

Readopt with amendment He-P 4047, effective 01-23-15 (Document #10764), to read as follows:

PART He-P 4047 USE OF RADIATION MACHINES: THERAPEUTIC RADIATION MACHINES

He-P 4047.01 Purpose. He-P 4047 establishes requirements, for which the registrant is responsible for use of therapeutic radiation machines.

He-P 4047.02 Scope. The provisions of He-P 4047 are in addition to, and are not substitutions for, other applicable provisions of these rules.

He-P 4047.03 Definitions. The following definitions apply specifically to Part He-P 4047 and are in addition to definitions in He-P 4003 and He-P 4041.

(a) “Absorbed dose (D)” means the mean energy imparted by ionizing radiation to matter, and is determined as the quotient of dE by dm, where dE is the mean energy imparted by ionizing radiation to matter of mass dm, and is expressed in the SI unit of joule per kilogram and the special name “gray” (Gy).

(b) “Absorbed dose rate” means absorbed dose per unit time for radiation machines with timers, or dose monitor unit per unit time for linear accelerators.

(c) “Air kerma (K)” means the kinetic energy released in air by ionizing radiation, and is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM, and is expressed in the SI unit of joule per kilogram, and the special name the “gray” (Gy).

(d) “Beam scattering foil” means a thin piece of material placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

(e) “Bent beam linear accelerator” means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

(f) “Conventional Simulator” means any x-ray system designed to produce the geometric conditions of the radiation therapy equipment.

(g) “Dose monitor unit (DMU)” means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(h) “Dosimetrist” means a person who generates and calculates radiation dose distributions under the direction of a medical physicist and a radiation oncologist.

(i) “Electronic brachytherapy” means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

(j) “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.

(k) “Electronic brachytherapy source” means the x-ray tube component used in an electronic brachytherapy device.

(l) “External beam radiation therapy” means therapeutic irradiation in which the source of radiation is at a distance from the body.

(m) “Field-flattening filter” means a filter used to homogenize the absorbed dose rate over the radiation field.

(n) “Gantry” means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

(o) “High energy external beam therapy” means photons and electrons with energies greater than equal to one MV or one MeV.

(p) “Intensity Modulated Radiation Therapy (IMRT)” means radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer based and automated optimization techniques.

(q) “Interruption of irradiation” means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(r) “Kilovolt (kV)” or “kilo electron volt (keV)” means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum.

(s) “Megavolt (MV)” or “mega electron volt (MeV)” means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum.

(t) “Misadministration” means the administration of an external beam radiation therapy dose:

- (1) Involving the wrong patient;
- (2) Involving the wrong treatment modality;
- (3) Involving the wrong treatment site;
- (4) When the treatment consists of 3 or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
- (5) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or
- (6) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(u) “Mobile Electronic Brachytherapy Service” means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

(v) “Monitor unit (MU)” means “dose monitor unit” as defined in He-P 4047.03(g).

(w) “Moving beam radiation therapy” means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution.

(x) “Nominal treatment distance” means:

(1) For electron radiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiation object along the central axis of the useful beam;

(2) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam; and

(3) For non-isocentric x-ray irradiation equipment, the distance along the central axis shall be that specified by the manufacturer.

(y) “Periodic quality assurance check” means a procedure which is performed to ensure that a previous calibration continues to be valid.

(z) “Phantom” means an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

(aa) “Practical range of electrons” means a classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays.

(ab) “Prescribed dose” means the total dose and dose per fraction as documented in the written directive.

(ac) “Primary dose monitoring system” means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

(ad) “Radiation field” means “useful beam” as defined in He-P 4041(dq).

(ae) “Radiation head” means the structure from which the useful beam emerges.

(af) “Radiation Therapy Physicist” means an individual qualified in accordance with He-P 4047.

(ag) “Recordable event” means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose.

(ah) “Redundant beam monitoring system” means a combination of 2 dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

(ai) “Scattered primary radiation” means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

(aj) “Secondary dose monitoring system” means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

(ak) “Shadow tray” means a device attached to the radiation head to support auxiliary beam blocking material.

(al) “Simulator” or “radiation therapy simulation system” means an x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

(am) “Source-skin distance (SSD)” means “target-skin distance” as defined in He-P 4047.03(ap).

(an) “Stationary beam radiation therapy” means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(ao) “Target” means that part of an x-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

(ap) “Target-skin distance (TSD)” means the distance measured along the beam axis from the center of the front surface of the x-ray target and/or electron virtual source to the surface of the irradiated object or patient.

(aq) “Therapeutic radiation machine” means x-ray or electron producing equipment designed and used for external beam radiation therapy. For the purpose of these regulations, devices used to administer electronic brachytherapy shall also be considered therapeutic machines.

(ar) “Virtual Simulator” means a computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine; and that allows import manipulation, display and storage of images from CT and/or other imaging modalities.

(as) “Virtual source” means a point from which radiation appears to originate.

(at) “Written directive” means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation which contains the total dose, dose per fraction, treatment site, and overall treatment period.

He-P 4047.04 General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.

(a) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts.

(b) The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with DHHS/RHS.

(c) The registrant shall ensure that the requirements of Part He-P 4047 are met in the operation of the therapeutic radiation machine(s).

(d) A therapeutic radiation machine which does not meet the provisions of these rules shall not be used for irradiation of patients.

(e) The registrant for any therapeutic radiation machine subject to He-P 4047 shall require the authorized user to be a physician who:

(1) Is certified in:

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

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

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

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

(2) Is in the active practice of therapeutic radiology, and has:

a. Completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit;

b. Completed 500 hours of supervised work experience; and

c. A minimum of 3 years supervised clinical experience.

(f) To satisfy the requirement for instruction in He-P 4047.04(e)(2)a., the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of ionization radiation; and

(4) Radiation biology.

(g) To satisfy the requirement for supervised work experience in He-P 4047.04(e)(2)b., training shall:

(1) Be under the supervision of an authorized user; and

(2) Include:

- a. Review of the full calibration measurements and periodic quality assurance checks;
- b. Evaluation of prepared treatment plans;
- c. Calculation of treatment times and patient treatment settings;
- d. Use of administrative controls to prevent misadministrations;
- e. Implementation of emergency procedures to be followed in the event of the abnormal operation of a external beam radiation therapy unit or console; and
- f. The checking and use of radiation survey meters.

(h) To satisfy the requirement for a period of supervised clinical experience in He-P 4047.04(e)(2)c., training shall include:

- (1) One year in a formal training program approved by:
 - a. The Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education; or
 - b. The Committee on Postdoctoral Training of the American Osteopathic Association; and
- (2) An additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user; and
- (3) The following training:
 - a. Examining individuals;
 - b. Reviewing individuals' case histories to determine their suitability for external beam radiation therapy treatment, and any limitations and contraindications;
 - c. Selecting proper dose;
 - d. Selecting how the dose is to be administered;
 - e. Calculating the external beam radiation therapy doses;
 - f. Collaborating with the authorized user in the review of patients' progress;
 - g. Considering of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation;
 - h. Post-administration follow-up; and
 - i. Post-administration review of case histories.

(i) Notwithstanding the requirements of He-P 4047.04(e)(1) and He-P 4047.04(e)(2), the registrant for any therapeutic radiation machine subject to He-P 4047 shall also submit the training of the prospective authorized user physician for DHHS/RHS review.

(j) A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by DHHS/RHS.

(k) The registrant for any therapeutic radiation machine subject to He-P 4047 shall require the radiation therapy physicist to be registered with DHHS/RHS, under the provisions of He-P 4040, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units, and either:

(1) Be certified by:

a. The American Board of Radiology in:

1. Therapeutic radiological physics;
2. Roentgen-ray and gamma-ray physics;
3. X-ray and radium physics; or
4. Radiological physics; or

b. The American Board of Medical Physics in Radiation Oncology Physics; or

c. The Canadian College of Medical Physics; or

(2) Alternately, the radiation therapy physicist shall meet the following requirements:

a. Hold a master's or doctor's degree in physics, medical physics, engineering, applied mathematics, biophysics, radiological physics, or health physics from an accredited college or university;

b. Have completed one year of full time training in therapeutic radiological physics;

c. Have completed one year full-time work experience under the supervision of a radiation therapy physicist at a medical institution; and

d. The training and work experience as required in He-P 4047.04 (2) above, shall be conducted in a clinical radiation facility that provides high-energy external beam radiation therapy.

(l) To meet the requirement in He-P 4047.04(k)(2)c. above, the individual shall have performed the tasks listed in He-P 4047.05(a) through (f), and He-P 4047.06(r) and (s), and He-P 4047.07(u) and (v), under the supervision of a radiation therapy physicist during the year of work experience.

(m) Notwithstanding the provisions of He-P 4047.04(k)(2) and (l), certification pursuant to He-P 4047.04(k)(1) shall be required on or before December 31, 1999 for all persons currently qualifying as a radiation therapy physicist pursuant to He-P 4047.04(k).

(n) Each individual who operates a therapeutic radiation machine for medical use shall:

(1) Be a registered radiation therapy technologist with the American Registry of Radiologic Technologists (ARRT); or

(2) Submit evidence that he or she has satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology; or

(3) Be a student working under the direct supervision and in the physical presence of a registered radiation therapy technologist.

(o) The names and training of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility.

(p) Information about former operators shall be retained for a period of at least 2 years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

(q) Written safety procedures and rules shall be developed by a radiation therapy physicist.

(r) Written safety procedures and rules shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine.

(s) The operator shall be able to demonstrate familiarity with the procedures and rules required in He-P 4047.04(q) and (r).

(t) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by an authorized user.

(u) The provision in He-P 4047.04(t) shall specifically prohibit deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

(v) Notwithstanding the provisions of He-P 4047.04(e)(1) and (e)(2), a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

(1) The visiting authorized user has the prior written permission of the registrant's management;

(2) The use occurs on behalf of an institution, or the institution's Radiation Safety Committee;

(3) The visiting authorized user meets the requirements established for authorized user(s) in He-P 4047.04(e)(1) and He-P 4047.04(e)(2); and

(4) The registrant maintains copies of all records specified by He-P 4047.04(v) for 5 years after the records are made.

(w) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in the provisions of the registrant's quality management program.

(x) All individuals associated with the operation of a therapeutic radiation machine shall comply with the provisions of the registrant's quality management program.

(y) All individuals associated with the operation of a therapeutic radiation machine shall be subject to the requirements of He-P 4020 through He-P 4022.

(z) The registrant shall maintain for inspection by DHHS/RHS the following information in a separate file or package for each therapeutic radiation machine:

(1) Report of acceptance testing;

(2) Records of all:

a. Surveys with date(s) performed;

b. Calibrations with date(s) performed;

c. Periodic, dated, quality assurance checks of the therapeutic radiation machine required by He-P 4047; and

d. The name(s) of person(s) who performed such activities;

(3) Records of:

a. Maintenance, with the date(s) it was performed;

b. Any modifications, with the date(s) the modifications were performed on the therapeutic radiation machine; and

c. The name(s) of person(s) who performed such services; and

(4) The signature of the person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

(aa) All records required by He-P 4047 shall be retained until disposal is authorized by DHHS/RHS unless another retention period is specifically authorized in He-P 4047.

(ab) All required records shall be retained in an active file from at least the time of generation until the next DHHS/RHS inspection.

(ac) Any required record generated prior to the last DHHS/RHS inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as DHHS/RHS authorizes final disposal.

He-P 4047.05 General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

(a) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated in accordance with He-P 4047.08.

(b) The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a qualified expert.

(c) The radiation protection survey shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation, the following requirements are met:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in He-P 4020.05; and

(2) Radiation levels in unrestricted areas do not exceed the limits specified in He-P 4020.13(a) and (b).

(d) In addition to the requirements of He-P 4047.05(a), a radiation protection survey shall also be performed prior to any subsequent medical use and:

(1) After making any change in the treatment room shielding;

(2) After making any change in the location of the therapeutic radiation machine within the treatment room;

(3) After relocating the therapeutic radiation machine to a different treatment room;
or

(4) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external radiation therapy treatment room.

(e) The survey record required in He-P 4047.05(d) shall include:

(1) All instances where the facility is in violation of applicable rules;

(2) The date of the measurements;

(3) The reason for the survey ;

(4) The manufacturer's name;

(5) Model number of the therapeutic radiation machine;

(6) Serial number of the therapeutic radiation machine;

(7) The instrument(s) used to measure radiation levels;

- (8) A diagram of the areas surrounding the treatment room that were surveyed;
- (9) The measured dose rate at several points in each area expressed in microsieverts or millirems per hour;
- (10) The calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and
- (11) The signature of the individual responsible for conducting the survey.

(f) If the results of the surveys required by He-P 4047.05(a) and (d) indicate any radiation levels in excess of the respective limit specified in He-P 4020, the registrant shall lock the control in the "OFF" position and not use the unit except as may be necessary to repair, replace, or test the therapeutic radiation machine, test the therapeutic radiation machine shielding, or test the treatment room shielding.

(g) If the survey required by He-P 4047.05(a) and (d) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by He-P 4020.13(a) and (b), before beginning the treatment program the registrant shall:

- (1) Equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with He-P 4020.13(a) and (b);
- (2) Perform the survey required by He-P 4047.05(a) again; and
- (3) Include in the record required by He-P 4047.05(e):
 - a. The results of the initial survey;
 - b. A description of the modification made to comply with He-P 4047.05(g)(1); and
 - c. The results of the second survey.

(h) The registrant shall have a dosimetry system available for use which has been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) as follows:

- (1) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60; and
- (2) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy or for an energy range appropriate for the radiation being measured.

(i) The calibration of the dosimetry system required in He-P 4047.05(h) shall have been performed within the previous 24 months, and after any servicing that may have affected system calibration.

(j) An independent survey shall be conducted by a radiation therapy physicist or qualified expert other than the person performing the original survey prior to the system being used except as described in He-P 4047.05(f).

(k) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system shall be compared with a system that has been calibrated in accordance with He-P 4047.05(h) through (j). This comparison shall have been performed within the previous 12 months, and after each servicing that may have affected system calibration. The quality assurance check system shall be the same system used to meet the requirements in He-P 4047.05(h) through (j).

(l) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for each therapeutic radiation machine.

(m) For each calibration, intercomparison, or comparison, the record shall include:

- (1) The date;
- (2) The model numbers of the instruments that were calibrated;
- (3) The serial numbers of the instruments that were calibrated, intercompared, compared, or used to meet the requirements in He-P 4047.05(h) through (k);
- (4) The correction factors that were determined;
- (5) The names of the individuals who performed the calibration, intercomparison, or comparison; and
- (6) Evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

(n) The registrant for any therapeutic radiation machine shall be able to furnish a copy of the records required in He-P 4047.05 to DHHS/RHS upon request, within 30 days following completion of the action that initiated the record requirement.

(o) Each registrant using radiation therapy machines shall establish and maintain a quality management program to provide high confidence that radiation will be administered as directed by the authorized user.

(p) The registrant shall make modifications to the quality management program to increase the program's efficiency.

(q) The quality management program required by He-P 4047.05(o) shall include written policies and procedures to meet the following specific objectives:

- (1) Prior to administration, a written directive shall be prepared for any external beam radiation therapy dose;
- (2) Notwithstanding He-P 4047.05(q)(1) above, a written revision to an existing written directive shall be acceptable provided that the revision is dated and signed by

an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

(3) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision;

(4) The written directive shall contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site and number of fractions;

(5) A written revision to an existing written directive shall be made provided that the revision is dated and signed by an authorized user prior to the administration of the therapeutic radiation machine dose, or the next fractional dose; and

(6) The registrant shall retain a copy of each written directive for 3 years.

(r) The registrant shall develop, implement and maintain written procedures to provide high confidence that:

(1) Prior to the administration of each course of radiation treatment, the patient's identity is verified, by more than one method, as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) The therapeutic radiation machine final treatment plans and related calculations are in accordance with the respective written directives by:

a. Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive; and

b. Verifying that any computer generated calculations are correctly transferred into consoles of authorized therapeutic medical units;

(4) Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken; and

(5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

(s) Each registrant using radiation therapy equipment shall have a quality management program that specifies staff, staff duties and responsibilities, equipment, and procedures.

(t) Each existing registrant shall submit to DHHS/RHS a copy of the written quality management program that has been implemented.

(u) The registrant shall include as a part of the quality management program the following:

(1) An evaluation of a representative sample of patient administrations and a review of all recordable events, and all misadministrations, if any, to verify compliance with all aspects of the quality management program;

(2) Reviews conducted at intervals not to exceed 12 months;

(3) An evaluation of each review to determine the effectiveness of the quality management program and, if necessary to make modifications to meet the requirements of these rules; and

(4) Records of each review, including the evaluations and findings of the review, which shall be retained for 3 years.

(v) Each registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation machine results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

(w) Other than events that result from intervention by a patient or human research subject each registrant shall report any event in which the administration of a therapeutic radiation machine therapy dose:

(1) Involved the wrong patient, wrong treatment modality or wrong treatment site; or

(2) The calculated weekly administered dose differing from the weekly prescribed dose by more than 30 percent; or

(3) The calculated total administered dose differing from the total prescribed dose by more than 20 percent of the total prescribed dose.

(x) The registrant shall evaluate and respond, within 30 days after discovery of a recordable event, by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, for 3 years, of the relevant facts, and the corrective action, if any, which was taken.

(y) The registrant shall evaluate each misadministration.

(z) The registrant shall take the following actions in response to a misadministration:

(1) Notify DHHS/RHS by telephone no later than the next business day after discovery of the misadministration;

(2) Submit a written report to DHHS/RHS within 15 days after discovery of the misadministration including:

- a. The registrant's name;
 - b. The prescribing physician's name;
 - c. A brief description of the event;
 - d. Why the event occurred;
 - e. The effect on the patient;
 - f. What improvements are needed to prevent recurrence;
 - g. Actions taken to prevent recurrence;
 - h. Whether the registrant notified the patient or the patient's responsible relative or guardian; and
 - i. What information was provided to the patient; but
 - j. Shall not include the patient's name or other information that could lead to identification of the patient;
- (3) Notify the referring physician;
- (4) Notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he/she will inform the patient or that, based on medical judgment, telling the patient would be harmful;
- (5) Notify the patient as soon as possible thereafter if the referring physician or patient cannot be reached within 24 hours;
- (6) Not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;
- (7) If a verbal notification is made, the registrant shall inform the patient, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested; and
- (8) Retain a record of each misadministration for 3 years, including:
- a. The names of all individuals involved;
 - b. The patient's Social Security number or other identification number;
 - c. A brief description of the event;
 - d. Why it occurred and the effect on the patient;

- e. What improvements are needed to prevent recurrence;
- f. The actions taken to prevent recurrence; and
- g. Whether the patient was notified or not.

(aa) Aside from the notification requirements in (z) above, nothing in this section shall affect any rights or duties of registrants and physicians in relation to each other, to the patient affected by the event, or to that patient's responsible relative or guardian.

He-P 4047.06 Therapeutic Radiation Machines of Less Than 500 kV.

(a) When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified as follows:

- (1) For 5 to 50 kV systems, the leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in any one-hour period;
- (2) For >50 and <500 kV systems:
 - a. The leakage air kerma rate measured at a distance of 1 meter from the target in any direction shall not exceed 1 cGy (1 rad) in any one-hour period;
 - b. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters; and
 - c. The air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour;
- (3) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in He-P 4047.06(a)(1) and (a)(2), for the specified operating conditions; and
- (4) Records on leakage radiation measurements shall be maintained after installation for inspection by DHHS/RHS.

(b) Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(c) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall meet the following requirements:

- (1) None shall transmit more than 5 percent of the useful beam for the most penetrating beam used; and
- (2) When adjustable or removable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(d) The filter system shall be so designed that:

- (1) Filters can not be accidentally displaced at any possible tube orientation;
- (2) An interlock system prevents irradiation if the proper filter is not in place;
- (3) The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at one meter under any operating conditions; and
- (4) Each filter shall be marked as to its material of construction and its thickness.

(e) The x-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture.

(f) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(g) The tube housing assembly shall be marked so that:

- (1) It is possible to determine the location of the source to within 5 millimeters; and
- (2) Such marking shall be readily accessible for use during calibration procedures.

(h) Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(i) A timer control device shall be provided to terminate the irradiation after a pre-set time interval and shall:

- (1) Have a display;
- (2) Be provided at the treatment control;
- (3) Have a pre-set time selector;
- (4) Have elapsed time or time remaining indicator;
- (5) Be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated;
- (6) Be able to reset the elapsed time indicator after irradiation is terminated and before irradiation can be re-initiated;
- (7) Terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;
- (8) Permit accurate pre-setting and determination of exposure times as short as 1 second;
- (9) Not permit an exposure if set at zero;

(10) Not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

(11) Be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

(j) The control panel, in addition to the displays required by other provisions in He-P 4047.06, shall have:

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

(2) An indication of whether x-rays are being produced;

(3) Means for indicating x-ray tube potential and current;

(4) Means for terminating exposure at any time;

(5) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

(6) A positive display of specific filter(s) in the beam.

(k) A control panel which may energize more than one x-ray tube shall:

(1) Activate only one x-ray tube at any time;

(2) Have an indication at the control panel identifying which x-ray tube is activated; and

(3) Have an indication at the tube housing assembly when that tube is energized.

(l) There shall be a means of determining the central axis target-to-skin distance to within 1 centimeter and of reproducing this measurement to within 2 millimeters thereafter.

(m) Shutters shall be required as follows:

(1) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly;

(2) After the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel; and

(3) An indication of shutter position shall appear at the control panel.

(n) Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall:

- (1) Be clearly labeled as such on the tube housing assembly; and
- (2) Be provided with a permanent warning device on the control panel that is activated when there is no additional filtration present, in order to indicate that the dose rate is very high.

(o) In addition to the shielding requirements of He-P 4047, the treatment room shall meet the following facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV:

- (1) Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel; and
- (2) A viewing system shall:
 - a. Be provided to permit continuous observation of the patient during irradiation;
 - b. Enable the operator to observe the patient from the control panel; and
 - c. Be operational for use of therapeutic radiation machine for patient irradiation.

(p) Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

- (1) All protective barriers shall be fixed except for entrance doors or beam interceptors;
- (2) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a shielded ceiling, inside the room;
- (3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued;
- (4) If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and re-initiating irradiation by manual action at the control panel; and
- (5) When any door referred to in He-P 4047.06(p) is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

(q) Full calibration of a therapeutic radiation machine shall be performed by, or under the direct supervision of, a radiation therapy physicist and shall meet the following requirements:

- (1) Full calibration shall be performed as follows:
 - a. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
 - b. At intervals not exceeding 1 year; and

- c. Before medical use under the following conditions:
 - 1. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the differences cannot be reconciled; and
 - 2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam;
- (2) Notwithstanding the requirements of He-P 4047.06(q)(1) c.1. above:
 - a. Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range;
 - b. If the repair, replacement, or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility; and
 - c. Any remaining energies may be validated with quality assurance check procedures against the criteria in He-P 4047.06(q)(1) c.1.;
- (3) For machines with energies greater than or equal to 10 KeV and less than or equal to 40 KeV full calibration shall include all measurements recommended for annual calibration by National Council on Radiation Protection (NCRP) Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 KeV to 50 MeV" (1981), which is incorporated by reference and included in Appendix A. For machines with energies greater than or equal to 40 kV and less than or equal to 300 kV, full calibration shall include all measurements recommended for annual calibration by "High Dose-Rate Brachytherapy Treatment Delivery" (1998), AAPM Task Group 59, and "AAPM Protocol for 40-300 kV X-Ray Beam Dosimetry in Radiotherapy and Radiobiology" (2001) by AAPM Task Group 61, both of which are incorporated by reference and included in Appendix A;
- (4) The registrant shall maintain a record of each calibration for the duration of the registration; and
- (5) The calibration record shall include:
 - a. The date of the calibration;
 - b. The manufacturer's name, model number, and serial number for both the therapeutic machine and the x-ray tube;
 - c. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and
 - d. The signature of the radiation therapy physicist responsible for performing the calibration.

(r) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to He-P 4047.06, which are capable of operation at greater than or equal to 50 kV, as follows:

- (1) The registrant shall perform quality assurance checks specified in He-P 4047.06(r) in accordance with written procedures established by the radiation therapy physicist;
- (2) The quality assurance check procedures required by He-P 4047.06(r)(1) shall specify:
 - a. The frequency at which tests or measurements are to be performed;
 - b. That the quality assurance check be performed during the calibration specified in He-P 4047.06(q); and
 - c. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration as specified by He-P 4047.06(q)(1);
- (3) The quality assurance check shall investigate the cause for a parameter exceeding a tolerance set by the radiation therapy physicist and correct such parameter before the system is used for patient irradiation;
- (4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as specified by He-P 4047.06(q)(1);
- (5) The registrant shall use the dosimetry system described in He-P 4047.05(k) to make the quality assurance check required in He-P 4047.06(r)(2);
- (6) The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within 30 days of the date that the check was performed;
- (7) The registrant shall ensure that the safety quality assurance checks of therapeutic radiation machines are performed at intervals not to exceed 30 days;
- (8) The registrant shall ensure that no therapeutic machine is used to administer radiation to humans unless the quality assurance checks will have been performed within the 30-day period immediately prior to said administration;
- (9) Safety quality assurance checks shall ensure proper operation of:
 - a. Electrical interlocks at each external beam radiation therapy room entrance;
 - b. Proper operation of the "BEAM-ON" and termination switches;
 - c. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

- d. Viewing systems; and
 - e. If applicable, electrically operated treatment room doors from inside and outside the treatment room;
- (10) The registrant shall maintain a record of each quality assurance check for 3 years; and
- (11) The quality assurance check records shall include:
- a. The date of the quality assurance check;
 - b. The manufacturer's name, model number, and serial number for the therapeutic radiation machine;
 - c. The manufacturer's name, model number, and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and
 - d. The signature of the individual who performed the periodic quality assurance check.
- (s) The following operating procedures shall be met:
- (1) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of He-P 4047.06(q) and He-P 4047.06(r) have been met;
 - (2) Therapeutic radiation machines shall not be left unattended unless secured pursuant to He-P 4047.06(j)(5);
 - (3) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;
 - (4) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV;
 - (5) If the tube housing is held, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;
 - (6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console;
 - (7) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV; and
 - (8) At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of He-P 4020.

(t) Each facility location authorized to use a therapeutic radiation machine in accordance with He-P 4047.06 shall:

- (1) Possess appropriately calibrated portable monitoring equipment;
- (2) As a minimum, include a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour; and
- (3) Require the survey instrument(s) to be operable and calibrated in accordance with He-P 4047.08.

He-P 4047.07 Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above).

(a) Each facility location authorized to use a therapeutic radiation machine in accordance with He-P 4047.07 shall possess, operable and calibrated in accordance with He-P 4047.08, portable monitoring equipment to include as a minimum a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour.

(b) Leakage radiation outside the maximum useful beam in photon and electron modes shall meet the following requirements:

- (1) The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance or patient plane, shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance when measurements are averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;
- (2) Except for the area defined in He-P 4047.07(b)(1), the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance when measurements are averaged over an area not exceeding 100 square centimeters;
- (3) The neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1, as amended, which is incorporated by reference and included in Appendix A;
- (4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in He-P 4047.07(b)(1)-(3) for the specified operating conditions; and
- (5) Records on leakage radiation measurements shall be maintained after installation for inspection by DHHS/RHS.

(c) Leakage radiation through beam limiting devices shall be as follows:

(1) For photon radiation, all adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 5 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 100 square centimeter radiation field or maximum available field size if less than 100 square centimeters;

(2) For electron radiation, all adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

a. For points beyond a line 7 centimeters outside the periphery of the useful beam, a maximum limit of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance; and

b. For points beyond a line 2 centimeters up to 7 centimeters outside the periphery of the useful beam, a maximum limit of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance;

(3) Measurements of leakage radiation through the beam limiting for photon radiation devices shall be:

a. Made with the beam limiting devices closed;

b. Made with any residual aperture blocked by at least 2 tenth value layers of suitable absorbing material;

c. Measured independently at the depth of maximum dose for each set of overlapping beam limiting device; and

d. The depth of maximum dose made using a radiation detector of area not exceeding 10 square centimeters;

(4) Measurements of leakage radiation through the electron applicators shall:

a. Be made with the electron beam directed into the air;

b. Use a radiation detector of area up to but not exceeding 1 square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector; and

c. Be made using one centimeter of water equivalent build up material; and

(5) Leakage radiation through beam limiting devices shall be determined for photon radiation and for electron radiation in radiation therapy machines which operate in both modes.

(d) Filters and wedges used in therapeutic radiation machines shall meet the following requirements:

- (1) Each wedge filter which is removable from the system shall be clearly marked with an identification number;
- (2) Each removable wedge filter shall have the nominal wedge angle appear on the wedge or wedge tray if permanently mounted to the tray;
- (3) If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;
- (4) If the absorbed dose rate information required by He-P 4047.07(i) relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools; and
- (5) For equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:
 - a. Irradiation shall not be possible until a selection of a filter or a positive selection to use “no filter” has been made at the treatment control panel, either manually or automatically;
 - b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - c. A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and
 - d. An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.
- (e) The registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 which is incorporated by reference and included in Appendix A.

(f) All therapeutic radiation machines subject to He-P 4047.07 shall meet the following requirements:

- (1) All therapeutic radiation machines shall be provided with:
 - a. Redundant beam monitoring systems which have sensors fixed in the useful beam during treatment to indicate the dose monitor unit rate;

b. At least 2 independently powered integrating dose meters if manufactured after July 1, 1998; and

c. At least one radiation detector incorporated into a useful beam monitoring system, if manufactured before July 1, 1998; and

(2) The detector and the system into which that detector is incorporated shall meet the following requirements:

a. Each detector shall be removable only with tools;

b. If the detector is movable, it shall be interlocked to prevent incorrect positioning;

c. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

d. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation;

e. The design of the beam monitoring systems shall ensure that the:

1. Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

2. Failure of either system shall terminate irradiation or prevent the initiation of radiation; and

f. Each beam monitoring system shall have a legible display at the treatment control panel which shall:

1. Maintain a reading until intentionally reset;

2. Have only one scale and no electrical or mechanical scale multiplying factors;

3. Utilize a design such that increasing dose is displayed by increasing numbers; and

4. In the event of power failure, the beam monitoring information displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

(g) Bent-beam linear accelerators shall be provided with auxiliary device(s) to monitor beam symmetry which:

(1) Shall be able to detect field asymmetry greater than 10 percent; and

(2) Shall be configured to terminate irradiation if the specifications above cannot be maintained.

(h) Selection and display of dose monitor units shall be as follows:

- (1) Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;
- (2) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;
- (3) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and
- (4) After termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

(i) A system shall be provided from whose readings the air kerma rate or absorbed dose rate a reference point can be calculated, and which meets the following requirements:

- (1) The dose monitor unit rate shall be displayed at the treatment control panel;
- (2) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum;
- (3) The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;
- (4) If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than 10 times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad);
- (5) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) for the specified operating conditions; and
- (6) Records of maximum value(s) shall be maintained at the installation for inspection by DHHS/RHS.

(j) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy shall be as follows:

- (1) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;
- (2) If the original design of the equipment includes a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15

percent or 40 dose monitor units, above the pre-selected number of dose monitor units, set at the control panel, has been detected by the secondary dose monitoring system; and

(3) An indicator on the control panel shall show which monitoring system has terminated radiation.

(k) It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(l) If a therapeutic radiation machine has an interrupt mode:

(1) It shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel;

(2) Following an interruption it shall be possible to restart irradiation by operator action without any re-selection of operating conditions; and

(3) If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(m) A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval as follows:

(1) A timer shall be provided which has a display at the treatment control panel;

(2) The time provided shall have a pre-set time selector and an elapsed time indicator;

(3) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated;

(4) After irradiation is terminated and before irradiation can be re-initiated, it shall be necessary to reset the elapsed time indicator; and

(5) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(n) Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

(2) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(3) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

(4) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(6) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(o) Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

(2) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation;

(3) After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

(4) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

(5) The selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1, which is incorporated by reference and included in Appendix A.

(p) Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(2) The mode of operation shall be displayed at the treatment control panel;

(3) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

(4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(5) Moving beam irradiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement as follows:

- a. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or one cm of linear motion differs by more than 20 percent from the selected value;
 - b. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected;
 - c. An interlock shall be provided to prevent motion of more than 5 degrees or 1 cm beyond the selected limits during moving beam radiation therapy;
 - d. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy; and
 - e. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;
- (6) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by He-P 4047.07(j); and
- (7) An interlock system shall be provided to terminate irradiation if movement:
- a. Occurs during stationary beam radiation therapy; or
 - b. Does not start or stops during moving beam radiation therapy unless stoppage is a pre-planned function.
- (q) In addition to shielding adequate to meet requirements of He-P 4047.09, the following design requirements are made for therapeutic radiation machines operating above 500 kV:
- (1) All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;
 - (2) The control panel shall:
 - a. Be located outside the treatment room;
 - b. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
 - c. Provide an indication or whether radiation is being produced; and
 - d. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine;
 - (3) Windows, mirrors, closed-circuit television, or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and

during irradiation and shall be so located that the operator may observe the patient from the treatment control panel;

(4) The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

(5) Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;

(6) The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

(7) Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

(8) Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued;

(9) If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and re-initiating irradiation by manual action at the control panel;

(10) If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with He-P4020.13, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

(11) At least one emergency power cutoff switch in addition to the termination switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion;

(12) All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

(13) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

(14) Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

(r) The services of the radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above.

(s) The radiation therapy physicist required in He-P 4047.07(r) shall be responsible for:

(1) Full calibration(s) required by He-P 4047.07(u);

- (2) Protection surveys required by He-P 4047.05;
 - (3) Supervision and review of dosimetry;
 - (4) Beam data acquisition and transfer for computerized dosimetry and supervision of its use;
 - (5) Quality assurance, including quality assurance check review required by He-P 4047.07(v)(6);
 - (6) Consultation with the authorized user in treatment planning, as needed; and
 - (7) Performing calculation and assessments regarding misadministrations.
- (t) The following operating procedures shall be required:
- (1) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures shall specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted;
 - (2) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;
 - (3) Therapeutic radiation machines shall not be made available for medical use unless the requirements of He-P 4047.05 and He-P 4047.07(u) and (v) have been met;
 - (4) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;
 - (5) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;
 - (6) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and
 - (7) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.
- (u) Acceptance testing, commissioning, and full calibration measurements shall be as follows:
- (1) Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine shall be performed by, or under the direct supervision of, a radiation therapy physicist;
 - (2) Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators" (1994) prepared by AAPM Radiation Therapy Task Group 45, which is incorporated by reference and included in Appendix A, and the manufacturer's contractual specifications;

- (3) Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;
- (4) Full calibration shall include measurement of all parameters required by Table II of “Comprehensive QA for Radiation Oncology” (1994) prepared by AAPM Radiation Therapy Committee Task Group 40, which Report and Table are incorporated by reference and included in Appendix A;
- (5) Full calibration shall be performed in accordance with “AAPM Code of Practice for Radiotherapy Accelerators” (1994) prepared by AAPM Radiation Therapy Task Group 45 which is incorporated by reference and included in Appendix A;
- (6) It shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II of “Comprehensive QA for Radiation Oncology” (1994) prepared by AAPM Radiation Therapy Committee Task Group 40, which is incorporated by reference and included in Appendix A;
- (7) The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits as follows:
 - a. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled;
 - b. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range;
 - c. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam;
 - d. If the repair, replacement, or modification does not affect all modes and/or energies, measurements shall be performed on the effected mode/energy that is in most frequent clinical use at the facility; and
 - e. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in He-P 4047.07(u)(7);
- (8) The registrant shall use the dosimetry system described in He-P 4047.05(h) and (i) to measure the radiation output for one set of exposure conditions;
- (9) The remaining radiation measurements required in He-P 4047.07(u)(2)-(6) may be made using a dosimetry system that indicates relative dose rates;
- (10) The registrant shall maintain a record of each calibration in an auditable form for the life of the therapeutic radiation machine; and
- (11) The record required in He-P 4047.07(u)(10) shall include:

- a. The date of the calibration;
 - b. The manufacturer's name;
 - c. Model number of the therapeutic machine;
 - d. Serial number of the therapeutic machine;
 - e. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and
 - f. The signature of the radiation therapy physicist responsible for performing the calibration.
- (v) Periodic quality assurance checks shall meet the following requirements:
- (1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to He-P 4047.07 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology" (1994), prepared by AAPM Radiation Therapy Committee Task Group 40, which is incorporated by reference and included in Appendix A;
 - (2) Quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology" (1994) prepared by AAPM Radiation Therapy Committee Task Group 40 which is incorporated by reference and included in Appendix A;
 - (3) Representative sampling as required in He-P 4047.07(v)(2) shall include all referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;
 - (4) The registrant shall use a dosimetry system which has been intercompared within the previous 12 months with the dosimetry system described in He-P 4047.05(h) and (i) to make the periodic quality assurance checks;
 - (5) The registrant shall perform periodic quality assurance checks in accordance with procedures established by the radiation therapy physicist;
 - (6) The registrant shall review the results of each periodic radiation output check according to the following procedures:
 - a. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance;
 - b. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

- c. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within 3 treatment days; and
 - d. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not exceed 30 days;
- (7) Therapeutic radiation machines subject to He-P 4047.07 shall have safety quality assurance checks listed in “Comprehensive QA for Radiation Oncology” (1994) prepared by AAPM Radiation Therapy Committee Task Group 40, which is incorporated by reference and included in Appendix A, performed at intervals not to exceed 7 days;
- (8) To satisfy the requirement of He-P 4047.07(v)(7), safety quality assurance checks shall ensure proper operation of:
- a. Electrical interlocks at each external beam radiation therapy room entrance;
 - b. The “BEAM-ON”, interrupt, and termination switches;
 - c. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
 - d. Viewing systems;
 - e. Electrically operated treatment room door(s) from inside and outside the treatment room; and
 - f. At least one emergency power cutoff switch, as follows:
 - 1. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis; and
 - 2. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.
- (9) The registrant shall promptly repair any system identified in He-P 4047.07(v)(8) that is not operating properly;
- (10) The registrant shall maintain a record of each quality assurance check required for 3 years; and
- (11) The record required in He-P 4047.07(v)(10) shall include:
- a. The date of the quality assurance check;
 - b. The manufacturer’s name;
 - c. The machine model number;

- d. The machine serial number;
 - e. The manufacturer's name, model number, and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and
 - f. The signature of the individual who performed the periodic quality assurance check.
- (w) For intensity modulated radiation therapy (IMRT), quality assurance checks shall:
- (1) Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient specific validation of treatment plan;
 - (2) Be performed in accordance with "Guidance document on delivery, treatment planning, and clinical implementation of IMRT" (2003) Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82, which is incorporated by reference and included in Appendix A;
 - (3) Be performed in accordance with the manufacturer's contractual specifications.

He-P 4047.08 Calibration of Survey Instruments.

- (a) The registrant shall ensure that the survey instruments used to show compliance with He-P 4047 have been calibrated as follows:
- (1) Before the first use;
 - (2) At intervals not to exceed 12 months; and
 - (3) Following repair.
- (b) To satisfy the requirements of He-P 4047.08(a), the registrant shall:
- (1) Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST); and
 - (2) Calibrate at least 2 points on each scale to be calibrated. These points shall be approximately 1/3 to 2/3 full-scale.
- (c) To satisfy the requirements of He-P 4047.08(b), the registrant shall:
- (1) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and
 - (2) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

(d) The registrant shall retain a record of each calibration required in He-P 4047.08(a) for 3 years.

(e) The record required in He-P 4047.08(d) shall include:

- (1) A description of the calibration procedure; and
- (2) A description of:
 - a. The source used;
 - b. The certified dose rates from the source;
 - c. The rates indicated by the instrument being calibrated;
 - d. The correction factors deduced from the calibration data;
 - e. The signature of the individual who performed the calibration; and
 - f. The date of calibration.

(f) The registrant may obtain the services of individuals registered or licensed by DHHS/RHS, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments.

He-P 4047.09 Shielding and Safety Design Requirements.

(a) Each therapeutic radiation machine subject to He-P 4047.06 or He-P 4047.07 shall be provided with such primary and secondary barriers as are necessary to ensure compliance with He-P 4020.05 and He-P 4020.13.

(b) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for DHHS/RHS approval prior to actual installation of the therapeutic radiation machine.

(c) The following minimum facility design information shall be submitted to DHHS/RHS with any request for the therapeutic radiation machine installation approval:

- (1) For any therapeutic radiation machine, the following basic facility information:
 - a. Name;
 - b. Telephone number;
 - c. The DHHS/RHS registration number of the individual responsible for preparation of the shielding plan;
 - d. Name and telephone number of the facility supervisor;
 - e. The facility street address;

- f. The facility room number for the therapeutic radiation machine;
 - g. Indication if this is a new structure or a modification to existing structure(s);
 - h. The primary barriers for all wall, floor, and ceiling areas struck by the useful beam;
 - i. All secondary barriers provided in all wall, floor, and ceiling areas not having primary barriers;
 - j. If commercial software is used to generate shielding requirements, the software name, version, and date of revision;
 - k. If the software used to generate shielding requirements is not in the open literature, quality control sample calculations to verify the result obtained with the software;
 - l. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;
 - m. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned, and any exterior wall(s), with distance to the closest area(s) where it is likely that individuals may be present; and
 - n. At least one example calculation which shows the methodology used to determine the amount of shielding required for each primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s), and shielding material in the facility.
- (2) In addition to the requirements listed in He-P 4047.09(c)(1), therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:
- a. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;
 - b. Maximum design workload for the facility to include:
 - 1. Total weekly radiation output expressed in gray (rad) or air kerma at 1 meter;
 - 2. Total beam-on time per day or week;
 - 3. The average treatment time per patient; and
 - 4. The anticipated number of patients to be treated per day or week; and
 - c. A facility blueprint/drawing indicating:

1. Scale;
2. Direction of North;
3. Normal location of the therapeutic radiation machine's radiation port(s);
4. The port's travel and traverse limits;
5. General direction(s) of the useful beam;
6. Locations of any windows and doors;
7. The location of the therapeutic radiation machine control panel;
8. The location of the operator's booth if the control panel is located inside the therapeutic radiation machine treatment room; and
9. The operator's station at the control panel has a protective barrier sufficient to ensure compliance with He-P 4020.05;

(3) In addition to the requirements listed in He-P 4047.09(c)(1), therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

a. Equipment specifications to include:

1. The manufacturer;
2. The model number of the therapeutic radiation machine;
3. The gray or rad at the isocenter;
4. The energy(s) and type(s) of radiation produced; and
5. The target to isocenter distance;

b. Maximum design workload for the facility including:

1. Total weekly radiation output expressed in gray rad at 1 meter;
2. Total beam-on time per day or week;
3. The average treatment time per patient; and
4. The anticipated number of patients to be treated per day or week;

c. Facility blueprint or drawing indicating:

1. The floor plan and elevation views each indicating relative orientation of the therapeutic radiation machine;

2. Type(s), thickness, and minimum density of shielding material(s);
 3. Direction of North; and
 4. The locations and size of all beam penetrations through each ceiling, wall, floor, details of the door(s) and maze shielding barrier; and
- d. A description of all assumptions that were in the shielding calculations including, but not limited to:
1. Design energy;
 2. Work-load;
 3. Presence of integral beam-stop in unit;
 4. Occupancy and use(s) of adjacent areas;
 5. Fraction of time that useful beam will intercept each permanent barrier for all walls, floor and ceiling; and
 6. "Allowed" radiation exposure in both restricted and unrestricted areas.

(4) In addition to the requirements listed in He-P 4047.09(c)(3), therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as minimum, the following additional information:

- a. The structural composition, thickness, minimum density, and location of all neutron shielding material;
- b. Description of all assumptions that were used in neutron shielding calculations including, but not limited to:
 1. Neutron spectra as a function of energy;
 2. Neutron fluence rate; and
 3. Absorbed dose and dose equivalent for neutrons in both restricted and unrestricted areas;
- c. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each restricted and unrestricted areas, entry door(s), maze and the neutron shielding material utilized in the facility; and
- d. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

He-P 4047.10 Quality Assurance For Radiation Therapy Simulation Systems. Quality assurance for a conventional or virtual simulator shall include:

- (a) Acceptance testing;
- (b) Periodic verification of system performance;
- (c) Be performed in accordance with “Comprehensive QA for Radiation Oncology,” (Updated by Table II)(1994) prepared by American Association of Physicists in Medicine (AAPM), Radiation Therapy Committee Task Group No. 40; or
- (d) Be performed in accordance with “Quality Assurance for Computed –Tomography Simulators and the Computed Tomography-Simulation Process” (2003) prepared by AAPM Radiation Therapy Committee Task Group 66 as incorporated by reference and included in Appendix A.

He-P 4047.11 Electronic Brachytherapy.

(a) Electronic brachytherapy devices shall be subject to the requirements of He-P 4047.11 and shall be exempt from the requirements of He-P 4047.06, and which are:

- (1) An electronic brachytherapy device that does not meet the requirement of He-P 4047.11 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) Each facility location authorized to use an electronic brachytherapy device shall possess appropriately calibrated portable monitoring equipment which shall as a minimum:

- (1) Include a portable radiation measurement survey instrument capable of measuring dose rate over the range of 10 μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour, and
- (2) Be operable and calibrated in accordance with He-P 4047.08 for the applicable electronic brachytherapy source energy.

(c) In addition to shielding adequate to meet the requirements of He-P 4047.09, the treatment room shall meet the following design requirements:

- (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;

(4) The electronic brachytherapy device shall not be used for patient irradiation unless patient can be observed;

(5) For electronic brachytherapy devices capable of operating below 50kV, radiation shielding for the staff in the room shall be available:

- a. Either as a portable shield; or
- b. As localized shielded material around the treatment site; and

(6) For electronic brachytherapy devices capable of operating at greater than 150 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:
 1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
 2. Cause the source to be shielded when an entrance door is opened; and
 3. 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) Each electronic brachytherapy device shall have the following electrical safety features:

(1) The high voltage transformer shall be electronically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment;

(2) The high voltage transformer shall be isolated from personnel 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; and

(4) Equipment manufactured shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents which are incorporated by reference and included in Appendix A:

- a. IEC 60601-1 1998 + A1+A2: 1995;
- b. IEC 60601-1-2:2001;
- c. IEC 60601-2-8: 1999; and
- d. IEC 60601-2-17; 2004.

(e) The control panel in addition to the displays required by other provisions in He-P 4047.11, 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; and
- (5) Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

(f) A suitable irradiation control device or timer shall be provided to terminate the irradiation after a preset time interval or integrated charge on a dosimeter-based monitor. Timers shall:

- (1) Be provided at the control panel and shall indicate planned setting and the time elapsed or remaining;
- (2) Not permit an exposure if set at zero;
- (3) 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 reinstated, it shall be necessary to reset the elapsed time indicator;
- (4) Terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation;
- (5) Permit setting of exposure times as short as 0.1 seconds; and
- (6) Be accurate to within 1 percent of the selected value or 0.1 seconds, whichever is greater.

(g) The services of a radiation therapy physicist shall be required in facilities having electronic brachytherapy devices. The radiation therapy 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 He-P 4047.11(j);

- (5) Consultation with the authorized user in treatment planning, as needed;
- (6) Performing calculations and assessments regarding patient treatments that may constitute a misadministration; and
- (7) Determining which persons in the treatment room require monitoring when the beam is energized.

(h) Operating procedures shall be as follows:

- (1) Only individuals approved by the authorized user, radiation safety officer or radiation therapy 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 He-P 4047.04(a), and He-P 4047.11(i) through He-P 4047.11(k) have been met;
- (3) The electronic brachytherapy device shall be secured to prevent unauthorized use;
- (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 equipment failures and the names of the individuals responsible for implementing corrective actions; and
 - b. The names and telephone numbers of the authorized users, radiation safety officer and the radiation therapy physicist to be contacted if the device or console operates abnormally;
- (7) A copy of the current operating and emergency procedures shall be maintained at the control console or panel during electronic brachytherapy device operation. If the 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 to inform the operator of the names and telephone numbers of the authorized users, the radiation safety officer, and the radiation therapy physicist to be contacted if the device or console operates abnormally; and

(9) The radiation safety officer, and an authorized user shall be notified as soon as possible if the patient has medical emergency, suffers injury or dies. The radiation safety officer or radiation therapy physicist shall inform the manufacturer of the event.

(10) If the radiation therapy physicist is not a full time employee of the registrant, the operating procedures, required in He-P 4047.11(h) shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

(i) Calibration procedures shall include:

(1) 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;

(2) Calibration of electronic brachytherapy source output shall utilize a dosimetry system described in He- 4047.05(h);

(3) Calibration of electronic brachytherapy source output shall include, as applicable, determination of:

a. The output within 2 percent 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 exposure control device;

d. Evaluation that the relative dose distribution about the source is within 5 percent of that expected; and

e. Source positioning accuracy within 1 millimeter of the applicator;

(4) Calibration of the x-ray source output required in by He-P 4047.11(i) above, shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, and if that published recommendation is not available, then from the manufacturer's suggested calibration protocol; and

(5) The registrant shall maintain a record of each calibration in an auditable form for the duration of registration. The record shall include:

a. The date of the calibration;

b. The manufacturer's name;

c. The model number and serial number for the electronic brachytherapy device;

d. A unique identifier for its electronic brachytherapy source;

- e. The model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and
 - f. The name and signature of the radiation therapy physicist responsible for performing the calibration.
- (j) Quality assurance checks shall be conducted as follows:
- (1) Quality assurance checks shall be performed on each electronic brachytherapy device subject to He-P 4047.11:
 - a. At the beginning of each day of use;
 - b. Each time the device is moved to a new room or site, intended to include each day of use at each operating location and
 - c. After each x-ray tube installation;
 - (2) The registrant shall perform periodic quality assurance checks required by He-P 4047.11(j)(1) in accordance with procedures established by the Radiation Therapy Physicist;
 - (3) To satisfy the requirements of He-P 4047.11(j)(1), radiation output quality assurance checks shall include as a minimum:
 - a. Verification that output of the electronic brachytherapy source falls within 3 percent of expected values, as appropriate for the device, as determined by:
 - 1. Output as a function of time, or
 - 2. Output as a function of setting on a monitor chamber;
 - b. Verification of the consistency of the dose distribution to within 3 percent of that found during calibration required by He-P 4047.11(i); and
 - c. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one mm.;
 - (4) The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in He-P 4047.05(h) to make the quality assurance checks required in He-P 4047.11(j)(3);
 - (5) The registrant shall review the results of each radiation output quality assurance check according to the following procedures:
 - a. An authorized user and radiation therapy 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 radiation therapy 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 user or radiation therapy physicist within 2 business days; and

c. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days;

(6) To satisfy the requirement of He-P 4047.11(i)(1), 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 He-P 4047.11(j)(6) 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 might be necessary to repair, replace, or check the malfunctioning system; and

(8) The registrant shall maintain a record of each quality assurance check required by He-P 4047.11(j)(3) and He-P 4047.11(j)(6) in an auditable form for 3 years as follows:

a. The record shall include:

1. Date of the quality assurance check;

2. Manufacturer's name, model number and serial number for the electronic brachytherapy device;

3. Name and signature of the individual who performed the periodic quality assurance check; and

4. Name and signature of the radiation therapy physicist who reviewed the quality assurance check; and

b. For radiation output quality assurance checks required by He-P 4047.11(j)(3), the record shall also include:

1. The unique identifier for the electronic brachytherapy source; and
2. The manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

(k) The registrant 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. All acceptance testing shall:

- (1) Be performed by, or under the direct supervision of, a radiation therapy physicist; and
 - (2) At a minimum, 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;
 - (3) Compare the position indicators in the applicator to the actual position of the source or planned dwell positions, as appropriate, at a time of commissioning; and
 - (4) Include procedures prior to each patient treatment regimen, for the parameters for the treatment to be evaluated and approved by the authorized user and the radiation therapy physicist for correctness through means independent of that used for the determination of the parameters.
- (l) The following training shall be required:
- (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 He-P 4047.11(h). If the interval between patients exceeds one year, retraining of the individuals shall be provided;

(2) In addition to the requirements of He-P 4047.04(e) for the therapeutic radiation machine authorized users and He-P 4047.04(k) for radiation therapy physicists, these individuals shall also receive device specific instruction initially from the manufacturer, and annually from either the manufacturer or other authorized manufacturer 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 FDA;
- d. Emergency procedures, including an emergency drill; and
- e. The registrant's quality assurance program; and

(3) A registrant shall retain a record of individuals receiving instruction required by He-P 4047.11(l)(1) and (2) for 3 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.

(m) A registrant 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; and
- (3) Perform, at each location on each day of use, all of the required quality assurance checks specified in He-P 4047.11(j) to assure proper operation of the device.

He-P 4047.12 Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage. A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

(a) The applicant or registrant has, at a minimum, provided DHHS/RHS with:

- (1) A detailed description of the device and its intended application(s):

- (2) Facility design requirements, including shielding and access control;
- (3) Documentation of appropriate training for authorized user physician(s) and radiation therapy physicist(s);
- (4) Methodology for measurement of dosages to be administered to patients or human research subjects;
- (5) Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;
- (6) Radiation safety precautions and instructions; and
- (7) Other information requested by DHHS/RHS in its review of the application.

(b) The applicant or registrant has received approval from DHHS/RHS to utilize the device in accordance with the regulations and specific conditions DHHS/RHS considers necessary for the medical use of the device.

Appendix A Incorporation by Reference Information

Rule	Title	Publisher; How to Obtain; and Cost
He-P 4047.06(q)(3)	“Dosimetry of X-Ray and Gamma –Ray Beams for Radiation Therapy in Energy Range 10 keV to 50 MeV” (1981)	National Council on Radiation Protection (NCRP), 7910 Woodmont Ave., Suite 400, Bethesda, MD 20814-3095, NCRPpubs@NCROnline.org Cost: \$374.
He-P 4047.06(q)(3)	“High Dose-Rate Brachytherapy Treatment Delivery” (1998)	American Association of Physicists in Medicine (AAPM) Radiation Task Group 59, One Physics Ellipse, College Park, MD 20740, www.aapm.org/pubs/report , Cost: Free.
He-P 4047.06(q)(3)	“AAPM Protocol for 40-300 kV X-ray Beam Dosimetry in Radiotherapy and Radiobiology” (2001)	American Association of Physicists in Medicine (AAPM) Radiation Task Group 61, One Physics Ellipse, College Park, MD 20740, www.aapm.org/pubs/report , Cost: Free.
He-P 4047.07(e) & (o)(5)	International Electrotechnical Commission (IEC) Document 60601-2-1	International Electrotechnical Commission (IEC), Regional Center for North America, 446 Main Street, 16 th Floor, Worcester, MA 01068, www.601.help.com/other_601_standard.html . Cost: \$185.00 (pdf) and \$213.00 (hardcopy).
He-P 4047.07(u)(2) & (5)	“AAPM Code of Practice for Radiotherapy Accelerators.” (1994)	American Association of Physicists in Medicine (AAPM) Radiation Task Group 45, One Physics Ellipse, College Park, MD 20740, www.aapm.org/pubs/report , Cost: Free.
He-P 4047.07 (u) (4)&(u)(6) (v)(1) & (v)(2) &(v)(7) & He-P	“Comprehensive QA for Radiation Oncology” (1994) (As Updated by Table II.)	American Association of Physicists in Medicine (AAPM) Radiation Task Group 40, One Physics Ellipse, College Park, MD 20740, www.aapm.org/pubs/report , Cost: Free.

Rule	Title	Publisher; How to Obtain; and Cost
4047.10(c)		
He-P 4047.07(w)(2)	“Guidance Document on Delivery, Treatment Planning and Clinical Implementation of IMRT: Report of the IMRT Subcommittee of the AAPM Radiation Therapy Committee.” (2003)	American Association of Physicists in Medicine (AAPM), Radiation Therapy Committee, IMRT Subcommittee, One Physics Ellipse, College Park, MD 20740, www.aapm.org/pubs/report , Cost: Free.
He-P 4047.10(d)	“Quality Assurance for Computed-Tomography Simulators and the Computed-Tomography-Simulation Process.” (2003)	American Association of Physicists in Medicine (AAPM) Radiation Task Group 66 One Physics Ellipse, College Park, MD 20740, www.aapm.org/pubs/report , Cost: Free.,
He-P 4047.11(d)(4) a.	International Electrotechnical Commission (IEC) Document 60601-1:1998 +A1 +A2: 1995	International Electrotechnical Commission (IEC), Regional Center for North America, 446 Main Street, 16 th Floor, Worcester, MA 01608, www.601help.com/other_601_standard/other_601_standard.html . Cost: \$185.00 (pdf) and \$213.00 (hardcopy).
He-P 4047.11(d)(4) b.	International Electrotechnical Commission (IEC) Document 60601-1-2: 2001	International Electrotechnical Commission (IEC) Regional Center for North America, 446 Main Street, 16 th Floor, Worcester, MA 01608, www.601help.com/other_601_standard/other_601_standard.html . Cost: \$185.00 (pdf) and \$213.00 (hardcopy).
He-P 4047.11(d)(4) c.	International Electrotechnical Commission (IEC) Document 60601-2-8:1999	International Electrotechnical Commission (IEC) Regional Center for North America, 446 Main Street, 16 th Floor, Worcester, MA 01608, www.601help.com/other_601_standard/other_601_standard.html . Cost: \$185.00 (pdf) and \$213.00 (hardcopy),
He-P 4047.11(d)(4) d.	International Electrotechnical Commission (IEC) Document 60601-2-17:2004	International Electrotechnical Commission (IEC), Regional Center for North America, 446 Main Street, 16 th Floor, Worcester, MA 01608, www.601help.com/other_601_standard/other_601_standard.html . Cost: \$185.00 (pdf) and \$213.00 (hardcopy).

Appendix B

RULE	STATE OR FEDERAL STATUTORY AUTHORITY
He-P 4047.01	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.02	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.03	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.04	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.05	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.06	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.07	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.08	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.09	RSA 125-F:1, F:2, F:5, II & V

He-P 4047.10	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.11	RSA 125-F:1, F:2, F:5, II & V
He-P 4047.12	RSA 125-F:1, F:2, F:5, II & V