

1 **216-RICR-40-20-5**

2 **TITLE 216 – DEPARTMENT OF HEALTH**

3 **CHAPTER 40 – PROFESSIONAL LICENSING & FACILITIES REGULATION**

4 **SUBCHAPTER 20 - RADIATION**

5 **PART 5 – THERAPEUTIC RADIATION MACHINES**

6 **5.1 Authority**

7 A. This Part is promulgated pursuant to the authority conferred under R.I. Gen.
8 Laws § [23-1.3-5\(f\)](#), as amended.

9 B. This Part establishes requirements, for which a registrant is responsible, for use
10 of therapeutic radiation machines. The provisions of this Part are in addition to,
11 and not in substitution for, other applicable provisions of this Subchapter.

12 C. The use of therapeutic radiation machines shall be by, or under the supervision
13 of, a licensed practitioner of the healing arts who meets the training/experience
14 criteria established by § 5.3.3 of this Part.

15 D. Provisions for Research Involving Human Subjects. A registrant may conduct
16 research involving human subjects using therapeutic radiation machines
17 provided that:

18 1. If the research will be conducted, funded, supported, or regulated by a
19 Federal Agency which has implemented the Federal Policy for the
20 Protection of Human Subjects, the registrant shall, before conducting
21 research:

- 22 a. Obtain review and approval of the research from an "Institutional
23 Review Board," as defined and described in the Federal Policy; and
24 b. Obtain "informed consent," as defined and described in the Federal
25 Policy, from the human research subject; or

26 2. If the research will not be conducted, funded, supported, or regulated by a
27 Federal agency that has implemented the Federal Policy, the registrant
28 shall, before conducting research:

- 29 a. Apply for and receive approval of a specific amendment to its
30 Agency registration; and
31 b. Obtain review and approval of the research from an "Institutional
32 Review Board," as defined and described in the Federal Policy; and

- 1 c. Obtain "informed consent," as defined and described in the Federal
2 Policy, from the human research subject.
- 3 E. FDA, Other Federal and State Requirements. Nothing in this Part relieves the
4 registrant from complying with applicable Agency, FDA, other federal, and State
5 requirements governing therapeutic radiation machines or auxiliary devices.
- 6 F. Electronic brachytherapy devices are subject to the requirements of § 5.11 of this
7 Part, and are exempt for the requirements of § 5.6 of this Part.
- 8 G. Any notifications, reports or correspondence required by this Part shall be
9 directed to the Agency using contact information specified in § 1.4 of this
10 Subchapter.

11 **5.2 Definitions**

12 Whenever used in this Part, the following terms shall be construed as follows:

13 “Absorbed dose (D)” means the mean energy imparted by ionizing radiation to
14 matter. Absorbed dose is determined as the quotient of dE by dM, where dE is
15 the mean energy imparted by ionizing radiation to matter of mass dM. The SI
16 unit of absorbed dose is joule per kilogram and the name of the unit of absorbed
17 dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is
18 being replaced by the gray.

19 “Absorbed dose rate” means absorbed dose per unit time, for machines with
20 timers, or dose monitor unit per unit time for linear accelerators.

21 “Accessible surface” means surface of equipment or of an equipment part that
22 can be easily or accidentally touched by persons without the use of a tool.

23 “Act” means Title 23, Chapter 1.3 of the General Laws of the State of Rhode
24 Island entitled “Radiation Control”.

25 “Added filtration” means any filtration which is in addition to the inherent filtration.

26 “Agency” means Rhode Island Radiation Control Agency (RCA), Center for
27 Health Facilities Regulation - Radiation Control Program, Rhode Island
28 Department of Health.

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

34 “Barrier” (See “Protective barrier”).

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

3 “Field-flattening filter” means a filter used to homogenize the absorbed dose rate
4 over the radiation field.

5 “Filter” means material placed in the useful beam to change beam quality in
6 therapeutic radiation machines subject to § 5.6 of this Part.

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

9 “Gray (Gy)” means the SI unit of absorbed dose, kerma, and specific energy
10 imparted equal to 1 joule per kilogram. The previous special unit of absorbed
11 dose (rad) is being replaced by the gray. [1 Gy=100 rad].

12 “Half-value layer (HVL)” means the thickness of a specified material which
13 attenuates X-radiation or gamma radiation to an extent such that the air kerma
14 rate, exposure rate or absorbed dose rate is reduced to one-half of the value
15 measured without the material at the same point.

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

19 “Interlock” means a device preventing the start or continued operation of
20 equipment unless certain predetermined conditions prevail.

21 “Interruption of irradiation” means the stopping of irradiation with the possibility of
22 continuing irradiation without resetting of operating conditions at the control
23 panel.

24 “Irradiation” means the exposure of a living being or matter to ionizing radiation.

25 “Isocenter” means the center of the sphere through which the useful beam axis
26 passes while the gantry moves through its full range of motions.

27 “Kilo electron volt (keV)” means the energy equal to that acquired by a particle
28 with one electron charge in passing through a potential difference of one
29 thousand volts in a vacuum. [Note: current convention is to use kV for photons
30 and keV for electrons.]

31 “Lead equivalent” means the thickness of the material in question affording the
32 same attenuation, under specified conditions, as lead.

33 “Leakage radiation” means radiation emanating from the radiation therapy
34 system except for the useful beam.

1 “Light field” means the area illuminated by light, simulating the radiation field.

2 “mA” means milliampere.

3 “Mega electron volt (MeV)” means the energy equal to that acquired by a particle
4 with one electron charge in passing through a potential difference of one million
5 volts in a vacuum. [Note: current convention is to use MV for photons and MeV
6 for electrons.]

7 “Misadministration” means an event that meets the criteria in § 5.5.2 of this Part.

8 “Mobile Electronic Brachytherapy Service” means transportation of an electronic
9 brachytherapy device to provide electronic brachytherapy at an address that is
10 not the address of record.

11 “Monitor unit (MU)” (See "Dose monitor unit").

12 “Moving beam radiation therapy” means radiation therapy with any planned
13 displacement of radiation field or patient/human research subject relative to each
14 other, or with any planned change of absorbed dose distribution. It includes arc,
15 skip, conformal, intensity modulation and rotational therapy.

16 “Nominal treatment distance” means:

- 17 1. For electron irradiation, the distance from the scattering foil, virtual source,
18 or exit window of the electron beam to the entrance surface of the
19 irradiated object along the central axis of the useful beam.
- 20 2. For X-ray irradiation, the virtual source or target to isocenter distance
21 along the central axis of the useful beam. For non-isocentric equipment,
22 this distance shall be that specified by the manufacturer.

23 “Patient” means an individual subjected to machine produced radiation for the
24 purpose(s) of medical therapy.

25 “Peak tube potential” means the maximum value of the potential difference
26 across the X-ray tube during an exposure.

27 “Periodic quality assurance check” means a procedure which is performed to
28 ensure that a previous parameter or condition continues to be valid.

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

31 “Practical range of electrons” corresponds to classical electron range where the
32 only remaining contribution to dose is from bremsstrahlung X-rays. A further
33 explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM
34 Radiation Therapy Committee Task Group 25" [Medical Physics 18(1): 73-109,
35 Jan/Feb 1991] and ICRU Report 35, "Radiation Dosimetry: Electron Beams with

1 Energies Between 1 and 50 MeV", International Commission on Radiation Units
2 and Measurements, September 15, 1984.

3 "Prescribed dose" means the total dose and dose per fraction as documented in
4 the written directive. The prescribed dose is an estimation from measured data
5 from a specified therapeutic radiation machine using assumptions that are
6 clinically acceptable for that treatment technique and historically consistent with
7 the clinical calculations previously used for patients treated with the same clinical
8 technique.

9 "Primary dose monitoring system" means a system which will monitor the useful
10 beam during irradiation and which will terminate irradiation when a pre-selected
11 number of dose monitor units have been delivered.

12 "Primary protective barrier" (See "Protective barrier").

13 "Radiation field" (See useful beam)

14 "Protective barrier" means a barrier of radiation absorbing material(s) used to
15 reduce radiation exposure. The types of protective barriers are as follows:

- 16 1. "Primary protective barrier" means the material, excluding filters, placed in
17 the useful beam.
18 2. "Secondary protective barrier" means the material which attenuates stray
19 radiation.

20 "Radiation detector" means a device which, in the presence of radiation provides,
21 by either direct or indirect means a signal or other indication suitable for use in
22 measuring one or more properties or quantities of incident radiation.

23 "Radiation head" means the structure from which the useful beam emerges.

24 "Recordable event" means the administration of a therapeutic radiation machine
25 dose when the calculated weekly administered dose differs by fifteen percent
26 (15%) or more from the weekly prescribed dose.

27 "Redundant beam monitoring system" means a combination of two (2)
28 independent dose monitoring systems in which each system is designed to
29 terminate irradiation in accordance with a pre-selected number of dose monitor
30 units.

31 "Registrant" means any person who is registered with the Agency and is legally
32 obligated to register with the Agency pursuant to this Subchapter and the Act.

33 "Registration" means registration with the Agency pursuant to this Subchapter
34 and the Act.

35 "R.I. Gen. Laws" means the General Laws of Rhode Island, as amended.

1 “Scattered radiation” means ionizing radiation emitted by interaction of ionizing
2 radiation with matter, the interaction being accompanied by a change in direction
3 of the radiation. Scattered primary radiation means that scattered radiation
4 which has been deviated in direction only by materials irradiated by the useful
5 beam.

6 “Secondary dose monitoring system” means a system which will terminate
7 irradiation in the event of failure of the primary dose monitoring system.

8 “Secondary protective barrier” (See "Protective barrier").

9 “Shadow tray” means a device attached to the radiation head to support auxiliary
10 beam blocking material.

11 “Shutter” means a device attached to the tube housing assembly which can
12 totally intercept the useful beam and which has a lead equivalency not less than
13 that of the tube housing assembly.

14 “Sievert (Sv)” means the SI unit of dose equivalent. The unit of dose equivalent
15 is the joule per kilogram. The previous special unit of dose equivalent (rem) is
16 being replaced by the sievert. [1 Sv=100 rem].

17 “Simulator (radiation therapy simulation system)” means any X-ray system
18 intended for localizing the volume to be exposed during radiation therapy and
19 establishing the position and size of the therapeutic irradiation field. [See:
20 Conventional Simulator and Virtual Simulator.]

21 “Source” means the region and/or material from which the radiation emanates.

22 “Source-skin distance (SSD)” [See Target-skin distance]

23 “Stationary beam radiation therapy” means radiation therapy without
24 displacement of one or more mechanical axes relative to the patient/human
25 research subject during irradiation.

26 “Stray radiation” means the sum of leakage and scattered radiation.

27 “Target” means that part of an X-ray tube or accelerator onto which is directed a
28 beam of accelerated particles to produce ionizing radiation or other particles.

29 “Target-skin distance (TSD)” means the distance measured along the beam axis
30 from the center of the front surface of the X-ray target and/or electron virtual
31 source to the surface of the irradiated object or patient/ human research subject.

32 “Tenth-value layer (TVL)” means the thickness of a specified material which
33 attenuates X-radiation or gamma radiation to an extent such that the air kerma
34 rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value
35 measured without the material at the same point.

1 “Termination of irradiation” means the stopping of irradiation in a fashion which
2 will not permit continuance of irradiation without the resetting of operating
3 conditions at the control panel.

4 “Therapeutic radiation machine” means X-ray or electron-producing equipment
5 designed and used for external beam radiation therapy. For the purpose of this
6 Subchapter, devices used to administer electronic brachytherapy shall also be
7 considered therapeutic radiation machines.

8 “Tube” means an X-ray tube, unless otherwise specified.

9 “Tube housing assembly” means the tube housing with tube installed. It includes
10 high-voltage and/or filament transformers and other appropriate elements when
11 such are contained within the tube housing.

12 “Useful beam” means the radiation emanating from the tube housing port or the
13 radiation head and passing through the aperture of the beam limiting device
14 when the exposure controls are in a mode to cause the therapeutic radiation
15 machine to produce radiation.

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

20 “Virtual source” means a point from which radiation appears to originate.

21 “Wedge filter” means a filter which effects continuous change in transmission
22 over all or a part of the useful beam.

23 “Written directive” means an order in writing for the administration of radiation to
24 a specific patient or human research subject, as specified in § 5.5.1 of this Part.

25 “X-ray tube” means any electron tube which is designed to be used primarily for
26 the production of X-rays.

27 **5.3 General Administrative Requirements for Facilities Using**
28 **Therapeutic Radiation Machines**

29 **5.3.1 Administrative Controls.** The registrant shall be responsible for directing the
30 operation of the therapeutic radiation machines which have been registered with
31 the Agency. The registrant or the registrant's agent shall ensure that the
32 requirements of this Part are met in the operation of the therapeutic radiation
33 machine(s).

34 **5.3.2** A therapeutic radiation machine which does not meet the provisions of this
35 Subchapter shall not be used for irradiation of patients/human research subjects.

1 **5.3.3 Training for Therapeutic Radiation Machine Authorized Users.** The
2 registrant for any therapeutic radiation machine subject to § 5.6 or § 5.7 of this
3 Part shall require the Authorized User to be a physician who:

4 A. Is certified in:

- 5 1. Radiation oncology or therapeutic radiology by the American Board of
6 Radiology or Radiology (combined diagnostic and therapeutic radiology
7 program) by the American Board of Radiology prior to 1976; or
- 8 2. Radiation oncology by the American Osteopathic Board of Radiology; or
- 9 3. Radiology, with specialization in radiotherapy, as a British "Fellow of the
10 Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
- 11 4. Therapeutic radiology by the Canadian Royal College of Physicians and
12 Surgeons; or

13 B. Is in the active practice of therapeutic radiology, and has completed two hundred
14 (200) hours of instruction in basic radiation techniques applicable to the use of an
15 external beam radiation therapy unit, five hundred (500) hours of supervised
16 work experience, and a minimum of three (3) years of supervised clinical
17 experience.

- 18 1. To satisfy the requirement for instruction, the classroom and laboratory
19 training shall include:

- 20 a. Radiation physics and instrumentation;
- 21 b. Radiation protection;
- 22 c. Mathematics pertaining to the use and measurement of ionization
23 radiation; and
- 24 d. Radiation biology.

- 25 2. To satisfy the requirement for supervised work experience, training shall
26 be under the supervision of an Authorized User and shall include:

- 27 a. Review of the full calibration measurements and periodic quality
28 assurance checks;
- 29 b. Evaluation of prepared treatment plans and calculation of treatment
30 times and patient/human research subject treatment settings;
- 31 c. Using administrative controls to prevent misadministrations;

- 1 d. Implementing emergency procedures to be followed in the event of
2 the abnormal operation of an external beam radiation therapy unit
3 or console; and
- 4 e. Checking and using radiation survey meters.
- 5 3. To satisfy the requirement for a period of supervised clinical experience,
6 training shall include one (1) year in a formal training program approved
7 by the Residency Review Committee for Radiology of the Accreditation
8 Council for Graduate Medical Education or the Committee on Postdoctoral
9 Training of the American Osteopathic Association and an additional two
10 (2) years of clinical experience in therapeutic radiology under the
11 supervision of an Authorized User. The supervised clinical experience
12 shall include:
 - 13 a. Examining individuals and reviewing their case histories to
14 determine their suitability for external beam radiation therapy
15 treatment, and any limitations/contraindications;
 - 16 b. Selecting proper dose and how it is to be administered;
 - 17 c. Calculating the therapeutic radiation machine doses and
18 collaborating with the Authorized User in the review of
19 patients'/human research subjects' progress and consideration of
20 the need to modify originally prescribed doses and/or treatment
21 plans as warranted by patients'/human research subjects' reaction
22 to radiation; and
 - 23 d. Post-administration follow-up & review of case histories.

- 24 C. Notwithstanding the requirements of §§ 5.3.3(A) and 5.3.3(B) of this Part, the
25 registrar for any therapeutic radiation machine subject to § 5.6 of this Part may
26 also submit the training of the prospective Authorized User physician for Agency
27 review on a case-by-case basis.
- 28 D. A physician shall not act as an Authorized User for any therapeutic radiation
29 machine until such time as said physician's training has been reviewed and
30 approved by the Agency.

31 **5.3.4 Training for Qualified Medical Physicist.** The registrant for any therapeutic
32 radiation machine subject to § 5.6 or § 5.7 of this Part shall require the Qualified
33 Medical Physicist to:

- 34 A. Be registered with the Agency, under the provisions of Part 3 of this Subchapter,
35 as a provider of radiation services in the area of calibration and compliance
36 surveys of external beam radiation therapy units. and
- 37 B. Be certified by the American Board of Radiology in:

- 1 1. Therapeutic radiological physics; or
 - 2 2. Roentgen-ray and gamma-ray physics; or
 - 3 3. X-ray and radium physics; or
 - 4 4. Radiological physics; or
 - 5 5. Therapeutic medical physics; or
- 6 C. Be certified by the American Board of Medical Physics in Radiation Oncology
7 Physics; or
- 8 D. Be certified by the Canadian College of Physicists in Medicine (CCPM) in
9 Radiation Oncology Physics.

10 **5.3.5 Qualifications of Operators**

- 11 A. Individuals who will be operating a therapeutic radiation machine for medical use
12 shall possess a current license as a Radiation Therapist in accordance with
13 Licensure of Radiographers, Nuclear Medicine Technologists, Radiation
14 Therapists and Radiologist Assistants [216-RICR-40-05-34], unless the individual
15 is specifically exempted from licensure by said regulations.
- 16 B. The names and training of all personnel currently operating a therapeutic
17 radiation machine shall be kept on file at the facility. Information on former
18 operators shall be retained for a period of at least two (2) years beyond the last
19 date they were authorized to operate a therapeutic radiation machine at that
20 facility.

- 21 **5.3.6** Written safety procedures and rules shall be developed by a Qualified Medical
22 Physicist and shall be available in the control area of a therapeutic radiation
23 machine, including any restrictions required for the safe operation of the
24 particular therapeutic radiation machine. The operator shall be able to
25 demonstrate familiarity with these rules.

- 26 **5.3.7** Individuals shall not be exposed to the useful beam except for medical therapy
27 purposes and unless such exposure has been ordered in writing by a therapeutic
28 radiation machine Authorized User. This provision specifically prohibits
29 deliberate exposure of an individual for training, demonstration or other non-
30 healing-arts purposes.

- 31 **5.3.8 Visiting Authorized User.** Notwithstanding the provisions of § 5.3.3(D) of this
32 Part, a registrant may permit any physician to act as a Visiting Authorized User
33 under the term of the registrant's Certificate of Registration for up to sixty (60)
34 days per calendar year under the following conditions:

- 1 A. The Visiting Authorized User has the prior written permission of the registrant's
2 management and, if the use occurs on behalf of an institution, the institution's
3 Radiation Safety Committee (where applicable); and
 - 4 B. The Visiting Authorized User meets the requirements established for Authorized
5 User(s) in §§ 5.3.3(A) and 5.3.3(B) of this Part; and
 - 6 C. The registrant shall maintain copies of the written permission required in §
7 5.3.8(A) of this Part and documentation that the Visiting Authorized User met the
8 requirements of § 5.3.8(B) of this Part for five (5) years from the date of the last
9 visit.
- 10 **5.3.9** All individuals associated with the operation of a therapeutic radiation machine
11 shall be instructed in and shall comply with the provisions of the registrant's
12 quality management program. In addition to the requirements of this Part, these
13 individuals are also subject to the requirements of §§ 1.7.1, 1.7.5 and 1.10.3 of
14 this Subchapter.

15 **5.3.10 Information and Maintenance Record and Associated Information.** The
16 registrant shall maintain the following information in a separate file or package for
17 each therapeutic radiation machine, for inspection by the Agency:

- 18 A. Report of acceptance testing.
- 19 B. Records of all surveys, calibrations, and periodic quality assurance checks of the
20 therapeutic radiation machine required by this Part, as well as the name(s) of
21 person(s) who performed such activities.
- 22 C. Records of maintenance and/or modifications performed on the therapeutic
23 radiation machine after 1 August 1978 as well as the name(s) of person(s) who
24 performed such services.
- 25 D. Signature of person authorizing the return of therapeutic radiation machine to
26 clinical use after service, repair, or upgrade.

27 **5.3.11 Records Retention.** All records required by this Part shall be retained until
28 disposal is authorized by the Agency unless another retention period is
29 specifically authorized in this Part. All required records shall be retained in an
30 active file from at least the time of generation until the next Agency inspection.
31 Any required record generated prior to the last Agency inspection may be
32 microfilmed or otherwise archived as long as a complete copy of said record can
33 be retrieved until such time as the Agency authorizes final disposal.

34 **5.3.12 Report and Notification of a Dose to an Embryo/Fetus**

- 35 A. A registrant shall report any dose to an embryo/fetus that is greater than 50 mSv
36 (5 rem) dose equivalent that is a result of an administration of radiation to a

1 pregnant individual unless the dose to the embryo/fetus was specifically
2 approved, in advance, by the referring physician.

3 B. The registrant shall notify the Agency by telephone no later than the next
4 calendar day after discovery of a dose to the embryo/fetus that requires a report
5 § 5.3.12(A) of this Part.

6 C. The registrant shall submit a written report to the Agency within fifteen (15) days
7 after discovery of a dose to the embryo/fetus that requires a report in § 5.3.12(A)
8 of this Part.

9 1. The written report shall include:

- 10 a. The registrant's name and registration number;
- 11 b. The name of the referring physician;
- 12 c. A brief description of the event;
- 13 d. Why the event occurred;
- 14 e. The effect, if any, on the embryo/fetus;
- 15 f. What actions, if any, have been taken or are planned to prevent
16 recurrence; and
- 17 g. Certification that the registrant notified the pregnant individual (or
18 the pregnant individual's responsible relative or guardian), and if
19 not, why not.

20 2. The report must not contain the individual's name or any other information
21 that could lead to identification of the individual.

22 D. The registrant shall provide notification of the event to the referring physician and
23 also notify the pregnant individual, no later than twenty-four (24) hours after
24 discovery of an event that would require reporting under § 5.3.12(A) of this Part,
25 unless the referring physician personally informs the registrant either that he or
26 she will inform the pregnant individual or that, based on medical judgment, telling
27 the pregnant individual would be harmful. The registrant is not required to notify
28 the pregnant individual without first consulting with the referring physician. If the
29 referring physician or pregnant individual cannot be reached within twenty-four
30 (24) hours, the registrant shall make the appropriate notifications as soon as
31 possible thereafter. The registrant may not delay any appropriate medical care
32 for the embryo/fetus, including any necessary remedial care as a result of the
33 event, because of any delay in notification. To meet the requirements of this
34 paragraph, the notification may be made to the pregnant individual's responsible
35 relative or guardian instead of the pregnant individual. If a verbal notification is
36 made, the registrant shall inform the pregnant individual, or the pregnant

1 individual's responsible relative or guardian, that a written description of the event
2 can be obtained from the registrant upon request. The registrant shall provide
3 such a written description if requested.

4 E. A registrant shall:

- 5 1. Annotate a copy of the report provided to the Agency with the:
6 a. Name of the pregnant individual who is the subject of the event;
7 and
8 b. Social security number or other identification number, if one has
9 been assigned, of the pregnant individual who is the subject of the
10 event; and
11 c. Provide a copy of the annotated report to the referring physician, if
12 other than the registrant, no later than fifteen (15) days after the
13 discovery of the event.

14 **5.4 General Technical Requirements for Facilities Using Therapeutic
15 Radiation Machines**

16 **5.4.1 Protection Surveys**

17 A. The registrant shall ensure that radiation protection surveys of all new facilities,
18 and existing facilities not previously surveyed are performed with an operable
19 radiation measurement survey instrument calibrated in accordance with § 5.8 of
20 this Part. The radiation protection survey shall be performed by, or under the
21 direction of, a Qualified Medical Physicist or a Certified Health Physicist and shall
22 verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with
23 the largest clinically available treatment field and with a scattering phantom in the
24 useful beam of radiation:

- 25 1. Radiation levels in restricted areas are not likely to cause personnel
26 exposures in excess of the limits specified in § 1.7.1(A) of this Subchapter;
27 and
28 2. Radiation levels in unrestricted areas do not exceed the limits specified in
29 §§ 1.8.1(A) and 1.8.1(B) of this Subchapter.

30 B. In addition to the requirements of § 5.4.1(A) of this Part, a radiation protection
31 survey shall also be performed prior to any subsequent medical use and:
32 1. After making any change in the treatment room shielding;
33 2. After making any change in the location of the therapeutic radiation
34 machine within the treatment room;

- 1 3. After relocating the therapeutic radiation machine; or
- 2 4. Before using the therapeutic radiation machine in a manner that could
3 result in increased radiation levels in areas outside the external beam
4 radiation therapy treatment room.
- 5 C. The survey record shall indicate all instances where the facility, in the opinion of
6 the Qualified Medical Physicist or a Certified Health Physicist, is in violation of
7 applicable regulations. The survey record shall also include the date of the
8 measurements, the reason the survey is required, the manufacturer's name,
9 model number and serial number of the therapeutic radiation machine, the
10 instrument(s) used to measure radiation levels, a plan of the areas surrounding
11 the treatment room that were surveyed, the measured dose rate at several points
12 in each area expressed in microsieverts or millirems per hour, the calculated
13 maximum level of radiation over a period of one (1) week for each restricted and
14 unrestricted area, and the signature of the individual responsible for conducting
15 the survey.
- 16 D. If the results of the surveys required by § 5.4.1(A) or §5.4.1(B) of this Part
17 indicate any radiation levels in excess of the respective limit specified in §
18 5.4.1(A) of this Part, the registrant shall lock the control in the "OFF" position and
19 not use the unit:
 - 20 1. Except as may be necessary to repair, replace, or test the therapeutic
21 radiation machine, the therapeutic radiation machine shielding, or the
22 treatment room shielding; or
 - 23 2. Until the registrant has received a specific exemption from the Agency.

5.4.2 Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program.

- 26 A. If the survey required by § 5.4.1 of this Part indicates that an individual in an
27 unrestricted area may be exposed to levels of radiation greater than those
28 permitted by §§ 1.8.1(A) and 1.8.1(B) of this Subchapter, before beginning the
29 treatment program the registrant shall:
 - 30 1. Either equip the unit with beam direction interlocks or add additional
31 radiation shielding to ensure compliance with §§ 1.8.1(A) and 1.8.1(B) of
32 this Subchapter;
 - 33 2. Perform the survey required by § 5.4.1 of this Part again; and
 - 34 3. Include in the report required by § 5.4.4 of this Part the results of the initial
35 survey, a description of the modification made to comply with § 5.4.2(a) of
36 this Part and the results of the second survey; or

- 1 4. Request and receive a registration amendment under § 1.8.1(C) of this
2 Subchapter that authorizes radiation levels in unrestricted areas greater
3 than those permitted by §§ 1.8.1(A) and 1.8.1(B) of this Subchapter.

4 **5.4.3 Dosimetry Equipment**

- 5 A. The registrant shall have a calibrated dosimetry system available for use. The
6 system shall have been calibrated by the National Institute for Standards and
7 Technology (NIST) or by an American Association of Physicists in Medicine
8 (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration
9 shall have been performed within the previous twenty-four (24) months and after
10 any servicing that may have affected system calibration.
- 11 1. For beams with energies greater than 1 MV (1 MeV), the dosimetry
12 system shall have been calibrated for Cobalt-60;
- 13 2. For beams with energies equal to or less than 1 MV (1 MeV), the
14 dosimetry system shall have been calibrated at an energy (energy range)
15 appropriate for the radiation being measured;
- 16 B. The registrant shall have available for use a dosimetry system for quality
17 assurance check measurements. To meet this requirement, the system may be
18 compared with a system that has been calibrated in accordance with § 5.4.3(A)
19 of this Part. This comparison shall have been performed within the previous
20 twelve (12) months and after each servicing that may have affected system
21 calibration. The quality assurance check system may be the same system used
22 to meet the requirement in § 5.4.3(A) of this Par.
- 23 C. The registrant shall maintain a record of each dosimetry system calibration,
24 intercomparison, and comparison for the duration of the license and/or
25 registration. For each calibration, intercomparison, or comparison, the record
26 shall include the date, the model numbers and serial numbers of the instruments
27 that were calibrated, inter-compared, or compared as required by §§ 5.4.3(A) and
28 5.4.3(B) of this Part, the correction factors that were determined, the names of
29 the individuals who performed the calibration, intercomparison, or comparison,
30 and evidence that the intercomparison was performed by, or under the direct
31 supervision and in the physical presence of, a Qualified Medical Physicist.

32 **5.4.4 Reports of External Beam Radiation Therapy Surveys and Measurements**

- 33 The registrant for any therapeutic radiation machine subject to §§ 5.6 or 5.7 of
34 this Part shall furnish a copy of the records required in §§ 5.4.1 and 5.4.2 of this
35 Part to the Agency within thirty (30) days following completion of the action that
36 initiated the record requirement.

37 **5.5 Quality Management Program**

38 **5.5.1 Scope and Applicability**

1 Each applicant or registrant subject to §§ 5.6, 5.7 or 5.11 of this Part shall
2 develop, implement and maintain a written quality management program to
3 provide high confidence that radiation will be administered as directed by the
4 Authorized User. The quality management program shall address, as a
5 minimum, the following specific objectives:

6 A. Written Directive

- 7 1. A written directive must be dated and signed by an Authorized User prior
8 to the administration of radiation;
- 9 2. Notwithstanding § 5.5.1(A)(1) of this Part, if, because of the
10 patient's/human research subject's condition, a delay in order to provide a
11 written revision to an existing written directive would jeopardize the pa-
12 tient's/human research subject's health, an oral revision to an existing
13 written directive shall be acceptable, provided that the oral revision is
14 documented immediately in writing in the patient's/human research
15 subject's record and a revised written directive is signed by an Authorized
16 User within forty-eight (48) hours of the oral revision;
- 17 3. The written directive shall contain the patient or human research subject's
18 name, the type and energy of the beam, the total dose, dose per fraction,
19 treatment site, and number of fractions.
- 20 4. A written revision to an existing written directive may be made provided
21 that the revision is dated and signed by an Authorized User prior to the
22 administration of the therapeutic radiation machine dose, or the next
23 fractional dose.
- 24 5. The registrant shall retain a copy of each written directive, in an auditable
25 form, for three (3) years after the date of administration.

26 B. Procedures for Administrations. The registrant shall develop, implement, and
27 maintain written procedures to provide high confidence that:

- 28 1. Prior to the administration of each course of radiation treatments, the
29 patient's/human research subject's identity is verified, by more than one
30 method, as the individual named in the written directive.
- 31 2. Therapeutic radiation machine final plans of treatment and related
32 calculations are in accordance with the respective written directives by:
33 a. Checking both manual and computer generated dose calculations
34 to verify they are correct and in accordance with the written
35 directive; and

- 1 b. Verifying that any manual and computer-generated calculations are
2 correctly transferred into the consoles of therapeutic radiation
3 machines;
- 4 3. Each administration is in accordance with the written directive. and
- 5 4. Any unintended deviation from the written directive is identified and
6 evaluated, and appropriate action is taken.
- 7 5. A registrant shall retain a copy of the procedures required by § 5.5.1(B) of
8 this Part for the duration of the registration.

9 5.5.2 Reports and Notifications of Misadministrations

- 10 A. A registrant shall report any event resulting from intervention by a patient or
11 human research subject in which the administration of therapeutic radiation
12 machine radiation results, or will result in, unintended permanent functional
13 damage to an organ or a physiological system as determined by a physician.
- 14 B. Other than events that result from intervention by a patient or human research
15 subject, a registrant shall report any event in which the administration of a
16 therapeutic radiation machine therapy dose:
 - 17 1. Involves the wrong patient, wrong treatment modality, or wrong treatment
18 site; or
 - 19 2. The calculated weekly administered dose differs from the weekly
20 prescribed dose by more than thirty percent (30%); or
 - 21 3. The calculated total administered dose differs from the total prescribed
22 dose by more than twenty percent (20%) of the total prescribed dose;
- 23 C. The registrant shall notify the Agency by telephone no later than the next
24 calendar day after discovery of the misadministration.
 - 25 1. All required notifications shall use Agency contact information specified in
26 § 1.4 of this Subchapter.
- 27 D. The registrant shall submit a written report to the Agency within fifteen (15) days
28 after discovery of the misadministration. The written report shall include:
 - 29 1. The registrant's name;
 - 30 2. The name of the prescribing physician;
 - 31 3. A brief description of the event;
 - 32 4. Why the event occurred;

- 1 5. The effect, if any, on the individuals(s) who received the
2 misadministration;
 - 3 6. Actions, if any, that have been taken, or are planned, to prevent
4 recurrence;
 - 5 7. Certification that the registrant notified the individual (or the individual's
6 responsible relative or guardian), and if not, why not; and
 - 7 8. If there was notification, what information was provided to the individual.
- 8 E. The report shall not contain the individual's name or any other information that
9 could lead to the identification of the individual. To meet the requirements of this
10 Section, the notification of the individual receiving the misadministration may be
11 made instead to that individual's responsible relative or guardian, when
12 appropriate.
- 13 F. 1. The registrant shall provide notification of the event to the referring
14 physician and also notify the individual who is the subject of the
15 misadministration no later than twenty-four (24) hours after its discovery,
16 unless the referring physician personally informs the registrant either that
17 he or she will inform the individual or that, based on medical judgment,
18 telling the individual would be harmful. The registrant is not required to
19 notify the individual without first consulting the referring physician. If the
20 referring physician or the affected individual cannot be reached within
21 twenty-four (24) hours, the registrant shall notify the individual as soon as
22 possible thereafter. The registrant shall not delay any appropriate medical
23 care for the individual, including any necessary remedial care as a result
24 of the misadministration, because of any delay in notification.
- 25 2. To meet the requirements of § 5.5.2(B)(1) of this Part, the notification of
26 the individual who is the subject of the misadministration may be made
27 instead to that individual's responsible relative or guardian. If a verbal
28 notification is made, the registrant shall inform the individual, or
29 appropriate responsible relative or guardian, that either a copy of the
30 report that was submitted to the Agency, or a written description of both
31 the event and the consequences as they may effect the can be obtained
32 from the registrant upon request. The registrant shall provide such a
33 written description if requested.
- 34 G. Aside from the notification requirement, nothing in § 5.5.2 of this Part affects any
35 rights or duties of registrants and physicians in relation to each other, to
36 individuals affected by the misadministration, or to that individual's responsible
37 relatives or guardians.
- 38 H. The registrant shall retain a record of a misadministration in accordance with §
39 5.5.3 of this Part. A copy of the record required shall be provided to the referring

1 physician if other than the registrant within fifteen (15) days after discovery of the
2 misadministration.

3 **5.5.3 Records of Misadministrations.**

4 A registrant shall retain a record of misadministrations reported in accordance
5 with § 5.5.2 of this Part for three (3) years. The record shall contain the following:

- 6 A. The registrant's name and the names of the individuals involved (including the
7 prescribing physician, allied health personnel, the individual who received the
8 misadministration, and the individual's referring physician, if applicable);
- 9 B. The social security number or other identification number, if one has been
10 assigned, of the individual who is the subject of the misadministration;
- 11 C. A brief description of the event; why it occurred; the effect, if any, on the
12 individual;
- 13 D. The actions, if any, taken or planned to prevent recurrence; and
- 14 E. Whether the registrant notified the individual (or the individual's responsible
15 relative or guardian) and, if not, whether such failure to notify was based on
16 guidance from the referring physician.

17 **5.5.4 Implementation of Quality Management Program**

18 As a part of the quality management program, the registrant shall:

- 19 A. Develop procedures for, and conduct a review of, the quality management
20 program including, since the last review, an evaluation of a representative
21 sample of patient/human research subject administrations, all recordable events,
22 and all misadministrations to verify compliance with all aspects of the quality
23 management program.
- 24 B. Conduct these reviews at intervals not to exceed twelve (12) months.
- 25 C. Evaluate each of these reviews to determine the effectiveness of the quality
26 management program and, if required, make modifications to meet the
27 requirements of § 5.5.1 of this Part; and
- 28 D. Maintain records of each review, including the evaluations and findings of the
29 review, in an auditable form, for three (3) years.

30 **5.5.5** The registrant shall evaluate and respond, within thirty (30) days after discovery
31 of the recordable event, to each recordable event by:

- 32 A. Assembling the relevant facts including the cause;
- 33 B. Identifying what, if any, corrective action is required to prevent recurrence; and

1 C. Retaining a record, in an auditable form, for three (3) years, of the relevant facts
2 and what corrective action, if any, was taken.

3 **5.5.6** The registrant may make modifications to the quality management program to
4 increase the program's efficiency provided the program's effectiveness is not
5 decreased.

6 **5.6 Therapeutic Radiation Machines of Less Than 500 kV**

7 **5.6.1 Leakage Radiation**

8 When the X-ray tube is operated at its maximum rated tube current for the
9 maximum kV, the leakage air kerma rate shall not exceed the value specified at
10 the distance specified for that classification of therapeutic radiation machine:

- 11 A. 5-50 kV Systems. The leakage air kerma rate measured at any position five (5)
12 centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad)
13 in any one (1) hour.
- 14 B. >50 and <500 kV Systems. The leakage air kerma rate measured at a distance
15 of one (1) meter from the target in any direction shall not exceed 1 cGy (1 rad) in
16 any one (1) hour. This air kerma rate measurement may be averaged over areas
17 no larger than one-hundred square centimeters (100 cm^2). In addition, the air
18 kerma rate at a distance of five (5) centimeters from the surface of the tube
19 housing assembly shall not exceed 30 cGy (30 rad) per hour.
- 20 C. For each therapeutic radiation machine, the registrant shall determine, or obtain
21 from the manufacturer, the leakage radiation existing at the positions specified in
22 §§ 5.6.1(A) and 5.6.1(B) of this part for the specified operating conditions.
23 Records on leakage radiation measurements shall be maintained at the
24 installation for inspection by the Agency.

25 **5.6.2 Permanent Beam Limiting Devices**

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

29 **5.6.3 Adjustable or Removable Beam Limiting Devices**

- 30 A. All adjustable or removable beam limiting devices, diaphragms, cones or blocks
31 shall not transmit more than 5 percent of the useful beam for the most
32 penetrating beam used.
- 33 B. When adjustable beam limiting devices are used, the position and shape of the
34 radiation field shall be indicated by a light beam.

35 **5.6.4 Filter System**

- 1 The filter system shall be so designed that:
- 2 A. Filters can not be accidentally displaced at any possible tube orientation;
- 3 B. For equipment installed after 1 August 1978, an interlock system prevents
4 irradiation if the proper filter is not in place;
- 5 C. The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per
6 hour at one (1) meter under any operating conditions; and
- 7 D. Each filter shall be marked as to its material of construction and its thickness.

8 **5.6.5 Tube Immobilization**

- 9 A. The X-ray tube shall be so mounted that it can not accidentally turn or slide with
10 respect to the housing aperture; and
- 11 B. The tube housing assembly shall be capable of being immobilized for stationary
12 portal treatments.

13 **5.6.6 Source Marking**

14 The tube housing assembly shall be so marked that it is possible to determine
15 the location of the source to within five (5) millimeters, and such marking shall be
16 readily accessible for use during calibration procedures.

17 **5.6.7 Beam Block**

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

22 **5.6.8 Timer**

23 A suitable irradiation control device shall be provided to terminate the irradiation
24 after a pre-set time interval.

- 25 A. A timer which has a display shall be provided at the treatment control panel. The
26 timer shall have a pre-set time selector and an elapsed time or time remaining
27 indicator.
- 28 B. The timer shall be a cumulative timer which activates with an indication of
29 "BEAM-ON" and retains its reading after irradiation is interrupted or terminated.
30 After irradiation is terminated and before irradiation can be reinitiated, it shall be
31 necessary to reset the elapsed time indicator.
- 32 C. The timer shall terminate irradiation when a pre-selected time has elapsed, if any
33 dose monitoring system present has not previously terminated irradiation.

- 1 D. The timer shall permit accurate pre-setting and determination of exposure times
2 as short as one (1) second.
- 3 E. The timer shall not permit an exposure if set at zero.
- 4 F. The timer shall not activate until the shutter is opened when irradiation is
5 controlled by a shutter mechanism unless calibration includes a timer error
6 correction to compensate for mechanical lag; and
- 7 G. Timer shall be accurate to within one percent (1%) of the selected value or 1
8 second, whichever is greater.

9 **5.6.9 Control Panel Functions**

10 The control panel, in addition to the displays required by other provisions in § 5.6
11 of this Part, shall have:

- 12 A. An indication of whether electrical power is available at the control panel and if
13 activation of the X-ray tube is possible.
- 14 B. An indication of whether X-rays are being produced.
- 15 C. Means for indicating X-ray tube potential and current.
- 16 D. The means for terminating an exposure at any time.
- 17 E. A locking device which will prevent unauthorized use of the therapeutic radiation
18 machine; and
- 19 F. For therapeutic radiation machines manufactured after 1 August 1978, a positive
20 display of specific filter(s) in the beam.

21 **5.6.10 Multiple Tubes**

22 When a control panel may energize more than one X-ray tube:

- 23 A. It shall be possible to activate only one X-ray tube at any time;
- 24 B. There shall be an indication at the control panel identifying which X-ray tube is
25 activated; and
- 26 C. There shall be an indication at the tube housing assembly when that tube is
27 energized.

28 **5.6.11 Target-to-Skin Distance (TSD).**

29 There shall be a means of determining the central axis TSD to within one (1)
30 centimeter and of reproducing this measurement to within two (2) millimeters
31 thereafter.

1 **5.6.12 Shutters**

2 Unless it is possible to bring the X-ray output to the prescribed exposure
3 parameters within five (5) seconds after the X-ray "ON" switch is energized, the
4 beam shall be attenuated by a shutter having a lead equivalency not less than
5 that of the tube housing assembly. In addition, after the unit is at operating
6 parameters, the shutter shall be controlled by the operator from the control panel.
7 An indication of shutter position shall appear at the control panel.

8 **5.6.13 Low Filtration X-ray Tubes**

9 Each therapeutic radiation machine equipped with a beryllium or other low-
10 filtration window shall be clearly labeled as such upon the tube housing assembly
11 and shall be provided with a permanent warning device on the control panel that
12 is activated when no additional filtration is present, to indicate that the dose rate
13 is very high.

14 **5.6.14 Facility Design Requirements for Therapeutic Radiation Machines Capable
15 of Operating in the Range 50 kV to 500 kV**

16 In addition to shielding adequate to meet requirements of § 5.9 of this Part, the
17 treatment room shall meet the following design requirements:

- 18 A. Aural Communication. Provision shall be made for continuous two-way aural
19 communication between the patient/human research subject and the operator at
20 the control panel.
- 21 B. Viewing Systems. Provision shall be made to permit continuous observation of
22 the patient/human research subject during irradiation and the viewing system
23 shall be so located that the operator can observe the patient/human research
24 subject from the control panel. The therapeutic radiation machine shall not be
25 used for patient/human research subject irradiation unless at least one viewing
26 system is operational.

27 **5.6.15 Additional Requirements**

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

- 30 A. All protective barriers shall be fixed except for entrance doors or beam
31 interceptors.
- 32 B. The control panel shall be located outside the treatment room.
- 33 C. Interlocks shall be provided such that all entrance doors, including doors to any
34 interior booths, shall be closed before treatment can be initiated or continued. If
35 the radiation beam is interrupted by any door opening, it shall not be possible to

- 1 restore the machine to operation without closing the door and reinitiating
2 irradiation by manual action at the control panel; and
- 3 D. When any door referred to in § 5.6.15(C) of this Part is opened while the X-ray
4 tube is activated, the air kerma rate at a distance of one (1) meter from the
5 source shall be reduced to less than 1 mGy (100 mrad) per hour.

6 **5.6.16 Full Calibration Measurements**

- 7 A. Full calibration of a therapeutic radiation machine subject to § 5.6 of this Part
8 shall be performed by, or under the direct supervision of, a Qualified Medical
9 Physicist:
- 10 1. Before the first medical use following installation or reinstallation of the
11 therapeutic radiation machine; and
- 12 2. At intervals not exceeding twelve (12) calendar months; and
- 13 3. Before medical use under the following conditions:
- 14 a. Whenever quality assurance check measurements indicate that the
15 radiation output differs by more than five percent (5%) from the
16 value obtained at the last full calibration and the difference cannot
17 be reconciled; and
- 18 b. Following any component replacement, major repair, or
19 modification of components that could significantly affect the
20 characteristics of the radiation beam.
- 21 4. Notwithstanding the requirements of § 5.6.16(A)(3) of this Part:
- 22 a. Full calibration of therapeutic radiation machines with multi-energy
23 capabilities is required only for those modes and/or energies that
24 are not within their acceptable range; and
- 25 b. If the repair, replacement or modification does not affect all
26 energies, full calibration shall be performed on the affected energy
27 that is in most frequent clinical use at the facility. The remaining
28 energies may be validated with quality assurance check procedures
29 against the criteria in § 5.6.16(A)(3)(a) of this Part.
- 30 B. To satisfy the requirement of § 5.6.16(A) of this Part, full calibration shall include
31 all measurements recommended for annual calibration by “AAPM Protocol for
32 40-300 kV X-ray Beam Dosimetry in Radiotherapy and Radiobiology”: AAPM
33 Report No. 76, prepared by AAPM Radiation Therapy Committee Task Group
34 #61.

1 C. The registrant shall maintain a record of each calibration in an auditable form for
2 the duration of the registration. The record shall include the date of the
3 calibration, the manufacturer's name, model number, and serial number for both
4 the therapeutic radiation machine and the X-ray tube, the model numbers and
5 serial numbers of the instruments used to calibrate the therapeutic radiation
6 machine, and the signature of the Qualified Medical Physicist responsible for
7 performing the calibration.

8 **5.6.17 Periodic Quality Assurance Checks**

- 9 A. Periodic quality assurance checks shall be performed on therapeutic radiation
10 machines subject to § 5.6 of this Part, which are capable of operation at greater
11 than or equal to 50 kV.
- 12 B. To satisfy the requirement of § 5.6.17(A) of this Part, quality assurance checks
13 shall meet the following requirements:
- 14 1. The registrant shall perform quality assurance checks in accordance with
15 written procedures established by the Qualified Medical Physicist; and
- 16 2. The quality assurance check procedures shall specify the frequency at
17 which tests or measurements are to be performed. The quality assurance
18 check procedures shall specify that the quality assurance check shall be
19 performed during the calibration specified in § 5.6.16(A) of this Part. The
20 acceptable tolerance for each parameter measured in the quality
21 assurance check, when compared to the value for that parameter
22 determined in the calibration specified in § 5.6.16(A) of this Part, shall be
23 stated.
- 24 C. The cause for a parameter exceeding a tolerance set by the Qualified Medical
25 Physicist shall be investigated and corrected before the system is used for
26 patient/human research subject irradiation.
- 27 D. Whenever a quality assurance check indicates a significant change in the
28 operating characteristics of a system, as specified in the Qualified Medical
29 Physicist's quality assurance check procedures, those elements of a full
30 calibration shall be performed, as required in § 5.6.16(A) of this Part, that are
31 necessary to determine that all affected parameters are within acceptable limits.
32 Other quality assurance check procedures should be repeated, as necessary, to
33 ensure that all system parameters are within acceptable limits.
- 34 E. The registrant shall use the dosimetry system described in § 5.4.3(B) of this Part
35 to make the quality assurance check required in § 5.6.17(B) of this Part.
- 36 F. The registrant shall have the Qualified Medical Physicist review and sign the
37 results of each radiation output quality assurance check within thirty (30) days of
38 the date that the check was performed.

- 1 G. The registrant shall ensure that safety quality assurance checks of therapeutic
2 radiation machines subject to § 5.6 of this Part are performed at intervals not to
3 exceed thirty (30) days.
- 4 H. Notwithstanding the requirements of §§ 5.6.17(F) and 5.6.17(G) of this Part, the
5 registrant shall ensure that no therapeutic radiation machine is used to
6 administer radiation to humans unless the quality assurance checks required by
7 §§ 5.6.17(F) and 5.6.17(G) of this Part have been performed within the thirty (30)
8 day period immediately prior to said administration.
- 9 I. To satisfy the requirement of § 5.6.17(G) of this Part, safety quality assurance
10 checks shall ensure proper operation of:
 - 11 1. Electrical interlocks at each external beam radiation therapy room
12 entrance;
 - 13 2. Proper operation of the "BEAM-ON" and termination switches;
 - 14 3. Beam condition indicator lights on the access door(s), control console, and
15 in the radiation therapy room;
 - 16 4. Viewing systems;
 - 17 5. If applicable, electrically operated treatment room doors from inside and
18 outside the treatment room;
- 19 J. The registrant shall maintain a record of each quality assurance check required
20 by §§ 5.6.17(A) and 5.6.17(G) of this Part for three (3) years. The record shall
21 include the date of the quality assurance check, the manufacturer's name, model
22 number, and serial number for the therapeutic radiation machine, the
23 manufacturer's name, model number and serial number of the instrument(s) used
24 to measure the radiation output of the therapeutic radiation machine, and the
25 signature of the individual who performed the periodic quality assurance check.

26 5.6.18 Operating Procedures

- 27 A. The therapeutic radiation machine shall not be used for irradiation of
28 patients/human research subjects unless the requirements of §§ 5.16 and 5.17 of
29 this Part have been met.
- 30 B. Therapeutic radiation machines shall not be left unattended unless secured
31 pursuant to § 5.6.9(E) of this Part.
- 32 C. When a patient/human research subject must be held in position for radiation
33 therapy, mechanical supporting or restraining devices shall be used.
- 34 D. The tube housing assembly shall not be held by an individual during operation
35 unless the assembly is designed to require such holding and the peak tube

1 potential of the system does not exceed 50 kV. In such cases, the holder shall
2 wear protective gloves and apron of not less than 0.5 millimeters lead
3 equivalency at 100 kV.

- 4 E. A copy of the current operating and emergency procedures shall be maintained
5 at the therapeutic radiation machine control console; and
- 6 F. No individual other than the patient/human research subject shall be in the
7 treatment room during exposures from therapeutic radiation machines operating
8 above 150 kV. At energies less than or equal to 150 kV, any individual, other
9 than the patient/human research subject, in the treatment room shall be
10 protected by a barrier sufficient to meet the requirements of § 1.7.1 of this
11 Subchapter.

12 **5.6.19 Possession of Survey Instrument(s)**

13 Each facility location authorized to use a therapeutic radiation machine in
14 accordance with § 5.6 of this Part shall possess appropriately calibrated portable
15 monitoring equipment. As a minimum, such equipment shall include a portable
16 radiation measurement survey instrument capable of measuring dose rates over
17 the range 10 μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The
18 survey instrument(s) shall be operable and calibrated in accordance with § 5.8 of
19 this Part.

20 **5.7 Therapeutic Radiation Machines - Photon Therapy Systems (500**
21 **kV and Above) and Electron Therapy Systems (500 keV and**
22 **Above)**

23 **5.7.1 Possession of Survey Instrument(s)**

24 Each facility location authorized to use a therapeutic radiation machine in
25 accordance with § 5.7 of this Part shall possess appropriately calibrated portable
26 monitoring equipment. As a minimum, such equipment shall include a portable
27 radiation measurement survey instrument capable of measuring dose rates over
28 the range 10 μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The
29 survey instrument(s) shall be operable and calibrated in accordance with § 5.5 of
30 this Part.

31 **5.7.2 Leakage Radiation Outside the Maximum Useful Beam in Photon and**
32 **Electron Modes.**

- 33 A. The absorbed dose due to leakage radiation (excluding neutrons) at any point
34 outside the maximum-sized useful beam, but within a circular plane of radius two
35 (2) meters which is perpendicular to and centered on the central axis of the
36 useful beam at the nominal treatment distance (i.e. patient/human research
37 subject plane), shall not exceed a maximum of 0.2 percent and an average of 0.1
38 percent of the absorbed dose on the central axis of the beam at the nominal

1 treatment distance. Measurements shall be averaged over an area not
2 exceeding one hundred square centimeters (100 cm^2) at a minimum of sixteen
3 (16) points uniformly distributed in the plane.

- 4 B. Except for the area defined in § 5.7.2 of this Part, the absorbed dose due to
5 leakage radiation (excluding neutrons) at one (1) meter from the electron path
6 between the electron source and the target or electron window shall not exceed
7 0.5 percent of the absorbed dose on the central axis of the beam at the nominal
8 treatment distance. Measurements shall be averaged over an area not
9 exceeding one hundred square centimeters (100 cm^2).
- 10 C. For equipment manufactured after 1 July 1999, the neutron absorbed dose
11 outside the useful beam shall be in compliance with International Electrotechnical
12 Commission (IEC) Document 601-2-1 (most current revision); and
- 13 D. For each therapeutic radiation machine, the registrant shall determine, or obtain
14 from the manufacturer, the leakage radiation existing at the positions specified in
15 §§ 5.7.2(A) through 5.7.2(C) of this Part for the specified operating conditions.
16 Records on leakage radiation measurements shall be maintained at the
17 installation for inspection by the Agency.

18 **5.7.3 Leakage Radiation Through Beam Limiting Devices**

- 19 A. Photon Radiation. All adjustable or interchangeable beam limiting devices shall
20 attenuate the useful beam such that at the nominal treatment distance, the
21 maximum absorbed dose anywhere in the area shielded by the beam limiting
22 device(s) shall not exceed two percent (2%) of the maximum absorbed dose on
23 the central axis of the useful beam measured in a one hundred square
24 centimeter (100 cm^2) radiation field, or maximum available field size if less than
25 one hundred square centimeters (100 cm^2).
- 26 B. Electron Radiation. All adjustable or interchangeable electron applicators shall
27 attenuate the radiation, including but not limited to photon radiation generated by
28 electrons incident on the beam limiting device and electron applicator and other
29 parts of the radiation head, such that the absorbed dose in a plane perpendicular
30 to the central axis of the useful beam at the nominal treatment distance shall not
31 exceed:
- 32 1. A maximum of two percent (2%) and average of 0.5 percent of the
33 absorbed dose on the central axis of the useful beam at the nominal
34 treatment distance. This limit shall apply beyond a line seven (7)
35 centimeters outside the periphery of the useful beam; and
- 36 2. A maximum of ten percent (10%) of the absorbed dose on the central axis
37 of the useful beam at the nominal treatment distance. This limit shall
38 apply beyond a line two (2) centimeters outside the periphery of the useful
39 beam.

C. Measurement of Leakage Radiation

1. Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two (2) tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters (10 cm^2);
 2. Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter (1 cm^2) suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one (1) centimeter of water equivalent build up material.

5.7.4 Filters/Wedges

- A. Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined.
 - B. If the absorbed dose rate information required by § 5.7.1 of this Part 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.
 - C. For equipment manufactured after 1 January 1985 which utilize a system of wedge filters, inter-changeable field flattening filters, or interchangeable beam scattering foils:
 - 1. 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;
 - 2. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - 3. 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
 - 4. An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room

1 does not agree with the filter and/or beam scattering foil selection
2 operation carried out at the treatment control panel.

3 **5.7.5 Stray Radiation in the Useful Beam**

4 For equipment manufactured after 1 July 1999, the registrant shall determine
5 during acceptance testing, or obtain from the manufacturer, data sufficient to
6 ensure that X-ray stray radiation in the useful electron beam, absorbed dose at
7 the surface during X-ray irradiation and stray neutron radiation in the useful X-ray
8 beam are in compliance with International Electrotechnical Commission (IEC)
9 Document 601-2-1 (most current revision).

10 **5.7.6 Beam Monitors**

11 All therapeutic radiation machines subject to § 5.7 of this Part shall be provided
12 with redundant beam monitoring systems. The detectors for these systems shall
13 be fixed in the useful beam during treatment to indicate the dose monitor unit
14 rate.

- 15 A. Equipment manufactured after 1 January 1985 shall be provided with at least two
16 (2) independently powered integrating dose meters. Alternatively, common
17 elements may be used if the production of radiation is terminated upon failure of
18 any common element.
- 19 B. Equipment manufactured on or before 1 January 1985 shall be provided with at
20 least one (1) radiation detector. This detector shall be incorporated into a useful
21 beam monitoring system.
- 22 C. The detector and the system into which that detector is incorporated shall meet
23 the following requirements:
 - 24 1. Each detector shall be removable only with tools and, if movable, shall be
25 interlocked to prevent incorrect positioning;
 - 26 2. Each detector shall form part of a beam monitoring system from whose
27 readings in dose monitor units the absorbed dose at a reference point can
28 be calculated;
 - 29 3. Each beam monitoring system shall be capable of independently
30 monitoring, interrupting, and terminating irradiation; and
 - 31 4. For equipment manufactured after 1 January 1985, the design of the
32 beam monitoring systems shall ensure that the:
 - 33 a. Malfunctioning of one system shall not affect the correct functioning
34 of the other system(s); and

- 1 b. Failure of either system shall terminate irradiation or prevent the
2 initiation of radiation.
- 3 5. Each beam monitoring system shall have a legible display at the treatment
4 control panel. For equipment manufactured after 1 January 1985, each
5 display shall:
- 6 a. Maintain a reading until intentionally reset;
- 7 b. Have only one (1) scale and no electrical or mechanical scale
8 multiplying factors;
- 9 c. Utilize a design such that increasing dose is displayed by
10 increasing numbers; and
- 11 d. In the event of power failure, the beam monitoring information
12 required in § 5.7.6(C)(5)(c) of this Part displayed at the control
13 panel at the time of failure shall be retrievable in at least one
14 system for a twenty (20) minute period of time.

15 **5.7.7 Beam Symmetry**

- 16 A. A bent-beam linear accelerator with beam flattening filter(s) subject to § 5.7 of
17 this Part shall be provided with auxiliary device(s) to monitor beam symmetry.
- 18 B. The device(s) referenced in § 5.7.7(A) of this Part shall be able to detect field
19 asymmetry greater than ten percent (10%). and
- 20 C. The device(s) referenced in § 5.7.7(A) of this Part shall be configured to
21 terminate irradiation if the specifications in § 5.7.7(B) of this Part can not be
22 maintained.

23 **5.7.8 Selection and Display of Dose Monitor Units**

- 24 A. Irradiation shall not be possible until a new selection of a number of dose monitor
25 units has been made at the treatment control panel.
- 26 B. The pre-selected number of dose monitor units shall be displayed at the
27 treatment control panel until reset manually for the next irradiation.
- 28 C. After termination of irradiation, it shall be necessary to reset the dosimeter
29 display before subsequent treatment can be initiated. and
- 30 D. For equipment manufactured after 1 January 1985, after termination of
31 irradiation, it shall be necessary for the operator to reset the pre-selected dose
32 monitor units before irradiation can be initiated.

33 **5.7.9 Air Kerma Rate/Absorbed Dose Rate**

- 1 For equipment manufactured after 1 January 1985, a system shall be provided
2 from whose readings the air kerma rate or absorbed dose rate at a reference
3 point can be calculated. [The radiation detectors specified in § 5.7.6 of this Part
4 may form part of this system.] In addition:
- 5 A. The dose monitor unit rate shall be displayed at the treatment control panel;
- 6 B. If the equipment can deliver under any conditions an air kerma rate or absorbed
7 dose rate at the nominal treatment distance more than twice the maximum value
8 specified by the manufacturer, a device shall be provided which terminates
9 irradiation when the air kerma rate or absorbed dose rate exceeds a value twice
10 the specified maximum. The dose rate at which the irradiation will be terminated
11 shall be a record maintained by the registrant;
- 12 C. If the equipment can deliver under any fault condition(s) an air kerma rate or
13 absorbed dose rate at the nominal treatment distance more than ten (10) times
14 the maximum value specified by the manufacturer, a device shall be provided to
15 prevent the air kerma rate or absorbed dose rate anywhere in the radiation field
16 from exceeding twice the specified maximum value and to terminate irradiation if
17 the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400
18 rad); and
- 19 D. For each therapeutic radiation machine, the registrant shall determine, or obtain
20 from the manufacturer, the maximum value(s) specified in §§ 5.7.9(B) and
21 5.7.9(C) of this Part for the specified operating conditions. Records of these
22 maximum value(s) shall be maintained at the installation for inspection by the
23 Agency.

24 **5.7.10 Termination of Irradiation by the Beam Monitoring System or Systems
25 During Stationary Beam Radiation Therapy**

- 26 A. Each primary system shall terminate irradiation when the pre-selected number of
27 dose monitor units has been detected by the system.
- 28 B. If the original design of the equipment included a secondary dose monitoring
29 system, that system shall be capable of terminating irradiation when not more
30 than fifteen percent (15%) or forty (40) dose monitor units above the pre-selected
31 number of dose monitor units set at the control panel has been detected by the
32 secondary dose monitoring system. and
- 33 C. For equipment manufactured after 1 January 1985, an indicator on the control
34 panel shall show which monitoring system has terminated irradiation.

35 **5.7.11 Termination of Irradiation**

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

1 **5.7.12 Interruption of Irradiation**

2 If a therapeutic radiation machine has an interrupt mode, it shall be possible to
3 interrupt irradiation and equipment movements at any time from the treatment
4 control panel. Following an interruption it shall be possible to restart irradiation
5 by operator action without any reselection of operating conditions. If any change
6 is made of a pre-selected value during an interruption, irradiation and equipment
7 movements shall be automatically terminated.

8 **5.7.13 Timer**

9 A suitable irradiation control device shall be provided to terminate the irradiation
10 after a pre-set time interval.

- 11 A. A timer shall be provided which has a display at the treatment control panel. The
12 timer shall have a pre-set time selector and an elapsed time indicator.
- 13 B. The timer shall be a cumulative timer which activates with an indication of
14 "BEAM-ON" and retains its reading after irradiation is interrupted or terminated.
15 After irradiation is terminated and before irradiation can be reinitiated, it shall be
16 necessary to reset the elapsed time indicator.
- 17 C. The timer shall terminate irradiation when a pre-selected time has elapsed, if the
18 dose monitoring systems have not previously terminated irradiation.

19 **5.7.14 Selection of Radiation Type**

20 Equipment capable of both X-ray therapy and electron therapy shall meet the
21 following additional requirements:

- 22 A. Irradiation shall not be possible until a selection of radiation type (X-rays or
23 electrons) has been made at the treatment control panel;
- 24 B. The radiation type selected shall be displayed at the treatment control panel
25 before and during irradiation;
- 26 C. An interlock system shall be provided to ensure that the equipment can
27 principally emit only the radiation type which has been selected;
- 28 D. An interlock system shall be provided to prevent irradiation with X-rays, except to
29 obtain an image, when electron applicators are fitted;
- 30 E. An interlock system shall be provided to prevent irradiation with electrons when
31 accessories specific for X-ray therapy are fitted; and
- 32 F. An interlock system shall be provided to prevent irradiation if any selected
33 operations carried out in the treatment room do not agree with the selected
34 operations carried out at the treatment control panel.

1 **5.7.15 Selection of Energy**

2 Equipment capable of generating radiation beams of different energies shall
3 meet the following requirements:

- 4 A. Irradiation shall not be possible until a selection of energy has been made at the
5 treatment control panel;
- 6 B. The nominal energy value selected shall be displayed at the treatment control
7 panel until reset manually for the next irradiation. After termination of irradiation,
8 it shall be necessary to reset the nominal energy value selected before
9 subsequent treatment can be initiated;
- 10 C. Irradiation shall not be possible until the appropriate flattening filter or scattering
11 foil for the selected energy is in its proper location; and
- 12 D. For equipment manufactured after 1 July 1999, the selection of energy shall be in
13 compliance with International Electrotechnical Commission (IEC) Document 601-
14 2-1 (most current revision).

15 **5.7.16 Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation
16 Therapy**

17 Therapeutic radiation machines capable of both stationary beam radiation
18 therapy and moving beam radiation therapy shall meet the following
19 requirements:

- 20 A. Irradiation shall not be possible until a selection of stationary beam radiation
21 therapy or moving beam radiation therapy has been made at the treatment
22 control panel.
- 23 B. The mode of operation shall be displayed at the treatment control panel.
- 24 C. An interlock system shall be provided to ensure that the equipment can operate
25 only in the mode which has been selected.
- 26 D. An interlock system shall be provided to prevent irradiation if any selected
27 parameter in the treatment room does not agree with the selected parameter at
28 the treatment control panel.
- 29 E. Moving beam radiation therapy shall be controlled to obtain the selected
30 relationships between incremental dose monitor units and incremental
31 movement.
- 32 1. For equipment manufactured after 1 January 1985:

- 1 a. Where angle terminates the irradiation in moving beam radiation
2 therapy, the dose monitor units delivered shall differ by less than
3 five percent (5%) from the dose monitor unit value selected;
- 4 b. An interlock shall be provided to prevent motion of more than five
5 (5) degrees or one (1) cm beyond the selected limits during moving
6 beam radiation therapy;
- 7 c. An interlock shall be provided to require that a selection of direction
8 be made at the treatment control panel in all units which are
9 capable of both clockwise and counter-clockwise moving beam
10 radiation therapy.
- 11 2. For equipment manufactured after 1 July 1999:
 - 12 a. An interlock system shall be provided to terminate irradiation if the
13 number of dose monitor units delivered in any ten (10) degrees of
14 rotation or one (1) cm of linear motion differs by more than twenty
15 percent (20%) from the selected value;
 - 16 b. Moving beam radiation therapy shall be controlled with both primary
17 position sensors and secondary position sensors to obtain the
18 selected relationships between incremental dose monitor units and
19 incremental movement.
- 20 F. Where the beam monitor system terminates the irradiation in moving beam
21 radiation therapy, the termination of irradiation shall be as required by § 5.7.10 of
22 this Part. and
- 23 G. For equipment manufactured after 1 January 1985, an interlock system shall be
24 provided to terminate irradiation if movement:
 - 25 1. Occurs during stationary beam radiation therapy; or
 - 26 2. Does not start or stops during moving beam radiation therapy unless such
27 stoppage is a pre-planned function.

**28 5.7.17 Facility Design Requirements for Therapeutic Radiation Machines
29 Operating above 500 kV**

- 30 In addition to shielding adequate to meet requirements of § 5.9 of this Part, the
31 following design requirements are made:
- 32 A. Protective Barriers. All protective barriers shall be fixed, except for access doors
33 to the treatment room or movable beam interceptors.
 - 34 B. Control Panel. In addition to other requirements specified in this Part, the control
35 panel shall also:

- 1 1. Be located outside the treatment room;
 - 2 2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
 - 3 3. Provide an indication of whether radiation is being produced; and
 - 4 4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine;
- 5 C. Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient/human research subject following positioning and during irradiation and shall be so located that the operator may observe the patient/human research subject from the treatment control panel. The therapeutic radiation machine shall not be used for patient/human research subject irradiation unless at least one viewing system is operational.
- 6 D. Aural Communications. Provision shall be made for continuous two-way aural communication between the patient/human research subject and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients/human research subjects unless continuous two-way aural communication is possible.
- 7 E. Room Entrances. 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 F. Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. 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 reinitiating irradiation by manual action at the control panel.
- 9 G. Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with §§ 1.8.1(A) and 1.8.1(B) of this Subchapter, 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).
- 10 H. Emergency Cutoff Switches. At least 1 emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by § 5.7.11 of this Part. 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.

- 1 I. Safety Interlocks. All safety interlocks shall be designed so that any defect or
2 component failure in the safety interlock system prevents or terminates operation
3 of the therapeutic radiation machine. and
- 4 J. Surveys for Residual Radiation. Surveys for residual activity shall be conducted
5 on all therapeutic radiation machines capable of generating photon and electron
6 energies above 10 MV prior to machining, removing, or working on therapeutic
7 radiation machine components which may have become activated due to photo-
8 neutron production.

9 5.7.18 Qualified Medical Physicist Support

- 10 A. The services of a Qualified Medical Physicist shall be required in facilities having
11 therapeutic radiation machines with energies of 500 kV and above. The
12 Qualified Medical Physicist shall be responsible for:
 - 13 1. Full calibration(s) required by § 5.7.20 of this Part and protection surveys
14 required by § 5.4.1 of this Part;
 - 15 2. Supervision and review of dosimetry;
 - 16 3. Beam data acquisition and transfer for computerized dosimetry, and
17 supervision of its use;
 - 18 4. Quality assurance, including quality assurance check review required by §
19 5.7.21(E) of this Part;
 - 20 5. Consultation with the Authorized User in treatment planning, as needed;
21 and
 - 22 6. Performing calculations/assessments regarding misadministrations.
- 23 B. If the Qualified Medical Physicist is not a full-time employee of the registrant, the
24 operating procedures required by § 5.7.19 of this Part shall also specifically
25 address how the Qualified Medical Physicist is to be contacted for problems or
26 emergencies, as well as the specific actions, if any, to be taken until the Qualified
27 Medical Physicist can be contacted.

28 5.7.19 Operating Procedures

- 29 A. No individual, other than the patient/human research subject, shall be in the
30 treatment room during treatment or during any irradiation for testing or calibration
31 purposes.
- 32 B. Therapeutic radiation machines shall not be made available for medical use
33 unless the requirements of §§ 5.4.1, 5.7.20 and 5.7.21 of this Part have been
34 met.

- 1 C. Therapeutic radiation machines, when not in operation, shall be secured to
2 prevent unauthorized use.
- 3 D. When adjustable beam limiting devices are used, the position and shape of the
4 radiation field shall be indicated by a light field.
- 5 E. If a patient/human research subject must be held in position during treatment,
6 mechanical supporting or restraining devices shall be used. and
- 7 F. A copy of the current operating and emergency procedures shall be maintained
8 at the therapeutic radiation machine control console.

5.7.20 Acceptance Testing, Commissioning and Full Calibration Measurements

- 10 A. Acceptance testing, commissioning and full calibration of a therapeutic radiation
11 machine subject to § 5.7 of this Part shall be performed by, or under the direct
12 supervision of, a Qualified Medical Physicist.
- 13 B. Acceptance testing and commissioning shall be performed in accordance with
14 "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47",
15 prepared by AAPM Radiation Therapy Task Group 45, and the manufacturer's
16 contractual specifications. Acceptance testing and commissioning shall be
17 conducted before the first medical use following installation or reinstallation of the
18 therapeutic radiation machine.
- 19 C. Full calibration shall include measurement of all applicable parameters required
20 by "Quality Assurance of Medical Accelerators: AAPM Report No. 142", and shall
21 be performed in accordance with "AAPM Code of Practice for Radiotherapy
22 Accelerators: AAPM Report No. 47", prepared by AAPM Radiation Therapy Task
23 Group 45. Although it shall not be necessary to complete all elements of a full
24 calibration at the same time, all applicable parameters (for all energies) shall be
25 completed at intervals not exceeding twelve (12) calendar months, unless a more
26 frequent interval is required in AAPM Report No. 142.
 - 27 1. AAPM Report 142 supersedes Table II of "Comprehensive QA for
28 Radiation Oncology: AAPM Report No. 46", prepared by AAPM Radiation
29 Therapy Task Group 40.
- 30 D. The Qualified Medical Physicist shall perform or directly supervise all elements of
31 a full calibration necessary to determine that all parameters are within acceptable
32 limits:
 - 33 1. Whenever quality assurance check measurements indicate that the
34 radiation output differs by more than five percent (5%) from the value
35 obtained at the last full calibration and the difference cannot be reconciled.
36 Therapeutic radiation machines with multi-energy and/or multi-mode
37 capabilities shall only require measurements for those modes and/or
38 energies that are not within their acceptable range; and

- 1 2. Following any component replacement, major repair, or modification of
2 components that could significantly affect the characteristics of the
3 radiation beam. If the repair, replacement or modification does not affect
4 all modes and/or energies, measurements shall be performed on the
5 affected mode/ energy that is in most frequent clinical use at the facility.
6 The remaining energies/modes may be validated with quality assurance
7 check procedures against the criteria in § 5.7.20(D)(1).
- 8 E. The registrant shall use the dosimetry system described in § 5.4.3(A) of this Part
9 to measure the radiation output for one set of exposure conditions. The
10 remaining radiation measurements required in §§ 5.7.20(B), (C) and (D) of this
11 Part may then be made using a dosimetry system that indicates relative dose
12 rates. and
- 13 F. The registrant shall maintain a record of each calibration in an auditable form for
14 the duration of the registration. The record shall include the date of the
15 calibration, the manufacturer's name, model number, and serial number for the
16 therapeutic radiation machine, the model numbers and serial numbers of the
17 instruments used to calibrate the therapeutic radiation machine, and the
18 signature of the Qualified Medical Physicist responsible for performance of the
19 calibration.
- 20 G. Therapy-Related Computer Systems. The registrant shall perform acceptance
21 testing on the treatment planning system of therapeutic radiation machine -
22 related computer systems in accordance with current published
23 recommendations from a recognized national professional association (when
24 available). In the absence of an acceptance testing protocol published by a
25 national professional association, the manufacturer's acceptance testing protocol
26 shall be followed.
- 27 1. Acceptance testing shall be performed by, or under the direct supervision
28 of, a Qualified Medical Physicist. At a minimum, the acceptance testing
29 shall include, as applicable, verification of:
- 30 a. The source-specific input parameters required by the dose
31 calculation algorithm;
- 32 b. The accuracy of dose calculations at representative points;
- 33 c. The accuracy of isodose plots and graphic displays;
- 34 d. The accuracy of the software used to determine radiation source
35 positions from radiographic images; and
- 36 e. If the treatment-planning system is different from the treatment-
37 delivery system, the accuracy of electronic transfer of the treatment
38 delivery parameters to the treatment delivery unit from the
39 treatment planning system.

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

5 **5.7.21 Periodic Quality Assurance Checks**

- 6 A. Periodic quality assurance checks shall be performed on all therapeutic radiation
7 machines subject to § 5.7 of this Part at intervals not to exceed those specified in
8 "Comprehensive QA for Radiation Oncology: AAPM Report No. 46, prepared by
9 AAPM Radiation Therapy Committee Task Group 40. All periodic quality
10 assurance checks with an annual frequency do not have to be performed at the
11 same time, but shall be completed during an interval not to exceed twelve (12)
12 consecutive calendar months.
- 13 B. The registrant shall use a dosimetry system which has been inter-compared
14 within the previous twelve (12) months with the dosimetry system described in §
15 5.4.3(A) of this Part to make the periodic quality assurance checks required in §
16 5.7.21(A).
- 17 C. The registrant shall perform periodic quality assurance checks required by §
18 5.7.21(A) of this Part in accordance with procedures established by the Qualified
19 Medical Physicist.
- 20 D. The registrant shall review the results of each periodic radiation output check
21 according to the following procedures:
- 22 1. The Authorized User or Qualified Medical Physicist shall be immediately
23 notified if any parameter is not within its acceptable tolerance. The
24 therapeutic radiation machine shall not be made available for subsequent
25 medical use until the Qualified Medical Physicist has determined that all
26 parameters are within their acceptable tolerances;
- 27 2. If all radiation output quality assurance check parameters appear to be
28 within their acceptable range, the quality assurance check shall be
29 reviewed and signed by either the Authorized User or Qualified Medical
30 Physicist within three (3) treatment days; and
- 31 3. The Qualified Medical Physicist shall review and sign the results of each
32 radiation output quality assurance check at intervals not to exceed thirty
33 (30) days.
- 34 E. Therapeutic radiation machines subject to § 5.7 of this Part shall have the
35 following safety quality assurance checks performed at intervals not to exceed
36 one (1) week:
- 37 1. Proper operation of the "BEAM-ON", interrupt and termination switches;

- 1 2. Beam condition indicator lights on the access doors, control console, and
2 in the radiation therapy room;
 - 3 3. Electrically operated treatment room door(s) from inside and outside the
4 treatment room;
- 5 F. The registrant shall promptly repair any system identified in §§ 5.7.21(A) and
6 5.7.21(E) of this Part that is not operating properly; and
- 7 G. The registrant shall maintain a record of each quality assurance check required
8 by §§ 5.7.21(A) and 5.7.21(E) of this Part for three (3) years. The record shall
9 include the date of the quality assurance check, the manufacturer's name, model
10 number, and serial number for the therapeutic radiation machine, the
11 manufacturer's name, model number and serial number of the instrument(s) used
12 to measure the radiation output of the therapeutic radiation machine, and the
13 signature of the individual who performed the periodic quality assurance check.

5.7.22 Quality Assurance Checks for IMRT

15 Quality assurance checks for IMRT shall:

- 16 A. Include commissioning and testing of the treatment planning and delivery
17 systems, routine quality assurance of the delivery system, and patient-specific
18 validation of treatment plans; and
 - 19 1. IMRT is a rapidly evolving modality and the QA program shall also evolve
20 to handle new issues that arise. "Guidance document on delivery,
21 treatment planning, and clinical implementation of IMRT: AAPM Report
22 No. 82", prepared by the IMRT subcommittee of the AAPM radiation
23 therapy committee, provides some suggestions on establishing such a QA
24 program.
- 25 B. Be performed in accordance with the manufacturer's contractual specifications.

5.8 Calibration of Survey Instruments

27 **5.8.1** The registrant shall ensure that the survey instruments used to show compliance
28 with Part 5 of this Subchapter have been calibrated before first use, at intervals
29 not to exceed twelve (12) months, and following repair.

30 **5.8.2** To satisfy the requirements of § 5.8.1 of this Part, the registrant shall:

- 31 A. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an
32 appropriate radiation source that is traceable to the National Institute of
33 Standards and Technology (NIST).
- 34 B. Calibrate at least two (2) points on each scale to be calibrated. These points
35 should be at approximately 1/3 and 2/3 of full-scale.

- 1 **5.8.3** To satisfy the requirements of § 5.8.2 of this Part, the registrant shall:
- 2 A. Consider a point as calibrated if the indicated dose rate differs from the
3 calculated dose rate by not more than 10 percent. and
- 4 B. Consider a point as calibrated if the indicated dose rate differs from the
5 calculated dose rate by not more than 20 percent if a correction factor or graph is
6 conspicuously attached to the instrument.
- 7 **5.8.4** The registrant shall retain a record of each calibration required in § 5.8.1 of this
8 Part for three (3) years. The record shall include:
- 9 A. A description of the calibration procedure. and
- 10 B. A description of the source used and the certified dose rates from the source,
11 and the rates indicated by the instrument being calibrated, the correction factors
12 deduced from the calibration data, the signature of the individual who performed
13 the calibration, and the date of calibration.
- 14 **5.8.5** The registrant may obtain the services of individuals licensed by the Agency, the
15 U.S. Nuclear Regulatory Commission or another Agreement State to perform
16 calibrations of survey instruments. Records of calibrations which contain
17 information required by §§ 5.8.4 of this Part shall be maintained by the registrant.

18 **5.9 Shielding and Safety Design Requirements**

- 19 **5.9.1** Each therapeutic radiation machine subject to §§ 5.6 or 5.7 of this Part shall be
20 provided with such primary and/or secondary barriers as are necessary to ensure
21 compliance with §§ 1.7.1 and 1.8.1 of this Subchapter.
- 22 **5.9.2** Facility design information for all new installations of a therapeutic radiation
23 machine or installations of a therapeutic radiation machine of higher energy into
24 a room not previously approved for that energy shall be submitted for Agency
25 approval prior to actual installation of the therapeutic radiation machine. The
26 minimum facility design information that must be submitted is contained in § 5.13
27 of this Part.

28 **5.10 Quality Assurance for Radiation Therapy Simulation Systems**

- 29 A. Quality assurance for a conventional or virtual simulator shall include acceptance
30 testing and periodic verification of system performance; and
- 31 B. Be performed in accordance with "Comprehensive QA for Radiation Oncology:
32 AAPM Report No. 46", prepared by AAPM Radiation Therapy Committee Task
33 Group 40, for a conventional simulator; or
- 34 C. Be performed in accordance with "Quality assurance for computed tomography
35 simulators and the computed tomography-simulation process: AAPM Report No.

1 83", prepared by AAPM Radiation Therapy Committee Task Group 66, for a
2 virtual simulator.

3 **5.11 Electronic Brachytherapy**

4 **5.11.1 Applicability**

5 Electronic brachytherapy devices shall be subject to the requirements of § 5.11
6 of this Part, and shall be exempt for the requirements of § 5.6 of this Part.

- 7 A. An electronic brachytherapy device that does not meet the requirements of §
8 5.11 of this Part shall not be used for irradiation of patients; and

9 B. An electronic brachytherapy device shall only be utilized for human use
10 applications specifically approved by the U.S. Food and Drug Administration
11 (FDA) unless participating in a research study approved by the registrant's
12 Institutional Review Board (IRB).

13 **5.11.2 Possession of Survey Instrument(s)**

14 Each facility location authorized to use an electronic brachytherapy device in
15 accordance with § 5.11 of this Part shall possess appropriately calibrated
16 portable monitoring equipment. As a minimum, such equipment shall include a
17 portable radiation measurement survey instrument capable of measuring dose
18 rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour.
19 The survey instrument(s) shall be operable and calibrated in accordance with §
20 5.8 of this Part for the applicable electronic brachytherapy source energy.

21 **5.11.3 Facility Design Requirements for Electronic Brachytherapy Devices**

22 In addition to shielding adequate to meet requirements of § 5.9 of this Part, the
23 treatment room shall meet the following design requirements:

- 24 A. If applicable, provision shall be made to prevent simultaneous operation of more
25 than one therapeutic radiation machine in a treatment room.

26 B. Access to the treatment room shall be controlled by a door at each entrance.

27 C. Each treatment room shall have provisions to permit continuous aural
28 communication and visual observation of the patient from the treatment control
29 panel during irradiation. The electronic brachytherapy device shall not be used
30 for patient irradiation unless the patient can be observed.

31 D. For electronic brachytherapy devices capable of operating below 50 kV, radiation
32 shielding for the staff in the treatment room shall be available, either as a
33 portable shield and/or as localized shielded material around the treatment site.

- 1 E. For electronic brachytherapy devices capable of operating at greater than 150
2 kV:
- 3 1. The control panel shall be located outside the treatment room;
- 4 2. Interlocks shall be provided such that all entrance doors shall be closed
5 before treatment can be initiated or continued. If the radiation beam is
6 interrupted by any door opening, it shall not be possible to restore the
7 electronic brachytherapy device to operation without closing the door and
8 reinitiating irradiation by manual action at the control panel; and
- 9 3. When any door referred to in § 5.11.3(E)(2) of this Part is opened while
10 the X-ray tube is activated, the air kerma rate at a distance of one (1)
11 meter from the source shall be reduced to less than 1 mGy (100 mrad) per
12 hour.
- 13 F. Facility design requirements for electronic brachytherapy devices which would
14 operate in the 50-150 kV range have intentionally been omitted because an
15 evaluation of this technology, as it existed at the time § 5.11 of this Subpart was
16 finalized, appears to indicate that such devices are not likely to be produced.

17 **5.11.4 Electrical Safety for Electronic Brachytherapy Devices**

- 18 A. The high voltage transformer shall be electrically isolated to prevent electrical
19 and magnetic interference with the surrounding environment and ancillary
20 equipment.
- 21 B. The high voltage transformer shall be isolated from personnel (e.g., operator)
22 and the environment by a protective housing that can only be accessed through
23 a cover requiring a tool for access or with electrical interlocks to prevent
24 operation while open.
- 25 C. The high voltage transformer shall have appropriate safety labels warning
26 personnel of potential electrical shock and/or heat related injuries.
- 27 D. Equipment manufactured after 1 January 2006 shall be in compliance with the
28 most current revision of the following International Electrotechnical Commission
29 (IEC) Documents:
- 30 1. IEC 60601-1:1998+A1+A2:1995;
- 31 2. IEC 60601-1-2:2001;
- 32 3. IEC 60601-2-8:1999; and
- 33 4. IEC 60601-2-17:2004.

34 **5.11.5 Control Panel Functions**

- 1 The control panel, in addition to the displays required by other provisions in §5.11
2 of this Part, shall:
- 3 A. Provide an indication of whether electrical power is available at the control panel
4 and if activation of the electronic brachytherapy source is possible;
- 5 B. Provide an indication of whether x-rays are being produced;
- 6 C. Provide a means for indicating electronic brachytherapy source potential and
7 current;
- 8 D. Provide the means for terminating an exposure at any time; and
- 9 E. Include an access control (locking) device that will prevent unauthorized use of
10 the electronic brachytherapy device.

11 **5.11.6 Timer**

12 A suitable irradiation control device (timer) shall be provided to terminate the
13 irradiation after a pre-set time interval or integrated charge on a dosimeter-based
14 monitor.

- 15 A. A timer shall be provided at the treatment control panel. The timer shall indicate
16 the planned setting and the time elapsed or remaining;
- 17 B. The timer shall not permit an exposure if set at zero;
- 18 C. The timer shall be a cumulative device that activates with an indication of
19 "BEAM-ON" and retains its reading after irradiation is interrupted or terminated.
20 After irradiation is terminated and before irradiation can be reinitiated, it shall be
21 necessary to reset the elapsed time indicator;
- 22 D. The timer shall terminate irradiation when a pre-selected time has elapsed, if any
23 dose monitoring system has not previously terminated irradiation.
- 24 E. The timer shall permit setting of exposure times as short as 0.1 second; and
- 25 F. The timer shall be accurate to within one percent (1%) of the selected value or
26 0.1 second, whichever is greater.

27 **5.11.7 Qualified Medical Physicist Support**

- 28 A. The services of a Qualified Medical Physicist shall be required in facilities having
29 electronic brachytherapy devices. The Qualified Medical Physicist shall be
30 responsible for:
- 31 1. Evaluation of the output from the electronic brachytherapy source;
- 32 2. Generation of the necessary dosimetric information;

- 1 3. Supervision and review of treatment calculations prior to initial treatment
2 of any treatment site;
 - 3 4. Establishing the periodic and day-of-use quality assurance checks and
4 reviewing the data from those checks as required in § 5.11.11 of this Part;
 - 5 5. Consultation with the Authorized User in treatment planning, as needed;
6 and
 - 7 6. Performing calculations/assessments regarding patient treatments that
8 may constitute a misadministration.
- 9 B. If the Qualified Medical Physicist is not a full-time employee of the registrant, the
10 operating procedures required by § 5.11.8 of this Part shall also specifically
11 address how the Qualified Medical Physicist is to be contacted for problems or
12 emergencies, as well as the specific actions, if any, to be taken until the Qualified
13 Medical Physicist can be contacted.

5.11.8 Operating Procedures

- 15 A. Only individuals approved by the Authorized User, Radiation Safety Officer, or
16 Qualified Medical Physicist shall be present in the treatment room during
17 treatment;
- 18 B. Electronic brachytherapy devices shall not be made available for medical use
19 unless the requirements of §§ 5.4, 5.11.9 and 5.11.10 of this Part have been met;
- 20 C. The electronic brachytherapy device shall be rendered inoperable, either by
21 hardware or password, when unattended by qualified staff or service personnel;
- 22 D. During operation, the electronic brachytherapy device operator shall monitor the
23 position of all persons in the treatment room, and all persons entering the
24 treatment room, to prevent unshielded exposure from the treatment beam;
- 25 E. If a patient must be held in position during treatment, mechanical supporting or
26 restraining devices shall be used;
- 27 F. Written procedures shall be developed, implemented, and maintained for
28 responding to an abnormal situation. These procedures shall include:
 - 29 1. Instructions for responding to equipment failures and the names of the
30 individuals responsible for implementing corrective actions; and
 - 31 2. The names and telephone numbers of the Authorized Users, the Qualified
32 Medical Physicist, and the Radiation Safety Officer to be contacted if the
33 device or console operates abnormally.

- 1 G. A copy of the current operating and emergency procedures shall be physically
2 located at the electronic brachytherapy device control console;
 - 3 1. If the control console is integral to the electronic brachytherapy device, the
4 required procedures shall be kept where the operator is located during
5 electronic brachytherapy device operation.
- 6 H. Instructions shall be posted at the electronic brachytherapy device control
7 console³⁰ to inform the operator of the names and telephone numbers of the
8 Authorized Users, the Qualified Medical Physicist, and the Radiation Safety
9 Officer to be contacted if the device or console operates abnormally; and
- 10 I. The Radiation Safety Officer, or his/her designee, and an Authorized User shall
11 be notified as soon as possible if the patient has a medical emergency, suffers
12 injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist
13 shall inform the manufacturer of the event.

14 5.11.9 Safety Precautions for Electronic Brachytherapy Devices

- 15 A. A Qualified Medical Physicist shall determine which persons in the treatment
16 room require monitoring when the beam is energized;
- 17 B. An Authorized User and a Qualified Medical Physicist shall be physically present
18 during the initiation of all patient treatments involving the electronic
19 brachytherapy device;
- 20 C. A Qualified Medical Physicist and either an Authorized User or a physician or
21 electronic brachytherapy device operator, under the supervision of an Authorized
22 User, who has been trained in the operation and emergency response for the
23 electronic brachytherapy device, shall be physically present during continuation
24 of all patient treatments involving the electronic brachytherapy device;
- 25 D. When shielding is required by § 5.11.3(D) of this Part, the electronic
26 brachytherapy device operator shall use a survey meter to verify proper
27 placement of the shielding immediately upon initiation of treatment. Alternatively,
28 a Qualified Medical Physicist shall designate shield locations sufficient to meet
29 the requirements of § 1.7.1 of this Subchapter for any individual, other than the
30 patient, in the treatment room; and
- 31 E. All personnel in the treatment room are required to remain behind shielding
32 during treatment. A Qualified Medical Physicist shall approve any deviation from
33 this requirement and shall designate alternative radiation safety protocols,
34 compatible with patient safety, to provide an equivalent degree of protection.

35 5.11.10 Electronic Brachytherapy Source Calibration Measurements

- 1 A. Calibration of the electronic brachytherapy source output for an electronic
2 brachytherapy device subject to § 5.11 of this Part shall be performed by, or
3 under the direct supervision of, a Qualified Medical Physicist;
- 4 B. Calibration of the electronic brachytherapy source output shall be made for each
5 electronic brachytherapy source, or after any repair affecting the x-ray beam
6 generation, or when indicated by the electronic brachytherapy source quality
7 assurance checks;
- 8 C. Calibration of the electronic brachytherapy source output shall utilize a dosimetry
9 system as described in § 5.4.3 of this Part;
- 10 D. Calibration of the electronic brachytherapy source output shall include, as
11 applicable, determination of:
 - 12 1. The output within two percent (2%) of the expected value, if applicable, or
13 determination of the output if there is no expected value;
 - 14 2. Timer accuracy and linearity over the typical range of use;
 - 15 3. Proper operation of back-up exposure control devices;
 - 16 4. Evaluation that the relative dose distribution about the source is within five
17 percent (5%) of that expected; and
 - 18 5. Source positioning accuracy to within one (1) millimeter within the
19 applicator;
- 20 E. Calibration of the x-ray source output required by § 5.11.10(A) through (D) of this
21 Part shall be in accordance with current published recommendations from a
22 recognized national professional association with expertise in electronic
23 brachytherapy (when available). In the absence of a calibration protocol
24 published by a national professional association, the manufacturer's calibration
25 protocol shall be followed.
- 26 F. The registrant shall maintain a record of each calibration in an auditable form for
27 the duration of the registration. The record shall include: the date of the
28 calibration; the manufacturer's name, model number and serial number for the
29 electronic brachytherapy device and a unique identifier for its electronic
30 brachytherapy source; the model numbers and serial numbers of the
31 instrument(s) used to calibrate the electronic brachytherapy device; and the
32 name and signature of the Qualified Medical Physicist responsible for performing
33 the calibration.

34 **5.11.11 Periodic and Day-of-Use Quality Assurance Checks for Electronic**
35 **Brachytherapy Devices**

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- 1 A. Quality assurance checks shall be performed on each electronic brachytherapy
2 device subject to § 5.11 of this Part:
 - 3 1. At the beginning of each day of use;
 - 4 2. Each time the device is moved to a new room or site; and
 - 5 a. *Site* is intended to include each day of use at each operating
6 location for a self-contained electronic brachytherapy unit
7 transported in a van or trailer. See § 5.11.14 of this Part for
8 additional clarification.
 - 9 3. After each x-ray tube installation.
- 10 B. The registrant shall perform periodic quality assurance checks required by §
11 5.11.11(A) of this Part in accordance with procedures established by the
12 Qualified Medical Physicist;
- 13 C. To satisfy the requirements of § 5.11.11(A) of this Part, radiation output quality
14 assurance checks shall include as a minimum:
 - 15 1. Verification that output of the electronic brachytherapy source falls within
16 three percent (3%) of expected values, as appropriate for the device, as
17 determined by:
 - 18 a. Output as a function of time, or
 - 19 b. Output as a function of setting on a monitor chamber.
 - 20 2. Verification of the consistency of the dose distribution to within three
21 percent (3%) of that found during calibration required by § 5.11.10 of this
22 Part; and
 - 23 3. Validation of the operation of positioning methods to ensure that the
24 treatment dose exposes the intended location within one (1) mm; and
- 25 D. The registrant shall use a dosimetry system that has been intercompared within
26 the previous twelve (12) months with the dosimetry system described in § 5.3(A)
27 of this Part to make the quality assurance checks required in § 5.11.11(C) of this
28 Part;
- 29 E. The registrant shall review the results of each radiation output quality assurance
30 check according to the following procedures:
 - 31 1. An Authorized User and Qualified Medical Physicist shall be immediately
32 notified if any parameter is not within its acceptable tolerance. The
33 electronic brachytherapy device shall not be made available for

- 1 subsequent medical use until the Qualified Medical Physicist has
2 determined that all parameters are within their acceptable tolerances;
- 3 2. If all radiation output quality assurance check parameters appear to be
4 within their acceptable range, the quality assurance check shall be
5 reviewed and signed by either the Authorized User or Qualified Medical
6 Physicist within two (2) days; and
- 7 3. The Qualified Medical Physicist shall review and sign the results of each
8 radiation output quality assurance check at intervals not to exceed thirty
9 (30) days.
- 10 F. To satisfy the requirements of § 5.11.11(A) of this Part, safety device quality
11 assurance checks shall, at a minimum, assure:
- 12 1. Proper operation of radiation exposure indicator lights on the electronic
13 brachytherapy device and on the control console;
- 14 2. Proper operation of viewing and intercom systems in each electronic
15 brachytherapy facility, if applicable;
- 16 3. Proper operation of radiation monitors, if applicable;
- 17 4. The integrity of all cables, catheters or parts of the device that carry high
18 voltages; and
- 19 5. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces,
20 and treatment spacers are free from any defects that interfere with proper
21 operation.
- 22 G. If the results of the safety device quality assurance checks required in §
23 5.11.11(F) of this Part indicate any malfunction, a registrant shall secure the
24 control console in the OFF position and not use the electronic brachytherapy
25 device except as may be necessary to repair, replace, or check the
26 malfunctioning items.
- 27 H. The registrant shall maintain a record of each quality assurance check required
28 by §§ 5.11.11(C) and 5.11.11(G) of this Part in an auditable form for three (3)
29 years.
- 30 1. The record shall include the date of the quality assurance check; the
31 manufacturer's name, model number and serial number for the electronic
32 brachytherapy device; the name and signature of the individual who
33 performed the periodic quality assurance check and the name and
34 signature of the Qualified Medical Physicist who reviewed the quality
35 assurance check;

- 1 2. For radiation output quality assurance checks required by § 5.11.11(C) of
2 this Part, the record shall also include the unique identifier for the
3 electronic brachytherapy source and the manufacturer's name; model
4 number and serial number for the instrument(s) used to measure the
5 radiation output of the electronic brachytherapy device.

6 **5.11.12 Therapy-Related Computer Systems**

7 The registrant shall perform acceptance testing on the treatment planning system
8 of electronic brachytherapy-related computer systems in accordance with current
9 published recommendations from a recognized national professional association
10 with expertise in electronic brachytherapy (when available). In the absence of an
11 acceptance testing protocol published by a national professional association, the
12 manufacturer's acceptance testing protocol shall be followed.

- 13 A. Acceptance testing shall be performed by, or under the direct supervision of, a
14 Qualified Medical Physicist. At a minimum, the acceptance testing shall include,
15 as applicable, verification of:

- 16 1. The source-specific input parameters required by the dose calculation
17 algorithm;
18 2. The accuracy of dose, dwell time, and treatment time calculations at
19 representative points;
20 3. The accuracy of isodose plots and graphic displays;
21 4. The accuracy of the software used to determine radiation source positions
22 from radiographic images; and
23 5. If the treatment-planning system is different from the treatment-delivery
24 system, the accuracy of electronic transfer of the treatment delivery
25 parameters to the treatment delivery unit from the treatment planning
26 system.

- 27 B. The position indicators in the applicator shall be compared to the actual position
28 of the source or planned dwell positions, as appropriate, at the time of
29 commissioning.

- 30 C. Prior to each patient treatment regimen, the parameters for the treatment shall be
31 evaluated and approved by the Authorized User and the Qualified Medical
32 Physicist for correctness through means independent of that used for the
33 determination of the parameters.

34 **5.11.13 Training**

- 35 A. A registrant shall provide instruction, initially and at intervals not to exceed twelve
36 (12) months, to all individuals who operate the electronic brachytherapy device,

1 as appropriate to the individual's assigned duties, in the operating procedures
2 identified in § 5.11.8 of this Part. If the interval between patients exceeds one
3 year, retraining of the individuals shall be provided before the next treatment is
4 administered.

- 5 B. In addition to the requirements of § 5.3.3 of this Part for therapeutic radiation
6 machine Authorized Users and § 5.3.4 of this Part for Qualified Medical
7 Physicists, these individuals shall also receive device specific instruction initially
8 from the manufacturer, and at intervals not to exceed twelve (12) months from
9 either the manufacturer or other qualified trainer. The training shall be of a
10 duration recommended by a recognized national professional association with
11 expertise in electronic brachytherapy (when available). In the absence of any
12 training protocol recommended by a national professional association, the
13 manufacturer's training protocol shall be followed. The training shall include, but
14 nor be limited to:
- 15 1. Device-specific radiation safety requirements;
16 2. Device operation;
17 3. Clinical use for the types of use approved by the FDA;
18 4. Emergency procedures, including an emergency drill; and
19 5. The registrant's Quality Assurance Program.

- 20 C. A registrant shall retain a record of individuals receiving instruction required by
21 §§ 5.11.13(A) and (B) of this Part for three (3) years. The record shall include a
22 list of the topics covered, the date of the instruction, the name(s) of the
23 attendee(s), and the name(s) of the individual(s) who provided the instruction.

24 **5.11.14 Mobile Electronic Brachytherapy Service**

25 A registrant providing mobile electronic brachytherapy service shall, as a
26 minimum:

- 27 A. Check each survey instrument for consistent response with a dedicated check
28 source before medical use at each address of use or on each day of use,
29 whichever is more restrictive. The registrant is not required to keep records of
30 these checks.
- 31 B. Account for the electronic brachytherapy source in the electronic brachytherapy
32 device before departure from the client's address.
- 33 C. Perform, at each location on each day of use, all of the required quality
34 assurance checks specified in § 5.11.11 of this Part to assure proper operation of
35 the device.

5.12 Other Use of Electronically-Produced Radiation To Deliver Therapeutic Radiation Dosage

5.12.1 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 the Agency 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 qualified medical 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 the Agency in its review of the application; and
- B. The applicant or registrant has received written approval from the Agency to utilize the device in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the device.

5.13 Information on Radiation Shielding Required for Plan Reviews

5.13.1 All Therapeutic Radiation Machines

- A. Basic facility information including: name, telephone number and Agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).
- B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

- 1 C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not
2 having primary barriers.

3 **5.13.2 Therapeutic Radiation Machines Up To 150 kV (Photons Only)**

4 In addition to the requirements listed in § 5.13.1 of this Part, therapeutic radiation
5 machine facilities which produce only photons with a maximum energy less than
6 or equal to 150 kV shall submit shielding plans which contain, as a minimum, the
7 following additional information:

- 8 A. Equipment specifications, including the manufacturer and model number of the
9 therapeutic radiation machine, as well as the maximum technique factors.
- 10 B. Maximum design workload for the facility including total weekly radiation output,
11 [expressed in gray (rad) or air kerma at 1 meter], total beam-on time per day or
12 week, the average treatment time per patient/human research subject, along with
13 the anticipated number of patients to be treated per day or week.
- 14 C. A facility blueprint/drawing indicating: scale [0.25 inch = 1 foot is typical]; direction
15 of North; normal location of the therapeutic radiation machine's radiation port(s);
16 the port's travel and traverse limits; general direction(s) of the useful beam;
17 locations of any windows and doors; and the location of the therapeutic radiation
18 machine control panel. If the control panel is located inside the therapeutic
19 radiation machine treatment room, the location of the operator's booth shall be
20 noted on the plan and the operator's station at the control panel shall be behind a
21 protective barrier sufficient to ensure compliance with § 1.7.1 of this Subchapter.
- 22 D. The structural composition and thickness or lead/concrete equivalent of all walls,
23 doors, partitions, floor, and ceiling of the room(s) concerned.
- 24 E. The type of occupancy of all adjacent areas inclusive of space above and below
25 the room(s) concerned. If there is an exterior wall, show distance to the closest
26 area(s) where it is likely that individuals may be present.

27 **5.13.3 Therapeutic Radiation Machines Over 150 kV**

28 In addition to the requirements listed in § 5.13.1 of this Part, therapeutic radiation
29 machine facilities which produce photons with a maximum energy in excess of
30 150 kV and/or electrons shall submit shielding plans which contain, as a
31 minimum, the following additional information:

- 32 A. Equipment specifications including the manufacturer and model number of the
33 therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s)
34 and type(s) of radiation produced [ie: photon, electron]. The target to isocenter
35 distance shall be specified.
- 36 B. Maximum design workload for the facility including total weekly radiation output
37 [expressed in gray (rad) at 1 meter], total beam-on time per day or week, the

1 average treatment time per patient, along with the anticipated number of patients
2 to be treated per day or week.

3 C. Facility blueprint/drawing [including both floor plan and elevation views] indicating
4 relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot
5 is typical], type(s), thickness and minimum density of shielding material(s),
6 direction of North, the locations and size of all penetrations through each
7 shielding barrier [ceiling, walls and floor], as well as details of the door(s) and
8 maze.

9 D. The structural composition and thickness or concrete equivalent of all walls,
10 doors, partitions, floor, and ceiling of the room(s) concerned.

11 E. The type of occupancy of all adjacent areas inclusive of space above and below
12 the room(s) concerned. If there is an exterior wall, show distance to the closest
13 area(s) where it is likely that individuals may be present.

14 F. Description of all assumptions that were in shielding calculations including, but
15 not limited to, design energy [ie: room may be designed for 6 MV unit although
16 only a 4 MV unit is currently proposed], work-load, presence of integral beam-
17 stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful
18 beam will intercept each permanent barrier [walls, floor and ceiling] and "allowed"
19 radiation exposure in both restricted and unrestricted areas.

20 G. At least one example calculation which shows the methodology used to
21 determine the amount of shielding required for each physical condition [ie:
22 primary and secondary/leakage barriers, restricted and unrestricted areas, small
23 angle scatter, entry door(s) and maze] and shielding material in the facility. If
24 commercial software is used to generate shielding requirements, also identify the
25 software used and the version/revision date.

26 5.13.4 Neutron Shielding

27 In addition to the requirements listed in § 5.13.3 of this Part, therapeutic radiation
28 machine facilities which are capable of operating above 10 MV shall submit
29 shielding plans which contain, as a minimum, the following additional information:

30 A. The structural composition, thickness, minimum density and location of all
31 neutron shielding material.

32 B. Description of all assumptions that were used in neutron shielding calculations
33 including, but not limited to, neutron spectra as a function of energy, neutron
34 fluence rate, absorbed dose and dose equivalent (due to neutrons) in both
35 restricted and unrestricted areas.

36 C. At least one example calculation which shows the methodology used to
37 determine the amount of neutron shielding required for each physical condition
38 [ie: restricted and unrestricted areas, entry door(s) and maze] and neutron

- 1 shielding material utilized in the facility. If commercial software is used to
2 generate shielding requirements, also identify the software used and the
3 version/revision date.
- 4 D. The method(s) and instrumentation which will be used to verify the adequacy of
5 all neutron shielding installed in the facility.
- 6 **5.13.5 References**
- 7 A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of
8 X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).
- 9 B. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators"
10 (1984).
- 11 C. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities"
12 (2003).
- 13 D. NCRP Report 151, "Structural Shielding Design and Evaluation for Megavoltage
14 X- and Gamma-Ray Radiotherapy Facilities. (2006).