) A handler shall retain a record of individuals receiving instruction required by paragraphs (M)(1) and (M)(2) for three years. The record shall include:

(a) A list of the topics covered;

(b) The date of the instruction;

(c) The name(s) of the attendee(s); and

(d) The name(s) of the individual(s) who provided the instruction.
(N) A handler providing mobile electronic brachytherapy service shall, as a minimum:

(1) Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.

(2) Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

(3) Perform, at each location on each day of use, all of the required quality assurance checks specified in paragraph (K) of this rule to assure proper operation of the device.
3701:1-67-11 Other uses of electronic radiation-generating equipment for therapeutic purposes.

A person shall not utilize, for therapeutic purposes, any electronic radiation-generating equipment that is not appropriately regulated under any existing category of therapy equipment, until:

(A) The handler has, at a minimum, provided the department with:

(1) A detailed description of the therapy equipment and its intended application(s);

(2) Facility design requirements, including shielding and access control;

(3) Documentation of appropriate training for authorized physicians, veterinarians and qualified medical physicists;

(4) Methodology for measurement of dosages to be administered to patients or human research subjects;

(5) Documentation regarding calibration, maintenance, and repair of the therapy equipment, as well as instruments and equipment necessary for radiation safety;

(6) Radiation safety precautions and instructions; and

(7) Other information requested by the department in its review of the application; and

(B) The handler has received written approval from the department to utilize the therapy equipment in accordance with the rules and specific conditions the department considers necessary to assure safe operation and to provide adequate radiation protection.
3701:1-67-12 Unintended treatment deviations and notifications of medical events.

(A) Any unintended treatment deviation from the written directive or approved treatment plan shall be identified, evaluated, documented and appropriate action taken by the handler.

(B) A handler shall report any medical event resulting from intervention of a human patient or human research subject in which the administration of radiation from therapy equipment results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

(C) A handler shall report, as a medical event, any treatment deviation, except for a treatment deviation that results from intervention by a human patient or human research subject in which the administration of radiation from therapy equipment involves:

1. The wrong patient; where wrong patient means administration of radiation to an individual using a treatment plan intended for another patient or human research subject; or

2. The wrong treatment; where wrong treatment means administration of radiation to a human patient or human research subject that does not conform to the written directive and the approved treatment plan; and

   (a) The administered dose over the entire treatment course differs from the prescribed dose as stated in the written directive by more than ten per cent for treatment courses consisting of three or fewer fractions; or

   (b) The administered dose over the entire treatment course differs from the prescribed dose by more than twenty per cent for treatment courses consisting of more than three fractions; or

   (c) The administered dose over any five consecutive fractions differs from the prescribed dose by more than thirty per cent; or

   (d) The administered dose to any critical structure:

   (i) Exceeds the critical dose limit established in the written directive or approved treatment plan by twenty per cent or more; and

   (ii) Has the potential to cause serious harm according to the current published recommendations from a recognized national professional organization with expertise in radiation oncology.

(D) For purposes of paragraphs (C)(2)(a), (C)(2)(b) and (C)(2)(c) of this rule, "administered dose" means:

1. The D95 (minimum dose to ninety-five per cent of the prescribed volume) for computer treatment plans; or

2. The dose to the prescription point for treatments prescribed to a point.

(E) The handler shall notify the department by telephone no later than the next calendar day after the handler ascertains that a medical event occurred.

(F) The handler shall submit a written report to the department within fifteen days after the initial report of the medical event. The written report must include:

1. The handler or registrant name;
(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individual who received the medical event;

(6) Actions, if any, that have been taken, or are planned, to prevent recurrence; and

(7) Certification that the handler notified the individual, or the individual's responsible relative or guardian, and if not, why not.

(G) The report shall not contain the individual's name or any other information that could lead to the identification of the individual.

(H) The handler shall provide notification of the medical event to the referring physician no later than twenty-four hours after its discovery. The handler shall also notify the individual who is the subject of the medical event no later than twenty-four hours after the initial notification, unless the authorized user or referring physician determines that, based on their medical judgment, informing the individual would be harmful. The handler is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four hours, the handler shall notify the individual as soon as possible thereafter. The handler may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual’s responsible relative or guardian. If a verbal notification is made, the handler shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the handler upon request. The handler shall provide such a written description if requested.

(I) Aside from the notification requirement, nothing in this section affects any rights or duties of handlers, registrants and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(J) The handler shall retain a record of each unintended deviation in accordance with paragraph (J)(K) of this rule. If the unintended deviation is a medical event, a copy of the record shall be provided to the referring physician if other than the handler within fifteen days after its discovery.

(K) The handler shall retain a record of each unintended deviation for three years. The record must contain the following:

(1) The handler or registrant's name and the names of the individuals involved;

(2) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the unintended deviation;

(3) A brief description of the event; why it occurred; the effect, if any, on the individual;

(4) The actions, if any, taken or planned to prevent recurrence; and

(5) Whether the handler or the registrant notified the individual, or the individual's responsible relative or
guardian; and, if not, whether such failure to notify was based on guidance from the referring physician.
The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.
Reason for Submission

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

a. ☐ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.

b. ☐ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.

c. ☒ Requires specific expenditures or the report of information as a condition of compliance.

d. ☒ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language. Please include the key provisions of the regulation as well as any proposed amendments.

These regulations require facilities using radiation therapy equipment to meet radiation safety, quality assurance and equipment standards for safe treatment of patients. Please see the attachment for a listing of specific amendments.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

Ohio Revised Code 3748.04

4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? If yes, please briefly explain the source and substance of the federal requirement.

No.
5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

N/A.

6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

These regulations are in place to assure that therapy radiation-generating equipment meet standards to deliver controlled doses of radiation to patients to effectively treat cancer while reducing unnecessary radiation to unattended areas, and the likelihood of accidents resulting in patient harm or death. These regulations are necessary for the radiation safety and protection of Ohio citizens.

7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The Agency measures success of facilities meeting, gaining or maintaining compliance with regulatory requirements through inspecting facilities with radiation therapy equipment. In turn, radiation therapy equipment and facilities meeting safe operational and quality assurance requirements demonstrate few incidents of radiation induced deaths or health effects.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

On August 7, 2019 announcements and agendas were sent out through public affairs and B Radiation list serve emails identifying that a Radiation-Generating Equipment Committee (REC) meeting would be held on August 16, 2019. The REC is formed by the Governor appointed Radiation Advisory Council and is composed of Ohio experts in the field of radiation to include medical physicists, radiologists, physicians, technologists and educators. The REC, and other medical professionals and members of the public were at the meeting to provide input in the review and development of the amended rules.
10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The input provided by the medical physicists, oncologists, radiation therapists, and other medical professionals and members of the public included technical and clinical expertise to help make the regulations representative of current practices while focusing on radiation safety.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The regulations are comparable with the State Suggested Regulations from the Conference of Radiation Control Program Directors developed by scientific professionals in the field of radiation safety.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn’t the Agency consider regulatory alternatives?

The regulations are comparable with the State Suggested Regulations from the Conference of Radiation Control Program Directors and the Code of Federal Regulations developed by scientific professionals in the field of radiation safety. This includes technical expertise of the medical physicists, oncologists and radiation therapists at the REC meetings. Many of these individuals are members of such organizations as the American Board of Radiology, American College of Radiology, American Association of Physicists in Medicine, American Registry of Radiologic Technologist, etc. There are no alternatives with as much expertise and experience.

13. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the required outcome, but don’t dictate the process the regulated stakeholders must use to achieve compliance.

These regulations are mostly performance based because they define the acceptable results with minimal description of the processes for achieving compliance.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

A review of Ohio regulations found reference but no duplication in regulation. Also, the Ohio Department of Health (ODH) is designated as Ohio’s radiation control agency in RC 3748.02 and solely implements and administers all Ohio regulations concerning the possession and use of radiation-generating equipment.
15. Please describe the Agency’s plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The regulations are implemented through registration and inspection of facilities where radiation therapy equipment is used. The registration reviewers and inspectors of radiation therapy facilities are given extensive training to ensure that regulations are applied consistently and predictably to the regulated community.

**Adverse Impact to Business**

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. **Identify the scope of the impacted business community; and**

There are currently 106 therapy radiation-generating equipment registrants in Ohio affected by these regulations. The registrants vary from small offices and clinics to large medical facilities. These regulations provide standards that businesses must follow in order to assure radiation safety to all members of the public.

b. **Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance); and**

These regulations provide standards that businesses must follow in order to assure radiation safety to all members of the public. Inspectors look to see how well the registrants adhere to the radiation safety regulations and their Radiation Quality Assurance Program. The costs of compliance vary according to the scope, scale and nature of the operation of the medical practice.

c. **Quantify the expected adverse impact from the regulation.**

   *The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.*

Costs vary according to the scope, scale and nature of the equipment in operation and of the practice. The average annual costs to comply with the regulations for a single accelerator/vault is around $205,702.00. The source of this cost analysis is from medical physicists working in Ohio medical facilities.
17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

These regulations are necessary to assure that radiation therapy equipment meet standards to deliver controlled doses of radiation to patients to effectively treat cancer while reducing unnecessary radiation to unattended areas, and the likelihood of accidents resulting in patient harm or death. The regulations are necessary for the radiation safety of therapy equipment operators, patients and the general public, and were developed in consultation with representation from the regulated community.

**Regulatory Flexibility**

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Yes, these regulations allow variances (alternative means to meet the regulations) if the variance does not pose a health and safety risk to operators, patients or general public.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The Department of Health may and often does utilize settlements facilitated by the Ohio Attorney General’s office to effectuate the intent of section 119.14 of the Revised Code. In addition, Ohio Revised Code 3748.17(A) requires the Director of Health to provide facilities with notice of any violation of Ohio Revised Code 3748, or any rules adopted under that Chapter. Facilities have thirty days to correct their violations before the Department assesses any fines or penalties not otherwise required by law. And further, the Bureau of Environmental Health and Radiation Protection does not, as a matter of course assess fines and penalties for paperwork violations.

20. What resources are available to assist small businesses with compliance of the regulation?

The Department of Health has health physicists and administrative staff available to provide advice and guidance for regulatory compliance. Plus, the X-ray Program’s website at the Department of Health provides instruction for completing applications and regulatory guidance documents.