PART XVI ELECTRONIC BRACHYTHERAPY

Rules 64E-5.1601 — 64E 5.1604 are effective March 12, 2009 and are designated as Revision 9 (R9).

PART XVI
ELECTRONIC BRACHYTHERAPY

R9 **64E-5.1601 Definitions.** The following definitions apply only in this part.

R9 (1) "AAPM" means the American Association of Physicists in Medicine,
R9 www.aapm.org.

R9 (2) "Authorized user" means a person who has met the requirements of subsection
R9 64E-5.1603(1), F.A.C.

R9 (3) "Authorized medical physicist" means a person who has met the requirements of
R9 subsection 64E-5.1603(2), F.A.C.

R9 (4) "Authorized operator" means a person who has met the requirements of
R9 subsection 64E-5.1603(3), F.A.C.

R9 (5) "Electronic brachytherapy" means a method of radiation therapy using
R9 electrically-generated x-rays to deliver a radiation dose at a distance of up to a
R9 few centimeters by intracavitary, intraluminal or interstitial application, or by
R9 applications with the source in contact with the body surface or very close to the
R9 body surface.

R9 (6) "Electronic brachytherapy device" or "device" means the system used to produce
R9 and deliver therapeutic radiation including the x-ray tube, the control mechanism,
R9 the cooling system, and the power source.

R9 (7) "Electronic brachytherapy source" or "source" means the x-ray tube component
R9 used in an electronic brachytherapy device.

R9 (8) "Medical event" means any event, except for an event that results from patient
R9 intervention, in which the administration of radiation results in:

R9 (a) A total dose delivered that differs from the prescribed dose by 20 percent
R9 or more;

R9 (b) A fractionated dose delivered that differs from the prescribed dose, for a
R9 single fraction, by 50 percent or more; or

R9 (c) A dose to the wrong individual or the wrong treatment site.

R9 (9) "Mobile electronic brachytherapy device" means a device which is transported
R9 from one address to be used at another address.

R9 (10) "Portable shielding" means shielding that can be easily moved into the primary or
R9 secondary beam in order to reduce the radiation exposure to the patient,
R9 occupational worker or a member of the public.

R9 Specific Authority: 404.051(4), 404.20, F.S.
R9 Law Implemented: 404.031, 404.051, 404.22, F.S
R9 History: New 03-12-2009

R9 **64E-5.1602 Administrative Requirements.**

R9 (1) Registration and Notification.

R9 (a) No electronic brachytherapy device may be used on a human without a
R9 current certificate of registration from the department.

R9 (b) An electronic brachytherapy device that is not operational and that is
R9 under the control of a registered vendor prior to final installation is exempt
R9 from the registration and fee requirements of this section.

R9 (c) A separate registration and radiation protection program are required for
R9 facilities for which one or more of the following applies:

R9 1. The facilities are not at the same physical address;

R9 2. The facilities are not under the same radiation safety program; or

R9 3. The facilities are not under the same management.

R9 (d) Each person who acquires an electronic brachytherapy device shall apply
R9 for registration of the radiation device with the department within 30 days
R13 after acquisition. Application for registration shall be on Form DH 1107,
R15 10/15, “Radiation Machine Facility Registration,” as incorporated in sub-
R9 paragraph 64E-5.511(2)(a)1., F.A.C. The application must include the
following documents:

R9 1. A list identifying the radiation safety officer and all authorized
R9 medical physicists, authorized operators, and authorized users
R9 except visiting authorized users, together with documentation of
R9 their training and education as described in Rule 64E-5.1603,
R9 F.A.C.;

R9 2. A copy of the most current record of surveys, calculations and
R9 quality assurance checks on each device;

R9 3. A current copy of the quality management program as described in
R9 subsection 64E-5.1604(3), F.A.C.;

R9 4. A current copy of the quality assurance program as described in
R9 subsection 64E-5.1604(4), F.A.C.; and

R9 5. A copy of the device manufacturer’s U.S. Food and Drug
R9 Administration certification; and

R9 6. Facility design information, which at a minimum must include:

R9 a. A diagram of the physical facility showing the location of the
R9 electronic brachytherapy treatment rooms;

R9 b. Whether the facility is a new structure or a modification to an
R9 existing structure; and

R9 c. The type and thickness of the portable shielding used for
R9 compliance and a procedure demonstrating the use of the
R9 shielding prior to treatment

R9 (e) The registrant shall update the registration on file with the department
R9 within 30 days of any change to any information reported in paragraph
R9 64E-5.1602(1)(d), F.A.C.

R9 (2) Installation, Maintenance or Repair.

R9 (a) Only a manufacturer's representative registered as a vendor under
R9 subsection 64E-5.511(3), F.A.C., shall install an electronic brachytherapy
R9 device.

R9 (b) Only a manufacturer's representative registered as a vendor under
R9 subsection 64E-5.511(3), F.A.C., or an authorized medical physicist shall
R9 adjust, repair, maintain, or service an electronic brachytherapy device in
R9 accordance with the manufacturer's guidelines.

R9 (c) A registrant shall retain a record of the installation, maintenance,
R9 adjustment, service and repair of an electronic brachytherapy device for 5
R9 years.

R9 (3) Fees. The registrant of an electronic brachytherapy device shall comply with the
R9 requirements of paragraph 64E-5.511(2)(b), F.A.C., and pay the fees for a
R9 medical accelerator unit.

Specific Authority: 404.051(4), 404.22, F.S.
Law Implemented: 404.051, 404.081(1), 404.22, F.S.
R15 History: New 03-12-2009, Amended 06-03-2015, 03-21-16

64E-5.1603 Training And Education.

R9 (1) Qualification of Authorized User.

R9 (a) The registrant shall require the authorized user to be a physician who:

R9 1. Is licensed by the department as a medical doctor or doctor of
R9 osteopathy;

R9 2. Has completed a manufacturer’s device-specific training as
R9 specified in subsection 64E-5.1603(5), F.AC.; and

R9 3. Is certified in:

R9 a. Radiation oncology or therapeutic radiology by the American
R9 Board of Radiology;

R9 b. Radiation oncology by the American Osteopathic Board of
R9 Radiology;

R9 c. Radiology, with specialization in radiotherapy, as a British
R9 "Fellow of the Faculty of Radiology" or "Fellow of the Royal
R9 College of Radiology"; or

R9 d. Therapeutic radiology by the Canadian Royal College of
R9 Physicians and Surgeons.

R9 (b) A physician shall not act as an authorized user for any electronic
R9 brachytherapy device until such time as said physician's training has been
R9 reviewed and approved by the department.

R9 (2) Qualification of Authorized Medical Physicist.

R9 (a) The registrant shall require the authorized medical physicist to be a
R9 person who:

R9 1. Is currently licensed pursuant to Section 483.901, F.S., as a
R9 therapeutic radiological physicist; and

R9 2. Has completed a manufacturer’s device-specific training as
R9 specified in subsection 64E-5.1603(5), F.A.C.

R9 (b) A medical physicist shall not act as an authorized medical physicist for any
R9 electronic brachytherapy device until such time as said physicist’s training
R9 has been reviewed and approved by the department

R9 (3) Qualification of Authorized Operator. A person, other than an authorized user, R9 who operates an electronic brachytherapy device to apply ionizing radiation to a R9 human, shall be:

R9 (a) Certified in accordance with the Chapter 468, Part IV,F.S., as a radiation R9 therapy technologist; and

R9 (b) Have completed a manufacturer's device-specific training as specified in R9 subsection 64E-5.1603(5), F.A.C.

R9 (4) Qualification of Radiation Safety Officer. The registrant shall require the radiation R9 safety officer to be a person who has completed a manufacturer's device specific R9 training as specified in subsection 64E-5.1603(5), F.A.C., and be:

R9 (a) An authorized user or authorized medical physicist; or

R9 (b) A person certified by:

R9 1. The American Board of Radiology in Radiology, Diagnostic R9 Radiology, Therapeutic Radiology, or Radiation Oncology;

V 2. The American Board of Health Physics in Comprehensive Health Physics;

R9 3. The American Board of Radiology in Radiological Physics, R9 Therapeutic Radiological Physics, or Medical Nuclear Physics;

R9 4. The American Board of Nuclear Medicine;

R9 5. The American Board of Science in Nuclear Medicine; or

R9 6. The American Board of Medical Physicists; or

R9 (c) A person who has completed classroom and laboratory training consisting R9 of the following:

R9 1. One hundred hours of radiation physics and instrumentation;

R9 2. Thirty hours of radiation protection;

R9 3. Twenty hours of mathematics pertaining to the use and R9 measurement of radiation;

R9 4. Twenty hours of radiation biology;

R9 5. Thirty hours of medical therapy training; and

R9 6. One year of full time experience in radiation safety at a medical R9 institution under the supervision of the individual identified as the R9 radiation safety officer.

R9 (5) Manufacturer's Training. The registrant shall require training in electronic
R9 brachytherapy device operation, safety procedures, and US Food & Drug
R9 Administration-approved clinical uses. All training taken to satisfy this
R9 requirement must have been completed within the 7 years preceding the date of
R9 application. This training requirement must be approved by the department and
R9 must be satisfied by:

R9 (a) Completion of a training program provided by the manufacturer; or

R9 (b) Completion of a training program which is provided by an institution
R9 approved by the manufacturer; or

R9 (c) Receiving training that is substantially equivalent to the manufacturer's
R9 training program from an authorized user or authorized medical physicist
R9 who is authorized to use the device on a department registration.

R9 (6) Annual Training.

R9 (a) The registrant shall provide radiation safety training, initially and at least
R9 annually, to all personnel providing patient care and treatment planning to
R9 patients.

R9 (b) The training should include device operation, safety procedures and
R9 clinical use updates.

R9 (7) Training Records. The registrant shall retain for three years a record of each
R9 individual receiving initial manufacturer's training and annual training.

R9 Specific Authority: 404.051(4), 404.22, F.S.
R9 Law Implemented: 404.051, 404.081(1), 404.22, F.S..
R9 History: New 03-12-2009.

64E-5.1604 General Technical Requirements For Electronic Brachytherapy Facilities.

R9 (1) Radiation Surveys.

R9 (a) The registrant shall ensure that a survey, as defined in subsection 64E-5.101(151), F.A.C., of all new facilities and existing facilities not previously surveyed, is performed with an operable radiation measurement survey instrument according to the requirements of Part III of Chapter 64E-5, F.A.C.

R9 (b) The survey shall be performed by, or under the direction of, an authorized medical physicist or radiation safety officer who shall determine and record whether radiation levels are in compliance with the dose limits of Part III of Chapter 64E-5, F.A.C. Portable shielding may be used to comply with these radiation dose limits. Such surveys shall be conducted with the electronic brachytherapy device controls, source position, portable shielding and site-specific scattering phantom all set so as to produce the highest radiation exposure level that could occur during treatment.

R9 (c) The survey record shall include: the date of the measurements; the reason the survey is required; the manufacturer's name, model number and serial number of the electronic brachytherapy device; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey.

R9 (d) A survey shall also be performed prior to any subsequent medical use, when:

R9 1. Making any change in the portable shielding;

R9 2. Making any change in the location where the electronic brachytherapy device is used within the treatment room; or

R9 3. Relocating the electronic brachytherapy device.

R9 (e) The registrant shall maintain the record of each survey for the duration of the registration.

R9 (2) Dosimetry Equipment.

R9 (a) For electronic brachytherapy devices, the calibration of the dosimetry system shall be for the source and energy or energies in use according to a current published protocol from a nationally-recognized professional association with expertise in electronic brachytherapy, such as the AAPM. In the absence of such a published protocol, the manufacturer’s current protocol shall be followed.

R9

R9 (b) The registrant shall have available for use a dosimetry system for quality
R9 assurance check measurements. The quality assurance check system
R9 may be the same system used to meet the requirement for calibration.

R9 (c) The registrant shall maintain a record of each dosimetry system
R9 calibration, intercomparison, and comparison for the duration of the
R9 registration. Each record shall include: the date; the model numbers and
R9 serial numbers of the instruments that were calibrated, inter-compared or
R9 compared; the names of the individuals who performed the calibration,
R9 intercomparison, or comparison, and; evidence that the intercomparison
R9 was performed by, or under the direct supervision and in the physical
R9 presence of, an authorized medical physicist of record.

R9 (3) Quality Management Program.

R9 (a) Each registrant under this part shall establish and maintain a written
R9 quality management program to provide a high confidence that electronic
R9 brachytherapy devices will be used as directed by the authorized user.
R9 The quality management program must include written policies and
R9 procedures to meet the following objectives:

R9 1. Except where a delay to provide a written directive as defined in
R9 subsection 64E-5.101(173), F.A.C., would jeopardize the patient's
R9 health as specified in sub-paragraphs 64E-5.1604(3)(a)2. and 3.,
R9 F.A.C., a written directive is prepared prior to administration of a
R9 therapeutic radiation dose;

R9 2. An oral directive is only acceptable when a delay to provide a
R9 written directive would jeopardize the patient's health because of
R9 the emergent nature of the patient's condition. The information
R9 contained in the oral directive must be documented immediately in
R9 the patient's record and a written directive prepared within 24 hours
R9 of the oral directive;

R9 3. An oral revision to an existing written directive is only acceptable
R9 when a delay to provide a written revision to an existing written
R9 directive would jeopardize the patient's health. The oral revision
R9 must be documented immediately in the patient's record and a
R9 revised written directive must be signed by the authorized user
R9 within 48 hours of the oral revision;

R9 4. A written directive that changes an existing written directive for any
R9 therapeutic radiation procedure is only acceptable if the revision is
R9 dated and signed by an authorized user prior to the administration
R9 of the therapeutic electronic brachytherapy dose, or the next
R9 electronic brachytherapy fractional dose;

R9 5. The patient's identity is verified by more than one method as the
R9 individual named in the written directive prior to administration;

6. The final plans of treatment and related calculations agree with the respective written directives;

7. Each administration agrees with the written directive; and

8. Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.

(b) The registrant shall retain for 3 years each written directive in an auditable form.

(c) The registrant shall develop procedures for and conduct a review of the quality management program including an evaluation of the following:

1. A representative sample of patient administrations within the review period, as described in a procedure submitted to the Department;

2. All recordable events, as defined in subsection 64E-5.101(123), F.A.C., within the review period; and

3. All medical events within the review period to verify compliance with all aspects of the quality management program.

(d) The review of the quality management program shall be conducted at intervals not to exceed 12 months. The registrant shall maintain a record of each dated review for inspection by the department in an auditable form for 3 years and shall include evaluations and findings of the review.

(e) The registrant shall evaluate each of these reviews to determine the effectiveness of the quality management program and make modifications to meet the objectives of the program.

(f) The registrant may make modifications to the quality management program to increase the program's efficiency as long as the program's effectiveness is not diminished. The registrant is required to submit any modifications to the quality management program to the department within 30 days after the modifications have been made.

(g) Within 30 days of discovery of each recordable event, as defined in subsection 64E-5.101(123), F.A.C., the registrant shall:

1. Assemble the relevant facts including the cause;

2. Identify and implement any corrective action required to prevent recurrence; and

3. Retain a record in an auditable form for 3 years of the relevant facts and any corrective action taken.

(h) Each registrant shall maintain records and reports of medical events until the termination of the registration.

R9 (4) Quality Assurance Program.

R9 (a) Each registrant shall develop and administer a written quality assurance program as a method of minimizing deviations from facility procedures and to document preventative measures taken prior to serious patient injury or medical event. The quality assurance program must include written procedures for performing:

R9 1. Treatment planning, chart and treatment field parameters;

R9 2. Patient simulation, verification of catheter placement and device exchange;

R9 3. Dose calculation and review; and

R9 4. Review of daily treatment records.

R9 (b) Deviations from the prescribed treatment or from the facility's quality assurance and operating procedures shall be investigated and brought to the attention of the authorized user, authorized medical physicist and radiation safety officer.

R9 (c) A review of the quality assurance program shall be conducted at intervals not to exceed 3 months and shall include all the deviations from the prescribed treatment. A signed record of each dated review shall be maintained for inspection by the department in an auditable form for 3 years and shall include evaluations and findings of the review.

R9 (5) Authority and Responsibilities.

R9 (a) Radiation Safety Officer.

R9 1. A registrant shall appoint a radiation safety officer responsible for implementing the radiation safety program. The registrant, through the radiation safety officer, shall ensure that radiation safety activities are performed in accordance with approved procedures and regulatory requirements in the daily operation of the electronic brachytherapy devices.

R9 2. The radiation safety officer shall promptly investigate and implement corrective actions as necessary regarding:

R9 a. Incidents as defined in Rule 64E-5.344, F.A.C.;

R9 b. Reportable events as defined in Rule 64E-5.345, F.A.C.; and

R9 c. Other deviations from approved radiation safety practice. A written report of these investigations and the corrective actions taken shall be given to management within 30 days of the incident, event or deviation.

R9 3. The radiation safety officer shall implement written policies and
R9 procedures to:

R9 a. Use electronic brachytherapy devices safely;

R9 b. Perform radiation surveys whenever necessary;

R9 c. Perform checks of survey instruments and other safety
R9 equipment;

R9 d. Train personnel who work in or frequent areas where
R9 radiation is present; and

R9 e. Keep a copy of all records and reports required by
R9 department regulations, a copy of these regulations, and a
R9 copy of each registration correspondence to the department,
R9 and the written policies and procedures required by the
R9 regulations.

R9 4. The radiation safety officer shall review at least every 3 months the
R9 occupational radiation exposure records of all personnel working
R9 with radiation therapy devices.

R9 (b) Authorized User. Authorized users shall:

R9 1. Be physically present during the initiation of each patient treatment;

R9 2. Be physically present during the continuation of each patient
R9 treatment or identify in writing a physician under the supervision of
R9 the authorized user who is trained in the operation of and
R9 emergency response for the device who will be physically present
R9 during the continuation of each patient treatment;

R9 3. Personally review the patient's case to assure that the therapeutic
R9 radiation procedure is appropriate; and

R9 4. Review the progress of the patient receiving therapy and modify the
R9 originally prescribed dose, if needed.

R9 (c) Visiting Authorized User.

R9 1. A registrant may permit any visiting authorized user to use an
R9 electronic brachytherapy device for medical use under the terms of
R9 the registrant’s registration and radiation protection program for 60
R9 days each year if:

R9 a. The visiting authorized user has the prior written permission
R9 of the registrant’s management;

R9 b. The registrant has a copy of an electronic brachytherapy
R9 device registration issued by the department or another state
R9 that identifies the visiting authorized user by name as an
R9 authorized user for medical use of an electronic
R9 brachytherapy device; and

R9 c. The visiting authorized user performs only those procedures
R9 for which he is specifically authorized by the registration
R9 described in sub-subparagraph 64E-5.1604(5)(c)1.b., F.A.C.

2. A registrant shall retain copies of the records specified in sub-paragraph 64E-5.1604(5)(c)1., F.A.C., for 5 years after the last visit of the visiting authorized user.

R9 (d) Authorized Medical Physicist. The authorized medical physicist shall:

R9 1. Be physically present during the initiation and continuation of each
R9 patient treatment.

R9 2. Evaluate the output from the electronic brachytherapy source;

R9 3. Generate the necessary dosimetry information;

R9 4. Review treatment calculations prior to initial treatment of any
R9 treatment site;

R9 5. Establish the quality assurance spot checks and review the data
R9 from those checks as required by the submitted procedures;

R9 6. Consult with the authorized user in treatment planning, as needed;
R9 and

R9 7. Perform calculations and assessments regarding patient treatments
R9 that may constitute medical events.

R9 (6) Operating Procedures. The registrant shall ensure compliance with the following
R9 procedures

R9 (a) An electronic brachytherapy device shall only be used as approved by the
R9 US Food and Drug Administration for human use.

R9 (b) When not in operation, the electronic brachytherapy device shall be
R9 secured from unauthorized use.

R9 (c) When a patient must be held in position for radiation therapy, mechanical
R9 supporting or restraining devices shall be used.

R9 (d) A copy of the current operating and emergency procedures shall be kept
R9 in close proximity to the electronic brachytherapy device and easily
R9 accessible to the operator.

R9 (e) No individual other than the patient shall be exposed during the treatment.

R9 (f) The radiation safety officer or his/her designee, and an authorized user, R9 shall be notified as soon as possible but no later than 24 hours after a R9 patient's, or human research subject's, medical emergency or death;

R9 (g) Only individuals approved by the authorized user, radiation safety officer, R9 or authorized medical physicist shall be present in the treatment room R9 during treatment and a written log shall be kept of all personnel present R9 during treatment;

R9 (h) Simultaneous operation of more than one radiation-producing device in a R9 treatment room shall be prohibited; and

R9 (i) The registrant shall develop, implement, and maintain written procedures R9 for responding to any situation in which the operator is unable to complete R9 the treatment in compliance with the written directive. These procedures R9 must include:

R9 1. Instructions for responding to equipment failures and the names of R9 the individuals responsible for implementing corrective actions;

R9 2. The process for restricting access to, and posting of, the treatment R9 area to minimize the risk of inadvertent exposure; and

R9 3. The names and telephone numbers of the authorized users, the R9 authorized medical physicist, and the radiation safety officer to be R9 contacted if the device operates abnormally.

R9 (7) Possession of a Survey Instrument. Each facility location authorized to use an R9 electronic brachytherapy device shall possess portable monitoring equipment. At R9 a minimum, such equipment shall include a portable radiation measurement R9 survey instrument capable of measuring dose rates over the range 0.1 R9 microsievert (0.01 millirem) per hour to 10 millisievert (1000 millirem) per hour. R9 All survey instruments shall be operable and calibrated annually.

R9 (8) Calibration.

R9 (a) Validation of the electronic brachytherapy source output shall be R9 performed by an authorized medical physicist.

R9 (b) Calibration validation measurements shall be made for each x-ray tube, or R9 after any repair affecting the x-ray beam generation, or when indicated by R9 the spot checks.

R9 (c) Calibration validation must include determination of:

R9 1. The output within 2% of the expected value, or determination of the R9 output if there is no expected value;

R9 2. Timer accuracy and linearity over the typical range of use;

R9 3. Proper operation of back-up exposure control devices;

R9 4. Evaluation that the relative dose distribution about the source is
R9 within 5% of that expected; and

R9 5. Source positioning accuracy to within 1 millimeter within the
R9 applicator;

R9 (d) The validation of the output shall use a dosimetry system as described by
R9 the facility's procedures to measure the output. Such procedures shall
R9 use a current published protocol from a nationally-recognized professional
R9 association with expertise in electronic brachytherapy, such as the AAPM.
R9 In the absence of such a published protocol, the manufacturer's current
R9 protocol shall be followed.

R9 (e) The registrant shall make calibration measurements required by this
R9 section according to a current published protocol from a nationally-
R9 recognized professional association with expertise in electronic
R9 brachytherapy, such as the AAPM. In the absence of such a published
R9 protocol, the manufacturer's current testing protocol shall be followed.

R9 (9) Routine and Day-Of-Use Periodic Spot Checks for Electronic Brachytherapy
R9 Devices and Dosimetry Equipment.

R9 (a) A registrant authorized to use electronic brachytherapy devices shall have
R9 a program to perform spot checks on each unit:

R9 1. At the beginning of each day of use of an electronic brachytherapy
R9 unit;

R9 2. Each time the unit is moved to a new room or site; and

R9 3. After each x-ray tube installation.

R9 (b) The authorized medical physicist shall:

R9 1. Establish written procedures for performing the spot checks;

R9 2. Supervise the making of the spot checks and review the spot check
R9 results within 2 days of completion; and

R9 3. Notify the registrant in writing of any failures detected during the
R9 spot checks, within 24 hours of the identification of the spot check
R9 failure.

R9 (c) The authorized user will prevent the clinical use of a malfunctioning device
R9 until the malfunction identified in the spot check has been evaluated and
R9 corrected or, if necessary, the equipment repaired.

R9 (d) The spot checks must, at a minimum, assure proper operation of:

R9 1. Radiation exposure indicator lights on the electronic brachytherapy
R9 device and on the control console; and

R9 2. The integrity of all cables, catheters or parts of the device.

R9 (e) Spot checks of dosimetry must include checks that the output of the
R9 electronic brachytherapy source falls within 3% of expected values, which
R9 include:

R9 1. Output as a function of time, or output as a function of setting on a
R9 monitor chamber; and

R9 2. Verification of the consistency of the dose distribution to within 3%
R9 of that found during calibration;

R9 3. Validation of the operation of positioning methods to assure that the
R9 treatment dose exposes the intended location within 1 mm; and

R9 4. Inspection of all treatment components (e.g., connecting guide
R9 tubes, transfer tubes, transfer-tube-applicator interfaces, treatment
R9 spacers) on the day of use for any imperfections.

R9 (f) A registrant shall retain a record of each spot check for 3 years. The
R9 record shall include:

R9 1. The date of the check;

R9 2. The manufacturer's name, model number, and serial number of the
R9 electronic brachytherapy source;

R9 3. Notations indicating the operability of electronic brachytherapy
R9 source exposure indicator lights, applicators, source-transfer tubes,
R9 transfer tube-applicator interfaces, and source-positioning
R9 accuracy; and

R9 4. The name and signature of the individual who performed the check.

R9 (10) Mobile Electronic Brachytherapy Devices. A registrant providing mobile
R9 electronic brachytherapy services shall:

R9 (a) Check all survey instruments before medical use at each address of use
R9 and on each day of use;

R9 (b) Account for the x-ray tube in the device before departure from the client’s
R9 address; and

R9 (c) Perform, at each location, all of the required periodic spot checks specified
R9 in subsection 64E-5.1604(9), F.A.C., to assure proper operation of the
R9 device.

R9 (11) Treatment Planning.

R9 (a) The authorized medical physicist shall perform acceptance testing on the R9 treatment planning system of therapy-related computer systems according R9 to a current published protocol from a nationally-recognized professional R9 association with expertise in electronic brachytherapy, such as the AAPM. R9 In the absence of such a published protocol, the manufacturer's current R9 protocol shall be followed. At a minimum, the acceptance testing shall R9 include verification of:

R9 1. The electronic brachytherapy source-specific input parameters R9 required by the dose-calculation algorithm;

R9 2. The accuracy of dose, dwell-time, and treatment-time calculations R9 at representative points;

R9 3. The accuracy of isodose plots and graphic displays;

R9 4. The accuracy of the software used to determine source positions R9 from images; and

R9 5. If the treatment-planning system is different from the treatment- R9 delivery system, the accuracy of electronic transfer of the R9 treatment-delivery parameters to the treatment-delivery unit from R9 the treatment-planning system.

R9 (b) The authorized medical physicist shall compare the position indicators in R9 the applicator to the actual position of the source or planned dwell R9 positions at the time of commissioning.

R9 (c) Prior to each patient treatment regimen, the authorized medical physicist R9 shall confirm the accuracy of the treatment parameters and dose.

R9 Specific Authority: 404.051(4), 404.22, F.S.
R9 Law Implemented: 404.051, 404.081(1), 404.22, F.S..
R9 History: New 03-12-2009.