



## Ohio Administrative Code Rule 3701:1-67-10 Electronic brachytherapy.

Effective: September 1, 2022

---

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 inoperable, 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) A record of each calibration in an auditable form for as long as the therapy facility exists. The record shall include:

(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.

(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.