



Michigan Department of Licensing and Regulatory Affairs
 Radiation Safety Section
Registration Conditions for Electronic Brachytherapy



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a. Applicability.

Under the provisions of rules R 333.5039(2) and R 333.5511, electronic brachytherapy devices shall be subject to the requirements of these registration conditions and the applicable requirements of Parts 4 and 5 of the Ionizing Radiation Rules.

b. Definitions.

"Electronic brachytherapy" means a form of radiation therapy where an electronic source of radiation is placed inside or close to the tumor or target tissue to deliver therapeutic radiation dosage.

"Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation 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.

"Transportable Electronic Brachytherapy Service" means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

c. Possession of Survey Instrument(s).

Each facility location authorized to use an electronic brachytherapy device shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable 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 instrument(s) shall be operable and calibrated for Cs¹³⁷ with applicable correction factors for electronic brachytherapy source energy. The survey instrument(s) shall have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

d. Facility Design Requirements for Electronic Brachytherapy Devices.

The shielding design of the treatment room shall be submitted to the department for review and approval. The treatment room shall meet the following design requirements:

- i. If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.
- ii. Access to the treatment room shall be controlled by a door at each entrance.
- iii. 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.
- iv. Radiation shielding for the staff in the treatment room shall be available, either as a portable shield and/or as localized shielded material around the treatment site.

e. Control Panel Functions.

The control panel, in addition to the displays required by other provisions of these registration conditions, shall:

- i. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;
- ii. Provide an indication of whether x-rays are being produced;
- iii. Provide a means for indicating electronic brachytherapy source potential and current;
- iv. Provide the means for terminating an exposure at any time; and
- v. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

f. 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.

- i. A timer shall be provided at the treatment control panel. The timer shall indicate the planned setting and the time elapsed or remaining;
- ii. The timer shall not permit an exposure if set at zero;
- iii. 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;
- iv. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.
- v. The timer shall permit setting of exposure times as short as 0.1 second; and
- vi. The timer shall be accurate to within 1 percent of the selected value or 0.1 second, whichever is greater.

g. Medical Physicist Support.

- i. The services of a medical physicist shall be required in facilities having electronic brachytherapy devices. The medical 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 registration condition (k);
 - (5) Consultation with the physician user in treatment planning, as needed; and
 - (6) Performing calculations/assessments regarding patient treatments that may constitute a misadministration.

- ii. If the medical physicist is not a full-time employee of the registrant, the operating procedures required by registration condition (h) shall also specifically address how the medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the medical physicist can be contacted.

h. Operating Procedures.

- i. Only individuals approved by the radiation protection supervisor or medical physicist shall be present in the treatment room during treatment;
- ii. Electronic brachytherapy devices shall not be made available for medical use unless the requirements of registration conditions (i), and (j) have been met;
- iii. The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;
- iv. 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;
- v. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;
- vi. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:
 - (1) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
 - (2) The names and telephone numbers of the individuals to be contacted if the device or console operates abnormally.
- vii. A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console^{1/};

i. Safety Precautions for Electronic Brachytherapy Devices.

- i. Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to radiation from electronic brachytherapy equipment;
- ii. A physician user and a medical physicist shall be physically present during the a patient's initial treatment involving the electronic brachytherapy device;

^{1/} 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.

- iii. A physician user shall be present in the facility during all subsequent patient treatments;
- iv. A medical physicist shall use a survey meter to verify proper placement of the shielding during the patient's initial treatment. A medical physicist shall designate shield locations sufficient to meet the requirements of the dose limits of Part 3 for any individual, other than the patient, in the treatment room for subsequent treatments; and
- v. All personnel in the treatment room are required to remain behind shielding during treatment. A 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.

- i. Calibration of the electronic brachytherapy source output for an electronic brachytherapy device shall be performed by, or under the direct supervision of, a medical physicist;
- ii. 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;
- iii. Calibration of the electronic brachytherapy source output shall utilize a calibrated dosimetry system. The dosimetry system shall have been calibrated at the applicable electronic brachytherapy source energy. The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration;
- iv. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:
 - (1) The output within 10% of the vendor supplied value, if applicable, or determination of the output if there is no expected value;
 - (2) Timer accuracy and linearity over the typical range of use;
 - (3) Proper operation of back-up exposure control devices;
 - (4) Evaluation that the output or air kerma of the source is within 5 % of that expected; and
 - (5) Source positioning accuracy to within 1 millimeter within the applicator;

- v. Calibration of the x-ray source output 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.
 - vi. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. 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 instrument(s) used to calibrate the electronic brachytherapy device; and the name and signature of the medical physicist responsible for performing the calibration.
- k. Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices.**
- i. Quality assurance checks shall be performed on each electronic brachytherapy device:
 - (1) At the beginning of each day of use;
 - (2) Each time the device is moved to a new room or site^{2/}; and
 - (3) After each x-ray tube installation.
 - ii. The registrant shall perform periodic quality assurance checks required by registration condition (k)(i) in accordance with procedures established by the medical physicist;
 - iii. Radiation output quality assurance checks shall be performed at the frequencies listed in registration condition (k)(i) and shall include as a minimum:
 - (1) Verification that output of the electronic brachytherapy source falls within 3 % of expected values, as appropriate for the device, as determined by:
 - (a) Output as a function of time, or
 - (b) Output as a function of setting on a monitor chamber.
 - (2) Verification of the consistency of the dose distribution to within 3% of that found during calibration; and

^{2/} *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. See condition (l) for additional clarification.

- (3) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within 1 mm; and
- v. The registrant shall review the results of each radiation output quality assurance check according to the following procedures:
 - (1) A physician user and 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 medical physicist has determined that all parameters are within their acceptable tolerances;
 - (2) 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 a physician user or the medical physicist within 2 days; and
 - (3) The medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.
- vi. To satisfy the requirements of registration condition (k)(i), safety device quality assurance checks shall, at a minimum, assure:
 - (1) Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;
 - (2) Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;
 - (3) Proper operation of radiation monitors, if applicable;
 - (4) The integrity of all cables, catheters or parts of the device that carry high voltages; and
 - (5) Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.
- vii. If the results of the safety device quality assurance checks required in registration condition (k)(vi) 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.
- viii. The registrant shall maintain a record of each quality assurance check required by registration conditions (k)(iii) and (k)(vii) in an auditable form for 3 years.

- (1) 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 medical physicist who reviewed the quality assurance check;
- (2) For radiation output quality assurance checks required by registration condition (k)(iii), the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

I. Transportable Electronic Brachytherapy Service.

A registrant providing transportable electronic brachytherapy service shall, as a minimum:

- i. Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.
- ii. Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.
- iii. Perform, at each location on each day of use, all of the required quality assurance checks specified in registration condition (k) to assure proper operation of the device.