**Section 360.130 Electronic Brachytheraphy**

a) Applicability. Electronic brachytherapy devices shall be subject to the requirements of this Section and shall be exempt from the requirements of Section 360.110, unless otherwise noted in this Section.

1) An electronic brachytherapy device that does not meet the requirements of this Section 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 U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board.

b) Possession of Survey Instruments. Each registrant using an electronic brachytherapy device in accordance with this Section shall possess appropriately calibrated portable monitoring equipment. At a minimum, the monitoring equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated within the prior 12 months for the applicable electronic brachytherapy source energy.

c) Facility Design Requirements for Electronic Brachytherapy Devices. Each electronic brachytherapy installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with 32 Ill. Adm. Code 340.

1) If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine 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.

d) Control Panel Functions. The control panel, in addition to the displays required by other provisions in this Section, 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 a means for terminating an exposure at any time; and

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

e) Timer. A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor. The timer shall operate according to the manufacturer's design specifications.

f) Therapeutic Radiological Physicist Support. The services of a therapeutic radiological physicist shall be required in facilities having electronic brachytherapy devices. The therapeutic radiological physicist shall be responsible for:

1) Evaluation of the output from the electronic brachytherapy source;

2) Generation of the necessary dosimetric information;

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

4) Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in subsection (j);

5) Consultation with the physician in treatment planning, as needed;

6) Performing calculations/assessments regarding patient treatments that may constitute a misadministration.

7) Determination of the need for shielding or safe distances for individuals in the room during electronic brachytherapy treatments, in accordance with the radiation dose limits of 32 Ill. Adm. Code Part 340;

8) Implementation of the use of shielding or safe distances as determined in subsection (f)(7).

g) Operating Procedures

1) Only individuals approved by the physician or therapeutic radiological 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 this Section 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 therapeutic radiologic physicist shall ensure that all persons in the treatment room, and all persons entering the treatment room, are prevented from exceeding the radiation dose limits of 32 Ill. Adm. Code Part 340.

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 equipment failures and the names of the individuals responsible for implementing corrective actions; and

B) The names and telephone numbers of the physician and the therapeutic radiological physicist 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.

8) Instructions shall be posted at the electronic brachytherapy device control console to inform the electronic brachytherapy device operator of the names and telephone numbers of the physician and the therapeutic radiological physicist to be contacted if the device or console operates abnormally.

h) Safety Precautions for Electronic Brachytherapy Devices

1) A therapeutic radiological physicist shall determine which persons in the treatment room require radiation monitoring when the beam is energized.

2) A physician and a therapeutic radiological physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device.

3) A therapeutic radiological physicist and either a physician or an electronic brachytherapy device operator, under the supervision of a physician, who has been trained in the operation of, and emergency response for, the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device.

4) A therapeutic radiological physicist shall designate shield locations or safe distances sufficient to meet the requirements of 32 Ill. Adm. Code 340 for any individual, other than the patient, in the treatment room;

5) All personnel in the treatment room are required to remain behind shielding or at a safe distance specified by the therapeutic radiological physicist during treatment. A therapeutic radiological 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.

i) Electronic Brachytherapy Source Calibration Measurements

1) Calibration of the electronic brachytherapy source output for an electronic brachytherapy device shall be performed by, or under the direct supervision of, a therapeutic radiological 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 that meets the requirements of subsection 360.110(d)(4).

4) Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

A) The output within 2% of the expected value, if applicable, or determination of the output if there is no expected value;

B) Timer accuracy 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 5% of that expected; and

E) Source positioning accuracy to within one millimeter within the applicator.

5) Calibration of the x-ray source output shall be in accordance with the manufacturer's calibration protocol.

6) The registrant shall maintain a record of each calibration in an auditable form for 5 years. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source; the model numbers and serial numbers of the instruments used to calibrate the electronic brachytherapy device; and the name and signature of the therapeutic radiological physicist responsible for performing the calibration.

j) Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices

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; and

C) After each x-ray tube installation.

2) The registrant shall perform periodic quality assurance checks required by subsection (j)(1) in accordance with procedures established by the therapeutic radiological physicist;

3) Quality assurance checks shall include, at a minimum:

A) Verification that output of the electronic brachytherapy source falls within 3% 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 3% of that found during calibration required by subsection (i); and

C) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within 1 mm.

4) The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in subsection (i)(3) to make the quality assurance checks required in this subsection (j).

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

A) A physician and therapeutic radiological 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 therapeutic radiological physicist has determined that all parameters are within their acceptable tolerances; and

B) The therapeutic radiological physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

6) 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 indicate the malfunction of any system, a registrant 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 registrant shall maintain a record of each quality assurance check in an auditable form for 3 years.

A) The record shall include the date of the quality assurance check; the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check; and the name and signature of the therapeutic radiological physicist who reviewed the quality assurance check; and

B) The record shall also include the unique identifier for the electronic brachytherapy source; the manufacturer's name; and the model number and serial number for the instruments used to measure the radiation output of the electronic brachytherapy device.

k) Therapy-Related Computer Systems. The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with the manufacturer's acceptance testing protocol.

1) Acceptance testing shall be performed by, or under the direct supervision of, a therapeutic radiological 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 physician and the therapeutic radiological physicist for correctness through means independent of that used for the determination of the parameters.

l) Training

1) A registrant 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 subsection (g). If the interval between patients exceeds one year, retraining of the individuals shall be provided.

2) Physicians, therapeutic radiological physicists, and electronic brachytherapy device operators shall 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 the manufacturer's training protocol. 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 FDA;

D) Emergency procedures, including an emergency drill; and

E) The registrant's quality assurance program.

3) A registrant shall retain a record of individuals receiving instruction required by this subsection (l) for 3 years. The record shall include a list of the topics covered, the date of the instruction, the names of the attendees, and the names of the individuals who provided the instruction.

m) Mobile Electronic Brachytherapy Service. A registrant providing mobile electronic brachytherapy service shall, as a minimum:

1) Check all radiation 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 subsection (j) to assure proper operation of the device.

(Source: Added at 38 Ill. Reg. 12031, effective May 29, 2014)