



**The 2007 AAPM response to the
CRCPD request for recommendations for the CRCPD's model
regulations for electronic brachytherapy**

January 2009

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Task Group Members

Bruce R. Thomadsen, Ph.D. (Chair)
University of Wisconsin at Madison

Peter J. Biggs, Ph.D.
Massachusetts General Hospital

Larry A. DeWerd, Ph.D.
University of Wisconsin ADCL

Charles W. Coffey II, Ph.D.
Vanderbilt University

Sou-Tung Chiu-Tsao, Ph.D.
Quality MediPhys LLC

Michael S. Gossman, M.Sc.
Tri-State Regional Cancer Center

Geoffrey S. Ibbott, Ph.D.
University of Texas, M. D. Anderson Cancer Center

Mohammad K. Islam, Ph.D.
Princess Margaret Hospital

Shirish K. Jani, Ph.D.
Sharp Memorial Hospital

M. Terry LaFrance, M.Sc.
Baystate Health Systems

Ali S. Meigooni, Ph.D.
University of Kentucky

Mark J. Rivard, Ph.D.
Tufts University School of Medicine

Varun Sehgal, Ph.D.
University of California at Irvine

Rene J. Smith, Ph.D.
Reading Hospital & Medical Center

David J. Keys, Ph.D. (Professional Council)
Medical Physics Services, Ltd

Matthias Benker (Consultant from Carl Zeiss Surgical GmbH)

Thomas W. Rusch, Ph.D. (Consultant from Xoft, Inc.)

Preface

The American Association of Physicists in Medicine (AAPM) formed a Task Group under the Unconventional Brachytherapy Working Group of the Brachytherapy Subcommittee and the Radiation Safety Subcommittee of the Therapy Physics Committee (TPC). This Task Group, TG-152, was formed on 22 February 2007, and had its report approved by TPC on April 27, 2007. The Science Council approved this preface and placing this report on the AAPM web site on 26 January 2009. At the formation of this Task Group, electronic brachytherapy beyond an intraoperative modality was an emerging technology for clinical practice and several states were proposing regulations. The charge of this task group was to propose a set of model regulations for consideration of the Council on Radiation Control Program Directors (CRCPD), which was to discuss possible model regulations at its May 2007 meeting. *This charge was executed. The AAPM suggestions are hereby made electronically available to the community.*

**Vj g'4229'CCRO 'tgur qpug'tq vj g'ETERF request for recommendations
for the CRCPD's model regulations for electronic brachytherapy**

X.2 Definitions: Suggested changes to the existing part X.2 of the CRCPD's Model State Regulations.

Add "Electronic Brachytherapy" means a method of radiation therapy using electrically generated x rays to deliver a radiation dose at a distance of up to a few centimeters by intracavitary, intraluminal or interstitial application, or by applications with the source in contact with the body surface or very close to the body surface.

Add Authorized Medical Physics needs to be defined.

Consider Changing the term, "Misadministration," and the definition.

General Clean Up

X.4.c. Dosimetry Equipment.

- v. For electronic brachytherapy, the registrant shall have a dosimetry system available for use in calibrating the treatment unit.
 - a. This system shall have been calibrated either by the National Institute of Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) and traceable to NIST. The calibration shall have been performed within the previous 24 months and after any servicing that might have affected system calibration.
 - b. The calibration of the dosimetry system shall be for the source and energy or energies in use.

Electronic Brachytherapy.

- a. Scope. Electronic Brachytherapy devices are exempted from the requirements of Section X.6 [Therapeutic Radiation Machines of Less Than 500 kV].
- b. Possession of Survey Instrument(s). Each facility location authorized to use an electronic brachytherapy treatment unit shall possess a radiation survey meter as described in section X4ci [General Technical Requirements for Facilities Using Therapeutic Radiation Machines: Dosimetry Equipment] that is calibrated in accordance with X.8 [Calibration of Survey Instruments].
- c. Facility Design Requirements for Electronic Brachytherapy Units. In addition to shielding adequate to meet requirements of X.9 [Shielding and Safety Design Requirements], the following design requirements are made:
 - i. Each treatment room shall have provisions to permit continuous aural communication and visual observation of the patient or the human research subject (hereafter, simply the patient) from the treatment control panel during irradiation. The electronic brachytherapy unit shall not be used for patient irradiation unless the patient can be observed.
 - ii. If applicable, provision shall be made to prevent simultaneous operation of more than one radiation-producing therapeutic device in a treatment room.
 - iii. For electronic brachytherapy units operated at accelerating potentials lower than 60 kV:
 - (1) Access to the treatment room shall be controlled by a door at each entrance.

(2) 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. The shielding shall be designed (in terms width, height, thickness and distance from the source) to limit the radiation exposure to all personnel within permissible limits.

iv. Electrical Safety:

(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 (e.g., operator) and the environment by 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) All electrical equipment shall follow Medical Electrical Equipment Standards or their revisions, where appropriate, particularly:

(a) IEC 60601-1:1998+A1+A2:1995 Medical Electrical Equipment - Part 1: General Requirements for Safety

(b) IEC 60601-1-2:2001 Medical Electrical Equipment. General Requirements for Safety. Collateral Standard. Electromagnetic Compatibility. Requirements and tests

(c) IEC 60601-2-8:1999 Medical Electrical Equipment - Part 2-8: Particular requirements for the safety of therapeutic x-ray equipment operating in the range from 10 kV to 1MV

(d) IEC 60601-2-17:2004 Medical Electrical Equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment

d. Treatment-unit Requirements.

i. The control panel shall provide:

a. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

b. An indication of whether x-rays are being produced;

c. A means for indicating x-ray tube potential and current;

d. The means for terminating an exposure at any time

ii. A suitable irradiation-control device shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

a. A dwell-duration display/timer or integrator shall be provided at the treatment control panel. The dwell-duration display/timer or integrator shall indicate planned setting as well as the time or signal elapsed or remaining;

b. The dwell-duration display/timer or integrator shall be a cumulative device that activates with an indication of the treatment delivery ("beam in use") and retains its reading after irradiation is interrupted or terminated.

c. The dwell-duration display/timer or integrator shall terminate irradiation when a pre-selected time or integrated signal has elapsed, if any dose monitoring system present has not previously terminated irradiation;

d. The dwell-duration display/timer or integrator shall permit setting of exposure times as short as 0.1 second;

e. The dwell-duration display/timer shall not permit an exposure if set at zero;

f. The dwell-duration display/timer shall be accurate to within 1 percent of the selected value or 0.1 second, whichever is greater.

e. Authorized Medical Physicist Support.

The services of an Authorized Medical Physicist shall be required in facilities using electronic brachytherapy units. The Authorized Medical Physicist shall be responsible for:

- i. Evaluation of the output from the electronic brachytherapy source;
- ii. Generation of the necessary dosimetric information;
- iii. Supervision and review of treatment calculations prior to initial treatment of any treatment site;
- iv. Establishing the quality assurance spot checks and reviewing the data from those checks as required in section (fill in number when done);
- v. Consultation with the authorized user in treatment planning, as needed; and
- vi. Perform calculations/assessments regarding patient treatments that may constitute medical events.

f. Operating Procedures.

- i. Only individuals approved by the Authorized User, Radiation Safety Officer, or Authorized Medical Physicist shall be present in the treatment room during treatment;
- ii. Protective shielding barriers shall be available for persons in the treatment room when the beam is energized. Personnel unable to remain behind the shielding should wear fluoroscopic aprons and thyroid shields when compatible with patient safety and necessary for the radiation exposure levels possibly encountered;
- iii. The Authorized Medical Physicist will determine which persons in the treatment room require monitoring when the beam is energized;
- iv. When the unit and/or shielding is portable, the operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment, or alternatively the Authorized Medical Physicist may define areas within the room and appropriate shield locations necessary to maintain safe radiation levels to the operator;
- v. An Authorized Medical Physicist shall be physically present from the initiation through the duration of all patient treatments involving the unit.
- vi. During operation, the 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;
- vii. The electronic brachytherapy unit shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;
- viii. A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy unit control console, which shall contain the manufacturer's contact information;
- ix. 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;
 - (2) The names and telephone numbers of Authorized Users, Authorized Medical Physicists, and the Radiation Safety Officer, to be contacted if the unit or console operates abnormally.
- x. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

- xi. The Radiation Safety Officer, or his/her designee, and an Authorized User shall be notified as soon as possible if the patient has a medical emergency, suffers injury or dies. The Radiation Safety Officer or the Authorized Medical Physicist shall inform the manufacturer of the event.

- g. X-ray Source Calibration Measurements.
 - i. Validation of the electronic brachytherapy x-ray source output shall be performed by, or under the personal supervision of, an Authorized Medical Physicist.
 - ii. Calibration validation measurements shall be made for each x-ray tube, or after any repair affecting the x-ray beam generation, or when indicated by the spot checks.
 - iii. Calibration validation must include, as applicable, determination of:
 - (1) The output within 2 % of the expected 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 relative dose distribution about the source is within 5 % of that expected;
 - (5) Source positioning accuracy to within 1 millimeter within the applicator;
 - iv. The validation of the output shall use a dosimetry system as described in X.4.c. [General Technical Requirements for Facilities Using Therapeutic Radiation Machines: Dosimetry Equipment] to measure the output.
 - v. The registrant shall make calibration measurements required by g.i. through g.iii of this section in accordance with any current recommendations from a recognized, national professional association (such as the American Association of Physicists in Medicine) for electronic brachytherapy when available. Equivalent alternative methods are acceptable. In the absence of a protocol by a national professional association, published protocol included in the device manufacturer's operator's manual should 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 unit and identification of the particular x-ray tube; the model numbers and serial numbers of the instruments used to calibrate the electronic brachytherapy unit; data and formulae used for the calibration and the signature of the Authorized Medical Physicist responsible for performing the calibration.

- h. Routine and Day-of-Use Periodic Spot checks for Electronic Brachytherapy Units.
 - i. A registrant authorized to use electronic brachytherapy units for medical use shall have a program to perform spot checks of each electronic brachytherapy facility and on each unit:
 - (1). At the beginning of each day of use of an electronic brachytherapy unit;
 - (2). Each time the unit is moved to a new room or site;
 - (3). After each x-ray tube installation.
 - ii. The registrant shall have the Authorized Medical Physicist establish written procedures for performing the spot checks.
 - (1). The Authorized Medical Physicist need not personally perform the spot check measurements, but maintains the responsibility for general supervision of the spot checks.
 - (2). If performed by someone else, the registrant shall require the Authorized Medical Physicist to review the results of each spot check within 2 days.
 - (3). The registrant shall maintain a record of the results of the spot check for the registrant.

- (4). The Authorized Medical Physicist shall notify the registrant as soon as possible in writing of any failures detected during the spot checks.
- iii. If the results of the checks required in section h.i. indicate the malfunction of any system, a registrant shall prevent clinical use of the system until repair.
- iv. A registrant shall retain a record of each check required by section h.i. in accordance with section i.
- v. To satisfy the requirements of section h.i., spot checks of safety devices must, at a minimum, assure proper operation of:
- (1). Radiation exposure indicator lights on the electronic brachytherapy unit and on the control console;
 - (2). Viewing and intercom systems in each electronic brachytherapy facility, if applicable;
 - (3). Radiation monitors, if applicable; and
 - (4). The integrity of all cables, catheters or parts of the device that carry high voltages.
- vi. To satisfy the requirements of section h.i., spot checks of dosimetry must include:
- (1). Checks that the output of the x-ray source falls within 3 % of expected values, which might include, as appropriate for the unit:
 - 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;
 - (3). Validation of the operation of positioning methods to assure that the treatment dose exposes the intended location within 1 mm; and
 - (4). Inspection of all treatment components (e.g., connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, treatment spacers) on the day of use for any imperfections.
- i. Records. A registrant shall retain a record of each check required for 3 years. The record shall include:
- i The date of the check;
 - ii The manufacturer's name, model number, and serial number of the electronic brachytherapy unit;
 - iii Notations indicating the operability of radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source-transfer tubes, and transfer tube-applicator interfaces, and source-positioning accuracy, as applicable ; and
 - iv The name and signature of the individual who performed the check.
- j. Treatment Planning
- i. Where applicable, the Authorized Medical Physicist shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:
 - (1) The source-specific input parameters required by the dose-calculation algorithm;
 - (2) The accuracy of dose, dwell-time (if applicable), and treatment-time calculations at representative points;
 - (3) The accuracy of isodose plots and graphic displays;
 - (4) The accuracy of the software used to determine source positions from images; and

(5) 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.

- ii. 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.
- iii. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the Authorized User and the Authorized Medical Physicist for correctness through means independent of that used for the determination of the parameters.

k. Training.

- i. A registrant shall provide instruction, initially to all individuals who operate the unit, as appropriate to the individual's assigned duties, in operating the unit. If the interval between patients exceeds one year, retraining of the individuals shall be provided.
- ii. The Authorized Users and Authorized Medical Physicists shall receive device specific instruction from the manufacturer, initially, and from trained persons annually.
- iii. The training shall be specific for the treatment unit, and of a duration as recommended by a national professional society (e.g., the American Association of Physicists in Medicine) if applicable, otherwise as specified by the device manufacturer, and shall include, but not be limited to:
 - (1) Unit-specific radiation safety requirements;
 - (2) Unit operation; and
 - (3) Emergency procedures, including an emergency drill.
- iv. A registrant shall retain a record of individuals receiving instruction required by this section for 3 years. The record shall include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.